

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-066857
Article Type:	Protocol
Date Submitted by the Author:	25-Jul-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
Keywords:	Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, EDUCATION & TRAINING (see Medical Education & Training), QUALITATIVE RESEARCH

SCHOLARONE™
Manuscripts

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

8
9 3 **Authors**

10 4 Ella Bracci¹, Michelle Allen², Hannah Carter², Liz Cyarto³, Trudy Dwyer⁴, Nick Graves^{2,5}, Xing
11 5 Lee³, Claudia Meyer⁶, Florin Oprescu⁷, Gill Harvey^{1,2}
12
13

14 6
15
16 7 ¹ Caring Futures Institute, College of Nursing and Health Sciences, Flinders University, Adelaide,
17 8 SA, Australia

19 9 ² Australian Centre for Health Services Innovation and Centre for Healthcare Transformation,
20 10 School of Public Health and Social Work, Queensland University of Technology, Queensland,
21 11 Australia
22

23 12 ³ School of Public Health and Social Work, Queensland University of Technology, Queensland,
24 13 Australia
25

26 14 ⁴ School of Nursing, Midwifery and Social Sciences, Central Queensland University,
27 15 Rockhampton, Australia.
28

29 16 ⁵ Duke-NUS Postgraduate Medical School, National University of Singapore, Singapore
30

31 17 ⁶ Bolton Clarke Research Institute, Forest Hill, Victoria, Australia
32

33 18 ⁷ School of Health and Behavioural Sciences, University of the Sunshine Coast, Sippy Downs,
34 19 Queensland, Australia
35

36
37 20
38
39 21 Corresponding author:

40
41 22 Gill Harvey

42
43 23 Professor of Health Services and Implementation Research, Matthew Flinders Fellow

44
45 24 Theme Lead – Better Systems, Caring Futures Institute

46
47 25 Co-Director, Aged Care Partnering Program, Aged Care Centre for Growth and Translational
48 26 Research
49

50 27 College of Nursing and Health Sciences

51
52 28 Flinders University

53
54 29 Email: gillian.harvey@flinders.edu.au
55

56 30
57
58
59
60

31 **Abstract**

32 Introduction

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

40 Methods and Analysis

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

51 Ethics and dissemination

52 Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
53 Committee (approval number: 170031) with administrative ethical approval granted by the
54 Queensland University of Technology University Human Research Ethics Committee
55 [2000000618]. Full ethical approval includes a waiver of consent for access to residents'
56 demographic, clinical and health services de-identified data. A separate health services data
57 linkage based on RAC home addresses will be sought through a Public Health Act (PHA)

1
2
3 58 application. Study findings will be disseminated through multiple channels, including journal
4
5 59 publications, conference presentations and interactive webinars with a stakeholder network.
6

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 **63 Strengths and limitations of this study**

- 15
16 64 • Theory-informed process evaluation, framed by the integrated-Promoting Action on
17
18 65 Research Implementation in Health Services framework and an intervention logic model.
19
20 66 • Process data from a range of sources to assess implementation processes and outcomes.
21
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 • Data relating to residents' experiences will be collected from family members and
31
32 72 nominated advocates, rather than directly from residents.
33

34
35
36 **74 Introduction**

37
38 75 When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face
39
40 76 increased risk of hospital associated complications and invasive interventions (1). Hospital
41
42 77 presentations and admissions amongst this population group are relatively high and there is
43
44 78 evidence to suggest some hospital encounters are avoidable (2). A report published by the
45
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 83 will reduce hospital presentations and admissions from RAC, from implementing models of care
55
56
57
58
59
60

1
2
3 84 that provide access to resources and improve the clinical skills and confidence of nursing staff
4
5 85 (5).
6

7
8 86 The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in
9
10 87 Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care
11
12 88 staff working in RAC. The aim was to empower and enable staff to identify and appropriately
13
14 89 respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE
15
16 90 demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital
17
18 91 transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+
19
20 92 builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable
21
22 93 hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge
23
24 94 randomized controlled effectiveness-implementation trial (9) with embedded economic and
25
26 95 process evaluation. Details of the trial, which involves 12 participating RAC homes in
27
28 96 metropolitan and regional Queensland, have been described in a previously published protocol
29
30 97 paper (10). This paper presents the protocol for the process evaluation component of the
31
32 98 study.
33

34 35 100 The EDDIE+ Intervention

36
37 101 EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them
38
39 102 the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract
40
41 103 infections, chest pain, falls and dyspnoea within the home setting. It comprises four
42
43 104 components: advanced clinical skills education and training (provided initially by a project-
44
45 105 funded nurse educator), decision support tools, provision of diagnostic equipment (for
46
47 106 example, bladder scanners and vital signs monitors) and implementation facilitation and
48
49 107 support (via a locally appointed clinical facilitator supported by a project implementation
50
51 108 facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation
52
53 109 framework, the integrated Promoting Action of Research Implementation in Health Services (i-
54
55 110 PARIHS) framework (11). i-PARIHS proposes that the successful implementation of evidence-
56
57 111 informed innovations results from the active facilitation of an innovation with the intended

1
2
3 112 recipients of implementation within their local, organisational and system context. As such,
4
5 113 attention to facilitation, engagement with RAC stakeholders, involvement of staff and
6
7 114 responsiveness to context are key features of EDDIE+.

8
9 115 By embedding implementation facilitation within the bundle of components that comprise
10
11 116 EDDIE+, implementation is integral to the intervention. Consistent with facilitation as an
12
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
17 119 and adaptable features of each EDDIE+ component [Table 1].

18
19 120 Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce
20
21 121 intended changes to processes and outcomes of care.

22
23 122 [Figure 1 about here]

24
25
26 123

27 28 124 **Methods and analysis**

29 30 125 Process evaluation

31
32
33 126 Process evaluations are increasingly recognised as an important part of developing and testing
34
35 127 complex interventions such as EDDIE+, which comprises multiple components and is being
36
37 128 implemented across multiple settings (12, 13). While the trial component of the study focuses
38
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
53 136 delivery of the intervention, or intervention failure, such as poor or inappropriate design (14).
54
55 137 This might inform planning of future interventions and implementation strategies.

EDDIE+ Component	Fixed element (core)	Flexible element (adaptable)
Advanced clinical skills education and training	Initial training mandatory for Registered Nurses, Enrolled Nurses, and Personal Care Workers	Mode of delivery Timing and organisation of sessions
	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 conditions covered Mode of delivery Staff involved in training
	Core set of educational materials	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 (e.g., track & trigger tool) Communication tool (e.g., ISBAR - (Introduction, Situation, 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 individual home needs
Implementation facilitation and support	Appointment of clinical facilitator	Role-sharing by 2 staff members
	Train-the-trainer model for clinical facilitator	Opt-in by other Registered Nurses
	Communication channel established for discussing concerns about resident deterioration and/or need for hospital transfer	Tailored to individual home needs

138 **Table 1: Core and adaptable components of EDDIE+ intervention**

1
2
3 139 To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will
4
5 140 follow published guidance on conducting and reporting studies with a process evaluation
6
7 141 component (12). Consistent with the application of i-PARIHS to inform the development of
8
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 Aims

19
20
21 148 The aim of the process evaluation is to track the implementation of EDDIE+ in the 12
22
23 149 participating RAC homes to:

- 24
25
26 150 1. Assess EDDIE+ intervention fidelity
- 27
28 151 2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family
29
30 152 members, EDDIE+ facilitators and wider stakeholders
- 31
32 153 3. Identify the mechanisms of impact
- 33
34 154 4. Identify contextual barriers and enablers of implementation.

35 36 Study Design and Data Collection

37
38
39 156 An embedded and formative mixed methods process evaluation will be undertaken. This will be
40
41 157 guided by a series of templates based on i-PARIHS to assess fidelity and acceptability of EDDIE+,
42
43 158 mechanisms of impact, and contextual barriers and enablers within and across the 12 regional
44
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
55 164 collection and analysis (Tables 2 and 3).

165

166

		Data Source						Data Analysis Approach	
i-PARIHS Constructs	Process Evaluation Component	EDDIE+ Check in Form	Comm and Activity Tracking	Context mapping	Interviews	Self- Efficacy Surveys	Family advocate questionnaire	Quantitative	Qualitative
Innovation and Recipients	Fidelity	✓	✓		✓			✓	✓
	Acceptability	✓	✓		✓		✓		✓
Facilitation	Mechanisms of Impact	✓			✓	✓		✓	✓
Context	Barriers and Enablers	✓	✓	✓	✓				✓

167 **Table 2. Overview of process evaluation data collection and analysis**

168

169

170

171

Data Source	Description	Purpose	Aim*
Communication and Activity Tracking	Conversational data, hours of training, details of home, education, and training, field notes	Provide picture of homes across the intervention period and record any critical time junctures	1, 3, 4
Baseline context mapping	Description of home characteristics before EDDIE+ intervention	Provide baseline overview of home, including likely barriers and enablers of implementation	4
Check In Forms	Hours of training, EDDIE+ activities, general updates	Describe EDDIE+ activities undertaken and program progress over intervention period	1, 2, 3, 4
Semi-structured interviews	Interviews with staff, residents and family members, EDDIE+ facilitators and external stakeholders	Understand stakeholder views and experiences of EDDIE+	2, 4
Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has improved efficacy and upskilled staff	3
Family member or nominated advocate questionnaire	Traffic light system with three questions related to the EDDIE+ program	Determine family members and advocates views on the program and impact	2

172 **Table 3: Description of process evaluation data sources**

173

174 *Aims - 1: Assess the EDDIE+ intervention fidelity; 2: Assess the acceptability and views of the EDDIE+ program from the perspective of staff, resident families,

175 EDDIE+ facilitators and external stakeholders; 3: Identify mechanisms of impact; 4: Identify contextual barriers and enablers to implementation success

1
2
3 176 i-PARIHS theoretical framing
4

5
6 177 *Innovation*
7

8 178 According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced
9
10 179 if there is support for the innovation to be implemented. The innovation in this case is EDDIE+,
11
12 180 an intervention to improve the identification and management of clinical deterioration in
13
14 181 residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is
15
16 182 more likely if key stakeholders including RAC staff, managers, residents, family members and
17
18 183 external care providers, agree with the idea of keeping residents at home where possible and
19
20 184 perceive implementation to be workable in practice. In relation to EDDIE+, this includes support
21
22 185 for the education and training offered and the introduction and use of new diagnostic
23
24 186 equipment. Therefore, it will be important to collect stakeholder views on the acceptability,
25
26 187 relevance, and importance of EDDIE+ within the context of the RAC home setting.

27 188 *Recipients*
28

29 189 i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family
30
31 190 members) need both 'want to' and 'can do' factors to achieve successful implementation (15).
32
33 191 RAC staff in particular have to be motivated to address the issue of clinical deterioration in
34
35 192 residents and have the capacity and capability to implement EDDIE+. These areas will be
36
37 193 explored as part of the data collection.

38
39 194 *Context*
40

41 195 Contextual factors at multiple levels are identified as important barriers or enablers of
42
43 196 implementation in i-PARIHS and will be examined as part of the process evaluation. The inner
44
45 197 context spans the local and organisational settings. At a local level, inner context refers to the
46
47 198 immediate place of implementation - the RAC home - and encompasses factors such as the
48
49 199 workplace culture, management and leadership support, workload, receptiveness, and
50
51 200 attitudes to change. The local context is embedded within the organisational context - the aged
52
53 201 care provider organisation - where factors relating to culture, leadership, support and resources
54
55 202 are also important. Outer context relates to the wider aged care system, including policy
56
57 203 drivers, regulatory standards and frameworks, other initiatives that influence the care of

1
2
3 204 deteriorating residents, and more general health, social and economic issues that affect aged
4
5 205 care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked
6
7 206 throughout the intervention phase of the study.
8

9 207 *Facilitation*

10
11
12 208 Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation,
13
14 209 comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's
15
16 210 role to assess innovation, recipient and contextual factors that present barriers to or enablers
17
18 211 of implementation and plan appropriate facilitation strategies to address these. The main
19
20 212 facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to
21
22 213 support implementation, with funding provided for backfill support. The clinical facilitator
23
24 214 receives additional support from the EDDIE+ project team including the nurse educator and the
25
26 215 project implementation facilitator. This is based on a model of internal-external facilitation (16).
27
28 216 The nurse educator is responsible for developing and delivering the training on clinical
29
30 217 deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator
31
32 218 will undertake the baseline context assessment and support the clinical facilitators to develop
33
34 219 facilitation skills. As part of the process evaluation, it will be important to collect data about the
35
36 220 different facilitator roles, the strategies used to facilitate implementation and how well these
37
38 221 worked.

