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Implementing an Allied Health Team Intervention to Improve the Care of Older Adults in the Emergency Department: Protocol for a Process Evaluation

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5 2 Adults in the Emergency Department: Protocol for a Process Evaluation
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35 **ABSTRACT**

36 **Introduction:** Health and Social Care Professionals (HSCPs) have increasingly
37 contributed to enhance the care of patients in Emergency Departments (EDs), particularly for
38 older adults who are frequent ED attendees with significant adverse outcomes. For the first
39 time, the effectiveness of a HSCP team intervention for older adults in the ED has been tested
40 in a large randomised controlled trial, providing an opportunity to explore the implementation
41 process for this type of intervention. This protocol describes a process evaluation that will to
42 investigate the implementation, delivery and impact of an HSCP team intervention in the ED.

43 **Methods and analysis:** Using the Medical Research Council (MRC) Framework for
44 process evaluations, we will employ a mixed-methods approach to provide a description of
45 the process of implementation and delivery of the HSCP intervention in the ED, evaluate its
46 fidelity, dose and reach, and explore the perceptions of key staff members in relations to the
47 mechanisms and contexts of impact at the levels of individuals, physical environment,
48 operations, communication and the broader hospital and healthcare system.

49 **Ethics and dissemination:** Ethical approval for this study was received from the HSE
50 Mid-Western Regional Hospital Research Ethics Committee (Ref: 103/18). All participants
51 will be invited to read and sign a written consent form prior to participation. The results of
52 this review will be disseminated through publication in a peer-review journal and presented at
53 relevant conferences.

52 **ARTICLE SUMMARY**

55 **Strengths and limitations of this study:**

- 1
2
3 57 - This is the first formal process evaluation of the implementation of a Health
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5 58 and Social Care Professional team caring for older patients in the emergency
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7 department.
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10 60 - The study will employ the Medical Research Council framework for process
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12 61 evaluations.
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14 62 - This study will adopt a mixed-methods approach and involve different
15
16 stakeholders to investigate the implementation, delivery and impact of the
17 63 allied health intervention.
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19 64
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21 65 - Findings will provide key information for future implementations of allied
22
23 health teams in emergency care settings.
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29 68 **Keywords:** Allied health; emergency department; process evaluation;
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31 69 implementation; interdisciplinary care; health service delivery.
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71 INTRODUCTION

72 Background

73 Complex interventions have been increasingly employed in an attempt to enhance
74 health service delivery as well as other societal issues [1]. Randomised controlled trials
75 (RCTs) are traditionally considered as the reference standard for establishing the
76 effectiveness of interventions [1,2]. Recent efforts have been made to include process
77 evaluations as a core component of investigations of effectiveness, as stated in a recent
78 Medical Research Council (MRC) guidance document [1]. Conducting a process evaluation
79 of an intervention, particularly in the case of complex quality improvement interventions, is
80 important to gain a deeper understanding of the mechanisms influencing effectiveness (or
81 lack of it), to explain discrepancies between expected and observed outcomes, to highlight
82 the complexities of an intervention and the impact of contextual factors on outcomes, and
83 thus to better inform implementation [2–4].

84 The MRC framework highlights three key functions of process evaluations: 1)
85 examining the implementation process and its content (fidelity-adaptation, dose and reach);
86 2) understanding the mechanisms of impact (participants' response to the intervention;
87 mediators; unexpected pathways and consequences); 3) investigating the influence of the
88 context of the intervention. Such a framework enables to capture the complexities of
89 developing and implementing a health service intervention, so to offer useful insights for
90 future quality improvement. In this process evaluation, we aim to use the MRC framework to
91 evaluate the process, delivery and impact of the implementation of an allied health team-
92 based intervention within an emergency setting.

93 **Intervention characteristics**

94 The present process evaluation will explore the process of implementation of the
95 OPTIMEND intervention (i.e., “Optimising early assessment and intervention by Health and
96 Social Care Professionals in the Emergency Department”). OPTIMEND is the first
97 randomised controlled trial aimed to measure the impact of early assessment and intervention
98 by a team of Health and Social Care Professionals (HSCPs) working in the Emergency
99 Department (ED) on the quality, safety and cost-effectiveness of care for older adults, as
100 compared to usual ED care. The HSCP team comprises of a senior physiotherapist, a senior
101 occupational therapist, and a senior medical social worker providing functional assessment,
102 early interventions and discharge plans to adults aged ≥ 65 years. A total of 354 participants
103 were recruited in the study from December 2018 until May 2019 and randomly allocated to
104 the HSCP intervention or ED usual care (i.e., medical team). Participants in both intervention
105 and control groups are followed-up through telephone assessment at 30 days, four and six
106 months after the ED index visit (ongoing until November 2019). Primary outcomes of the
107 trial include ED length of stay and rates of hospital admissions. Secondary outcomes include
108 function and quality of life (baseline and follow-up), satisfaction with care, ED re-visits and
109 healthcare utilisation (follow-up), and cost-effectiveness.

110 Following the MRC framework for complex interventions [1], the design of the trial
111 was informed by a systematic review of the existing international literature regarding the
112 effectiveness of HSCP interventions in the ED [5]. A qualitative study was also conducted
113 with a range of stakeholders including ED patients and their families, ED staff, HSCPs and
114 pre-hospital staff to explore their views on the role and impact of HSCPs working in teams in
115 the ED. A paper reporting the findings of this phase is currently in submission. We also
116 carried out an analysis of routine observational data to describe the flow of patients who
117 attend a large Irish ED without a dedicated HSCP team in the ED. Allied health team services

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3 118 in the ED are routine practice in certain areas, such as in Australia [6]; however, the evidence
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5 119 on the impact HSCP teams on the quality, safety and cost-effectiveness of care is limited and
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7 120 heterogeneous. For this reason, there is a dearth of evaluations available on the
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10 121 implementation, delivery and impact of this model of care, often limited to investigations of
11
12 122 acceptability or patient/staff satisfaction [7–9]. The OPTIMEND is the first study
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14 123 internationally to test the effectiveness an ED-based HSCP team intervention by adopting a
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16
17 124 robust methodology, thus offering the opportunity to evaluate its implementation.

125 **Theoretical framework**

126 The causal assumptions of the intervention and theoretical framework guiding this
127 evaluation are outlined in the logic model presented in Figure 1, based on logic models
128 recommended elsewhere [2,10]. A key input for the intervention came from the emergency
129 care national priorities set by the ED taskforce within the Health Service Executive (HSE) in
130 Ireland, which included improving workforce and interdisciplinary care in emergency
131 settings in order to enhance patient and process outcomes [11]; following this, funding was
132 secured for the design and implementation of an HSCP team intervention in the ED of a
133 regional hospital in Ireland with a large catchment area, using the MRC framework for
134 complex interventions. A synthesis of the evidence on this model of care and consultations
135 with relevant stakeholders, as described in the previous section, informed the development of
136 the intervention. Key assumptions of this HSCP intervention were that having a
137 multidisciplinary team of professionals with specialised skills in the care of the older person
138 would enhance the quality and timeliness of decision-making (ED processes), and that this
139 would result in shorter stay for older adults as well as reduced rates of unnecessary hospital
140 admissions (ED performance). Ultimately, it is expected that the intervention will benefit
141 patient's health outcomes by promoting better functioning and quality of life than usual ED

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3 142 care, higher satisfaction with the care received, and a better use of primary and community
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5 143 care.
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8 144 [FIGURE 1 HERE]
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11 145 Figure legend: Fig. 1. HSCP intervention logic model
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17 147 **Objectives**

