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:	*BMJ Open*
Manuscript ID	bmjopen-2019-032645
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
Keywords:	Allied health, Emergency department, Process evaluation, Implementation, Interdisciplinary care, Health service delivery

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

Authors: Marica Cassarino[1], Úna Cronin[2], Katie Robinson[1], Rosie Quinn[3], Fiona Boland[4], Marie E. Ward[5], Rosa McNamara[6], Margaret O'Connor[7,8], Gerard McCarthy[9], Damien Ryan[2,7], Rose Galvin[1]

Correspondence: Dr Marica Cassarino, marica.cassarino@ul.ie, School of Allied Health, Faculty of Education and Health Sciences, University of Limerick, Ireland.

Authors' information:

[1] School of Allied Health, Faculty of Education and Health Sciences, Health Research Institute, University of Limerick, Ireland. Rose Galvin: rose.galvin@ul.ie; Katie Robinson: katie.robinson@ul.ie

[2] Retrieval, Emergency and Disaster Medicine Research and Development Unit (REDSPoT), Emergency Department, University Hospital Limerick, Dooradoyle, Limerick, Ireland; unaAB.cronin@hse.ie; damien.ryan@hse.ie

[3]Emergency Department, Our Lady of Lourdes Hospital Drogheda, Ireland; rosie.quinn@hse.ie

[4] HRB Centre for Primary Care Research, Royal College of Surgeons in Ireland, Dublin, Ireland; fionaboland@rcsi.ie

[5] School of Psychology, Trinity College, the University of Dublin, Dublin 2, Ireland; marie.ward@tcd.ie

[6] Emergency Department, St. Vincent University Hospital, Dublin, Ireland; rosamcnamara@svhg.ie

[7] Graduate Entry Medical School, Faculty of Education and Health Sciences, University of Limerick, Ireland

[8] Department of Ageing and Therapeutics, University Hospital Limerick, Dooradoyle, Limerick, Ireland; oconmargaret@gmail.com

[9] Emergency Department, Cork University Hospital, Cork, Ireland; gerard.mccarthy@hse.ie

Word count (excluding title page, abstract, references, figures and tables): 2,689

ABSTRACT

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

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

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

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is the first formal process evaluation of the implementation of a Health and Social Care Professional team caring for older patients in the emergency department.
- The study will employ the Medical Research Council framework for process evaluations.
- This study will adopt a mixed-methods approach and involve different stakeholders to investigate the implementation, delivery and impact of the allied health intervention.
- Findings will provide key information for future implementations of allied health teams in emergency care settings.

Keywords: Allied health; emergency department; process evaluation; implementation; interdisciplinary care; health service delivery.

INTRODUCTION

Background

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

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

Intervention characteristics

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

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

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

Theoretical framework

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

care, higher satisfaction with the care received, and a better use of primary and community care.

[*FIGURE 1 HERE*]

Figure legend: Fig. 1. HSCP intervention logic model

Objectives

Based on the characteristics and assumptions of the OPTIMEND trial, the aim of this process evaluation is to understand the functioning and effects of the OPTIMEND intervention by examining how the intervention was delivered and received in practice. In line with the MRC guidelines for process evaluations of complex interventions [2], the study has the following objectives to achieve this aim:

1. To describe and analyse the implementation of the OPTIMEND trial (what was delivered and how), including an exploration of the intervention fidelity, dose and reach;
2. To explore the mechanisms of impact within the intervention (i.e., barriers and facilitators of implementation in relation to participants' responses, potential mediators and unexpected pathways);
3. To highlight contextual influences on impact, delivery and acceptability (i.e., individuals, physical environment, ED processes and relations, hospital and healthcare system).

METHODS AND ANALYSIS

Design

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

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

Participants

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

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

- the clinical team involved in the intervention (senior physiotherapist, senior occupational therapist, senior medical social worker, research nurse);
- ED doctors (4-5 participants),
- ED nurses (4-5 participants);
- Other hospital staff members who contributed to the development and implementation of the intervention (e.g., Informatics, Planning and Performance Department; Departments managers; other HSCPs).

Participant recruitment will be conducted through convenience and snowball sampling, with prospective participants being identified by the research team and the clinical team involved in the intervention. The clinical team will also act as gatekeepers linking potential participants with the researcher managing enrolment (MC); furthermore, study leaflets will be distributed at UHL. Prospective participants will be provided with an information sheet outlining the evaluation aim and procedure; written informed consent will be sought prior to participation. Ethical approval for the study was received from the HSE Mid-Western Regional Hospital Research Ethics Committee (REC 103/18) in September 2018. At the time of submission of this protocol, participants recruitment is ongoing and expected to be completed by the end of July 2019.