38 222 Process evaluation elements

39
40 223 *Fidelity*

41
42
43 224 Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance
44
45 225 at mandatory EDDIE+ training by nurses and personal care workers, number of EDDIE+ sessions
46
47 226 delivered/attended, use of the new equipment, and recruitment and retention of clinical
48
49 227 facilitators. These data will be extracted from EDDIE+ check in forms completed by the
50
51 228 nominated clinical facilitator at each site and the communication and tracking data collected
52
53 229 from the project team, including education attendance records [see Supplementary file].
54
55 230 Additional data sources will be used to determine any critical time junctures such as COVID-19
56
57
58
59
60

1
2
3 231 lockdowns, infection outbreaks and other events that may have impacted the implementation
4
5 232 of EDDIE+.

6
7 233 *Acceptability*

8
9
10 234 Data will be collected on the acceptability of EDDIE+ from the perspective of four stakeholder
11
12 235 groups: RAC staff including Registered Nurses, Enrolled Nurses and Personal Care Workers,
13
14 236 family members or nominated advocates of residents, clinical facilitators, and local and external
15
16 237 stakeholders [see Tables 2 & 3]. Semi-structured interviews will be conducted with these
17
18 238 different groups to ascertain their views about EDDIE+. Family members and nominated
19
20 239 advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted
21
22 240 the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how
23
24 241 it was implemented to determine what they found most and least helpful about EDDIE+ and
25
26 242 whether they thought the intervention was transferable to other RAC homes [see
27
28 243 Supplementary file]. Additionally, a three-question traffic light survey will be distributed to
29
30 244 family members and nominated advocates to determine if their experience with EDDIE+ was
31
32 245 positive, negative, or neutral, if EDDIE+ impacted the care of their loved one in a good way, and
33
34 246 their views on whether EDDIE+ should be introduced into other RAC homes [see Supplementary
35
36 247 file].

37 248 *Mechanisms of impact*

38
39 249 As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce
40
41 250 improvements in resident, staff, and system level outcomes through mechanisms including
42
43 251 enhanced staff knowledge and skills, increased staff confidence and sense of empowerment,
44
45 252 and greater confidence of family members and external care providers in the ability of RAC
46
47 253 home staff to provide appropriate clinical care for residents. These mechanisms will be
48
49 254 explored through several data sources. RAC staff will be requested to complete a self-efficacy
50
51 255 survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to
52
53 256 evaluate reported changes in staff confidence and capability. Questionnaire data will be
54
55 257 supplemented with data from semi-structured interviews conducted with RAC staff, clinical
56
57 258 facilitators, managers, and external care providers, such as general practitioners, to assess

259 mechanisms relating to confidence, staff empowerment and skills and knowledge
260 development.

261 *Understanding barriers and enablers*

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

272 Setting and participant recruitment for process evaluation

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

280 Quantitative Data

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

1
2
3 286 Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire
4
5 287 (17). The questionnaire comprises three sections. Section one provides information about the
6
7 288 staff member's demographics, their role at the facility, years worked at the facility, years
8
9 289 worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10
10
11 290 statements related to job self-efficacy. The statements include job related confidence and
12
13 291 ability, having the required skills to perform the job well and how they compare themselves to
14
15 292 others in the field. Section three is a 5-point Likert scale with 7 statements related to team self-
16
17 293 efficacy. Section three has questions related to team members' skills, abilities and effectiveness
18
19 294 in relation to completing their own tasks and functioning as a team.

20 295 Qualitative Data

21
22
23 296 Qualitative data will be primarily collected from a series of semi-structured interviews with
24
25 297 staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse
26
27 298 educator, project implementation facilitator and external stakeholders. Interviewees will be
28
29 299 recruited by email and direct correspondence. Participation will be voluntary and informed
30
31 300 consent will be obtained prior to the conduct of the interview. Additional qualitative data will
32
33 301 be extracted from communication tracking field notes, baseline context assessments and check
34
35 302 in forms where relevant. These data will address multiple aims of the process evaluation such
36
37 303 as the acceptability of EDDIE+, contextual barriers and enablers, and the mechanisms of action
38
39 304 (Table 2).

40 305 *Staff, Local and External Stakeholder interviews*

41
42
43 306 At intervention completion the RAC staff, including those in managerial positions, and external
44
45 307 stakeholders such as GPs and allied health providers, will be invited to participate in semi-
46
47 308 structured interviews. Interviews will be up to 30 minutes in length and completed via
48
49 309 telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of
50
51 310 implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and
52
53 311 factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes[see
54
55 312 Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse
56
57
58
59
60

1
2
3 313 educator and project implementation facilitator after the completion of the trial to ascertain
4
5 314 their reflections and experience of the EDDIE+ intervention and implementation process.
6

7
8 315 *Family and nominated advocate interviews*
9

10 316 At intervention completion, family members and nominated advocates of residents, including
11
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

30 326 Data Analysis
31

32
33 327 *Quantitative Data*
34

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

46 333 *Qualitative Data*
47

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
57 338 extracted from the baseline context mapping as well as communication, activity tracking and
58

1
2
3 339 check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not
4
5 340 align with the i-PARIHS framework will be analysed using a descriptive qualitative approach
6
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
13 344 is attained and no new themes emerge.

15 345 *Integrating results of data analysis*

16
17 346 Process evaluation data analysis will be undertaken independently of the analysis of the
18
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.

25 350 Patient and public involvement

26
27 351 No resident or public involvement in the design of the process evaluation. Family members and
28
29 352 nominated advocates of residents will be invited to participate in interviews and surveys as part
30
31 353 of the process evaluation.

34 354 **Ethics and dissemination**

35
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
48 361 application. Group or individual interviews will require written consent prior to
49
50 362 commencement. Protocol amendments will be submitted as variations to the approving ethics
51
52 363 committees at time of identification. Additionally, the project manager will notify committees
53
54 364 in the circumstance of protocol deviations and adverse events in accordance with local
55
56 365 procedures.

1
2
3 366 Study findings will be disseminated through traditional academic channels, such as journal
4
5 367 publications and conference presentations, alongside more interactive strategies, including
6
7 368 engagement with a stakeholder network established to embed knowledge translation within
8
9 369 the research.

10 11 370 **Discussion**

12
13
14 371 Early detection and management of deterioration in residents of aged care homes could result
15
16 372 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
22 375 that did not control for external trends. Following the success of EDDIE in a single site, a
23
24 376 modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled
25
26 377 trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+
27
28 378 with the aim of confirming preliminary findings and strengthening the evidence base for wider
29
30 379 implementation. The embedded process evaluation will explore whether the scaled-up
31
32 380 intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable
33
34 381 from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+
35
36 382 improved outcomes (or not), and contextual barriers and enablers that may have influenced
37
38 383 implementation. A mixed method, theory-informed approach will provide an in-depth
39
40 384 evaluation of the EDDIE+ program and valuable insights into determinants of implementation
41
42 385 success across multiple sites. This could help to identify key factors to consider in the future
43
44 386 development and implementation of hospital avoidance programs such as EDDIE+.

45
46 387

47 388 **Supplementary information**

48 389 Supplementary file – example data collection tools

49 50 51 390 **Contributors**

52
53 391 HC, NG, XL, GH, TD, EC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the
54
55 392 development of the process evaluation. EB and GH drafted the manuscript with input from all

393 contributing authors. All authors critically revised the manuscript and approved the final
394 version to be published.

395 **Competing interests**

396 None declared.

397 **Funding**

398 This project is funded by a National Health and Medical Research Council Medical Research
399 Future Fund grant (GNT1177501) and led by Queensland University of Technology. The funding
400 body did not have a role in the study design and subsequent protocol paper, nor are the
401 funders involved with ongoing data collection, management, analysis, and interpretation.

402 **Acknowledgements**

403 A collaborative research agreement is established between QUT and partnering institutions. We
404 thank the following partnering institutions: Flinders University, Central Queensland University,
405 Bolton Clarke, University of the Sunshine Coast, Metro North Hospital and Health Service and
406 University of Newcastle.

407 **References**

- 408 1. Dwyer R, Gabbe B, Stoelwinder JU, Lowthian J. A systematic review of outcomes following
409 emergency transfer to hospital for residents of aged care facilities. *Age Ageing*. 2014;43(6):759-66.
- 410 2. Spector WD, Limcangco R, Williams C, Rhodes W, Hurd D. Potentially avoidable hospitalizations
411 for elderly long-stay residents in nursing homes. *Med Care*. 2013;51(8):673-81.
- 412 3. Australian Medical Association. Putting health back into aged care. Barton, ACT; 2021.
- 413 4. Carusone SC, Loeb M, Lohfeld L. Pneumonia care and the nursing home: a qualitative descriptive
414 study of resident and family member perspectives. *BMC Geriatr*. 2006;6:2.
- 415 5. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Managing the deteriorating nursing home resident
416 after the introduction of a hospital avoidance programme: a nursing perspective. *Scand J Caring Sci*.
417 2017;31(2):312-22.
- 418 6. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Nursing staff intentions towards managing
419 deteriorating health in nursing homes: A convergent parallel mixed-methods study using the theory of
420 planned behaviour. *Journal of clinical nursing*. 2018;27(5-6):e992-e1003.
- 421 7. Carter HE, Lee XJ, Dwyer T, O'Neill B, Jeffrey D, Doran CM, et al. The effectiveness and cost
422 effectiveness of a hospital avoidance program in a residential aged care facility: a prospective cohort
423 study and modelled decision analysis. *BMC Geriatr*. 2020;20(1):527.
- 424 8. O'Neill B, Dwyer T, Parkinson L, Reid-Searl K. Identifying the core components of a nursing home
425 hospital avoidance program. *Int J Older People Nurs*. 2022.
- 426 9. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid
427 designs: combining elements of clinical effectiveness and implementation research to enhance public
428 health impact. *Med Care*. 2012;50(3):217-26.

- 1
2
3 429 10. Carter HE, Lee XJ, Farrington A, Shield C, Graves N, Cyarto EV, et al. A stepped-wedge
4 430 randomised controlled trial assessing the implementation, effectiveness and cost-consequences of the
5 431 EDDIE+ hospital avoidance program in 12 residential aged care homes: study protocol. *BMC Geriatr.*
6 432 2021;21(1):347.
- 7
8 433 11. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful
9 434 implementation of knowledge into practice. *Implement Sci.* 2016;11(1):33.
- 10 435 12. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of
11 436 complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.
- 12 437 13. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for
13 438 developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ.*
14 439 2021;374:n2061.
- 15 440 14. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised
16 441 controlled trials of complex interventions. *BMJ.* 2006;332(7538):413.
- 17
18 442 15. Weiner B. A theory of organizational readiness for change. *Implement Sci.* 2009;4(1):67.
- 19 443 16. Harvey G, Kitson A. *Implementing Evidence-Based Practice in Healthcare: A facilitation guide.*
20 444 Abingdon, Oxon.: Routledge; 2015.
- 21 445 17. Riggs ML, Warka J, Babasa B, Betancourt R, Hooker S. Development and Validation of Self-
22 446 Efficacy and Outcome Expectancy Scales for Job-Related Applications. *Educ Psychol Measur.*
23 447 1994;54(3):793-802.
- 24 448 18. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health.*
25 449 2000;23(4):334-40.
- 26 450 19. Colorafi KJ, Evans B. *Qualitative Descriptive Methods in Health Science Research.* *HERD.*
27 451 2016;9(4):16-25.