18
19 148 Based on the characteristics and assumptions of the OPTIMEND trial, the aim of this
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21
22 149 process evaluation is to understand the functioning and effects of the OPTIMEND
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24 150 intervention by examining how the intervention was delivered and received in practice. In
25
26 151 line with the MRC guidelines for process evaluations of complex interventions [2], the study
27
28 152 has the following objectives to achieve this aim:
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32 153 1. To describe and analyse the implementation of the OPTIMEND trial (what was
33
34 154 delivered and how), including an exploration of the intervention fidelity, dose and
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36 155 reach;
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38 156 2. To explore the mechanisms of impact within the intervention (i.e., barriers and
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40 157 facilitators of implementation in relation to participants' responses, potential
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42 158 mediators and unexpected pathways);
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44 159 3. To highlight contextual influences on impact, delivery and acceptability (i.e.,
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46 160 individuals, physical environment, ED processes and relations, hospital and
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48 161 healthcare system).
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163 **METHODS AND ANALYSIS**

164 **Design**

165 The process evaluation will employ a mixed-methods approach to address the above
166 objectives in relation to a HSCP intervention in the ED tested within a randomised controlled
167 trial; the trial for which this process evaluation will be conducted is registered on
168 ClinicalTrials.gov, NCT03739515; registered on 12th November 2018.

169 The reporting of this protocol aligns with the Standard Protocol Items for Clinical
170 Trials (SPIRIT) guidelines [12], and a full reporting SPIRIT checklist is presented in
171 Supplementary File 1. However, given the nature of the study (i.e., not a trial but a process
172 evaluation), the protocol has been written by incorporating appropriate elements of the
173 Criteria for Reporting the Development and Evaluation of Complex Interventions in
174 Healthcare (revised guideline CReDECI 2) [13], particularly in relation to reporting the
175 development and evaluation of the intervention. Key considerations suggested by the MRC
176 [2] will be made in relation to the relations between the quantitative and qualitative
177 components of the evaluation, and the relation of the process evaluation to other evaluation
178 components (trial outcomes on clinical and cost effectiveness).

180 **Participants**

181 The evaluation will involve key staff members working in the hospital where the
182 OPTIMEND intervention was carried out (University Hospital Limerick, Ireland), including
183 the HSCPs who implemented the intervention and other staff members who worked in the ED
184 during the OPTIMEND trial and/or contributed to the development and implementation of
185 the intervention. Given the characteristics of the setting and the fact that the intervention was

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3 186 conducted at one site only, it is anticipated that around 20-25 participants will complete the
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5 187 study. Specifically, the following participant categories will be included in the study:

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8 188 - the clinical team involved in the intervention (senior physiotherapist, senior
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10 189 occupational therapist, senior medical social worker, research nurse);
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13 190 - ED doctors (4-5 participants),
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15 191 - ED nurses (4-5 participants);
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18 192 - Other hospital staff members who contributed to the development and
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20 193 implementation of the intervention (e.g., Informatics, Planning and Performance
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22 194 Department; Departments managers; other HSCPs).

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25 195 Participant recruitment will be conducted through convenience and snowball
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27 196 sampling, with prospective participants being identified by the research team and the clinical
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29 197 team involved in the intervention. The clinical team will also act as gatekeepers linking
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31 198 potential participants with the researcher managing enrolment (MC); furthermore, study
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33 199 leaflets will be distributed at UHL. Prospective participants will be provided with an
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35 200 information sheet outlining the evaluation aim and procedure; written informed consent will
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37 201 be sought prior to participation. Ethical approval for the study was received from the HSE
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39 202 Mid-Western Regional Hospital Research Ethics Committee (REC 103/18) in September
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41 203 2018. At the time of submission of this protocol, participants recruitment is ongoing and
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43 204 expected to be completed by the end of July 2019.
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49 205 **Outcomes and Measures**

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51 206 Using the MRC process evaluation framework, the study will focus on the measures
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53 207 and research questions outlined in Table 1. The process of implementation will be described
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55 208 in terms of activities and processes put in place for the development and delivery of the
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57 209 implementation, the fidelity of the intervention (adherence to protocol and evidence as well
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3 210 as adaptations), its dose and reach. Mechanisms internal to the intervention will be
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5 211 investigated in relation to the participants' interaction with the intervention, potential
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7 212 mediators and unexpected pathways. Lastly, using a system approach, potential facilitators
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9 213 and barriers to implementation outside of the intervention will be explored at the level of
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11 214 individuals, the ED physical environment, procedures, communication and the broader
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13 215 healthcare system.
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20 217 [TABLE 1 HERE. See end of manuscript]
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26 219 **Data collection and analysis**

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29 220 As described in Table 1, a mix of quantitative and qualitative methods will be used to
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31 221 address the objectives of this process evaluation.
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34 222 The content and process of delivery will be evaluated quantitatively through the
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36 223 intervention activity logs. The implementation will also be investigated in terms of fidelity,
37
38 224 dose and reach. Fidelity is a central measure in process evaluations [4] which provides
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40 225 information on the extent to which the intervention was delivered as planned or adapted to a
41
42 226 specific context. Although maintaining appropriate levels of fidelity has been suggested to
43
44 227 enhance the impact of intervention [14], debates on the tension between intervention fidelity
45
46 228 and adaption are ongoing, translating into a variety of frameworks attempting to
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48 229 conceptualise fidelity [2]. For the purpose of this process evaluation, we will use the
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50 230 framework proposed by Carroll and colleagues [4] in relation to implementation fidelity for
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52 231 health services interventions and the MRC guidelines [2] to integrate a quantification of
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54 232 adherence, dose and reach with a qualitative exploration of mechanisms of impact within and
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56 233 beyond the intervention. The trial activity logs and recruitment logs will be analysed to
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3 234 quantify and describe the intervention delivery, comparisons will be made with the trial
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5 235 protocol and evidence base (i.e., systematic review) to evaluate adherence and dose;
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7 236 descriptive quantitative analyses of participants lost at follow-up will be carried to quantify
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9 237 attrition. Potential modifications will be quantified and described with the help of the clinical
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11 238 team using Stirman's framework for interventions adaptations [15]; a detailed evaluation
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13 239 form is included in Supplementary File 2, which focuses on what was modified and at what
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15 240 level of delivery, the nature of the modification, and the agents of the modification.
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20 241 The qualitative elements of the implementation will be explored via semi-structured
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22 242 interviews and focus groups. An interview schedule is presented in Supplementary File 3,
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24 243 with questions tailored to the trial clinical team and to other staff members. The members of
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26 244 the trial clinical team will be interviewed as a group to describe the process of
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28 245 implementation and delivery, as well as discuss its acceptability and impact; group interviews
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30 246 will also be organised with other members of staff, paying attention to capture the different
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32 247 perspectives of multiple professionals. In addition, prospective participants who do not wish
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34 248 or are not able to take part in the focus groups will be invited to participate in 1:1 semi-
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36 249 structured interviews. Group and individual interviews have a number of strengths and
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38 250 weakness which make it preferable to adopt a flexible approach [16]: On one hand, working
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40 251 with a group facilitates participants who might have time restrictions or feel at ease
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42 252 contributing as a member of a group; on the other hand, individual interviews provide space
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44 253 to individuals who may be unwilling to contribute within a group and can help to elicit more
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46 254 personal and truthful responses because removing potential biases related to group dynamics
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48 255 and social desirability. The interviews and focus groups will be audio recorded and
49
50 256 transcribed. The data will be inputted in the software NVivo version 11 Plus (QSR
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52 257 International Pty Ltd) and analysed using the six steps of thematic analysis [17,18], with the
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54 258 aim to highlight the central themes related to the research questions above. While the analysis
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3 259 will be data driven, the evaluation is informed by an existing framework, thus emerging
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5 260 themes will be compared with the framework to evaluate fit.
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8 261 By integrating the data collected quantitatively and qualitatively, our analysis will
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10 262 focus on providing a description of the process of implementation as well as considerations of
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12 263 the feasibility and acceptability of the intervention as perceived by key stakeholders involved.
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16 264 All electronic and hardcopy data will be stored safely by the research team and
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18 265 retained in accordance to the data management policies and procedures of the University of
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20 266 Limerick, Ireland. Access to the data will be limited to the research team members involved
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22 267 in data analysis (MC, KR, RG).
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29 269 **Patient and public involvement statement**

