

# A randomised controlled trial exploring the impact of a dedicated Health and Social Care Professionals team in the Emergency Department on the quality, safety, clinical and cost-effectiveness of care for older adults: Study Protocol

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## Study protocol

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# Abstract

**Background :** Older people are frequent Emergency Department (ED) users who present with complex issues that are linked to poorer health outcomes post-index visit, often have increased ED length of stay and tend to have raised healthcare costs. Encouraging evidence suggests that ED teams involving health and social care professionals (HSCPs) can contribute to enhanced patient flow and improved patient experience by improving care decision-making and thus promoting timely and effective care. However, the evidence supporting the impact of HSCPs teams assessing and intervening with older adults in the ED is limited and identifies important methodological limitations, highlighting the need for more robust and comprehensive investigations of this model of care. This study aims to evaluate the impact of a dedicated ED-based HSCP team on the quality, safety, clinical and cost-effectiveness of care of older adults when compared to usual care. **Methods :** The study is a single-site randomised controlled trial whereby patients aged  $\geq 65$  years who present to the ED of a large Irish hospital will be randomised to the experimental group (ED-based HSCP assessment and intervention) or the control group (usual ED care). The recruitment target is 320 participants. The HSCP team will provide a comprehensive functional assessment as well as interventions to promote a safe discharge for the patient. The primary outcome is ED length of stay (from arrival to discharge). Secondary outcomes include: rates of hospital admissions from the ED, ED re-visits, unplanned hospital admissions and healthcare utilisation at 30-days, four and six-month follow-up; patient functional status and quality of life (at baseline and follow-up); patient satisfaction; costs-effectiveness in terms of costs associated with ED-based HSCP compared to usual care; and perceptions on implementation by ED staff members. **Discussion :** This is the first randomised controlled trial testing the impact of HSCPs working in teams in the ED on the quality, safety, clinical and cost-effectiveness of care for older patients. The findings of the study will provide important information on the effectiveness of this model of care for future implementation. **Trial registration :** ClinicalTrials.gov, NCT03739515; registered on 12 th November 2018. Protocol version 1. URL: <https://clinicaltrials.gov/ct2/show/NCT03739515>

## Background

Internationally, emergency departments (EDs) face significant challenges in delivering high quality and timely patient care set against a background of increasing patient numbers and limited hospital resources [1, 2]. An increasing ageing population and a higher number of individuals with multimorbidities are among the main demographic drivers of incremental ED attendances [3, 4], which in turn lead to ED crowding. Research has demonstrated that ED crowding contributes to a reduction in the quality of patient care, delays in commencement of treatment, increased length of the hospital admission, poorer adherence to recognised clinical guidelines and increased overall costs [4, 5].

Evidence from international studies demonstrates that Health and Social Care Professionals (HSCPs) such as physiotherapists, occupational therapists and medical social workers can play a role in the ED in reducing length of patient stay, avoiding unnecessary hospital admissions and improving patient experience [6–9]. Furthermore, promoting interdisciplinary care in the ED has been shown to enhance

decision-making and contribute to timely and safe patient care, particularly for older adults [10–12]. A recent systematic review [6] demonstrated that care coordination teams comprising of HSCPs (including physiotherapists, occupational therapists and medical social workers) that provide early assessment and intervention to older adults in the ED can contribute to safer discharges and increase patient and staff satisfaction; however, the quality of the evidence is mixed, primarily due to inherent weaknesses in study designs and heterogeneity of patient groups and outcomes of interest.

The overall aim of the study is to examine the impact of a dedicated team of Health and Social Care Professionals (HSCPs) in the Emergency Department (ED) on the quality, safety, clinical and cost-effectiveness of care of older adults in the ED.

The objectives of the study are as follows:

1. To implement a HSCP team including a whole time equivalent senior physiotherapist (PT), senior occupational therapist (OT) and senior medical social worker (MSW) in the Emergency Department at University Hospital Limerick (Ireland) for a period of six months.
2. To examine if early assessment and intervention by the HSCP team improves the quality, safety, clinical and cost-effectiveness of care among older adults who present to the ED, as compared to usual care.
3. To conduct a process evaluation for the HSCP intervention through focus group interviews with the HSCP team and representation from the wider ED staff regarding the implementation, delivery and acceptability of the intervention.