29
30 452
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

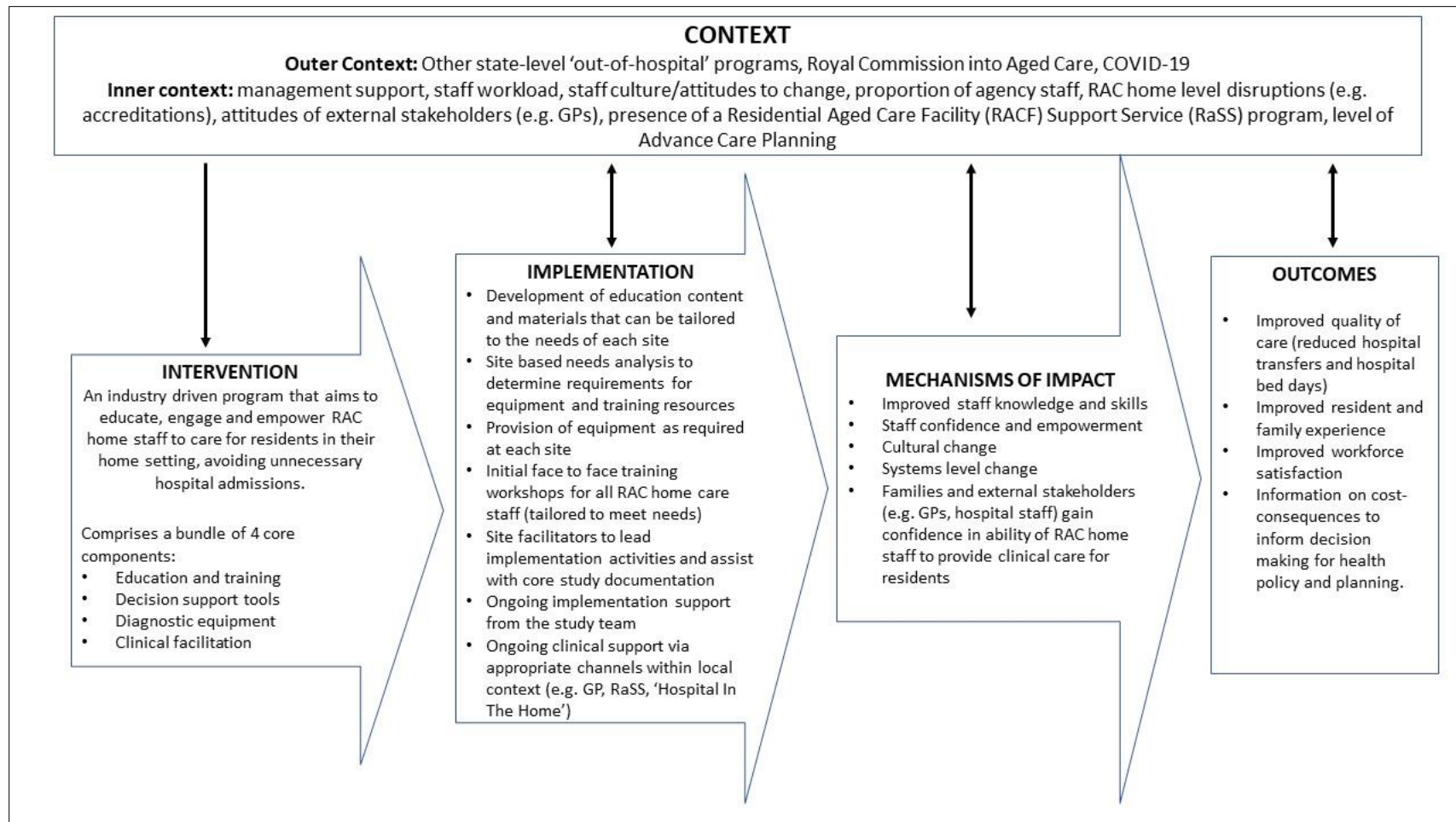


Figure 1: EDDIE+ intervention logic model

1
2
3 **EDDIE+ Supplementary file – examples of data collection tools**
4
5
6

7
8 **S1:** Family member interview guide
9

10 **S2:** Stakeholder interview guide
11

12 **S3:** Staff self-efficacy survey (RN, EN, PCW)
13

14 **S4:** Family member or nominated advocate questionnaire
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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?

S2: Stakeholder interview guide

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 style="list-style-type: none"> 1. Can you describe how the intervention was implemented? 2. Was the intervention implemented according to the implementation plan? 3. Who were the key stakeholders to get on board with the intervention? 4. To what extent were the needs and preferences of clients considered when deciding to implement the intervention?
What about the intervention worked?	<ol style="list-style-type: none"> 1. What did you like about the program? 2. What has been most helpful to you? 3. What were implementation facilitators?
What about the intervention didn't work?	<ol style="list-style-type: none"> 1. What didn't you like about the program? 2. What has been least helpful to you?
What factors will be important for scale-up and/or sustainability?	<ol style="list-style-type: none"> 1. How do you think this would work in other RAC homes? 2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	<ol style="list-style-type: none"> 1. What would need to be considered?

1
2
3 **S3: Staff self-efficacy survey (RN, EN, PCW)**
4
5



16
17
18
19
20
21
22
23
24
25
26

Researching Early Detection of Deterioration In Elderly residents

Nurse and carer questionnaire

27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

This survey will ask some general questions about you, as well as some questions about your role at Bolton 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.

42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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, please tell us a bit about yourself:**

1. Age _____ years

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.

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 the care your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feel 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.



3. I think the EDDIE+ program should be introduced in other Residential Aged Care homes.



Thank you for completing this survey.

BMJ Open

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:	<i>BMJ Open</i>
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
Primary Subject Heading:	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

SCHOLARONE™
Manuscripts

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

8
9 3 **Authors**

10 4 Ella Bracci¹, Michelle Allen², Hannah Carter², Liz Cyarto³, Trudy Dwyer⁴, Nick Graves^{2,5}, Xing
11 5 Lee³, Claudia Meyer⁶, Florin Oprescu⁷, Gill Harvey^{1,2}
12
13

14 6
15
16 7 ¹ Caring Futures Institute, College of Nursing and Health Sciences, Flinders University, Adelaide,
17 8 SA, Australia

19 9 ² Australian Centre for Health Services Innovation and Centre for Healthcare Transformation,
20 10 School of Public Health and Social Work, Queensland University of Technology, Queensland,
21 11 Australia
22

23 12 ³ School of Public Health and Social Work, Queensland University of Technology, Queensland,
24 13 Australia
25

26 14 ⁴ School of Nursing, Midwifery and Social Sciences, Central Queensland University,
27 15 Rockhampton, Australia.
28

29 16 ⁵ Duke-NUS Postgraduate Medical School, National University of Singapore, Singapore
30

31 17 ⁶ Bolton Clarke Research Institute, Forest Hill, Victoria, Australia
32

33 18 ⁷ School of Health and Behavioural Sciences, University of the Sunshine Coast, Sippy Downs,
34 19 Queensland, Australia
35

36
37 20
38
39 21 Corresponding author:

40
41 22 Gill Harvey

42
43 23 Professor of Health Services and Implementation Research, Matthew Flinders Fellow

44
45 24 Theme Lead – Better Systems, Caring Futures Institute

46
47 25 Co-Director, Aged Care Partnering Program, Aged Care Centre for Growth and Translational
48 26 Research
49

50 27 College of Nursing and Health Sciences

51
52 28 Flinders University

53
54 29 Email: gillian.harvey@flinders.edu.au
55

56 30
57
58
59
60

- 1
2
3 31 Number of references: 19
4
5 32 Abstract count: 299
6
7 33 Word count: 4394 (with tables); 3911 (without tables)
8
9
10
11
12
13
14
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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)

1
2
3 62 application. Study findings will be disseminated through multiple channels, including journal
4
5 63 publications, conference presentations and interactive webinars with a stakeholder network.
6

7
8 **64 Trial registration:**

9
10 65 The trial is prospectively registered with the Australia New Zealand Clinical Trial Registry
11
12 66 (ACTRN12620000507987, registered 23/04/2020).

13
14 **67 Strengths and limitations of this study**

- 15
16 68 • Theory-informed process evaluation, framed by the integrated-Promoting Action on
17
18 69 Research Implementation in Health Services framework and an intervention logic model.
19
20 70 • Process data from a range of sources to assess implementation processes and outcomes.
21
22 71 • Outcomes could help inform planning for future development and implementation of
23
24 72 hospital avoidance strategies in residential aged care facilities.
25
26 73 • High staff turnover and workload within the residential aged care sector may impact staff
27
28 74 availability to participate in surveys and interviews.
29
30 75 • Data relating to residents' experiences will be collected from family members and
31
32 76 nominated advocates, rather than directly from residents.
33

34 **77 Introduction**

35
36 78 When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face
37
38 79 increased risk of hospital associated complications and invasive interventions (1). Hospital
39
40 80 presentations and admissions amongst this population group are relatively high and there is
41
42 81 evidence to suggest some hospital encounters are avoidable (2). A report published by the
43
44 82 Australian Medical Association estimated 27,000 potentially preventable admissions from RAC
45
46 83 homes in Australia in 2021, equating to 160,000 bed days with a cost of \$312 million Australian
47
48 84 dollars (3). RAC residents, family members and staff express a preference for care to be
49
50 85 provided in their home where possible (4). Previous research indicates that this is possible and
51
52 86 will reduce hospital presentations and admissions from RAC, from implementing models of care
53
54 87 that provide access to resources and improve the clinical skills and confidence of nursing staff
55
56 88 (5).
57
58
59
60

1
2
3 89 The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in
4
5 90 Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care
6
7 91 staff working in RAC. The aim was to empower and enable staff to identify and appropriately
8
9 92 respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE
10
11 93 demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital
12
13 94 transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+
14
15 95 builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable
16
17 96 hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge
18
19 97 randomized controlled effectiveness-implementation trial (9) with embedded economic and
20
21 98 mixed methods process evaluation. Details of the trial, which involves 12 participating RAC
22
23 99 homes in metropolitan and regional Queensland, have been described in a previously published
24
25 100 trial protocol paper (10). This paper presents the protocol for the process evaluation
26
27 101 component of the study. Process evaluations are increasingly recognised as an important part
28
29 102 of developing and testing complex interventions such as EDDIE+, which comprises multiple
30
31 103 components and is implemented across multiple sites (12, 13). Process evaluations often
32
33 104 include assessing an intervention's fidelity, namely, if the intervention was implemented as
34
35 105 intended, the acceptability of an intervention from various stakeholder perspectives, the
36
37 106 mechanism of impact, or what initiates a change, and an assessment of barriers and enablers to
38
39 107 implementation.

108 The EDDIE+ Intervention

40
41 109 EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them
42
43 110 the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract
44
45 111 infections, chest pain, falls and dyspnoea within the home setting. It comprises four
46
47 112 components: advanced clinical skills education and training (provided initially by a project-
48
49 113 funded nurse educator), decision support tools, provision of diagnostic equipment (for
50
51 114 example, bladder scanners and vital signs monitors) and implementation facilitation and
52
53 115 support (via a locally appointed clinical facilitator supported by a project implementation
54
55 116 facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation
56
57 117 framework, the integrated Promoting Action of Research Implementation in Health Services (i-

1
2
3 118 PARIHS) framework (11). i-PARIHS proposes that the successful implementation of evidence-
4
5 119 informed innovations results from the active facilitation of an innovation with the intended
6
7 120 recipients of implementation within their local, organisational and system context. As such,
8
9 121 attention to facilitation, engagement with RAC stakeholders, involvement of staff and
10
11 122 responsiveness to context are key features of EDDIE+.

12
13 123 By embedding implementation facilitation within the bundle of components that comprise
14
15 124 EDDIE+, implementation is integral to the intervention. Consistent with facilitation as a primary
16
17 125 implementation strategy, clinical facilitators can tailor the implementation of EDDIE+ according
18
19 126 to their own home's needs. This will be achieved through the identification of core and
20
21 127 adaptable features of each EDDIE+ component [Table 1].

22
23 128 Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce
24
25 129 intended changes to processes and outcomes of care.

26
27 130 [Figure 1 about here]

28
29
30 131

31 32 132 **Methods and analysis**

33 34 133 Process evaluation

35
36
37 134 While the trial component of the study focuses on intervention effectiveness, the process
38
39 135 evaluation aims to understand how and why the intervention works in real-world contexts. This
40
41 136 involves examining whether the intervention has been implemented as planned and resulted in
42
43 137 expected outcomes. Understanding whether and how an intervention is affecting change can
44
45 138 provide insights into the processes of implementation and the extent to which these account
46
47 139 for positive or negative study outcomes. This is particularly helpful if the actual study outcomes
48
49 140 differ from expected outcomes, enabling the study team to understand whether there has been
50
51 141 implementation failure, such as poor delivery of the intervention, or intervention failure, such
52
53 142 as poor or inappropriate design (14). This might inform planning of future interventions and
54
55 143 implementation strategies.

EDDIE+ Component	Fixed element (core)	Flexible element (adaptable)
Advanced clinical skills education and training	Initial training mandatory for Registered Nurses, Enrolled Nurses, and Personal Care Workers	Mode of delivery Timing and organisation of sessions
	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 conditions covered Mode of delivery Staff involved in training
	Core set of educational materials	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 (e.g., track & trigger tool) Communication tool (e.g., ISBAR - (Introduction, Situation, 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 individual home needs
Implementation facilitation and support	Appointment of clinical facilitator	Role-sharing by 2 staff members
	Train-the-trainer model for clinical facilitator	Opt-in by other Registered Nurses
	Communication channel established for discussing concerns about resident deterioration and/or need for hospital transfer	Tailored to individual home needs

144 **Table 1: Core and adaptable components of EDDIE+ intervention**

1
2
3 145 To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will
4
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 Aims

19
20
21 154 The aim of the process evaluation is to track the implementation of EDDIE+ in the 12
22
23 155 participating RAC homes to:

- 24
25
26 156 1. Assess EDDIE+ intervention fidelity
- 27
28 157 2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family
29
30 158 members, EDDIE+ facilitators and wider stakeholders
- 31
32 159 3. Identify the mechanisms of impact
- 33
34 160 4. Identify contextual barriers and enablers of implementation.