Outcomes and Measures

Using the MRC process evaluation framework, the study will focus on the measures and research questions outlined in Table 1. The process of implementation will be described in terms of activities and processes put in place for the development and delivery of the implementation, the fidelity of the intervention (adherence to protocol and evidence as well

as adaptations), its dose and reach. Mechanisms internal to the intervention will be investigated in relation to the participants' interaction with the intervention, potential mediators and unexpected pathways. Lastly, using a system approach, potential facilitators and barriers to implementation outside of the intervention will be explored at the level of individuals, the ED physical environment, procedures, communication and the broader healthcare system.

[*TABLE 1 HERE. See end of manuscript*]

Data collection and analysis

As described in Table 1, a mix of quantitative and qualitative methods will be used to address the objectives of this process evaluation.

The content and process of delivery will be evaluated quantitatively through the intervention activity logs. The implementation will also be investigated in terms of fidelity, dose and reach. Fidelity is a central measure in process evaluations [4] which provides information on the extent to which the intervention was delivered as planned or adapted to a specific context. Although maintaining appropriate levels of fidelity has been suggested to enhance the impact of intervention [14], debates on the tension between intervention fidelity and adaption are ongoing, translating into a variety of frameworks attempting to conceptualise fidelity [2]. For the purpose of this process evaluation, we will use the framework proposed by Carroll and colleagues [4] in relation to implementation fidelity for health services interventions and the MRC guidelines [2] to integrate a quantification of adherence, dose and reach with a qualitative exploration of mechanisms of impact within and beyond the intervention. The trial activity logs and recruitment logs will be analysed to

quantify and describe the intervention delivery, comparisons will be made with the trial protocol and evidence base (i.e., systematic review) to evaluate adherence and dose; descriptive quantitative analyses of participants lost at follow-up will be carried to quantify attrition. Potential modifications will be quantified and described with the help of the clinical team using Stirman's framework for interventions adaptations [15]; a detailed evaluation form is included in Supplementary File 2, which focuses on what was modified and at what level of delivery, the nature of the modification, and the agents of the modification.

The qualitative elements of the implementation will be explored via semi-structured interviews and focus groups. An interview schedule is presented in Supplementary File 3, with questions tailored to the trial clinical team and to other staff members. The members of the trial clinical team will be interviewed as a group to describe the process of implementation and delivery, as well as discuss its acceptability and impact; group interviews will also be organised with other members of staff, paying attention to capture the different perspectives of multiple professionals. In addition, prospective participants who do not wish or are not able to take part in the focus groups will be invited to participate in 1:1 semi-structured interviews. Group and individual interviews have a number of strengths and weakness which make it preferable to adopt a flexible approach [16]: On one hand, working with a group facilitates participants who might have time restrictions or feel at ease contributing as a member of a group; on the other hand, individual interviews provide space to individuals who may be unwilling to contribute within a group and can help to elicit more personal and truthful responses because removing potential biases related to group dynamics and social desirability. The interviews and focus groups will be audio recorded and transcribed. The data will be inputted in the software NVivo version 11 Plus (QSR International Pty Ltd) and analysed using the six steps of thematic analysis [17,18], with the aim to highlight the central themes related to the research questions above. While the analysis

will be data driven, the evaluation is informed by an existing framework, thus emerging themes will be compared with the framework to evaluate fit.

By integrating the data collected quantitatively and qualitatively, our analysis will focus on providing a description of the process of implementation as well as considerations of the feasibility and acceptability of the intervention as perceived by key stakeholders involved.

All electronic and hardcopy data will be stored safely by the research team and retained in accordance to the data management policies and procedures of the University of Limerick, Ireland. Access to the data will be limited to the research team members involved in data analysis (MC, KR, RG).

Patient and public involvement statement

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

DISCUSSION

Process evaluations have increasingly become an important component of investigations of the effectiveness of health service interventions [1]. Despite there are

encouraging studies that support the benefits of introducing HSCPs to the ED and promoting interdisciplinary team care, the available evidence on the effectiveness of HSCP team interventions in the ED is limited and presents heterogenous methodologies [5]. The completion of the first randomised controlled trial testing the impact of this model of care on patient and process outcomes in a large ED offers the opportunity to gather information on the process of implementation, delivery and impact, particularly in relation to its feasibility and the facilitators and barriers influencing its development, delivery and impact. Adopting the MRC framework for process evaluations [1] will help to ensure that key aspects of the implementation process are explored and that the complexities of the intervention are captured in details at multiple levels (from individuals to the healthcare system); furthermore, involving different healthcare professionals in the evaluation will enhance the richness of information gathered, particularly in terms of the practical elements of developing and implementing a complex intervention in a dynamic healthcare setting. While we do not envisage any practical and operational issues arising during the study, the evaluation will be overseen by an interdisciplinary steering group of experts in allied health and emergency care that will ensure the rigorous conduct of the study. The findings of this process evaluation will be integrated with the results on the clinical and cost-effectiveness of the trial (currently in data collection status) to provide insights on the viability of this model of care and formulate recommendations for future implementation in other emergency care settings.