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31 270 This process evaluation will not involve patients directly, as their perceptions of the
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33 271 intervention are investigated as part of the effectiveness study (currently in progress) and it
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35 272 was felt that involving patients in the process evaluation as well may cause a burden without
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37 273 providing novel information. The research questions of this study were informed by the need
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39 274 for quality and timeliness of assessment and intervention in the ED expressed by health
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41 275 service users at a Patient and Public Involvement initiative organised by the Health Service
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43 276 Executive's Advocacy Unit in Ireland ([https://www.hse.ie/eng/about/who/qid/person-family-
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45 277 engagement/listening-reports/listening-report-16.pdf](https://www.hse.ie/eng/about/who/qid/person-family-engagement/listening-reports/listening-report-16.pdf)).
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53 279 **DISCUSSION**

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55 280 Process evaluations have increasingly become an important component of
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57 281 investigations of the effectiveness of health service interventions [1]. Despite there are
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3 282 encouraging studies that support the benefits of introducing HSCPs to the ED and promoting
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5 283 interdisciplinary team care, the available evidence on the effectiveness of HSCP team
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7 284 interventions in the ED is limited and presents heterogenous methodologies [5]. The
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9 285 completion of the first randomised controlled trial testing the impact of this model of care on
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11 286 patient and process outcomes in a large ED offers the opportunity to gather information on
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13 287 the process of implementation, delivery and impact, particularly in relation to its feasibility
14
15 288 and the facilitators and barriers influencing its development, delivery and impact. Adopting
16
17 289 the MRC framework for process evaluations [1] will help to ensure that key aspects of the
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19 290 implementation process are explored and that the complexities of the intervention are
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21 291 captured in details at multiple levels (from individuals to the healthcare system); furthermore,
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23 292 involving different healthcare professionals in the evaluation will enhance the richness of
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25 293 information gathered, particularly in terms of the practical elements of developing and
26
27 294 implementing a complex intervention in a dynamic healthcare setting. While we do not
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29 295 envisage any practical and operational issues arising during the study, the evaluation will be
30
31 296 overseen by an interdisciplinary steering group of experts in allied health and emergency care
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33 297 that will ensure the rigorous conduct of the study. The findings of this process evaluation will
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35 298 be integrated with the results on the clinical and cost-effectiveness of the trial (currently in
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37 299 data collection status) to provide insights on the viability of this model of care and formulate
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39 300 recommendations for future implementation in other emergency care settings.
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302 **ETHICS AND DISSEMINATION**

303 Ethical approval for this study was received from the HSE Mid-Western Regional
304 Hospital Research Ethics Committee (Ref: 103/18). All participants will be invited to read
305 and sign a written consent form prior to participation. The results of this review will be

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3 306 disseminated through publication in a peer-review journal and presented at relevant
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5 307 conferences.

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11 309 **Study status:** At the time of submission, the status of this study is currently
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13 310 “Recruiting”. Recruitment for the study commenced in June 2019 and it is anticipated to be
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16 311 completed by the end of July 2019.

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22 313 **List of abbreviations**

23
24 314 CReDECI 2 = Criteria for Reporting the Development and Evaluation of Complex
25
26 315 Interventions in Healthcare version 2

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29 316 ED = Emergency Department

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32 317 HSCP = Health and Social Care Professional

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35 318 HSE = Health Service Executive

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38 319 MRC = Medical Research Council

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41 320 OPTIMEND = Optimising early assessment and intervention by Health and Social
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43 321 Care Professionals in the Emergency Department

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46 322 SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

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49 323 UHL = University Hospital Limerick

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324 **STATEMENTS**

325 **Data statement:** Data sharing is not applicable to this article as no datasets were
326 generated or analysed for this protocol. The qualitative data collected during the study will be
327 stored electronically at the University of Limerick (Ireland) and be made available by the
328 authors on request.

329 **Acknowledgements:** Not applicable

330 **Authors' contributions:** MC and RG were major contributors in writing the protocol.
331 MC and RG designed the study. MC, RG, UC and KR participated in data collection and
332 analysis. RQ, FB, MW, RMN, MOC, GMC and DR participated in the project design and
333 critically appraised and edited the manuscript. RG is the guarantor of the study. All authors
334 read and approved the final manuscript.

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337 not involved in the design of the study and collection, analysis, interpretation of data, or in
338 writing the manuscript.

339 **Competing interests:** The authors declare that they have no competing interests

340 **Participant consent:** All prospective participants for the study will be provided with
341 an information sheet outlining the objectives of the study and given time to ask questions. All
342 participants will be asked to read and sign a written consent form prior to take part.

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Table 1 – Measures, research questions and data collection

Dimension	Measure	Research questions	Data source	Analysis type
Implementation	Process	How was the intervention developed and delivered?	Team activity logs Interviews/Focus groups	Quantitative descriptive
		What inputs, resources and structures were put into place?		
	Fidelity (Adherence)	To which extent did the intervention align or diverge from the protocol or international practice? What types of adaptations were made to fit the specific context of care delivery?	Trial protocol Systematic review Interviews/Focus groups	Quantitative descriptive
		Dose	What was the duration, coverage and frequency of the intervention?	
Mechanisms	Reach	What proportion of the target population (eligible patients) were enrolled in the intervention? What was the attrition rate?	Recruitment logs	Quantitative
	Participants' responses to and interaction with intervention	How did the patients feel about being involved in the intervention?	Interviews/Focus groups	Qualitative and quantitative
		How did other staff members feel about the intervention?	Data on patients' satisfaction	
	Mediators	What aspects of the intervention influenced its implementation (people, operations, relations)?	Interviews/Focus groups	Qualitative
Unexpected pathways and consequences	Was there something about the intervention that was unexpected and might have influenced its implementation?	Interviews/Focus groups	Qualitative	
Context	Barriers and facilitators	What factors external to the intervention influenced its implementation and in which way? Consider multiple levels: 1) Individuals; 2) ED physical environment; 3) ED operations; 4) ED relations; 5) broader	Interviews/Focus groups	Qualitative

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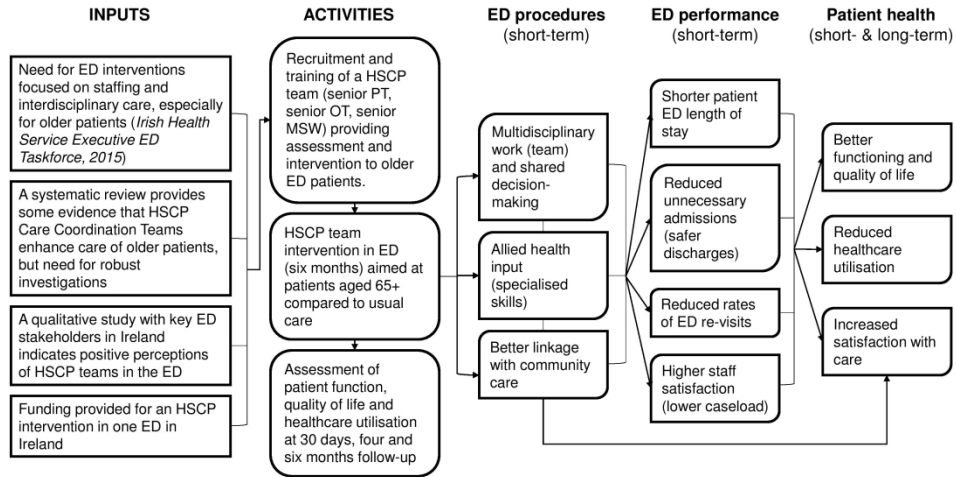
hospital or healthcare
system