35 36 Study Design and Data Collection

37
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
43 164 mechanisms of impact, and contextual barriers and enablers within and across the 12 regional
44
45 165 and metropolitan homes. Data from all four intervention phases of the stepped wedge trial will
46
47 166 be collected and analysed. These are the preparation, baseline exposure, intervention
48
49 167 introduction and intervention exposure phases.

50
51 168 We first summarise how the theoretical propositions of the i-PARIHS framework inform the
52
53 169 questions of interest within the process evaluation, before describing the methods of data
54
55 170 collection and analysis (Tables 2 and 3).

171

172

		Data Source						Data Analysis Approach	
i-PARIHS Constructs	Process Evaluation Component	EDDIE+ Check in Form	Comm and Activity Tracking	Context mapping	Interviews	Self- Efficacy Surveys	Family advocate questionnaire	Quantitative	Qualitative
Innovation and Recipients	Fidelity	✓	✓		✓			✓	✓
	Acceptability	✓	✓		✓		✓		✓
Facilitation	Mechanisms of Impact	✓			✓	✓		✓	✓
Context	Barriers and Enablers	✓	✓	✓	✓				✓

173 **Table 2. Overview of process evaluation data collection and analysis**

174

175

176

177

Data Source	Description	Purpose	Aim*
Communication and Activity Tracking	Conversational data, hours of training, details of home, education, and training, field notes	Provide picture of homes across the intervention period and record any critical time junctures	1, 3, 4
Baseline context mapping	Description of home characteristics before EDDIE+ intervention	Provide baseline overview of home, including likely barriers and enablers of implementation	4
Check In Forms	Hours of training, EDDIE+ activities, general updates	Describe EDDIE+ activities undertaken and program progress over intervention period	1, 2, 3, 4
Semi-structured interviews	Interviews with staff, residents and family members, EDDIE+ facilitators and external stakeholders	Understand stakeholder views and experiences of EDDIE+	2, 4
Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has improved efficacy and upskilled staff	3
Family member or nominated advocate questionnaire	Traffic light system with three questions related to the EDDIE+ program	Determine family members and advocates views on the program and impact	2

178 **Table 3: Description of process evaluation data sources**

179

180 *Aims - 1: Assess the EDDIE+ intervention fidelity; 2: Assess the acceptability and views of the EDDIE+ program from the perspective of staff, resident families,

181 EDDIE+ facilitators and external stakeholders; 3: Identify mechanisms of impact; 4: Identify contextual barriers and enablers to implementation success

1
2
3 182 i-PARIHS theoretical framing
4

5
6 183 *Innovation*
7

8 184 According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced
9
10 185 if there is support for the innovation to be implemented. The innovation in this case is EDDIE+,
11
12 186 an intervention to improve the identification and management of clinical deterioration in
13
14 187 residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is
15
16 188 more likely if key stakeholders including RAC staff, managers, residents, family members and
17
18 189 external care providers, agree with the idea of keeping residents at home where possible and
19
20 190 perceive implementation to be workable in practice. In relation to EDDIE+, this includes support
21
22 191 for the education and training offered and the introduction and use of new diagnostic
23
24 192 equipment. Therefore, it will be important to collect stakeholder views on the acceptability,
25
26 193 relevance, and importance of EDDIE+ within the context of the RAC home setting.

27 194 *Recipients*
28

29 195 i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family
30
31 196 members) need both 'want to' and 'can do' factors to achieve successful implementation (15).
32
33 197 RAC staff in particular have to be motivated to address the issue of clinical deterioration in
34
35 198 residents and have the capacity and capability to implement EDDIE+. These areas will be
36
37 199 explored as part of the data collection.

38
39 200 *Context*
40

41 201 Contextual factors at multiple levels are identified as important barriers or enablers of
42
43 202 implementation in i-PARIHS and will be examined as part of the process evaluation. The inner
44
45 203 context spans the local and organisational settings. At a local level, inner context refers to the
46
47 204 immediate place of implementation - the RAC home - and encompasses factors such as the
48
49 205 workplace culture, management and leadership support, workload, receptiveness, and
50
51 206 attitudes to change. The local context is embedded within the organisational context - the aged
52
53 207 care provider organisation - where factors relating to culture, leadership, support and resources
54
55 208 are also important. Outer context relates to the wider aged care system, including policy
56
57 209 drivers, regulatory standards and frameworks, other initiatives that influence the care of

1
2
3 210 deteriorating residents, and more general health, social and economic issues that affect aged
4
5 211 care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked
6
7 212 throughout the intervention phase of the study.

9 213 *Facilitation*

11 214 Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation,
12
13 215 comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's
14
15 216 role to assess innovation, recipient and contextual factors that present barriers to or enablers
16
17 217 of implementation and plan appropriate facilitation strategies to address these. The main
18
19 218 facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to
20
21 219 support implementation, with funding provided for backfill support. The clinical facilitator
22
23 220 receives additional support from the EDDIE+ project team including the nurse educator and the
24
25 221 project implementation facilitator. This is based on a model of internal-external facilitation (16).
26
27 222 The nurse educator is responsible for developing and delivering the training on clinical
28
29 223 deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator
30
31 224 will undertake the baseline context assessment and support the clinical facilitators to develop
32
33 225 facilitation skills. As part of the process evaluation, it will be important to collect data about the
34
35 226 different facilitator roles, the strategies used to facilitate implementation and how well these
36
37 227 worked.

38 228 Process evaluation elements

40 229 *Fidelity*

42 230 Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance
43
44 231 at mandatory EDDIE+ training by nurses and personal care workers (expressed as a percentage
45
46 232 of total staff employed who attended training), number of EDDIE+ sessions delivered/attended,
47
48 233 use of the new equipment, and recruitment and retention of clinical facilitators. These data will
49
50 234 be extracted from EDDIE+ check in forms completed by the nominated clinical facilitator at
51
52 235 each site and the communication and tracking data collected from the project team, including
53
54 236 education attendance records [see Supplementary file]. Additional data sources will be used to

1
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
7
8 239 *Acceptability*

9
10 240 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
20 245 advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted
21
22 246 the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how
23
24 247 it was implemented to determine what they found most and least helpful about EDDIE+ and
25
26 248 whether they thought the intervention was transferable to other RAC homes [see
27
28 249 Supplementary files S1 and S2 for interview guides]. Additionally, a three-question traffic light
29
30 250 survey will be distributed to family members and nominated advocates to determine if their
31
32 251 experience with EDDIE+ was positive, negative, or neutral, if EDDIE+ impacted the care of their
33
34 252 loved one in a good way, and their views on whether EDDIE+ should be introduced into other
35
36 253 RAC homes [see Supplementary file S3].

37
38
39 254 *Mechanisms of impact*

40
41 255 As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce
42
43 256 improvements in resident, staff, and system level outcomes through mechanisms including
44
45 257 enhanced staff knowledge and skills, increased staff confidence and sense of empowerment,
46
47 258 and greater confidence of family members and external care providers in the ability of RAC
48
49 259 home staff to provide appropriate clinical care for residents. These mechanisms will be
50
51 260 explored through several data sources. RAC staff will be requested to complete a self-efficacy
52
53 261 survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to
54
55 262 evaluate reported changes in staff confidence and capability [Supplementary file S4].
56
57 263 Questionnaire data will be supplemented with data from semi-structured interviews conducted
58
59 264 with RAC staff, clinical facilitators, managers, and external care providers, such as general
60

1
2
3 265 practitioners, to assess mechanisms relating to confidence, staff empowerment and skills and
4
5 266 knowledge development [Supplementary files S1 and S2].
6

7 267 *Understanding barriers and enablers*

8
9
10 268 Consistent with the i-PARIHS framework, barriers and enablers to implementation will be
11
12 269 explored in relation to the EDDIE+ intervention (acceptability and feasibility), recipient
13
14 270 characteristics (RAC staff 'want to' and 'can do' factors) and the inner and outer context.
15
16 271 During semi-structured interviews, RAC staff and wider stakeholders will be asked to provide
17
18 272 specific examples of barriers and enablers of EDDIE+, what worked well (or less well) in their
19
20 273 own RAC home and what would need to be considered for future implementation in other
21
22 274 facilities. Supplementary information related to barriers and enablers will be extracted from the
23
24 275 baseline context mapping, communication and activity tracking spreadsheets and check in
25
26 276 forms completed by clinical facilitators and the nurse educator and project implementation
27
28 277 facilitator.

28 278 Setting and participant recruitment for process evaluation

29
30
31 279 Twelve Bolton Clarke Residential Aged Care Facilities in Queensland, Australia have been
32
33 280 recruited to participate in the EDDIE+ study. The stepped wedge design involved 4 phases
34
35 281 (preparation, baseline/usual care exposure, intervention introduction and intervention
36
37 282 exposure) that took place from March 2021 to May 2022. The process evaluation will be
38
39 283 conducted from May to September 2022 with data from all participating homes. This will
40
41 284 include recruitment of RAC staff, clinical facilitators, family members of residents (where
42
43 285 applicable), and local and external stakeholders including GPs, home managers and allied
44
45 286 health managers [see Table 2].
46

47 287 Quantitative Data

48
49 288 Quantitative data will be extracted from baseline context mapping, communication, activity
50
51 289 tracking and check in sheets, and resident family awareness questionnaires [see Table 2]. These
52
53 290 data will include the hours of EDDIE+ training, days of intervention exposure, home structure
54
55 291 (bed number, staff, occupancy), local services, and communication mechanisms. The evaluation
56
57 292 of these data will inform intervention fidelity.
58

1
2
3 293 Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire
4
5 294 (17). The questionnaire comprises three sections. Section one provides information about the
6
7 295 staff member's demographics, their role at the facility, years worked at the facility, years
8
9 296 worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10
10
11 297 statements related to job self-efficacy. The statements include job related confidence and
12
13 298 ability, having the required skills to perform the job well and how they compare themselves to
14
15 299 others in the field. Section three is a 5-point Likert scale with 7 statements related to team self-
16
17 300 efficacy. Section three has questions related to team members' skills, abilities, and
18
19 301 effectiveness in relation to completing their own tasks and functioning as a team.

20 302 Qualitative Data

21
22
23 303 Qualitative data will be primarily collected from a series of semi-structured interviews with
24
25 304 staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse
26
27 305 educator, project implementation facilitator and external stakeholders. Interviewees will be
28
29 306 recruited by email and direct correspondence. Staff at participating RAC sites will be invited to
30
31 307 participate in an interview by the project implementation facilitator during one of the end of
32
33 308 intervention site visits. Relevant family members and stakeholders from the participating RAC
34
35 309 homes will be identified by the EDDIE+ facilitator and BC investigators and details forwarded to
36
37 310 the QUT project team. The QUT project team will then make contact through email
38
39 311 correspondence. Once written consent is obtained, interviewee details will be passed on
40
41 312 through email to investigators leading the process evaluation (EB and GH) who will coordinate a
42
43 313 mutual time for the interview.

44 314 Participation will be voluntary and informed consent will be obtained prior to the conduct of
45
46 315 the interview. Additional qualitative data will be extracted from communication tracking field
47
48 316 notes, baseline context assessments and check in forms where relevant. These data will address
49
50 317 multiple aims of the process evaluation such as the acceptability of EDDIE+, contextual barriers
51
52 318 and enablers, and the mechanisms of action (Table 2).

53 54 319 *Staff, Local and External Stakeholder interviews*

1
2
3 320 At intervention completion the RAC staff, including those in managerial positions, and external
4
5 321 stakeholders such as GPs and allied health providers, will be invited to participate in semi-
6
7 322 structured interviews. Interviews will be up to 30 minutes in length and completed via
8
9 323 telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of
10
11 324 implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and
12
13 325 factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes [see
14
15 326 Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse
16
17 327 educator and project implementation facilitator after the completion of the trial to ascertain
18
19 328 their reflections and experience of the EDDIE+ intervention and implementation process.

20 329 *Family and nominated advocate interviews*

21
22
23 330 At intervention completion, family members and nominated advocates of residents, including
24
25 331 those who have and those who have not experienced clinical deterioration, will be invited to
26
27 332 participate in a short interview either via telephone or using Microsoft Teams. Interviews with
28
29 333 family members and advocates are anticipated to take around 15 minutes dependent upon
30
31 334 interviewee responses and knowledge of the program. Questions will explore their awareness
32
33 335 and experience of EDDIE+.

34
35 336 All interviewees who have signed the consent form and completed an interview will be
36
37 337 allocated a unique identifier to maintain confidentiality. No identifiable information will be
38
39 338 reported in the findings from these interviews. Interviews will take place up to four months
40
41 339 post-trial with a maximum of 30 interviews per stakeholder group across the 12 sites.