ETHICS AND DISSEMINATION

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

disseminated through publication in a peer-review journal and presented at relevant conferences.

Study status: At the time of submission, the status of this study is currently "Recruiting". Recruitment for the study commenced in June 2019 and it is anticipated to be completed by the end of July 2019.

List of abbreviations

CReDECI 2 = Criteria for Reporting the Development and Evaluation of Complex Interventions in Healthcare version 2

ED = Emergency Department

HSCP = Health and Social Care Professional

HSE = Health Service Executive

MRC = Medical Research Council

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

SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

UHL = University Hospital Limerick

STATEMENTS

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

Acknowledgements: Not applicable

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

Funding: This research is supported by the Health Research Board of Ireland through the Research Collaborative for Quality and Patient Safety (RCQPS 2017-2). The sponsor is not involved in the design of the study and collection, analysis, interpretation of data, or in writing the manuscript.

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

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

REFERENCES

1 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655. doi:10.1136/bmj.a1655

2 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* Published Online First: 2015. doi:10.1136/bmj.h1258

3 Hulscher MEJL, Laurant MGH, Grol RPTM. Process evaluation on quality improvement interventions. *Qual Saf Heal Care* 2003;**12**:40–6. doi:10.1136/qhc.12.1.40

4 Carroll C, Patterson M, Wood S, *et al.* A conceptual framework for implementation fidelity. *Implement Sci* 2007;**2**:40. doi:10.1186/1748-5908-2-40

5 Cassarino M, Robinson K, Quinn R, *et al.* Effectiveness of early assessment and intervention by interdisciplinary teams including health and social care professionals in the emergency department: protocol for a systematic review. *BMJ Open* 2018;**8**:e023464. doi:10.1136/bmjopen-2018-023464

6 Gardner G, Gardner A, Middleton S, *et al.* Mapping workforce configuration and operational models in Australian emergency departments: a national survey. *Aust Heal Rev* 2018;**42**:340. doi:10.1071/AH16231

7 Holmes C, Hollebon D, Scranney A, *et al.* Embedding an allied health service in the Nelson Hospital Emergency Department: A retrospective report of a six month pilot project. *New Zeal J Physiother* 2016;**44**:17–25. doi:10.15619/NZJP/44.1.03

8 Moss JE, Flower CL, Houghton LM, *et al.* A multidisciplinary Care Coordination Team improves emergency department discharge planning practice. *Med J ...* 2002;**177**:427–31.http://europepmc.org/abstract/MED/12381253

9 Corbett HM, Lim WK, Davis SJ, *et al.* Care coordination in the Emergency Department: improving outcomes for older patients. *Aust Heal Rev* 2005;**29**:43–50. doi:10.1071/AH050043

10 Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implement Sci* 2010;**5**:67. doi:10.1186/1748-5908-5-67

11 HSE. Emergency Department Task Force. 2015.

12 Chan AW, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: Defining standard protocol items for clinical trials. Ann. Intern. Med. 2013. doi:10.7326/0003-4819-158-3-201302050-00583

13 Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: Revised guideline (CReDECI 2). *Trials* 2015;**16**:204. doi:10.1186/s13063-015-0709-y

14 Dusenbury L, Brannigan R, Falco M, *et al.* A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003;**18**:237–56. doi:10.1093/her/18.2.237

15 Stirman SW, Miller CJ, Toder K, *et al.* Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci* 2013;**8**:65. doi:10.1186/1748-5908-8-65

16 Stewart DW, Shamdasani PN. *Focus groups : theory and practice*. https://books.google.ie/books?hl=en&lr=&id=YU0XBAAAQBAJ&oi=fnd&pg=PP1&

dq=focus+groups+limitations&ots=bDrREIX3Gx&sig=VtCXWwTg1L9pJBWt-C8o8cOJNEk&redir_esc=y#v=onepage&q=focus groups limitations&f=false (accessed 15 May 2019).

17 Braun V, Clarke V, Terry G. Thematic analysis. *Qual Res Clin Heal Psychol* 2012;**24**:95–114.

18 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. doi:10.1191/1478088706qp063oa

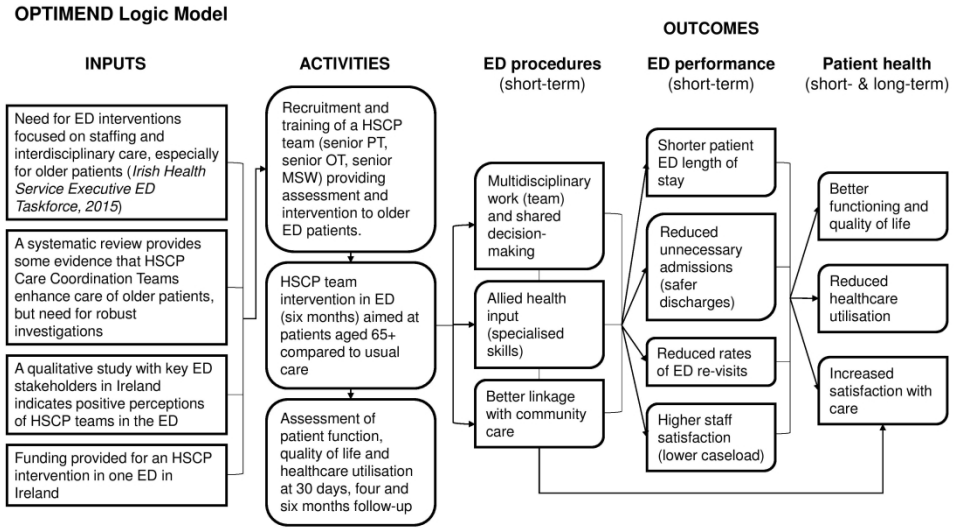
Table 1 – Measures, research questions and data collection

Dimension	Measure	Research questions	Data source	Analysis type
Implementation	Process	How was the intervention developed and delivered? What inputs, resources and structures were put into place?	Team activity logs Interviews/Focus groups	Quantitative descriptive
	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?	Team activity logs Recruitment logs	Quantitative descriptive
	Reach	What proportion of the target population (eligible patients) were enrolled in the intervention? What was the attrition rate?	Recruitment logs	Quantitative
Mechanisms	Participants' responses to and interaction with intervention	How did the patients feel about being involved in the intervention? How did other staff members feel about the intervention?	Interviews/Focus groups Data on patients' satisfaction	Qualitative and quantitative
	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

	hospital or healthcare system

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

398



HSCP intervention logic model

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Introduction			
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_____
	6b	Explanation for choice of comparators	___NA_____
Objectives	7	Specific objectives or hypotheses	___8_____
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_____
Methods: Participants, interventions, and outcomes			
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_____
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_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___NA_____
	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_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___NA_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___NA_____
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____
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_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10-11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10-11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	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
Methods: Monitoring			
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
	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
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
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3, 10, 16
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

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	____NA_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	____NA_____
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_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	____16_____
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_____
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_____
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_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	____NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____NA_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	____10, Suppl file 3___
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_____

*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" 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	

HSCP team ED intervention – Process evaluation protocol

Supplementary File 3 – Interview schedule

Trial clinical team (40-60 minutes focus group)

Implementation

1. Tell me about the preparation phase prior to implementation of the trial: What types of activities were carried to prepare for the trial?
2. Could you describe a typical day of the intervention?
3. Do you think that the implementation was carried as planned or were there adaptations made? If so, which?
4. How did you feel about the recruitment part of the trial?

Mechanisms

5. How do you think the patients felt about being involved in the intervention?
6. How do you think other staff members felt about the intervention?
7. What, in your opinion, worked well in the intervention and what might have worked better?
8. Do you recall anything unexpected occurring during the intervention that might have influenced its implementation?

Context

9. What factors external to the intervention do you think have influenced its implementation?

Recommendations for future practice

10. What recommendations would you make should the intervention be considered for other emergency departments in the future?

Other staff members (focus group or 1:1 interview)

Implementation

1. How were you informed or came to know about the OPTIMEND intervention?
2. If you were working in the ED during the intervention, how would you describe your interaction with the OPTIMEND team?

Mechanisms

3. How do you think the patients felt about being involved in the intervention?
4. How do you think other staff members felt about the intervention?
5. What, in your opinion, worked well in the intervention and what might have worked better?
6. Do you recall anything unexpected occurring during the intervention that might have influenced its implementation?

Context

7. What factors external to the intervention do you think have influenced its implementation?

Recommendations for future practice

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

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:	*BMJ Open*
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

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

Authors: Marica Cassarino[1], Úna Cronin[2], Katie Robinson[1], Rosie Quinn[3], Fiona Boland[4], Marie E. Ward[5], Rosa McNamara[6], Margaret O'Connor[7,8], Gerard McCarthy[9], Damien Ryan[2,7], Rose Galvin[1]

Correspondence: Dr Marica Cassarino, marica.cassarino@ul.ie, School of Allied Health, Faculty of Education and Health Sciences, University of Limerick, Ireland.

Authors' information:

[1] School of Allied Health, Faculty of Education and Health Sciences, Health Research Institute, University of Limerick, Ireland. Rose Galvin: rose.galvin@ul.ie; Katie Robinson: katie.robinson@ul.ie

[2] Retrieval, Emergency and Disaster Medicine Research and Development Unit (REDSPoT), Emergency Department, University Hospital Limerick, Dooradoyle, Limerick, Ireland; unaAB.cronin@hse.ie; damien.ryan@hse.ie

[3]Emergency Department, Our Lady of Lourdes Hospital Drogheda, Ireland; rosie.quinn@hse.ie

[4] HRB Centre for Primary Care Research, Royal College of Surgeons in Ireland, Dublin, Ireland; fionaboland@rcsi.ie

[5] School of Psychology, Trinity College, the University of Dublin, Dublin 2, Ireland; marie.ward@tcd.ie

[6] Emergency Department, St. Vincent University Hospital, Dublin, Ireland; rosamcnamara@svhg.ie

[7] Graduate Entry Medical School, Faculty of Education and Health Sciences, University of Limerick, Ireland

[8] Department of Ageing and Therapeutics, University Hospital Limerick, Dooradoyle, Limerick, Ireland; oconmargaret@gmail.com

[9] Emergency Department, Cork University Hospital, Cork, Ireland; gerard.mccarthy@hse.ie

Word count (excluding title page, abstract, references, figures and tables): 2,689

ABSTRACT

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

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

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

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is the first formal process evaluation of the implementation of a Health and Social Care Professional team caring for older patients in the emergency department.
- The study will employ the Medical Research Council framework for process evaluations.
- This study will adopt a mixed-methods approach and involve different stakeholders to investigate the implementation, delivery and impact of the allied health intervention.
- Group interviews may introduce biases related to group dynamics and social desirability that we will attempt to overcome using also individual interviews and quantitative data.
- Findings will provide key information for future implementations of allied health teams in emergency care settings.

Keywords: Allied health; emergency department; process evaluation; implementation; interdisciplinary care; health service delivery.

INTRODUCTION

Background

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

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

Intervention characteristics

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

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

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

Theoretical framework

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

care, higher satisfaction with the care received, and a better use of primary and community care.

[*FIGURE 1 HERE*]

Figure legend: Fig. 1. HSCP intervention logic model

Objectives

Based on the characteristics and assumptions of the OPTIMEND trial, the aim of this process evaluation is to understand the functioning and effects of the OPTIMEND intervention by examining how the intervention was delivered and received in practice. In line with the MRC guidelines for process evaluations of complex interventions [2], the study has the following objectives to achieve this aim:

1. To describe and analyse the implementation of the OPTIMEND trial (what was delivered and how), including an exploration of the intervention fidelity, dose and reach;
2. To explore the mechanisms of impact within the intervention (i.e., barriers and facilitators of implementation in relation to participants' responses, potential mediators and unexpected pathways);
3. To highlight contextual influences on impact, delivery and acceptability (i.e., individuals, physical environment, ED processes and relations, hospital and healthcare system).

METHODS AND ANALYSIS

Design

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

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

Participants

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

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

- the clinical team involved in the intervention (senior physiotherapist, senior occupational therapist, senior medical social worker, research nurse);
- ED doctors (4-5 participants),
- ED nurses (4-5 participants);
- Other hospital staff members who contributed to the development and implementation of the intervention (e.g., Informatics, Planning and Performance Department; Departments managers; other HSCPs).

Participant recruitment will be conducted through convenience and snowball sampling, with prospective participants being identified by the research team and the clinical team involved in the intervention. The clinical team will also act as gatekeepers linking potential participants with the researcher managing enrolment (MC); furthermore, study leaflets will be distributed at UHL. Prospective participants will be provided with an information sheet outlining the evaluation aim and procedure; written informed consent will be sought prior to participation. Ethical approval for the study was received from the HSE Mid-Western Regional Hospital Research Ethics Committee (REC 103/18) in September 2018. At the time of submission of this protocol, participants recruitment is ongoing and expected to be completed by the end of July 2019.

Outcomes and Measures

Using the MRC process evaluation framework, the study will focus on the measures and research questions outlined in Table 1. The process of implementation will be described in terms of activities and processes put in place for the development and delivery of the implementation, the fidelity of the intervention (adherence to protocol and evidence as well

as adaptations), its dose and reach. Mechanisms internal to the intervention will be investigated in relation to the participants' interaction with the intervention, potential mediators and unexpected pathways. Lastly, using a system approach, potential facilitators and barriers to implementation outside of the intervention will be explored at the level of individuals, the ED physical environment, procedures, communication and the broader healthcare system.

[*TABLE 1 HERE. See end of manuscript*]

Data collection and analysis

As described in Table 1, a mix of quantitative and qualitative methods will be used to address the objectives of this process evaluation.

The content and process of delivery will be evaluated quantitatively through the intervention activity logs. The implementation will also be investigated in terms of fidelity, dose and reach. Fidelity is a central measure in process evaluations [4] which provides information on the extent to which the intervention was delivered as planned or adapted to a specific context. Although maintaining appropriate levels of fidelity has been suggested to enhance the impact of intervention [14], debates on the tension between intervention fidelity and adaption are ongoing, translating into a variety of frameworks attempting to conceptualise fidelity [2]. For the purpose of this process evaluation, we will use the framework proposed by Carroll and colleagues [4] in relation to implementation fidelity for health services interventions and the MRC guidelines [2] to integrate a quantification of adherence, dose and reach with a qualitative exploration of mechanisms of impact within and beyond the intervention. The trial activity logs and recruitment logs will be analysed to

quantify and describe the intervention delivery, comparisons will be made with the trial protocol and evidence base (i.e., systematic review) to evaluate adherence and dose; descriptive quantitative analyses of participants lost at follow-up will be carried to quantify attrition. Potential modifications will be quantified and described with the help of the clinical team using Stirman's framework for interventions adaptations [15]; a detailed evaluation form is included in Supplementary File 2, which focuses on what was modified and at what level of delivery, the nature of the modification, and the agents of the modification.

The qualitative elements of the implementation will be explored via semi-structured interviews and focus groups. An interview schedule is presented in Supplementary File 3, with questions tailored to the trial clinical team and to other staff members. The members of the trial clinical team will be interviewed as a group to describe the process of implementation and delivery, as well as discuss its acceptability and impact; group interviews will also be organised with other members of staff, paying attention to capture the different perspectives of multiple professionals. In addition, prospective participants who do not wish or are not able to take part in the focus groups will be invited to participate in 1:1 semi-structured interviews. Group and individual interviews have a number of strengths and weakness which make it preferable to adopt a flexible approach [16]: On one hand, working with a group facilitates participants who might have time restrictions or feel at ease contributing as a member of a group; on the other hand, individual interviews provide space to individuals who may be unwilling to contribute within a group and can help to elicit more personal and truthful responses because removing potential biases related to group dynamics and social desirability. The interviews and focus groups will be audio recorded and transcribed. The data will be inputted in the software NVivo version 11 Plus (QSR International Pty Ltd) and analysed using the six steps of thematic analysis [17,18], with the aim to highlight the central themes related to the research questions above. While the analysis

will be data driven, the evaluation is informed by an existing framework, thus emerging themes will be compared with the framework to evaluate fit.

By integrating the data collected quantitatively and qualitatively, our analysis will focus on providing a description of the process of implementation as well as considerations of the feasibility and acceptability of the intervention as perceived by key stakeholders involved.

All electronic and hardcopy data will be stored safely by the research team and retained in accordance to the data management policies and procedures of the University of Limerick, Ireland. Access to the data will be limited to the research team members involved in data analysis (MC, KR, RG).

Patient and public involvement statement

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

DISCUSSION

Process evaluations have increasingly become an important component of investigations of the effectiveness of health service interventions [1]. Despite there are

encouraging studies that support the benefits of introducing HSCPs to the ED and promoting interdisciplinary team care, the available evidence on the effectiveness of HSCP team interventions in the ED is limited and presents heterogenous methodologies [5]. The completion of the first randomised controlled trial testing the impact of this model of care on patient and process outcomes in a large ED offers the opportunity to gather information on the process of implementation, delivery and impact, particularly in relation to its feasibility and the facilitators and barriers influencing its development, delivery and impact. Adopting the MRC framework for process evaluations [1] will help to ensure that key aspects of the implementation process are explored and that the complexities of the intervention are captured in details at multiple levels (from individuals to the healthcare system); furthermore, involving different healthcare professionals in the evaluation will enhance the richness of information gathered, particularly in terms of the practical elements of developing and implementing a complex intervention in a dynamic healthcare setting. While we do not envisage any practical and operational issues arising during the study, the evaluation will be overseen by an interdisciplinary steering group of experts in allied health and emergency care that will ensure the rigorous conduct of the study. The findings of this process evaluation will be integrated with the results on the clinical and cost-effectiveness of the trial (currently in data collection status) to provide insights on the viability of this model of care and formulate recommendations for future implementation in other emergency care settings.

ETHICS AND DISSEMINATION

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

disseminated through publication in a peer-review journal and presented at relevant conferences.

Study status: At the time of submission, the status of this study is currently "Recruiting". Recruitment for the study commenced in June 2019 and it is anticipated to be completed by the end of July 2019.

List of abbreviations

CReDECI 2 = Criteria for Reporting the Development and Evaluation of Complex Interventions in Healthcare version 2

ED = Emergency Department

HSCP = Health and Social Care Professional

HSE = Health Service Executive

MRC = Medical Research Council

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

SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

UHL = University Hospital Limerick

STATEMENTS

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

Acknowledgements: Not applicable

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

Funding: This research is supported by the Health Research Board of Ireland through the Research Collaborative for Quality and Patient Safety (RCQPS 2017-2). The sponsor is not involved in the design of the study and collection, analysis, interpretation of data, or in writing the manuscript.

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

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

REFERENCES

1 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655. doi:10.1136/bmj.a1655

2 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* Published Online First: 2015. doi:10.1136/bmj.h1258

3 Hulscher MEJL, Laurant MGH, Grol RPTM. Process evaluation on quality improvement interventions. *Qual Saf Heal Care* 2003;**12**:40–6. doi:10.1136/qhc.12.1.40

4 Carroll C, Patterson M, Wood S, *et al.* A conceptual framework for implementation fidelity. *Implement Sci* 2007;**2**:40. doi:10.1186/1748-5908-2-40

5 Cassarino M, Robinson K, Quinn R, *et al.* Effectiveness of early assessment and intervention by interdisciplinary teams including health and social care professionals in the emergency department: protocol for a systematic review. *BMJ Open* 2018;**8**:e023464. doi:10.1136/bmjopen-2018-023464

6 Gardner G, Gardner A, Middleton S, *et al.* Mapping workforce configuration and operational models in Australian emergency departments: a national survey. *Aust Heal Rev* 2018;**42**:340. doi:10.1071/AH16231

7 Holmes C, Hollebon D, Scranney A, *et al.* Embedding an allied health service in the Nelson Hospital Emergency Department: A retrospective report of a six month pilot project. *New Zeal J Physiother* 2016;**44**:17–25. doi:10.15619/NZJP/44.1.03

8 Moss JE, Flower CL, Houghton LM, *et al.* A multidisciplinary Care Coordination Team improves emergency department discharge planning practice. *Med J ...* 2002;**177**:427–31.http://europepmc.org/abstract/MED/12381253

9 Corbett HM, Lim WK, Davis SJ, *et al.* Care coordination in the Emergency Department: improving outcomes for older patients. *Aust Heal Rev* 2005;**29**:43–50. doi:10.1071/AH050043

10 Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implement Sci* 2010;**5**:67. doi:10.1186/1748-5908-5-67

11 HSE. Emergency Department Task Force. 2015.

12 Chan AW, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: Defining standard protocol items for clinical trials. Ann. Intern. Med. 2013. doi:10.7326/0003-4819-158-3-201302050-00583

13 Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: Revised guideline (CReDECI 2). *Trials* 2015;**16**:204. doi:10.1186/s13063-015-0709-y

14 Dusenbury L, Brannigan R, Falco M, *et al.* A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003;**18**:237–56. doi:10.1093/her/18.2.237

15 Stirman SW, Miller CJ, Toder K, *et al.* Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci* 2013;**8**:65. doi:10.1186/1748-5908-8-65

16 Stewart DW, Shamdasani PN. *Focus groups : theory and practice*. https://books.google.ie/books?hl=en&lr=&id=YU0XBAAAQBAJ&oi=fnd&pg=PP1&

dq=focus+groups+limitations&ots=bDrREIX3Gx&sig=VtCXWwTg1L9pJBWt-C8o8cOJNEk&redir_esc=y#v=onepage&q=focus groups limitations&f=false (accessed 15 May 2019).