Notes. Measures based on the Medical Research Council (MRC) Framework for process evaluations [1]

398

For peer review only

OPTIMEND Logic Model



HSCP intervention logic model



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	__ 1 __
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	__ 9 __
	2b	All items from the World Health Organization Trial Registration Data Set	__ 9 __
Protocol version	3	Date and version identifier	__ NA __
Funding	4	Sources and types of financial, material, and other support	__ 16 __
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	__ 1-2, 16 __
	5b	Name and contact information for the trial sponsor	__ 16 __
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__ 16 __
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__ NA __

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ___ 5-8 ___

4

5

6 6b Explanation for choice of comparators ___ NA ___

7

8 Objectives 7 Specific objectives or hypotheses ___ 8 ___

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) ___ 9 ___

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ___ 9-10 ___

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ___ 9-10 ___

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered ___ NA ___

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) ___ NA ___

26

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28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) ___ NA ___

29

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31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial ___ NA ___

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ___ 10-11, 20 ___

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40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ___ 11-13 ___

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1 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including _____10-11_____

2 clinical and statistical assumptions supporting any sample size calculations

3

4 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size _____10-11_____

5

6 **Methods: Assignment of interventions (for controlled trials)**

7

8 Allocation:

9

10 Sequence 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any _____NA_____

11 generation factors for stratification. To reduce predictability of a random sequence, details of any planned restriction

12 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants

13 or assign interventions

14

15

16 Allocation 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, _____NA_____

17 concealment opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

18 mechanism

19

20 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to _____NA_____

21 interventions

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23

24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome _____NA_____

25 assessors, data analysts), and how

26

27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's _____NA_____

28 allocated intervention during the trial

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31 **Methods: Data collection, management, and analysis**

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33 Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related _____11-13_____

34 methods processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of

35 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.

36 Reference to where data collection forms can be found, if not in the protocol

37

38

39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be _____NA_____

40 collected for participants who discontinue or deviate from intervention protocols

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1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___ 11-13 ___
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___ 11-13 ___
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___ NA ___
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___ NA ___
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___ 12, 13 ___
17				
18				
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22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___ 12 ___
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___ NA ___
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___ NA ___
29				
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31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___ 3, 10, 16 ___
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___ NA ___
38				
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___ NA ___
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___ NA ___
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___ 11-13 ___
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___ 16 ___
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___ 13 ___
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___ NA ___
17				
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19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___ 3, 14 ___
21				
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24		31b	Authorship eligibility guidelines and any intended use of professional writers	___ NA ___
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___ NA ___
27				
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29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	___ 10, Suppl file 3 ___
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___ NA ___
35				
36				

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

HSCP team intervention in the ED

Supplementary File 2 – Adaptation evaluation form

Evaluation form for trial adaptations (based on Stirman et al., 2013)

Dimension	Description
WHAT was modified?	
- Content	
- Context	
If content modification, what was the nature of the modification?	
- Tailoring/tweaking/refining	
- Adding elements	
- Removing/skipping elements	
- Shortening	
- Lengthening	
- Substituting	
- Reordering of segments	
- Integrating intervention into different framework	
- Integrating another treatment	
- Repeating elements	
- Loosening structure	
- Departing from intervention	
If context modification, which of the following apply?	
- Format	
- Setting	
- Personnel	
- Population	
By WHOM were modifications made?	
- Individual practitioner/facilitator	
- Team	
- Non-program staff	
- Administration	
- Program developer	
- Researcher	
- Coalition of stakeholders	
- Unknown/unspecified	
At what LEVEL OF DELIVERY?	
- Individual patient level	
- Group level	
- Individual practitioner level	
- Clinic/unit level	
- Hospital level	
- Network level	
- System level	

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3 HSCP team ED intervention – Process evaluation protocol
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6 **Supplementary File 3 – Interview schedule**
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11 Trial clinical team (40-60 minutes focus group)
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14 **Implementation**
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18 1. Tell me about the preparation phase prior to implementation of the trial: What
19 types of activities were carried to prepare for the trial?
20
21
22 2. Could you describe a typical day of the intervention?
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24
25 3. Do you think that the implementation was carried as planned or were there
26 adaptations made? If so, which?
27
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29 4. How did you feel about the recruitment part of the trial?
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31

32 **Mechanisms**
33

- 34
35 5. How do you think the patients felt about being involved in the intervention?
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37 6. How do you think other staff members felt about the intervention?
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40 7. What, in your opinion, worked well in the intervention and what might have
41 worked better?
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43
44 8. Do you recall anything unexpected occurring during the intervention that might
45 have influenced its implementation?
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49 **Context**
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52 9. What factors external to the intervention do you think have influenced its
53 implementation?
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57 **Recommendations for future practice**
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3 10. What recommendations would you make should the intervention be considered for
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5 other emergency departments in the future?
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11 Other staff members (focus group or 1:1 interview)
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14 Implementation
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- 16
17 1. How were you informed or came to know about the OPTIMEND intervention?
18
19 2. If you were working in the ED during the intervention, how would you describe
20 your interaction with the OPTIMEND team?
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25 Mechanisms
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28 3. How do you think the patients felt about being involved in the intervention?
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30 4. How do you think other staff members felt about the intervention?
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32 5. What, in your opinion, worked well in the intervention and what might have
33 worked better?
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35 6. Do you recall anything unexpected occurring during the intervention that might
36 have influenced its implementation?
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42 Context
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45 7. What factors external to the intervention do you think have influenced its
46 implementation?
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50 Recommendations for future practice
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53 8. What recommendations would you make should the intervention be considered for
54 other emergency departments in the future?
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BMJ Open

Implementing an Allied Health Team Intervention to Improve the Care of Older Adults in the Emergency Department: Protocol for a Process Evaluation

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032645.R1
Article Type:	Protocol
Date Submitted by the Author:	28-Jun-2019
Complete List of Authors:	Cassarino, Marica; University of Limerick Faculty of Education and Health Sciences, School of Allied Health Cronin, Una; University Hospital Limerick, Retrieval, Emergency and Disaster Medicine Research and Development Unit (REDSPoT) Robinson, Katie; University of Limerick Faculty of Education and Health Sciences, School of Allied Health Quinn, Rosie; Our Lady of Lourdes Hospital, Emergency Department Boland, Fiona; Royal College of Surgeons Ireland, 123 St Stephens Green, HRB Centre For Primary Care Research, Division of Population Health Sciences (PHS) Ward, Marie; Trinity College Dublin, School of Psychology MacNamara, Rosa; St. Vincent's University Hospital, Emergency Department O'Connor, Margaret; UHL, McCarthy, Gerard; Cork University Hospital, Emergency Department Ryan, Damien; University Hospital Limerick, Retrieval, Emergency and Disaster Medicine Research and Development Unit (REDSPoT) Galvin, Rose; University of Limerick Faculty of Education and Health Sciences, School of Allied Health
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Emergency medicine
Keywords:	Allied health, Emergency department, Process evaluation, Implementation, Interdisciplinary care, Health service delivery