42 43 340 Data Analysis

44 45 46 341 *Quantitative Data*

47
48 342 Descriptive statistics related to the process evaluation (counts, mean, standard deviations) will
49
50 343 be analysed in Microsoft Excel to determine the communication level and engagement from
51
52 344 each site based on the quantity of emails, meetings, and phone calls. Job-related and team-
53
54 345 related self-efficacy data from nursing and personal care workers will be subject to descriptive
55
56 346 and inferential analysis using SPSS to assess whether EDDIE+ improved staff's perceived self-

1
2
3 347 efficacy post-intervention. The baseline self-efficacy survey will be completed immediately prior
4
5 348 to the participant's (RN, EN, PCW) first EDDIE+ training session while post intervention self-
6
7 349 efficacy surveys will be provided to staff between the final two weeks of the intervention
8
9 350 exposure and up to two weeks post trial.

10
11 351 Internal consistency of job-related and team-related self-efficacy will be assessed separately
12
13 352 using Cronbach's Alpha. Differences between mean baseline and post intervention scores on
14
15 353 the self-efficacy measures will be assessed using t-tests, to determine if there is a statistically
16
17 354 significant ($p < .05$) change in job-related self-efficacy and team-related self-efficacy. Linear
18
19 355 regression will be used to determine the contribution of staff-related factors including role,
20
21 356 experience, age, gender, and location, to changes in job-related and team-related self-efficacy
22
23 357 scores. Missing outcome data from staff lost to follow-up will be treated as missing completely
24
25 358 at random (MCAR) and handled using complete case analysis.

26 27 359 *Qualitative Data*

28
29
30 360 Semi-structured Interviews will be digitally recorded with consent from the interviewee and
31
32 361 transcribed using Microsoft software. Once transcribed and checked for accuracy, interview
33
34 362 transcripts will be mapped against the i-PARIHS constructs of innovation, recipients, context,
35
36 363 and facilitation using NVivo qualitative data software. Additionally, qualitative data will be
37
38 364 extracted from the baseline context mapping as well as communication, activity tracking and
39
40 365 check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not
41
42 366 align with the i-PARIHS framework will be analysed using a descriptive qualitative approach
43
44 367 (18). Transcripts will be read by two members of the project team with qualitative research
45
46 368 experience and content analysis will be used to code data, group codes into categories and
47
48 369 identify major themes (19). The analysis will be complete once agreement between researchers
49
50 370 is attained and no new themes emerge.

51 371 *Integrating results of data analysis*

52
53 372 Process evaluation data analysis will be undertaken independently of the analysis of the
54
55 373 effectiveness data from the trial. Once the trial results are available, combined analysis will be

1
2
3 374 undertaken to determine the extent to which the process evaluation helps explain the main
4
5 375 trial findings.

6
7
8 376 Patient and public involvement

9
10 377 There is no planned resident or public involvement in the design of the process evaluation due
11
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
18 381 process evaluation.

19
20 382 **Ethics and dissemination**

21
22 383 Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
23
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
36 390 commencement. Protocol amendments will be submitted as variations to the approving ethics
37
38 391 committees at time of identification. Additionally, the project manager will notify committees
39
40 392 in the circumstance of protocol deviations and adverse events in accordance with local
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
49 397 the research.

50
51 398 **Discussion**

52
53 399 Early detection and management of deterioration in residents of aged care homes could result
54
55 400 in a decrease of avoidable and unnecessary hospital transfers. The original EDDIE program was

1
2
3 401 considered feasible, well received, and reduced total hospital bed days by 41% (6, 7). However,
4
5 402 these promising results were inferred using a relatively small sample size and a pre-post design
6
7 403 that did not control for external trends. Following the success of EDDIE in a single site, a
8
9 404 modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled
10
11 405 trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+
12
13 406 with the aim of confirming preliminary findings and strengthening the evidence base for wider
14
15 407 implementation. The embedded process evaluation will explore whether the scaled-up
16
17 408 intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable
18
19 409 from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+
20
21 410 improved outcomes (or not), and contextual barriers and enablers that may have influenced
22
23 411 implementation. A mixed method, theory-informed approach will provide an in-depth
24
25 412 evaluation of the EDDIE+ program and valuable insights into determinants of implementation
26
27 413 success across multiple sites. This could help to identify key factors to consider in the future
28
29 414 development and implementation of hospital avoidance programs such as EDDIE+.

30 415 **Limitations**

31
32 416 Direct resident involvement in the evaluation of EDDIE+ would strengthen the process
33
34 417 evaluation, however, this is not achievable during a pandemic that has led to strict visitor
35
36 418 lockdowns in RAC. As an alternative strategy, data to reflect residents' experiences will be
37
38 419 collected from family members and nominated advocates.

39
40 420 Another potential limitation is that EDDIE+ is being implemented and evaluated with a single
41
42 421 aged care provider in Queensland which could compromise transferability to other aged care
43
44 422 settings and providers. However, the RAC facilities involved in EDDIE+ represent a range of
45
46 423 metropolitan and rural settings and different socioeconomic populations across Queensland.
47
48 424 Furthermore, the original EDDIE intervention was undertaken with a different aged care
49
50 425 provider allowing for some comparison. Applying the i-PARIHS framework to collect and analyse
51
52 426 data at an individual facility level will enable us to identify the detailed relationships between
53
54 427 contextual factors, implementation processes and outcomes, which could inform future scale-
55
56 428 up of EDDIE+. Future studies and process evaluations could further explore the generalisability

1
2
3 429 and applicability to other aged care facilities and directly involve residents in the feedback and
4
5 430 evaluation of such programs.
6

7 431 **Supplementary information**

8
9 432 Supplementary file – example data collection tools
10

11 433 **Contributors**

12
13 434 HC, NG, XL, GH, TD, LC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the
14
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
19 437 version.
20

21 438 **Competing interests**

22
23 439 None declared.
24

25 440 **Funding**

26
27 441 This project is funded by a National Health and Medical Research Council Medical Research
28
29 442 Future Fund grant (GNT1177501) and led by Queensland University of Technology. The funding
30
31 443 body did not have a role in the study design and subsequent protocol paper, nor are the
32
33 444 funders involved with ongoing data collection, management, analysis, and interpretation.
34

35 445 **Acknowledgements**

36
37 446 A collaborative research agreement is established between QUT and partnering institutions. We
38
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
43 449 University of Newcastle.
44

45 450 **References**

- 46
47 451 1. Dwyer R, Gabbe B, Stoelwinder JU, Lowthian J. A systematic review of outcomes following
48 452 emergency transfer to hospital for residents of aged care facilities. *Age Ageing*. 2014;43(6):759-66.
49 453 2. Spector WD, Limcangco R, Williams C, Rhodes W, Hurd D. Potentially avoidable hospitalizations
50 454 for elderly long-stay residents in nursing homes. *Med Care*. 2013;51(8):673-81.
51 455 3. Australian Medical Association. Putting health back into aged care. Barton, ACT; 2021.
52 456 4. Carusone SC, Loeb M, Lohfeld L. Pneumonia care and the nursing home: a qualitative descriptive
53 457 study of resident and family member perspectives. *BMC Geriatr*. 2006;6:2.
54
55
56
57
58
59
60

- 1
2
3 458 5. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Managing the deteriorating nursing home resident
4 459 after the introduction of a hospital avoidance programme: a nursing perspective. *Scand J Caring Sci.*
5 460 2017;31(2):312-22.
- 6 461 6. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Nursing staff intentions towards managing
7 462 deteriorating health in nursing homes: A convergent parallel mixed-methods study using the theory of
8 463 planned behaviour. *Journal of clinical nursing.* 2018;27(5-6):e992-e1003.
- 9 464 7. Carter HE, Lee XJ, Dwyer T, O'Neill B, Jeffrey D, Doran CM, et al. The effectiveness and cost
10 465 effectiveness of a hospital avoidance program in a residential aged care facility: a prospective cohort
11 466 study and modelled decision analysis. *BMC Geriatr.* 2020;20(1):527.
- 12 467 8. O'Neill B, Dwyer T, Parkinson L, Reid-Searl K. Identifying the core components of a nursing home
13 468 hospital avoidance program. *Int J Older People Nurs.* 2022.
- 14 469 9. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid
15 470 designs: combining elements of clinical effectiveness and implementation research to enhance public
16 471 health impact. *Med Care.* 2012;50(3):217-26.
- 17 472 10. Carter HE, Lee XJ, Farrington A, Shield C, Graves N, Cyarto EV, et al. A stepped-wedge
18 473 randomised controlled trial assessing the implementation, effectiveness and cost-consequences of the
19 474 EDDIE+ hospital avoidance program in 12 residential aged care homes: study protocol. *BMC Geriatr.*
20 475 2021;21(1):347.
- 21 476 11. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful
22 477 implementation of knowledge into practice. *Implement Sci.* 2016;11(1):33.
- 23 478 12. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of
24 479 complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.
- 25 480 13. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for
26 481 developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ.*
27 482 2021;374:n2061.
- 28 483 14. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised
29 484 controlled trials of complex interventions. *BMJ.* 2006;332(7538):413.
- 30 485 15. Weiner B. A theory of organizational readiness for change. *Implement Sci.* 2009;4(1):67.
- 31 486 16. Harvey G, Kitson A. *Implementing Evidence-Based Practice in Healthcare: A facilitation guide.*
32 487 Abingdon, Oxon.: Routledge; 2015.
- 33 488 17. Riggs ML, Warka J, Babasa B, Betancourt R, Hooker S. Development and Validation of Self-
34 489 Efficacy and Outcome Expectancy Scales for Job-Related Applications. *Educ Psychol Measur.*
35 490 1994;54(3):793-802.
- 36 491 18. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health.*
37 492 2000;23(4):334-40.
- 38 493 19. Colorafi KJ, Evans B. *Qualitative Descriptive Methods in Health Science Research.* *HERD.*
39 494 2016;9(4):16-25.

495

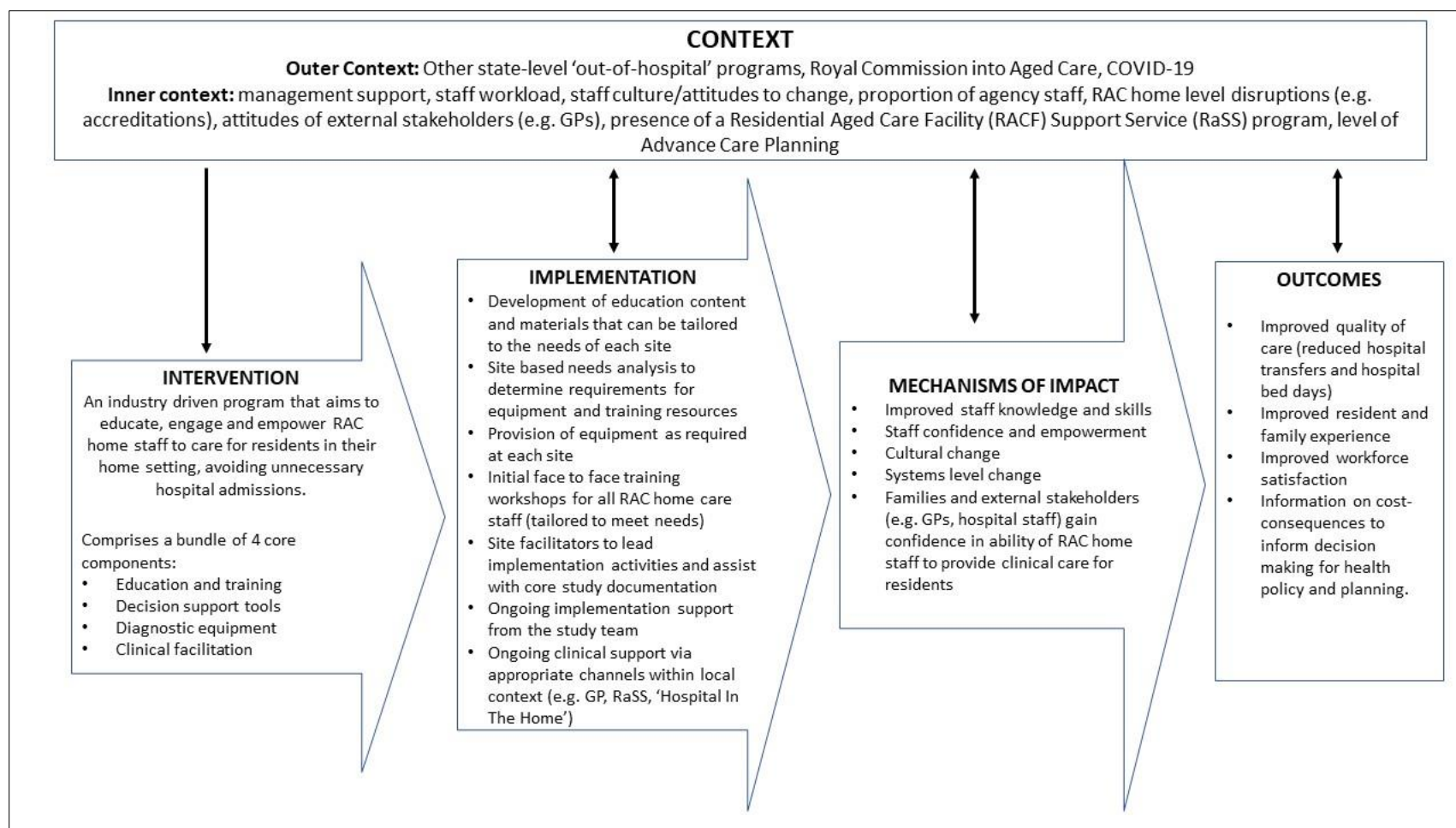


Figure 1: EDDIE+ intervention logic model

1
2
3 **EDDIE+ Supplementary file – examples of data collection tools**
4
5

6 **S1:** Family member interview guide
7

8 **S2:** Stakeholder interview guide
9

10 **S3:** Family member or nominated advocate questionnaire
11
12

13 **S4:** Staff self-efficacy survey (RN, EN, PCW)
14
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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?