17 Braun V, Clarke V, Terry G. Thematic analysis. *Qual Res Clin Heal Psychol* 2012;**24**:95–114.

18 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. doi:10.1191/1478088706qp063oa

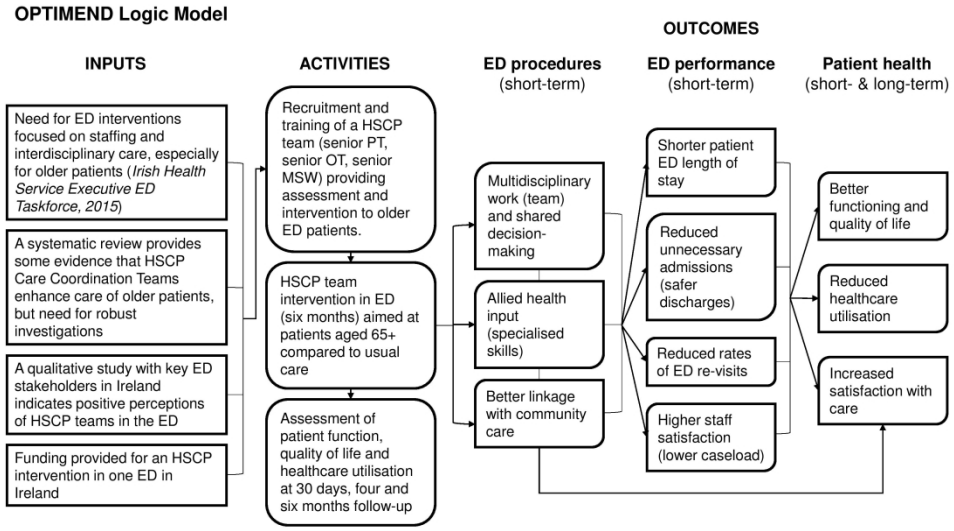
Table 1 – Measures, research questions and data collection

Dimension	Measure	Research questions	Data source	Analysis type
Implementation	Process	How was the intervention developed and delivered? What inputs, resources and structures were put into place?	Team activity logs Interviews/Focus groups	Quantitative descriptive
	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?	Team activity logs Recruitment logs	Quantitative descriptive
	Reach	What proportion of the target population (eligible patients) were enrolled in the intervention? What was the attrition rate?	Recruitment logs	Quantitative
Mechanisms	Participants' responses to and interaction with intervention	How did the patients feel about being involved in the intervention? How did other staff members feel about the intervention?	Interviews/Focus groups Data on patients' satisfaction	Qualitative and quantitative
	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

	hospital or healthcare system

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

401



HSCP intervention logic model

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Introduction			
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_____
	6b	Explanation for choice of comparators	___NA_____
Objectives	7	Specific objectives or hypotheses	___8_____
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_____
Methods: Participants, interventions, and outcomes			
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_____
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_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___NA_____
	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_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___NA_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___NA_____
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____
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_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10-11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10-11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	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
Methods: Monitoring			
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
	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
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
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3, 10, 16
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

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	____NA_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	____NA_____
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_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	____16_____
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_____
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_____
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_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	____NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____NA_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	____10, Suppl file 3___
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_____

*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" 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	

HSCP team ED intervention – Process evaluation protocol

Supplementary File 3 – Interview schedule

Trial clinical team (40-60 minutes focus group)

Implementation

1. Tell me about the preparation phase prior to implementation of the trial: What types of activities were carried to prepare for the trial?
2. Could you describe a typical day of the intervention?
3. Do you think that the implementation was carried as planned or were there adaptations made? If so, which?
4. How did you feel about the recruitment part of the trial?

Mechanisms

5. How do you think the patients felt about being involved in the intervention?
6. How do you think other staff members felt about the intervention?
7. What, in your opinion, worked well in the intervention and what might have worked better?
8. Do you recall anything unexpected occurring during the intervention that might have influenced its implementation?

Context

9. What factors external to the intervention do you think have influenced its implementation?

Recommendations for future practice

10. What recommendations would you make should the intervention be considered for other emergency departments in the future?

Other staff members (focus group or 1:1 interview)

Implementation

1. How were you informed or came to know about the OPTIMEND intervention?
2. If you were working in the ED during the intervention, how would you describe your interaction with the OPTIMEND team?

Mechanisms

3. How do you think the patients felt about being involved in the intervention?
4. How do you think other staff members felt about the intervention?
5. What, in your opinion, worked well in the intervention and what might have worked better?
6. Do you recall anything unexpected occurring during the intervention that might have influenced its implementation?

Context

7. What factors external to the intervention do you think have influenced its implementation?

Recommendations for future practice

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