SCHOLARONE™
Manuscripts

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2
3 **Title:** Implementing an Allied Health Team Intervention to Improve the Care of Older
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5 2 Adults in the Emergency Department: Protocol for a Process Evaluation
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4 35 **ABSTRACT**

5
6 36 **Introduction:** Health and Social Care Professionals (HSCPs) have increasingly
7
8 37 contributed to enhance the care of patients in Emergency Departments (EDs), particularly for
9
10 38 older adults who are frequent ED attendees with significant adverse outcomes. For the first
11
12 39 time, the effectiveness of a HSCP team intervention for older adults in the ED has been tested
13
14 40 in a large randomised controlled trial, providing an opportunity to explore the implementation
15
16 41 process for this type of intervention. This protocol describes a process evaluation that will to
17
18 42 investigate the implementation, delivery and impact of an HSCP team intervention in the ED.
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23 43 **Methods and analysis:** Using the Medical Research Council (MRC) Framework for
24
25 44 process evaluations, we will employ a mixed-methods approach to provide a description of
26
27 45 the process of implementation and delivery of the HSCP intervention in the ED, evaluate its
28
29 46 fidelity, dose and reach, and explore the perceptions of key staff members in relations to the
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31 47 mechanisms and contexts of impact at the levels of individuals, physical environment,
32
33 48 operations, communication and the broader hospital and healthcare system.
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37 49 **Ethics and dissemination:** Ethical approval for this study was received from the HSE
38
39 50 Mid-Western Regional Hospital Research Ethics Committee (Ref: 103/18). All participants
40
41 51 will be invited to read and sign a written consent form prior to participation. The results of
42
43 52 this review will be disseminated through publication in a peer-review journal and presented at
44
45 53 relevant conferences.
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52 55 **ARTICLE SUMMARY**

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55 56 **Strengths and limitations of this study:**
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3 57 - This is the first formal process evaluation of the implementation of a Health
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5 58 and Social Care Professional team caring for older patients in the emergency
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7 department.
8 59
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10 60 - The study will employ the Medical Research Council framework for process
11
12 61 evaluations.
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14 62 - This study will adopt a mixed-methods approach and involve different
15
16 stakeholders to investigate the implementation, delivery and impact of the
17 63 allied health intervention.
18
19 64
20
21 65 - Group interviews may introduce biases related to group dynamics and social
22
23 desirability that we will attempt to overcome using also individual interviews
24 66 and quantitative data.
25
26 67
27
28 68 - Findings will provide key information for future implementations of allied
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30 health teams in emergency care settings.
31 69
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36 71 **Keywords:** Allied health; emergency department; process evaluation;
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38 72 implementation; interdisciplinary care; health service delivery.
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74 INTRODUCTION

75 Background

76 Complex interventions have been increasingly employed in an attempt to enhance
77 health service delivery as well as other societal issues [1]. Randomised controlled trials
78 (RCTs) are traditionally considered as the reference standard for establishing the
79 effectiveness of interventions [1,2]. Recent efforts have been made to include process
80 evaluations as a core component of investigations of effectiveness, as stated in a recent
81 Medical Research Council (MRC) guidance document [1]. Conducting a process evaluation
82 of an intervention, particularly in the case of complex quality improvement interventions, is
83 important to gain a deeper understanding of the mechanisms influencing effectiveness (or
84 lack of it), to explain discrepancies between expected and observed outcomes, to highlight
85 the complexities of an intervention and the impact of contextual factors on outcomes, and
86 thus to better inform implementation [2–4].

87 The MRC framework highlights three key functions of process evaluations: 1)
88 examining the implementation process and its content (fidelity-adaptation, dose and reach);
89 2) understanding the mechanisms of impact (participants' response to the intervention;
90 mediators; unexpected pathways and consequences); 3) investigating the influence of the
91 context of the intervention. Such a framework enables to capture the complexities of
92 developing and implementing a health service intervention, so to offer useful insights for
93 future quality improvement. In this process evaluation, we aim to use the MRC framework to
94 evaluate the process, delivery and impact of the implementation of an allied health team-
95 based intervention within an emergency setting.

96 **Intervention characteristics**

97 The present process evaluation will explore the process of implementation of the
98 OPTIMEND intervention (i.e., “Optimising early assessment and intervention by Health and
99 Social Care Professionals in the Emergency Department”). OPTIMEND is the first
100 randomised controlled trial aimed to measure the impact of early assessment and intervention
101 by a team of Health and Social Care Professionals (HSCPs) working in the Emergency
102 Department (ED) on the quality, safety and cost-effectiveness of care for older adults, as
103 compared to usual ED care. The HSCP team comprises of a senior physiotherapist, a senior
104 occupational therapist, and a senior medical social worker providing functional assessment,
105 early interventions and discharge plans to adults aged ≥ 65 years. A total of 354 participants
106 were recruited in the study from December 2018 until May 2019 and randomly allocated to
107 the HSCP intervention or ED usual care (i.e., medical team). Participants in both intervention
108 and control groups are followed-up through telephone assessment at 30 days, four and six
109 months after the ED index visit (ongoing until November 2019). Primary outcomes of the
110 trial include ED length of stay and rates of hospital admissions. Secondary outcomes include
111 function and quality of life (baseline and follow-up), satisfaction with care, ED re-visits and
112 healthcare utilisation (follow-up), and cost-effectiveness.

113 Following the MRC framework for complex interventions [1], the design of the trial
114 was informed by a systematic review of the existing international literature regarding the
115 effectiveness of HSCP interventions in the ED [5]. A qualitative study was also conducted
116 with a range of stakeholders including ED patients and their families, ED staff, HSCPs and
117 pre-hospital staff to explore their views on the role and impact of HSCPs working in teams in
118 the ED. A paper reporting the findings of this phase is currently in submission. We also
119 carried out an analysis of routine observational data to describe the flow of patients who
120 attend a large Irish ED without a dedicated HSCP team in the ED. Allied health team services

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2
3 121 in the ED are routine practice in certain areas, such as in Australia [6]; however, the evidence
4
5 122 on the impact HSCP teams on the quality, safety and cost-effectiveness of care is limited and
6
7 123 heterogeneous. For this reason, there is a dearth of evaluations available on the
8
9
10 124 implementation, delivery and impact of this model of care, often limited to investigations of
11
12 125 acceptability or patient/staff satisfaction [7–9]. The OPTIMEND is the first study
13
14 126 internationally to test the effectiveness an ED-based HSCP team intervention by adopting a
15
16
17 127 robust methodology, thus offering the opportunity to evaluate its implementation.
18
19

20 128 **Theoretical framework**

21
22 129 The causal assumptions of the intervention and theoretical framework guiding this
23
24 130 evaluation are outlined in the logic model presented in Figure 1, based on logic models
25
26 131 recommended elsewhere [2,10]. A key input for the intervention came from the emergency
27
28 132 care national priorities set by the ED taskforce within the Health Service Executive (HSE) in
29
30 133 Ireland, which included improving workforce and interdisciplinary care in emergency
31
32 134 settings in order to enhance patient and process outcomes [11]; following this, funding was
33
34 135 secured for the design and implementation of an HSCP team intervention in the ED of a
35
36
37 136 regional hospital in Ireland with a large catchment area, using the MRC framework for
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39
40 137 complex interventions. A synthesis of the evidence on this model of care and consultations
41
42 138 with relevant stakeholders, as described in the previous section, informed the development of
43
44 139 the intervention. Key assumptions of this HSCP intervention were that having a
45
46 140 multidisciplinary team of professionals with specialised skills in the care of the older person
47
48 141 would enhance the quality and timeliness of decision-making (ED processes), and that this
49
50 142 would result in shorter stay for older adults as well as reduced rates of unnecessary hospital
51
52 143 admissions (ED performance). Ultimately, it is expected that the intervention will benefit
53
54 144 patient's health outcomes by promoting better functioning and quality of life than usual ED
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3 145 care, higher satisfaction with the care received, and a better use of primary and community
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5 146 care.
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8 147 [FIGURE 1 HERE]
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10
11 148 Figure legend: Fig. 1. HSCP intervention logic model
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17 150 **Objectives**

18
19 151 Based on the characteristics and assumptions of the OPTIMEND trial, the aim of this
20
21
22 152 process evaluation is to understand the functioning and effects of the OPTIMEND
23
24 153 intervention by examining how the intervention was delivered and received in practice. In
25
26 154 line with the MRC guidelines for process evaluations of complex interventions [2], the study
27
28
29 155 has the following objectives to achieve this aim:

- 30
31
32 156 1. To describe and analyse the implementation of the OPTIMEND trial (what was
33
34 157 delivered and how), including an exploration of the intervention fidelity, dose and
35
36 158 reach;
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38
39 159 2. To explore the mechanisms of impact within the intervention (i.e., barriers and
40
41 160 facilitators of implementation in relation to participants' responses, potential
42
43 161 mediators and unexpected pathways);
44
45 162 3. To highlight contextual influences on impact, delivery and acceptability (i.e.,
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48 163 individuals, physical environment, ED processes and relations, hospital and
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50 164 healthcare system).
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166 **METHODS AND ANALYSIS**

167 **Design**

168 The process evaluation will employ a mixed-methods approach to address the above
169 objectives in relation to a HSCP intervention in the ED tested within a randomised controlled
170 trial; the trial for which this process evaluation will be conducted is registered on
171 ClinicalTrials.gov, NCT03739515; registered on 12th November 2018.

172 The reporting of this protocol aligns with the Standard Protocol Items for Clinical
173 Trials (SPIRIT) guidelines [12], and a full reporting SPIRIT checklist is presented in
174 Supplementary File 1. However, given the nature of the study (i.e., not a trial but a process
175 evaluation), the protocol has been written by incorporating appropriate elements of the
176 Criteria for Reporting the Development and Evaluation of Complex Interventions in
177 Healthcare (revised guideline CReDECI 2) [13], particularly in relation to reporting the
178 development and evaluation of the intervention. Key considerations suggested by the MRC
179 [2] will be made in relation to the relations between the quantitative and qualitative
180 components of the evaluation, and the relation of the process evaluation to other evaluation
181 components (trial outcomes on clinical and cost effectiveness).

183 **Participants**

184 The evaluation will involve key staff members working in the hospital where the
185 OPTIMEND intervention was carried out (University Hospital Limerick, Ireland), including
186 the HSCPs who implemented the intervention and other staff members who worked in the ED
187 during the OPTIMEND trial and/or contributed to the development and implementation of
188 the intervention. Given the characteristics of the setting and the fact that the intervention was

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2
3 189 conducted at one site only, it is anticipated that around 20-25 participants will complete the
4
5 190 study. Specifically, the following participant categories will be included in the study:

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8 191 - the clinical team involved in the intervention (senior physiotherapist, senior
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10 192 occupational therapist, senior medical social worker, research nurse);
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13 193 - ED doctors (4-5 participants),
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15 194 - ED nurses (4-5 participants);
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18 195 - Other hospital staff members who contributed to the development and
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20 196 implementation of the intervention (e.g., Informatics, Planning and Performance
21
22 197 Department; Departments managers; other HSCPs).

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24
25 198 Participant recruitment will be conducted through convenience and snowball
26
27 199 sampling, with prospective participants being identified by the research team and the clinical
28
29 200 team involved in the intervention. The clinical team will also act as gatekeepers linking
30
31 201 potential participants with the researcher managing enrolment (MC); furthermore, study
32
33 202 leaflets will be distributed at UHL. Prospective participants will be provided with an
34
35 203 information sheet outlining the evaluation aim and procedure; written informed consent will
36
37 204 be sought prior to participation. Ethical approval for the study was received from the HSE
38
39 205 Mid-Western Regional Hospital Research Ethics Committee (REC 103/18) in September
40
41 206 2018. At the time of submission of this protocol, participants recruitment is ongoing and
42
43 207 expected to be completed by the end of July 2019.
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49 208 **Outcomes and Measures**

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51 209 Using the MRC process evaluation framework, the study will focus on the measures
52
53 210 and research questions outlined in Table 1. The process of implementation will be described
54
55 211 in terms of activities and processes put in place for the development and delivery of the
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57 212 implementation, the fidelity of the intervention (adherence to protocol and evidence as well
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3 213 as adaptations), its dose and reach. Mechanisms internal to the intervention will be
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5 214 investigated in relation to the participants' interaction with the intervention, potential
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7 215 mediators and unexpected pathways. Lastly, using a system approach, potential facilitators
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9 216 and barriers to implementation outside of the intervention will be explored at the level of
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11 217 individuals, the ED physical environment, procedures, communication and the broader
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13 218 healthcare system.
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21 220 [TABLE 1 HERE. See end of manuscript]
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27 222 **Data collection and analysis**

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29 223 As described in Table 1, a mix of quantitative and qualitative methods will be used to
30
31 224 address the objectives of this process evaluation.
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34 225 The content and process of delivery will be evaluated quantitatively through the
35
36 226 intervention activity logs. The implementation will also be investigated in terms of fidelity,
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38 227 dose and reach. Fidelity is a central measure in process evaluations [4] which provides
39
40 228 information on the extent to which the intervention was delivered as planned or adapted to a
41
42 229 specific context. Although maintaining appropriate levels of fidelity has been suggested to
43
44 230 enhance the impact of intervention [14], debates on the tension between intervention fidelity
45
46 231 and adaption are ongoing, translating into a variety of frameworks attempting to
47
48 232 conceptualise fidelity [2]. For the purpose of this process evaluation, we will use the
49
50 233 framework proposed by Carroll and colleagues [4] in relation to implementation fidelity for
51
52 234 health services interventions and the MRC guidelines [2] to integrate a quantification of
53
54 235 adherence, dose and reach with a qualitative exploration of mechanisms of impact within and
55
56 236 beyond the intervention. The trial activity logs and recruitment logs will be analysed to
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3 237 quantify and describe the intervention delivery, comparisons will be made with the trial
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5 238 protocol and evidence base (i.e., systematic review) to evaluate adherence and dose;
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7
8 239 descriptive quantitative analyses of participants lost at follow-up will be carried to quantify
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10 240 attrition. Potential modifications will be quantified and described with the help of the clinical
11
12 241 team using Stirman's framework for interventions adaptations [15]; a detailed evaluation
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14 242 form is included in Supplementary File 2, which focuses on what was modified and at what
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16
17 243 level of delivery, the nature of the modification, and the agents of the modification.