S2: Stakeholder interview guide

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 style="list-style-type: none"> 1. Can you describe how the intervention was implemented? 2. Was the intervention implemented according to the implementation plan? 3. Who were the key stakeholders to get on board with the intervention? 4. To what extent were the needs and preferences of clients considered when deciding to implement the intervention?
What about the intervention worked?	<ol style="list-style-type: none"> 1. What did you like about the program? 2. What has been most helpful to you? 3. What were implementation facilitators?
What about the intervention didn't work?	<ol style="list-style-type: none"> 1. What didn't you like about the program? 2. What has been least helpful to you?
What factors will be important for scale-up and/or sustainability?	<ol style="list-style-type: none"> 1. How do you think this would work in other RAC homes? 2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	<ol style="list-style-type: none"> 1. What would need to be considered?

S3: 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 the care your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feel 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.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

3. I think the EDDIE+ program should be introduced in other Residential Aged Care homes.



Thank you for completing this survey.

For peer review only

ABOUT YOU**First, please tell us a bit about yourself:**

1. Age _____ years

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 **d** 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.

BMJ Open

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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-066857.R2
Article Type:	Protocol
Date Submitted by the Author:	30-Jan-2023
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
Primary Subject Heading:	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

SCHOLARONE™
Manuscripts

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

8
9 3 **Authors**

10 4 Ella Bracci¹, Michelle Allen², Hannah Carter², Liz Cyarto³, Trudy Dwyer⁴, Nick Graves^{2,5}, Xing
11 5 Lee³, Claudia Meyer⁶, Florin Oprescu⁷, Gill Harvey^{1,2}
12
13

14 6
15
16 7 ¹ Caring Futures Institute, College of Nursing and Health Sciences, Flinders University, Adelaide,
17 8 SA, Australia

19 9 ² Australian Centre for Health Services Innovation and Centre for Healthcare Transformation,
20 10 School of Public Health and Social Work, Queensland University of Technology, Queensland,
21 11 Australia
22

23 12 ³ School of Public Health and Social Work, Queensland University of Technology, Queensland,
24 13 Australia
25

26 14 ⁴ School of Nursing, Midwifery and Social Sciences, Central Queensland University,
27 15 Rockhampton, Australia.
28

29 16 ⁵ Duke-NUS Postgraduate Medical School, National University of Singapore, Singapore
30

31 17 ⁶ Bolton Clarke Research Institute, Forest Hill, Victoria, Australia
32

33 18 ⁷ School of Health and Behavioural Sciences, University of the Sunshine Coast, Sippy Downs,
34 19 Queensland, Australia
35

36
37 20
38
39 21 Corresponding author:

40
41 22 Gill Harvey

42
43 23 Professor of Health Services and Implementation Research, Matthew Flinders Fellow

44
45 24 Theme Lead – Better Systems, Caring Futures Institute

46
47 25 Co-Director, Aged Care Partnering Program, Aged Care Centre for Growth and Translational
48 26 Research
49

50 27 College of Nursing and Health Sciences

51
52 28 Flinders University

53
54 29 Email: gillian.harvey@flinders.edu.au
55

56 30
57
58
59
60

- 1
- 2
- 3 31 Number of references: 19
- 4
- 5 32 Abstract count: 299
- 6
- 7 33 Word count: 4394 (with tables); 3911 (without tables)
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 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
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

For peer review only

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)

1
2
3 62 application. Study findings will be disseminated through multiple channels, including journal
4
5 63 publications, conference presentations and interactive webinars with a stakeholder network.
6

7
8 **Trial registration:**

9
10 65 The trial is prospectively registered with the Australia New Zealand Clinical Trial Registry
11
12 66 (ACTRN12620000507987, registered 23/04/2020).
13

14
15 **Strengths and limitations of this study**

- 16
17 68 • Theory-informed process evaluation, framed by the integrated-Promoting Action on
18
19 69 Research Implementation in Health Services framework and an intervention logic model.
20
21 70 • Process data from a range of sources to assess implementation processes and outcomes.
22
23 71 • Outcomes could help inform planning for future development and implementation of
24
25 72 hospital avoidance strategies in residential aged care facilities.
26
27 73 • High staff turnover and workload within the residential aged care sector may impact staff
28
29 74 availability to participate in surveys and interviews.
30
31 75 • Data relating to residents' experiences will be collected from family members and
32
33 76 nominated advocates, rather than directly from residents.

34
35 **Introduction**

36
37 78 When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face
38
39 79 increased risk of hospital associated complications and invasive interventions (1). Hospital
40
41 80 presentations and admissions amongst this population group are relatively high and there is
42
43 81 evidence to suggest some hospital encounters are avoidable (2). A report published by the
44
45 82 Australian Medical Association estimated 27,000 potentially preventable admissions from RAC
46
47 83 homes in Australia in 2021, equating to 160,000 bed days with a cost of \$312 million Australian
48
49 84 dollars (3). RAC residents, family members and staff express a preference for care to be
50
51 85 provided in their home where possible (4). Previous research indicates that this is possible and
52
53 86 will reduce hospital presentations and admissions from RAC, from implementing models of care
54
55 87 that provide access to resources and improve the clinical skills and confidence of nursing staff
56
57 88 (5).
58
59
60

1
2
3 89 The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in
4
5 90 Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care
6
7 91 staff working in RAC. The aim was to empower and enable staff to identify and appropriately
8
9 92 respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE
10
11 93 demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital
12
13 94 transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+
14
15 95 builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable
16
17 96 hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge
18
19 97 randomized controlled effectiveness-implementation trial (9) with embedded economic and
20
21 98 mixed methods process evaluation. Details of the trial, which involves 12 participating RAC
22
23 99 homes in metropolitan and regional Queensland, have been described in a previously published
24
25 100 trial protocol paper (10). This paper presents the protocol for the process evaluation
26
27 101 component of the study. Process evaluations are increasingly recognised as an important part
28
29 102 of developing and testing complex interventions such as EDDIE+, which comprises multiple
30
31 103 components and is implemented across multiple sites (11,12). Process evaluations often include
32
33 104 assessing an intervention's fidelity, namely, if the intervention was implemented as intended,
34
35 105 the acceptability of an intervention from various stakeholder perspectives, the mechanism of
36
37 106 impact, or what initiates a change, and an assessment of barriers and enablers to
38
39 107 implementation.

108 The EDDIE+ Intervention

40
41 109 EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them
42
43 110 the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract
44
45 111 infections, chest pain, falls and dyspnoea within the home setting. It comprises four
46
47 112 components: advanced clinical skills education and training (provided initially by a project-
48
49 113 funded nurse educator), decision support tools, provision of diagnostic equipment (for
50
51 114 example, bladder scanners and vital signs monitors) and implementation facilitation and
52
53 115 support (via a locally appointed clinical facilitator supported by a project implementation
54
55 116 facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation
56
57 117 framework, the integrated Promoting Action of Research Implementation in Health Services (i-

1
2
3 118 PARIHS) framework (13). i-PARIHS proposes that the successful implementation of evidence-
4
5 119 informed innovations results from the active facilitation of an innovation with the intended
6
7 120 recipients of implementation within their local, organisational and system context. As such,
8
9 121 attention to facilitation, engagement with RAC stakeholders, involvement of staff and
10
11 122 responsiveness to context are key features of EDDIE+.

12
13 123 By embedding implementation facilitation within the bundle of components that comprise
14
15 124 EDDIE+, implementation is integral to the intervention. Consistent with facilitation as a primary
16
17 125 implementation strategy, clinical facilitators can tailor the implementation of EDDIE+ according
18
19 126 to their own home's needs. This will be achieved through the identification of core and
20
21 127 adaptable features of each EDDIE+ component [Table 1].

22
23 128 Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce
24
25 129 intended changes to processes and outcomes of care.

26
27 130 [Figure 1 about here]

28
29
30 131

31 32 132 **Methods and analysis**

33 34 133 Process evaluation

35
36
37 134 While the trial component of the study focuses on intervention effectiveness, the process
38
39 135 evaluation aims to understand how and why the intervention works in real-world contexts. This
40
41 136 involves examining whether the intervention has been implemented as planned and resulted in
42
43 137 expected outcomes. Understanding whether and how an intervention is affecting change can
44
45 138 provide insights into the processes of implementation and the extent to which these account
46
47 139 for positive or negative study outcomes. This is particularly helpful if the actual study outcomes
48
49 140 differ from expected outcomes, enabling the study team to understand whether there has been
50
51 141 implementation failure, such as poor delivery of the intervention, or intervention failure, such
52
53 142 as poor or inappropriate design (14). This might inform planning of future interventions and
54
55 143 implementation strategies.

EDDIE+ Component	Fixed element (core)	Flexible element (adaptable)
Advanced clinical skills education and training	Initial training mandatory for Registered Nurses, Enrolled Nurses, and Personal Care Workers	Mode of delivery Timing and organisation of sessions
	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 conditions covered Mode of delivery Staff involved in training
	Core set of educational materials	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 (e.g., track & trigger tool) Communication tool (e.g., ISBAR - (Introduction, Situation, 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 individual home needs
Implementation facilitation and support	Appointment of clinical facilitator	Role-sharing by 2 staff members
	Train-the-trainer model for clinical facilitator	Opt-in by other Registered Nurses
	Communication channel established for discussing concerns about resident deterioration and/or need for hospital transfer	Tailored to individual home needs

144 **Table 1: Core and adaptable components of EDDIE+ intervention**

1
2
3 145 To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will
4
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 Aims

19
20
21 154 The aim of the process evaluation is to track the implementation of EDDIE+ in the 12
22
23 155 participating RAC homes to:

- 24
25
26 156 1. Assess EDDIE+ intervention fidelity
- 27
28 157 2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family
29
30 158 members, EDDIE+ facilitators and wider stakeholders
- 31
32 159 3. Identify the mechanisms of impact
- 33
34 160 4. Identify contextual barriers and enablers of implementation.

35 36 Study Design and Data Collection

37
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
43 164 mechanisms of impact, and contextual barriers and enablers within and across the 12 regional
44
45 165 and metropolitan homes. Data from all four intervention phases of the stepped wedge trial will
46
47 166 be collected and analysed. These are the preparation, baseline exposure, intervention
48
49 167 introduction and intervention exposure phases.

50
51 168 We first summarise how the theoretical propositions of the i-PARIHS framework inform the
52
53 169 questions of interest within the process evaluation, before describing the methods of data
54
55 170 collection and analysis (Tables 2 and 3).

171

172

		Data Source						Data Analysis Approach	
i-PARIHS Constructs	Process Evaluation Component	EDDIE+ Check in Form	Comm and Activity Tracking	Context mapping	Interviews	Self-Efficacy Surveys	Family advocate questionnaire	Quantitative	Qualitative
Innovation and Recipients	Fidelity	✓	✓		✓			✓	✓
	Acceptability	✓	✓		✓		✓		✓
Facilitation	Mechanisms of Impact	✓			✓	✓		✓	✓
Context	Barriers and Enablers	✓	✓	✓	✓				✓

173 **Table 2. Overview of process evaluation data collection and analysis**

174

175

176

177

Data Source	Description	Purpose	Aim*
Communication and Activity Tracking	Conversational data, hours of training, details of home, education, and training, field notes	Provide picture of homes across the intervention period and record any critical time junctures	1, 3, 4
Baseline context mapping	Description of home characteristics before EDDIE+ intervention	Provide baseline overview of home, including likely barriers and enablers of implementation	4
Check In Forms	Hours of training, EDDIE+ activities, general updates	Describe EDDIE+ activities undertaken and program progress over intervention period	1, 2, 3, 4
Semi-structured interviews	Interviews with staff, residents and family members, EDDIE+ facilitators and external stakeholders	Understand stakeholder views and experiences of EDDIE+	2, 4
Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has improved efficacy and upskilled staff	3
Family member or nominated advocate questionnaire	Traffic light system with three questions related to the EDDIE+ program	Determine family members and advocates views on the program and impact	2

178 **Table 3: Description of process evaluation data sources**

179

180 *Aims - 1: Assess the EDDIE+ intervention fidelity; 2: Assess the acceptability and views of the EDDIE+ program from the perspective of staff, resident families,

181 EDDIE+ facilitators and external stakeholders; 3: Identify mechanisms of impact; 4: Identify contextual barriers and enablers to implementation success

1
2
3 182 i-PARIHS theoretical framing
4

5
6 183 *Innovation*
7

8 184 According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced
9
10 185 if there is support for the innovation to be implemented. The innovation in this case is EDDIE+,
11
12 186 an intervention to improve the identification and management of clinical deterioration in
13
14 187 residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is
15
16 188 more likely if key stakeholders including RAC staff, managers, residents, family members and
17
18 189 external care providers, agree with the idea of keeping residents at home where possible and
19
20 190 perceive implementation to be workable in practice. In relation to EDDIE+, this includes support
21
22 191 for the education and training offered and the introduction and use of new diagnostic
23
24 192 equipment. Therefore, it will be important to collect stakeholder views on the acceptability,
25
26 193 relevance, and importance of EDDIE+ within the context of the RAC home setting.

27 194 *Recipients*
28

29 195 i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family
30
31 196 members) need both 'want to' and 'can do' factors to achieve successful implementation (15).
32
33 197 RAC staff in particular have to be motivated to address the issue of clinical deterioration in
34
35 198 residents and have the capacity and capability to implement EDDIE+. These areas will be
36
37 199 explored as part of the data collection.

38
39 200 *Context*
40

41 201 Contextual factors at multiple levels are identified as important barriers or enablers of
42
43 202 implementation in i-PARIHS and will be examined as part of the process evaluation. The inner
44
45 203 context spans the local and organisational settings. At a local level, inner context refers to the
46
47 204 immediate place of implementation - the RAC home - and encompasses factors such as the
48
49 205 workplace culture, management and leadership support, workload, receptiveness, and
50
51 206 attitudes to change. The local context is embedded within the organisational context - the aged
52
53 207 care provider organisation - where factors relating to culture, leadership, support and resources
54
55 208 are also important. Outer context relates to the wider aged care system, including policy
56
57 209 drivers, regulatory standards and frameworks, other initiatives that influence the care of

1
2
3 210 deteriorating residents, and more general health, social and economic issues that affect aged
4
5 211 care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked
6
7 212 throughout the intervention phase of the study.
8

9 213 *Facilitation*

10
11 214 Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation,
12
13 215 comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's
14
15 216 role to assess innovation, recipient and contextual factors that present barriers to or enablers
16
17 217 of implementation and plan appropriate facilitation strategies to address these. The main
18
19 218 facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to
20
21 219 support implementation, with funding provided for backfill support. The clinical facilitator
22
23 220 receives additional support from the EDDIE+ project team including the nurse educator and the
24
25 221 project implementation facilitator. This is based on a model of internal-external facilitation (16).
26
27 222 The nurse educator is responsible for developing and delivering the training on clinical
28
29 223 deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator
30
31 224 will undertake the baseline context assessment and support the clinical facilitators to develop
32
33 225 facilitation skills. As part of the process evaluation, it will be important to collect data about the
34
35 226 different facilitator roles, the strategies used to facilitate implementation and how well these
36
37 227 worked.

38 228 Process evaluation elements

39 229 *Fidelity*

40
41
42 230 Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance
43
44 231 at mandatory EDDIE+ training by nurses and personal care workers (expressed as a percentage
45
46 232 of total staff employed who attended training), number of EDDIE+ sessions delivered/attended,
47
48 233 use of the new equipment, and recruitment and retention of clinical facilitators. These data will
49
50 234 be extracted from EDDIE+ check in forms completed by the nominated clinical facilitator at
51
52 235 each site and the communication and tracking data collected from the project team, including
53
54 236 education attendance records [see Supplementary file]. Additional data sources will be used to
55
56
57

1
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
7
8 239 *Acceptability*

9
10 240 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
20 245 advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted
21
22 246 the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how
23
24 247 it was implemented to determine what they found most and least helpful about EDDIE+ and
25
26 248 whether they thought the intervention was transferable to other RAC homes [see
27
28 249 Supplementary files S1 and S2 for interview guides]. Additionally, a three-question traffic light
29
30 250 survey will be distributed to family members and nominated advocates to determine if their
31
32 251 experience with EDDIE+ was positive, negative, or neutral, if EDDIE+ impacted the care of their
33
34 252 loved one in a good way, and their views on whether EDDIE+ should be introduced into other
35
36 253 RAC homes [see Supplementary file S3].

37
38
39 254 *Mechanisms of impact*

40
41 255 As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce
42
43 256 improvements in resident, staff, and system level outcomes through mechanisms including
44
45 257 enhanced staff knowledge and skills, increased staff confidence and sense of empowerment,
46
47 258 and greater confidence of family members and external care providers in the ability of RAC
48
49 259 home staff to provide appropriate clinical care for residents. These mechanisms will be
50
51 260 explored through several data sources. RAC staff will be requested to complete a self-efficacy
52
53 261 survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to
54
55 262 evaluate reported changes in staff confidence and capability [Supplementary file S4].
56
57 263 Questionnaire data will be supplemented with data from semi-structured interviews conducted
58
59 264 with RAC staff, clinical facilitators, managers, and external care providers, such as general
60

1
2
3 265 practitioners, to assess mechanisms relating to confidence, staff empowerment and skills and
4
5 266 knowledge development [Supplementary files S1 and S2].
6

7 267 *Understanding barriers and enablers*

8
9
10 268 Consistent with the i-PARIHS framework, barriers and enablers to implementation will be
11
12 269 explored in relation to the EDDIE+ intervention (acceptability and feasibility), recipient
13
14 270 characteristics (RAC staff 'want to' and 'can do' factors) and the inner and outer context.
15
16 271 During semi-structured interviews, RAC staff and wider stakeholders will be asked to provide
17
18 272 specific examples of barriers and enablers of EDDIE+, what worked well (or less well) in their
19
20 273 own RAC home and what would need to be considered for future implementation in other
21
22 274 facilities. Supplementary information related to barriers and enablers will be extracted from the
23
24 275 baseline context mapping, communication and activity tracking spreadsheets and check in
25
26 276 forms completed by clinical facilitators and the nurse educator and project implementation
27
28 277 facilitator.

28 278 Setting and participant recruitment for process evaluation

29
30
31 279 Twelve Bolton Clarke Residential Aged Care Facilities in Queensland, Australia have been
32
33 280 recruited to participate in the EDDIE+ study. The stepped wedge design involved 4 phases
34
35 281 (preparation, baseline/usual care exposure, intervention introduction and intervention
36
37 282 exposure) that took place from March 2021 to May 2022. The process evaluation will be
38
39 283 conducted from May to September 2022 with data from all participating homes. This will
40
41 284 include recruitment of RAC staff, clinical facilitators, family members of residents (where
42
43 285 applicable), and local and external stakeholders including GPs, home managers and allied
44
45 286 health managers [see Table 2].
46

47 287 Quantitative Data

48
49 288 Quantitative data will be extracted from baseline context mapping, communication, activity
50
51 289 tracking and check in sheets, and resident family awareness questionnaires [see Table 2]. These
52
53 290 data will include the hours of EDDIE+ training, days of intervention exposure, home structure
54
55 291 (bed number, staff, occupancy), local services, and communication mechanisms. The evaluation
56
57 292 of these data will inform intervention fidelity.
58

1
2
3 293 Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire
4
5 294 (17). The questionnaire comprises three sections. Section one provides information about the
6
7 295 staff member's demographics, their role at the facility, years worked at the facility, years
8
9 296 worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10
10
11 297 statements related to job self-efficacy. The statements include job related confidence and
12
13 298 ability, having the required skills to perform the job well and how they compare themselves to
14
15 299 others in the field. Section three is a 5-point Likert scale with 7 statements related to team self-
16
17 300 efficacy. Section three has questions related to team members' skills, abilities, and
18
19 301 effectiveness in relation to completing their own tasks and functioning as a team.

20 302 Qualitative Data

21
22
23 303 Qualitative data will be primarily collected from a series of semi-structured interviews with
24
25 304 staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse
26
27 305 educator, project implementation facilitator and external stakeholders. Interviewees will be
28
29 306 recruited by email and direct correspondence. Staff at participating RAC sites will be invited to
30
31 307 participate in an interview by the project implementation facilitator during one of the end of
32
33 308 intervention site visits. Relevant family members and stakeholders from the participating RAC
34
35 309 homes will be identified by the EDDIE+ facilitator and BC investigators and details forwarded to
36
37 310 the QUT project team. The QUT project team will then make contact through email
38
39 311 correspondence. Once written consent is obtained, interviewee details will be passed on
40
41 312 through email to investigators leading the process evaluation (EB and GH) who will coordinate a
42
43 313 mutual time for the interview.

44 314 Participation will be voluntary and informed consent will be obtained prior to the conduct of
45
46 315 the interview. Additional qualitative data will be extracted from communication tracking field
47
48 316 notes, baseline context assessments and check in forms where relevant. These data will address
49
50 317 multiple aims of the process evaluation such as the acceptability of EDDIE+, contextual barriers
51
52 318 and enablers, and the mechanisms of action (Table 2).

53 54 319 *Staff, Local and External Stakeholder interviews*

1
2
3 320 At intervention completion the RAC staff, including those in managerial positions, and external
4
5 321 stakeholders such as GPs and allied health providers, will be invited to participate in semi-
6
7 322 structured interviews. Interviews will be up to 30 minutes in length and completed via
8
9 323 telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of
10
11 324 implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and
12
13 325 factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes [see
14
15 326 Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse
16
17 327 educator and project implementation facilitator after the completion of the trial to ascertain
18
19 328 their reflections and experience of the EDDIE+ intervention and implementation process.

20 329 *Family and nominated advocate interviews*

21
22
23 330 At intervention completion, family members and nominated advocates of residents, including
24
25 331 those who have and those who have not experienced clinical deterioration, will be invited to
26
27 332 participate in a short interview either via telephone or using Microsoft Teams. Interviews with
28
29 333 family members and advocates are anticipated to take around 15 minutes dependent upon
30
31 334 interviewee responses and knowledge of the program. Questions will explore their awareness
32
33 335 and experience of EDDIE+.

34
35 336 All interviewees who have signed the consent form and completed an interview will be
36
37 337 allocated a unique identifier to maintain confidentiality. No identifiable information will be
38
39 338 reported in the findings from these interviews. Interviews will take place up to four months
40
41 339 post-trial with a maximum of 30 interviews per stakeholder group across the 12 sites.

42 43 340 Data Analysis

44 45 46 341 *Quantitative Data*

47
48 342 Descriptive statistics related to the process evaluation (counts, mean, standard deviations) will
49
50 343 be analysed in Microsoft Excel to determine the communication level and engagement from
51
52 344 each site based on the quantity of emails, meetings, and phone calls. Job-related and team-
53
54 345 related self-efficacy data from nursing and personal care workers will be subject to descriptive
55
56 346 and inferential analysis using SPSS to assess whether EDDIE+ improved staff's perceived self-

1
2
3 347 efficacy post-intervention. The baseline self-efficacy survey will be completed immediately prior
4
5 348 to the participant's (RN, EN, PCW) first EDDIE+ training session while post intervention self-
6
7 349 efficacy surveys will be provided to staff between the final two weeks of the intervention
8
9 350 exposure and up to two weeks post trial.

10
11 351 Internal consistency of job-related and team-related self-efficacy will be assessed separately
12
13 352 using Cronbach's Alpha. Differences between mean baseline and post intervention scores on
14
15 353 the self-efficacy measures will be assessed using t-tests, to determine if there is a statistically
16
17 354 significant ($p < .05$) change in job-related self-efficacy and team-related self-efficacy. Linear
18
19 355 regression will be used to determine the contribution of staff-related factors including role,
20
21 356 experience, age, gender, and location, to changes in job-related and team-related self-efficacy
22
23 357 scores. Missing outcome data from staff lost to follow-up will be treated as missing completely
24
25 358 at random (MCAR) and handled using complete case analysis.

26 27 359 *Qualitative Data*

28
29
30 360 Semi-structured Interviews will be digitally recorded with consent from the interviewee and
31
32 361 transcribed using Microsoft software. Once transcribed and checked for accuracy, interview
33
34 362 transcripts will be mapped against the i-PARIHS constructs of innovation, recipients, context,
35
36 363 and facilitation using NVivo qualitative data software. Additionally, qualitative data will be
37
38 364 extracted from the baseline context mapping as well as communication, activity tracking and
39
40 365 check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not
41
42 366 align with the i-PARIHS framework will be analysed using a descriptive qualitative approach
43
44 367 (18). Transcripts will be read by two members of the project team with qualitative research
45
46 368 experience and content analysis will be used to code data, group codes into categories and
47
48 369 identify major themes (19). The analysis will be complete once agreement between researchers
49
50 370 is attained and no new themes emerge.

51 371 *Integrating results of data analysis*

52
53 372 Process evaluation data analysis will be undertaken independently of the analysis of the
54
55 373 effectiveness data from the trial. Once the trial results are available, combined analysis will be

1
2
3 374 undertaken to determine the extent to which the process evaluation helps explain the main
4
5 375 trial findings.

6
7
8 376 Patient and public involvement

9
10 377 There is no planned resident or public involvement in the design of the process evaluation due
11
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
18 381 process evaluation.

19
20 382 **Ethics and dissemination**

21
22 383 Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
23
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
36 390 commencement. Protocol amendments will be submitted as variations to the approving ethics
37
38 391 committees at time of identification. Additionally, the project manager will notify committees
39
40 392 in the circumstance of protocol deviations and adverse events in accordance with local
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
49 397 the research.

50
51 398 **Discussion**

52
53 399 Early detection and management of deterioration in residents of aged care homes could result
54
55 400 in a decrease of avoidable and unnecessary hospital transfers. The original EDDIE program was

1
2
3 401 considered feasible, well received, and reduced total hospital bed days by 41% (6, 7). However,
4
5 402 these promising results were inferred using a relatively small sample size and a pre-post design
6
7 403 that did not control for external trends. Following the success of EDDIE in a single site, a
8
9 404 modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled
10
11 405 trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+
12
13 406 with the aim of confirming preliminary findings and strengthening the evidence base for wider
14
15 407 implementation. The embedded process evaluation will explore whether the scaled-up
16
17 408 intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable
18
19 409 from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+
20
21 410 improved outcomes (or not), and contextual barriers and enablers that may have influenced
22
23 411 implementation. A mixed method, theory-informed approach will provide an in-depth
24
25 412 evaluation of the EDDIE+ program and valuable insights into determinants of implementation
26
27 413 success across multiple sites. This could help to identify key factors to consider in the future
28
29 414 development and implementation of hospital avoidance programs such as EDDIE+.

30 415 **Limitations**

31
32 416 Direct resident involvement in the evaluation of EDDIE+ would strengthen the process
33
34 417 evaluation, however, this is not achievable during a pandemic that has led to strict visitor
35
36 418 lockdowns in RAC. As an alternative strategy, data to reflect residents' experiences will be
37
38 419 collected from family members and nominated advocates.

39
40 420 Another potential limitation is that EDDIE+ is being implemented and evaluated with a single
41
42 421 aged care provider in Queensland which could compromise transferability to other aged care
43
44 422 settings and providers. However, the RAC facilities involved in EDDIE+ represent a range of
45
46 423 metropolitan and rural settings and different socioeconomic populations across Queensland.
47
48 424 Furthermore, the original EDDIE intervention was undertaken with a different aged care
49
50 425 provider allowing for some comparison. Applying the i-PARIHS framework to collect and analyse
51
52 426 data at an individual facility level will enable us to identify the detailed relationships between
53
54 427 contextual factors, implementation processes and outcomes, which could inform future scale-
55
56 428 up of EDDIE+. Future studies and process evaluations could further explore the generalisability

1
2
3 429 and applicability to other aged care facilities and directly involve residents in the feedback and
4
5 430 evaluation of such programs.
6

7 431 **Supplementary information**

8
9 432 Supplementary file – example data collection tools
10

11 433 **Contributors**

12
13 434 HC, NG, XL, GH, TD, LC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the
14
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
19 437 version.
20

21 438 **Competing interests**

22
23 439 None declared.
24

25 440 **Funding**

26
27 441 This project is funded by a National Health and Medical Research Council Medical Research
28
29 442 Future Fund grant (GNT1177501) and led by Queensland University of Technology. The funding
30
31 443 body did not have a role in the study design and subsequent protocol paper, nor are the
32
33 444 funders involved with ongoing data collection, management, analysis, and interpretation.
34

35 445 **Acknowledgements**

36
37 446 A collaborative research agreement is established between QUT and partnering institutions. We
38
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
43 449 University of Newcastle.
44

45 450 **References**

- 46
47 451 1. Dwyer R, Gabbe B, Stoelwinder JU, Lowthian J. A systematic review of outcomes following
48 452 emergency transfer to hospital for residents of aged care facilities. *Age Ageing*. 2014;43(6):759-66.
49 453 2. Spector WD, Limcangco R, Williams C, Rhodes W, Hurd D. Potentially avoidable hospitalizations
50 454 for elderly long-stay residents in nursing homes. *Med Care*. 2013;51(8):673-81.
51 455 3. Australian Medical Association. Putting health back into aged care. Barton, ACT; 2021.
52 456 4. Carusone SC, Loeb M, Lohfeld L. Pneumonia care and the nursing home: a qualitative descriptive
53 457 study of resident and family member perspectives. *BMC Geriatr*. 2006;6:2.
54
55
56
57
58
59
60

5. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Managing the deteriorating nursing home resident after the introduction of a hospital avoidance programme: a nursing perspective. *Scand J Caring Sci.* 2017;31(2):312-22.
6. O'Neill BJ, Dwyer T, Reid-Searl K, Parkinson L. Nursing staff intentions towards managing deteriorating health in nursing homes: A convergent parallel mixed-methods study using the theory of planned behaviour. *Journal of clinical nursing.* 2018;27(5-6):e992-e1003.
7. Carter HE, Lee XJ, Dwyer T, O'Neill B, Jeffrey D, Doran CM, et al. The effectiveness and cost effectiveness of a hospital avoidance program in a residential aged care facility: a prospective cohort study and modelled decision analysis. *BMC Geriatr.* 2020;20(1):527.
8. O'Neill B, Dwyer T, Parkinson L, Reid-Searl K. Identifying the core components of a nursing home hospital avoidance program. *Int J Older People Nurs.* 2022.
9. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* 2012;50(3):217-26.
10. Carter HE, Lee XJ, Farrington A, Shield C, Graves N, Cyarto EV, et al. A stepped-wedge randomised controlled trial assessing the implementation, effectiveness and cost-consequences of the EDDIE+ hospital avoidance program in 12 residential aged care homes: study protocol. *BMC Geriatr.* 2021;21(1):347.
11. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.
12. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ.* 2021;374:n2061.
13. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implement Sci.* 2016;11(1):33.
14. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ.* 2006;332(7538):413.
15. Weiner B. A theory of organizational readiness for change. *Implement Sci.* 2009;4(1):67.
16. Harvey G, Kitson A. *Implementing Evidence-Based Practice in Healthcare: A facilitation guide.* Abingdon, Oxon.: Routledge; 2015.
17. Riggs ML, Warka J, Babasa B, Betancourt R, Hooker S. Development and Validation of Self-Efficacy and Outcome Expectancy Scales for Job-Related Applications. *Educ Psychol Measur.* 1994;54(3):793-802.
18. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health.* 2000;23(4):334-40.
19. Colorafi KJ, Evans B. *Qualitative Descriptive Methods in Health Science Research.* HERD. 2016;9(4):16-25.

495

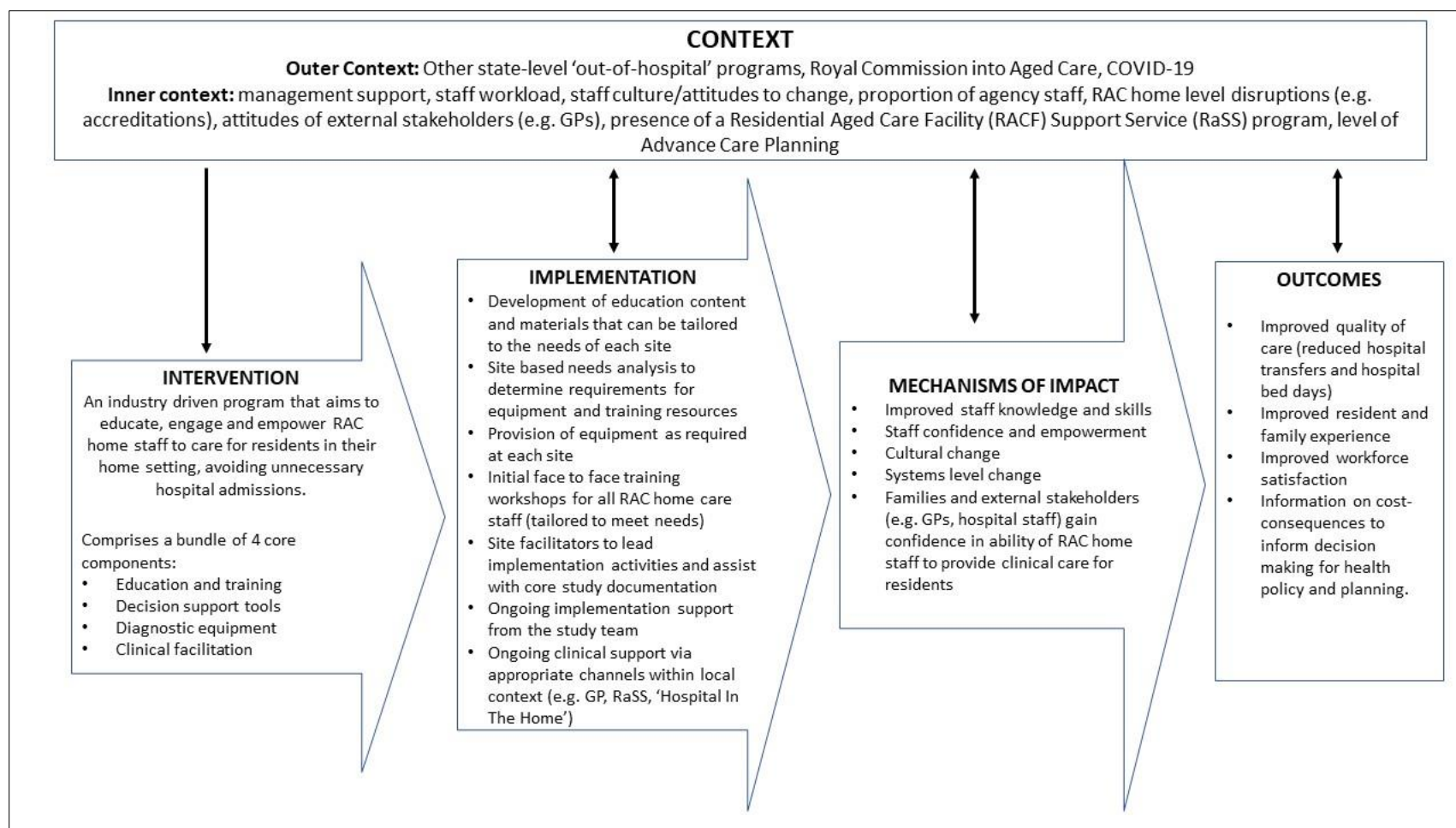


Figure 1: EDDIE+ intervention logic model

1
2
3 **EDDIE+ Supplementary file – examples of data collection tools**
4
5

6 **S1:** Family member interview guide
7

8 **S2:** Stakeholder interview guide
9

10 **S3:** Family member or nominated advocate questionnaire
11
12

13 **S4:** Staff self-efficacy survey (RN, EN, PCW)
14
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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?

S2: Stakeholder interview guide

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 style="list-style-type: none"> 1. Can you describe how the intervention was implemented? 2. Was the intervention implemented according to the implementation plan? 3. Who were the key stakeholders to get on board with the intervention? 4. To what extent were the needs and preferences of clients considered when deciding to implement the intervention?
What about the intervention worked?	<ol style="list-style-type: none"> 1. What did you like about the program? 2. What has been most helpful to you? 3. What were implementation facilitators?
What about the intervention didn't work?	<ol style="list-style-type: none"> 1. What didn't you like about the program? 2. What has been least helpful to you?
What factors will be important for scale-up and/or sustainability?	<ol style="list-style-type: none"> 1. How do you think this would work in other RAC homes? 2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	<ol style="list-style-type: none"> 1. What would need to be considered?

S3: 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 the care your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feel 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.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
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
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

3. I think the EDDIE+ program should be introduced in other Residential Aged Care homes.



Thank you for completing this survey.

For peer review only

ABOUT YOU**First, please tell us a bit about yourself:**

1. Age _____ years

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 **d** 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.