## Methods And Design

### Design

The study represents a single-centre parallel group randomised controlled trial which will compare assessment and/or interventions carried by a HSCP team, comprised of a senior physiotherapist, a senior occupational therapist and a senior medical social worker, in the ED with usual ED care. The CONSORT standardised reporting guidelines will be followed to ensure the standardised conduct and reporting of the research. This protocol has been registered on ClinicalTrials.gov (NCT03739515) and prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (see Figure 1). The checklist is presented in Additional File 1.

### Setting

The study will take place in the ED of University Hospital Limerick (UHL), a 562-bed regional hospital with a large catchment area in the Western region of the Republic of Ireland. Follow-up assessment will take place via telephone interviews.

### Participants

All adults aged  $\geq 65$  years who present to the Emergency Department at University Hospital Limerick between December 2018 and May 2019 (inclusive) are considered eligible for inclusion to the study provided that they meet the following inclusion criteria:

- Capacity (MMSE  $\geq 17$ ) and willingness to provide informed consent
- Off baseline mobility and functional status
- Medically stable (where relevant\*\*) and presenting with any of the complaints presented in Table 1, as per Manchester Triage System 2-5 [13].

**Table 1** Presenting complaint as per Manchester Triage System [13]

Before medical work-up*	After medical work-up**
Limb problems	Chest pain
Falls	Shortness of breath
Unwell adult	Abdominal pain
Back pain	Headache
Urinary problems	
Ear and facial problems	

\*HSCP team will proactively treat these individuals without prior assessment by physician

\*\*HSCP team will await medical clearance prior to assessment and intervention

Exclusion criteria:

- Aged under 65 years
- Medically unstable
- Neither the patient nor the carer can communicate in English sufficiently to complete consent or baseline assessment;
- Presentation and discharge outside of HSCP operational hours. Similar to other studies, the HSCP team is operational between the hours of 8am and 5pm Monday-Friday. Therefore, individuals who present to the ED and are discharged outside of these hours will not be included in the study.

This study is pragmatic in nature and to reflect the realities of clinical practice in the ED, both the triage nurses and treating physicians will act as gatekeepers at the UHL site and inform eligible participants about the study. This method is chosen as the medical condition of participants will change over the course of the index admission.

## Consent

If participants and carers (where relevant) wish to hear more about the study, the triage nurse/treating physician will inform the dedicated research nurse or a member of the HSCP team who will provide them with an information sheet and further discuss the nature of the project with them. Participants will be offered an opportunity to ask questions about participation in the study. Prospective participants will then be asked to sign a consent form. Participants will have the duration of their index admission to consider

participation in the study. Consent and mechanisms relating to data controlling and processing will be compliant with the EU General Data Protection Regulation 2016/679 and also in compliance with the Data Protection Act 2018 [(Section 36(2)) (Health Research) Regulations 2018].

## **Randomisation**

Should participants explicitly consent to participate in the study, they will undergo a baseline assessment of function and quality of life by the research nurse or member of the HSCP team. To minimise the possibility of selection bias, a researcher independent of the recruitment process (MC) will complete random group allocation: Computer generated random numbers in blocks of 20 will be created using an Internet based system (<https://www.randomizer.org/>); the allocation equivalent to each number will be written in a sheet that will be placed in sealed opaque envelopes. These numbers will be stored in the pre-sealed envelopes in a locked drawer in the Emergency Department. Allocation will be revealed by the research nurse employed in the trial after recruitment of eligible participants and the conduct of the baseline assessment. Allocation will be revealed by accessing and opening the next envelope in the sequence and providing the randomisation information to the research team and patient simultaneously. After allocation is revealed, participants will either receive the HSCP intervention or routine care (control group).

## **Power calculation**

We estimated our sample size based on our primary outcomes (ED length of stay and admission rates). Using data from the Patient Experience Time (PET) database employed in the ED at UHL, the average ED length of stay for patients aged 65 and older for the period 2016-2017 was 13.95 hours (SD = 12.49) and around 52% were admitted to ward after the index visit [14]. Estimating a 40% decrease in ED length of stay in the intervention group (mean hours = 8.37, SD = 7.50) and a 20% decrease in admission rates (32% vs. 52%) , and with a 20% attrition rate to follow-up, a sample size of 304 patients (152 in each group) is required to achieve 90% power with two-tailed tests at an alpha level of 0.05.

## **Experimental and control interventions**

### ***Intervention***

Participants in the intervention group will be assessed by one or more members of the dedicated HSCP team (physiotherapy, occupational therapy and medical social work). This will include a holistic assessment of mobility, functional, cognitive and psychosocial abilities. Similarly, interventions prescribed by the HSCP team will be based on subjective and objective assessment of patients; individualised discharge care plans will be instituted from the emergency department in order to promote safe, supported discharge home. All assessments and interventions will be included in the medical chart of individual participants and communicated back to the ED team. To reduce the risk of contamination in the control group, the HSCP team's activities will be limited only to the patients allocated to the intervention.

## ***Control group***

The comparison group will receive routine care for the duration of their stay in the ED. Currently, there is no dedicated team of HSCPs to assess and intervene with older adults who present to the ED at UHL. Ad-hoc services are provided by allied health professionals (i.e., physiotherapists or medical social workers not involved in the HSCP intervention for this study) if they are bleeped from their departments by the ED medical staff. This process will continue for the duration of the trial and will be recorded.

## **Outcomes**

A range of primary and secondary outcomes will be assessed to identify the potential impact of the intervention on quality, safety, clinical- and cost-effectiveness of care. The primary outcomes of the study are duration of patient ED stay (mean hours from time of arrival to discharge or admission) and the incidence of inpatient admission from the ED (defined as the proportion of patients who are admitted to hospital after their index visits). Secondary outcomes will include the duration of hospital admission after the ED index visit, as well as the number of ED re-attendances, nursing home admissions, unplanned hospital visits (and duration of stay) and mortality within 30 days, four months and six months of the initial index visit. Healthcare utilisation (visits to GP, public health nurse, home help, private consultations, outpatient department visits, or allied health services) will also be captured at 30 days, four months and six months. Assessment of patient oriented outcomes include the Barthel Index for Activities of Daily Living [15] as a global measure of function and the EuroQoL's 5-Level of the EQ-5D (EQ-5D-5L) to measure health-related quality of life [16], which will be conducted at baseline as well as at follow-up (30 days and six months, with quality of life also assessed at four months).

In addition, patient satisfaction with their index visit will be explored using the 18-item Patient Satisfaction Questionnaire (PSQ-18) [17] at the time of the visit.

An economic analysis will estimate the incremental cost effectiveness of the HSCP team from the perspective of the Irish public health service, as compared to usual care. We will estimate health care costs from reference costs from national data sources. Participants' responses to the EQ-5D-5L questionnaire will be used to estimate health states utilities using the Irish value set [18] and Quality-Adjusted Life Years (QALYs) for each treatment group will be estimated across all timepoints.

Lastly, a process evaluation will be conducted through a mixed quantitative-qualitative design to describe the implementation of the intervention as well as investigate the mechanisms and contextual influences of the implementation as perceived by the HSCP team and representation from the wider ED staff. A detailed study protocol for the process evaluation is available elsewhere [19].

## **Data collection and management**

Outcome assessment at baseline and at the end of the visit will be conducted by a research nurse blinded to the patient allocation in order to reduce potential detection bias. A chart review will take place by the

research nurse to ascertain demographic details. Outcome assessment at follow-up (30 days, four months and six months post-index visit) will be conducted via telephone call.

## **Data Analysis**

Each participant in the study will be assigned a numerical code in order to link data collected at baseline to the data collected at follow-up at 30 days, four and six months. Aggregate data will be anonymised. Appropriate descriptive statistics will be used to describe the baseline characteristics of study participants. These will include proportions, percentages, ranges, means and standard deviations and medians and interquartile ranges (where data are not normally distributed). Differences between the two groups in terms of ED length of stay and hospital length of stay will be analysed using an independent samples t-test if meeting the assumptions of normality; otherwise, we will employ the nonparametric alternative Wilcoxon-Mann Whitney test with bootstrapping to calculate an effect size 95% confidence interval (CI). The risk of hospital admission rates after the index visit, as well as ED re-visits, unplanned hospital admissions, nursing home admissions and healthcare utilisation at follow-up, will be estimated as Odds Ratios (ORs) with 95% CI using a logistic regression, with analyses on follow-up measures adjusted for patient's age and ISAR score at baseline. Patients' function and quality of life at follow up will be explored through an analysis of covariance (ANCOVA) adjusting for patient's age, baseline ISAR score, baseline Barthel index (for function) and baseline quality of life (for quality of life). Differences in patient satisfaction with their index visit will be analysed using an independent samples t-test with 95% confidence interval.

Considering the cost-effectiveness analysis, as per the Irish Health Information and Quality Authority (HIQA) guidance [20], the primary endpoint of the cost-effectiveness analysis will be costs, QALYs and the Incremental Cost Effectiveness Ratio (ICER). Analysis of uncertainty of the joint distribution of cost and QALYs between the two arms of the study will be presented on a cost-effectiveness acceptability curve to indicate the probability that the HSCP intervention will be cost effective, based on available trial data and across various willingness to pay thresholds.

## **Monitoring**

Participants will be under the medical care of their treating physician for the duration of their ED stay. Participants who are admitted to UHL as an inpatient will be transferred to a relevant ward following their ED stay where their medical care will be transferred to the relevant team. Participants who are discharged from the ED to the community setting or nursing home will be discharged to the care of their GP. The GP will be informed of their participation in the study. Participants may also be referred to community nursing, allied health professionals or community care teams. Once the study is completed, the health of participants will be monitored by their GP or treating physician (if the participant is an inpatient).

## **Discussion**



Based on the results of a systematic review [6], this is the first randomised controlled trial to examine the impact of a HSCP team on the quality, timeliness and cost-effectiveness of care of older adults in the ED when compared to usual care. Previous randomised controlled studies have focused mainly on single HSCPs working as members of ED teams [21, 22], while studies that have described HSCP teams have employed nonrandomised designs [23, 24]. Our study employs a controlled and robust design which is the most appropriate to demonstrate the efficacy of this model of care. The range of outcomes assessed in the study will enable to provide detailed conclusions on impact both at patient and process level. Furthermore, we will provide information on effectiveness both through a cost analysis and a qualitative investigation of feasibility involving ED staff members. The findings of the study will offer useful recommendations for future implementation.

A potential issue related to the study includes the fact that, due to the nature of the intervention, patients and ED staff members involved in the study cannot be blinded to allocation. While this may increase the risk of performance bias, an open procedure reflects realities of clinical practice in the ED. Another issue is linked to the HSCP working hours (8am-5pm Monday to Friday) which may result in missing eligible patients who present out-of-hours. However, we will capture crude estimates of these presentations to report the generalisability of the trial. Furthermore, as agreed with the team and the ED medical/nursing staff before the commencement of participant recruitment, the HSCP team's scope will be limited only to patients involved in the trial; however, a risk of contamination cannot entirely be ruled out as ED medical and nursing staff collaborating with the HSCP team could be influenced in their procedures if taking care of patients in the control group.

## **Trial Status**

At the time of the manuscript submission (June 2019), the status of the trial is "Recruitment completed". Participant recruitment began on the 3<sup>rd</sup> December 2018 and was completed on the 31<sup>st</sup> May 2019 (inclusive). Follow-up data collection is estimated to be completed by November 2019 (inclusive).

## **List Of Abbreviations**

ADLs = Activities of daily living

CERC = Clinical Education and Research Centre

CI = Confidence Interval

CONSORT = Consolidated Standards of Reporting Trials

ED = Emergency Department

EQ-5D-5L = 5-level EuroQoL 5D version

GP = General Practitioner

HIQA = Health Information and Quality Authority

HSCP = Health and Social Care Professional

ICER = Incremental Cost Effectiveness Ratio

MMSE = Mini Mental State Examination

QALYs = Quality-Adjusted Life Years

SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

## Declarations

**Ethics approval and consent to participate:** The study received ethical approval from the Health Service Executive (HSE) Mid-Western Regional Hospital Research Ethics Committee (Ref: 103/18). Written informed consent has been obtained from all study participants.

**Consent for publication:** Not applicable.

**Availability of data and material:** Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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

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**Authors' contributions:** MC and RG were major contributors in writing the protocol. RG, DR, KR, GMC, and RQ designed the study. IOS, ES, SW, and CD piloted the study. IOS, ES, SW, CD, DT, FB, MEW, RMN, MOC and GMC 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.

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## Figures

TIMEPOINT	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				
			ED discharge	30 days (Telephone)	4 months (Tel.)	6 months (Tel.)	6-9 months
Eligibility screen	X						
Informed consent	X						
Baseline Assessment	X						
Randomization		X					
INTERVENTIONS:							
HSCP intervention							
Usual care		←————→					
ASSESSMENTS:		←————→					
Descriptive data	X						
Functional status	X			X		X	
Quality of life	X			X	X	X	
ED length of stay			X				
Hospital admissions			X				
ED revisits				X	X	X	
Hospital visit (and duration of stay)s				X	X	X	
Nursing home admission				X		X	
Mortality				X		X	
Healthcare utilization				X	X	X	
Patient satisfaction			X				
Process evaluation							X

Figure 1

Study schedule

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [AdditionalFile1.pdf](#)