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20 244 The qualitative elements of the implementation will be explored via semi-structured
21
22 245 interviews and focus groups. An interview schedule is presented in Supplementary File 3,
23
24 246 with questions tailored to the trial clinical team and to other staff members. The members of
25
26
27 247 the trial clinical team will be interviewed as a group to describe the process of
28
29 248 implementation and delivery, as well as discuss its acceptability and impact; group interviews
30
31 249 will also be organised with other members of staff, paying attention to capture the different
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34 250 perspectives of multiple professionals. In addition, prospective participants who do not wish
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36 251 or are not able to take part in the focus groups will be invited to participate in 1:1 semi-
37
38 252 structured interviews. Group and individual interviews have a number of strengths and
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41 253 weakness which make it preferable to adopt a flexible approach [16]: On one hand, working
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43 254 with a group facilitates participants who might have time restrictions or feel at ease
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45 255 contributing as a member of a group; on the other hand, individual interviews provide space
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47 256 to individuals who may be unwilling to contribute within a group and can help to elicit more
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49
50 257 personal and truthful responses because removing potential biases related to group dynamics
51
52 258 and social desirability. The interviews and focus groups will be audio recorded and
53
54 259 transcribed. The data will be inputted in the software NVivo version 11 Plus (QSR
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57 260 International Pty Ltd) and analysed using the six steps of thematic analysis [17,18], with the
58
59 261 aim to highlight the central themes related to the research questions above. While the analysis
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3 262 will be data driven, the evaluation is informed by an existing framework, thus emerging
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5 263 themes will be compared with the framework to evaluate fit.
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8 264 By integrating the data collected quantitatively and qualitatively, our analysis will
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10 265 focus on providing a description of the process of implementation as well as considerations of
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12 266 the feasibility and acceptability of the intervention as perceived by key stakeholders involved.
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16 267 All electronic and hardcopy data will be stored safely by the research team and
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18 268 retained in accordance to the data management policies and procedures of the University of
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20 269 Limerick, Ireland. Access to the data will be limited to the research team members involved
21
22 270 in data analysis (MC, KR, RG).
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28 29 272 **Patient and public involvement statement**

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31 273 This process evaluation will not involve patients directly, as their perceptions of the
32
33 274 intervention are investigated as part of the effectiveness study (currently in progress) and it
34
35 275 was felt that involving patients in the process evaluation as well may cause a burden without
36
37 276 providing novel information. The research questions of this study were informed by the need
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39 277 for quality and timeliness of assessment and intervention in the ED expressed by health
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41 278 service users at a Patient and Public Involvement initiative organised by the Health Service
42
43 279 Executive's Advocacy Unit in Ireland ([https://www.hse.ie/eng/about/who/qid/person-family-
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47 280 engagement/listening-reports/listening-report-16.pdf](https://www.hse.ie/eng/about/who/qid/person-family-engagement/listening-reports/listening-report-16.pdf)).
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53 282 **DISCUSSION**

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55 283 Process evaluations have increasingly become an important component of
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57 284 investigations of the effectiveness of health service interventions [1]. Despite there are
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3 285 encouraging studies that support the benefits of introducing HSCPs to the ED and promoting
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5 286 interdisciplinary team care, the available evidence on the effectiveness of HSCP team
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7 287 interventions in the ED is limited and presents heterogenous methodologies [5]. The
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9 288 completion of the first randomised controlled trial testing the impact of this model of care on
10
11 289 patient and process outcomes in a large ED offers the opportunity to gather information on
12
13 290 the process of implementation, delivery and impact, particularly in relation to its feasibility
14
15 291 and the facilitators and barriers influencing its development, delivery and impact. Adopting
16
17 292 the MRC framework for process evaluations [1] will help to ensure that key aspects of the
18
19 293 implementation process are explored and that the complexities of the intervention are
20
21 294 captured in details at multiple levels (from individuals to the healthcare system); furthermore,
22
23 295 involving different healthcare professionals in the evaluation will enhance the richness of
24
25 296 information gathered, particularly in terms of the practical elements of developing and
26
27 297 implementing a complex intervention in a dynamic healthcare setting. While we do not
28
29 298 envisage any practical and operational issues arising during the study, the evaluation will be
30
31 299 overseen by an interdisciplinary steering group of experts in allied health and emergency care
32
33 300 that will ensure the rigorous conduct of the study. The findings of this process evaluation will
34
35 301 be integrated with the results on the clinical and cost-effectiveness of the trial (currently in
36
37 302 data collection status) to provide insights on the viability of this model of care and formulate
38
39 303 recommendations for future implementation in other emergency care settings.
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305 **ETHICS AND DISSEMINATION**

306 Ethical approval for this study was received from the HSE Mid-Western Regional
307 Hospital Research Ethics Committee (Ref: 103/18). All participants will be invited to read
308 and sign a written consent form prior to participation. The results of this review will be

1
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3 309 disseminated through publication in a peer-review journal and presented at relevant
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5 310 conferences.

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11 312 **Study status:** At the time of submission, the status of this study is currently
12
13 313 “Recruiting”. Recruitment for the study commenced in June 2019 and it is anticipated to be
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15 314 completed by the end of July 2019.

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22 316 **List of abbreviations**

23
24 317 CReDECI 2 = Criteria for Reporting the Development and Evaluation of Complex
25
26 318 Interventions in Healthcare version 2

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29 319 ED = Emergency Department

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32 320 HSCP = Health and Social Care Professional

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35 321 HSE = Health Service Executive

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38 322 MRC = Medical Research Council

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41 323 OPTIMEND = Optimising early assessment and intervention by Health and Social
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43 324 Care Professionals in the Emergency Department

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46 325 SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

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49 326 UHL = University Hospital Limerick

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3 327 **STATEMENTS**
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9 328 **Data statement:** Data sharing is not applicable to this article as no datasets were
10
11 329 generated or analysed for this protocol. The qualitative data collected during the study will be
12
13 330 stored electronically at the University of Limerick (Ireland) and be made available by the
14
15 331 authors on request.

16
17
18 332 **Acknowledgements:** Not applicable

19
20
21 333 **Authors' contributions:** MC and RG were major contributors in writing the protocol.
22
23 334 MC and RG designed the study. MC, RG, UC and KR participated in data collection and
24
25 335 analysis. RQ, FB, MW, RMN, MOC, GMC and DR participated in the project design and
26
27 336 critically appraised and edited the manuscript. RG is the guarantor of the study. All authors
28
29 337 read and approved the final manuscript.

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32
33 338 **Funding:** This research is supported by the Health Research Board of Ireland through
34
35 339 the Research Collaborative for Quality and Patient Safety (RCQPS 2017-2). The sponsor is
36
37 340 not involved in the design of the study and collection, analysis, interpretation of data, or in
38
39 341 writing the manuscript.

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42
43 342 **Competing interests:** The authors declare that they have no competing interests

44
45
46 343 **Participant consent:** All prospective participants for the study will be provided with
47
48 344 an information sheet outlining the objectives of the study and given time to ask questions. All
49
50 345 participants will be asked to read and sign a written consent form prior to take part.

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Table 1 – Measures, research questions and data collection

Dimension	Measure	Research questions	Data source	Analysis type
Implementation	Process	How was the intervention developed and delivered?	Team activity logs Interviews/Focus groups	Quantitative descriptive
		What inputs, resources and structures were put into place?		
	Fidelity (Adherence)	To which extent did the intervention align or diverge from the protocol or international practice? What types of adaptations were made to fit the specific context of care delivery?	Trial protocol Systematic review Interviews/Focus groups	Quantitative descriptive
		Dose	What was the duration, coverage and frequency of the intervention?	
Mechanisms	Reach	What proportion of the target population (eligible patients) were enrolled in the intervention? What was the attrition rate?	Recruitment logs	Quantitative
	Participants' responses to and interaction with intervention	How did the patients feel about being involved in the intervention?	Interviews/Focus groups	Qualitative and quantitative
		How did other staff members feel about the intervention?	Data on patients' satisfaction	
	Mediators	What aspects of the intervention influenced its implementation (people, operations, relations)?	Interviews/Focus groups	Qualitative
Unexpected pathways and consequences	Was there something about the intervention that was unexpected and might have influenced its implementation?	Interviews/Focus groups	Qualitative	
Context	Barriers and facilitators	What factors external to the intervention influenced its implementation and in which way? Consider multiple levels: 1) Individuals; 2) ED physical environment; 3) ED operations; 4) ED relations; 5) broader	Interviews/Focus groups	Qualitative

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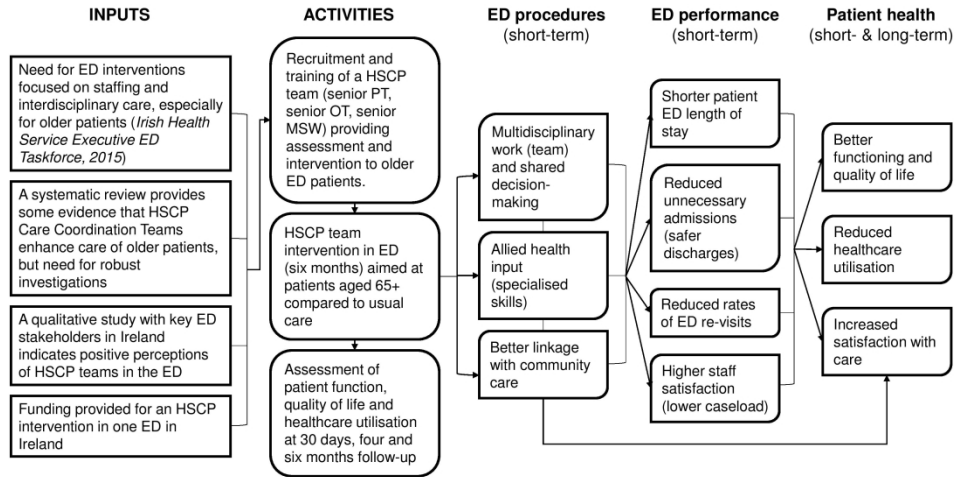
hospital or healthcare
system

Notes. Measures based on the Medical Research Council (MRC) Framework for process evaluations [1]

401

For peer review only

OPTIMEND Logic Model



HSCP intervention logic model



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	__ 1 __
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	__ 9 __
	2b	All items from the World Health Organization Trial Registration Data Set	__ 9 __
Protocol version	3	Date and version identifier	__ NA __
Funding	4	Sources and types of financial, material, and other support	__ 16 __
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	__ 1-2, 16 __
	5b	Name and contact information for the trial sponsor	__ 16 __
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__ 16 __
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__ NA __

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ___ 5-8 ___

4

5

6 6b Explanation for choice of comparators ___ NA ___

7

8 Objectives 7 Specific objectives or hypotheses ___ 8 ___

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) ___ 9 ___

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14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ___ 9-10 ___

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18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ___ 9-10 ___

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22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered ___ NA ___

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25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) ___ NA ___

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27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) ___ NA ___

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial ___ NA ___

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ___ 10-11, 20 ___

35

36

37

38

39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ___ 11-13 ___

41

42

43

44

45

46

1 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including _____10-11_____

2 clinical and statistical assumptions supporting any sample size calculations

3

4 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size _____10-11_____

5

6 **Methods: Assignment of interventions (for controlled trials)**

7

8 Allocation:

9

10 Sequence 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any _____NA_____

11 generation factors for stratification. To reduce predictability of a random sequence, details of any planned restriction

12 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants

13 or assign interventions

14

15

16 Allocation 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, _____NA_____

17 concealment opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

18 mechanism

19

20 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to _____NA_____

21 interventions

22

23

24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome _____NA_____

25 assessors, data analysts), and how

26

27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's _____NA_____

28 allocated intervention during the trial

29

30

31 **Methods: Data collection, management, and analysis**

32

33 Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related _____11-13_____

34 methods processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of

35 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.

36 Reference to where data collection forms can be found, if not in the protocol

37

38

39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be _____NA_____

40 collected for participants who discontinue or deviate from intervention protocols

41

42

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___ 11-13 ___
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___ 11-13 ___
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___ NA ___
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___ NA ___
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___ 12, 13 ___
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___ 12 ___
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___ NA ___
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___ NA ___
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___ 3, 10, 16 ___
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___ NA ___
38				
39				
40				
41				
42				
43				
44				
45				
46				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___ NA ___
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___ NA ___
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___ 11-13 ___
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___ 16 ___
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___ 13 ___
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___ NA ___
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___ 3, 14 ___
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	___ NA ___
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___ NA ___
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	___ 10, Suppl file 3 ___
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___ NA ___
35				
36				

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

HSCP team intervention in the ED

Supplementary File 2 – Adaptation evaluation form

Evaluation form for trial adaptations (based on Stirman et al., 2013)

Dimension	Description
WHAT was modified?	
- Content	
- Context	
If content modification, what was the nature of the modification?	
- Tailoring/tweaking/refining	
- Adding elements	
- Removing/skipping elements	
- Shortening	
- Lengthening	
- Substituting	
- Reordering of segments	
- Integrating intervention into different framework	
- Integrating another treatment	
- Repeating elements	
- Loosening structure	
- Departing from intervention	
If context modification, which of the following apply?	
- Format	
- Setting	
- Personnel	
- Population	
By WHOM were modifications made?	
- Individual practitioner/facilitator	
- Team	
- Non-program staff	
- Administration	
- Program developer	
- Researcher	
- Coalition of stakeholders	
- Unknown/unspecified	
At what LEVEL OF DELIVERY?	
- Individual patient level	
- Group level	
- Individual practitioner level	
- Clinic/unit level	
- Hospital level	
- Network level	
- System level	

1
2
3 HSCP team ED intervention – Process evaluation protocol
4
5

6 **Supplementary File 3 – Interview schedule**
7
8
9

10
11 Trial clinical team (40-60 minutes focus group)
12
13

14
15 **Implementation**
16

- 17
18 1. Tell me about the preparation phase prior to implementation of the trial: What
19 types of activities were carried to prepare for the trial?
20
21
22 2. Could you describe a typical day of the intervention?
23
24
25 3. Do you think that the implementation was carried as planned or were there
26 adaptations made? If so, which?
27
28
29 4. How did you feel about the recruitment part of the trial?
30
31

32 **Mechanisms**
33

- 34
35 5. How do you think the patients felt about being involved in the intervention?
36
37
38 6. How do you think other staff members felt about the intervention?
39
40
41 7. What, in your opinion, worked well in the intervention and what might have
42 worked better?
43
44
45 8. Do you recall anything unexpected occurring during the intervention that might
46 have influenced its implementation?
47
48

49 **Context**
50

- 51
52 9. What factors external to the intervention do you think have influenced its
53 implementation?
54
55

56
57 **Recommendations for future practice**
58
59
60

- 1
2
3 10. What recommendations would you make should the intervention be considered for
4
5 other emergency departments in the future?
6
7
8
9

11 Other staff members (focus group or 1:1 interview)
12
13

14 Implementation
15
16

- 17 1. How were you informed or came to know about the OPTIMEND intervention?
18
19 2. If you were working in the ED during the intervention, how would you describe
20 your interaction with the OPTIMEND team?
21
22
23
24

25 Mechanisms
26
27

- 28 3. How do you think the patients felt about being involved in the intervention?
29
30 4. How do you think other staff members felt about the intervention?
31
32 5. What, in your opinion, worked well in the intervention and what might have
33 worked better?
34
35 6. Do you recall anything unexpected occurring during the intervention that might
36 have influenced its implementation?
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42 Context
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- 45 7. What factors external to the intervention do you think have influenced its
46 implementation?
47
48
49

50 Recommendations for future practice
51
52

- 53 8. What recommendations would you make should the intervention be considered for
54 other emergency departments in the future?
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