ISRCTN60481756 https://doi.org/10.1186/ISRCTN60481756

SAFER 2: Support and Assessment for Fall Emergency Referrals 2

Submission date	Recruitment status	[X] Prospectively registered
03/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2017	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Background and study aims
The aim of this study is to measure the costs and benefits of a protocol for emergency ambulance paramedics to use when caring for older people who have fallen, allowing the paramedic to assess and refer appropriate patients to a community-based falls service.

Who can participate?
Patients aged 65 and over living within the study area who have fallen and for whom a 999 call is made.

What does the study involve?
Ambulance stations in three participating services (London, Wales, East Midlands) are randomly allocated to either the intervention group or the control group. The control group paramedics continue to provide care according to their standard practice. The intervention group paramedics receive additional training, protocols and clinical support to enable them to assess older people and decide whether they need to be taken to the Emergency Department (ED) straight away, or whether they could benefit from being left at home with a referral to a falls service. We compare the costs, processes and outcomes of care for the patients attended by paramedics with the new protocols with those patients attended by paramedics delivering usual care. The most important outcomes are those related to further falls - subsequent 999 calls and ED attendances for falls. We also compare the two groups of patients in terms of fall-related injuries, hospital admissions, quality of life, fear of falling and deaths, and the time spent, costs of care (and any knock on effects) to the NHS, other services, patients and carers. We also gather in-depth information from patients, carers and health care providers (paramedics, ambulance service managers, and falls service staff) about how the new service works, and about any factors which encourage or hinder its use.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
April 2009 to September 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof Helen Snooks
h.a.snooks@swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Helen Snooks

Contact details
Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP
+44 (0)1792 513418
h.a.snooks@swansea.ac.uk

Additional identifiers

Protocol serial number
HTA 07/01/21

Study information

Scientific Title
Care of older people who fall: evaluation of the clinical and cost effectiveness of new protocols for emergency ambulance personnel to assess and refer to appropriate community based care - a cluster randomised controlled trial

Acronym
SAFER 2

Study objectives
To assess the benefits and costs for patients and the NHS of new protocols allowing paramedics to assess and refer older people who have fallen to community based care.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved by MREC for Wales February 2010, ref: 09_MRE09_61

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Falls in older people

Interventions
Health technology being assessed: a protocol for the care of older people who have fallen, allowing emergency ambulance personnel to assess and refer patients to appropriate community based care. To maximise effectiveness, training, clinical support and referral arrangements will be agreed and implemented in each service as part of the intervention. Costs, processes and outcomes of care for patients, NHS and social care will be compared for patients attended by paramedics based at intervention stations and trained to use the new protocol, with those attended by paramedics based at control stations, delivering usual care.
Total duration of interventions: 15 months

Previous interventions until 25/07/2012:
Total duration of interventions: 7 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 25/07/2012:
The rate of further contacts with emergency healthcare providers (999 calls, ED attendances, emergency admissions or death) - both for any cause and specifically for falls, as summarised by:
1. Proportion of patients who suffer these events
2. Interval to first event
3. Event rate

Previous primary outcome measures until 25/07/2012:
Patient outcome indicators at 1 and 6 months
(From routinely collected data from the ambulance service and ED)
- Further emergency healthcare contacts (999 call or ED attendance) for fall per recruited faller and time to first contact

Key secondary outcome(s)
Current secondary outcome measures as of 25/07/2012:
1. Duration of inpatient episodes
2. Fractures arising from further falls

3. Self-reported further falls
4. Health-related quality of life, as measured by the SF12
5. 'Fear of falling' as measured by the Modified Falls Efficacy Scale
6. Patient satisfaction as measured by the Quality of Care Monitor
7. Change in place of residence
8. Pathway of care as measured by routine ambulance service data on of proportions conveyed to ED, referred to falls service, referred to other providers, or left at scene without further care
9. Durations of: ambulance service job cycle; episode of care; time to falls service response
10. Compliance with guidelines for ambulance service clinical documentation; and referrals; and for falls services follow up
11. Costs of care to NHS and personal social services, estimated by routine data from participating services
12. Self-reported costs incurred by patients and carers
13. Views of ambulance service paramedics, managers and partners on implementation of the intervention
14. Experience and satisfaction of patients receiving the intervention

Previous secondary outcome measures until 25/07/2012:
1. Patient outcome indicators at 1 and 6 months:
1.1. Emergency hospital admission (and those that are fall related) and length of stay
1.2. Further falls: health related quality of life and self-efficacy - 'fear of falling' (Self-report questionnaire, SF-12® Health Survey, Euroqol EQ-5D, modified Falls Efficacy Scale [mFES])
1.3. Injuries related to further falls, radiologically confirmed (from ED card); place of residence (self-report questionnaire)
1.4. Deaths (from coroners/register of deaths)
1.5. Patient satisfaction and experience (self-report questionnaire, Quality of Care Monitor, semi structured interview)

2. Processes of care: (routine ambulance service, ED data)
The following data will be collected systematically throughout the trial:
2.1. Proportions at index fall: conveyed to ED; referred to falls service and other providers; left at scene with no further care
2.2. Times: spent on scene; ambulance service and total care episode; to falls service response; wider ambulance response times
2.3. Quality of care compliance with: ambulance service treatment and referral protocols including clinical documentation; falls service protocol for follow up contact
2.4. Views of ambulance service paramedics; managers and partner providers of care, concerning implementation of the service

3. Costs of care related to a fall to the NHS and personal social services, and wider system effects (routine service data):
3.1. Incurred by patients and carers, related to care provided (self-report questionnaire). Patient outcome indicators will be recorded at 1 and 6 months after index fall.

Completion date
30/09/2013

Eligibility

Key inclusion criteria

1. Both males and females, aged 65 and over
2. Patients who have fallen and for whom a 999 call is made
3. The faller has to live within the study area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
In order to maximise generalisability of findings to this group of frail patients with complex needs, no patients will be excluded due to other conditions or competence.

Date of first enrolment
01/04/2009

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea University
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Swansea University (UK)

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2015		Yes	No
Results article	results	01/03/2017		Yes	No
Protocol article	protocol	12/11/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes