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Evaluation of the costs and benefits of computerised on-scene decision support for emergency ambulance personnel to assess and plan appropriate care for older people who have fallen: a randomised controlled trial

Submission date	Recruitment status
20/03/2007	No longer recruiting
Registration date	**Overall study status**
01/05/2007	Completed
Last Edited	**Condition category**
06/07/2018	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0200055

Study information

Scientific Title
Evaluation of the costs and benefits of computerised on-scene decision support for emergency ambulance personnel to assess and plan appropriate care for older people who have fallen: a randomised controlled trial

Acronym
SAFER (Support and Assessment for Fall Emergency Referrals)

Study objectives
To assess costs and benefits of hand-held Computerised Decision Support (CDS) technology for the on-scene assessment and care of older people who fall and call the emergency ambulance service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration submission pending

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Older fallers

Interventions

The intervention being evaluated is an IT innovation of CDS software on a hand-held Tablet PC for use on scene by ambulance crews to make decisions about the clinical and social care needs of patients that have called the 999 ambulance service. The innovation is part of a complex intervention with four components: 1) training - both clinical and technology based; 2) decision-support guidance to assess and plan care for older fallers; 3) the hardware and software and 4) referral to community based care providers. The package will be evaluated as a whole, in line with the recommendations of the MRC for evaluating complex interventions to improve health, as the component parts are interdependent and should not be separated out for the sole purpose of testing.

The technology will allow the traditional ambulance service Patient Report Form to be replaced with a digital record on the Tablet PC, and trained crews will be expected to use the computer to create an electronic record for every call. When the crew member attends a patient that meets the inclusion criteria for this study, the additional functionality of the decision support for assessing falls will also be used to assess whether the older person who has fallen should be taken to Accident & Emergency (A&E) department or offered an alternative care plan. The CDS prompts the assessment and examination of any injuries associated with the fall, as well as co-morbidity that may have contributed to the fall (such as breathlessness or chest pain) and the patients psycho-social needs (such as their mental state and their ability to undertake activities of daily living). An assessment of environmental risk is also included. Based on these assessments, the CDS suggests an appropriate care plan (such as patient advice, referral to specific community based services etc.).

Paramedics allocated to the intervention group will receive additional training (four days) in the use of the CDS. Following initial training there will be a pre-trial period of one month during which trained crews will be expected to practise using the hand-held computer in place of paper Patient Record Forms, and the CDS for falls assessment as and when appropriate. Towards the end of this period, their use of the CDS will be audited to ensure that they have achieved proficiency. Training will be carried out with groups of 6 paramedics and will last four days, split so that 3 initial days are followed up with one further day after three weeks of practice. Training consists of systematic demonstration of the mechanics and functionality of the software coupled with practice and supervised structured and unstructured role play. Critical reflection and discussion is undertaken and encouraged throughout the training programme. Knowledge reviews are carried out at certain points of the process to ensure competence and understanding of key aspects of the software functionality.

To meet the primary study objective, the technology will be tested with paramedics at two study sites (South Wales, East of England). It is intended that crews that have been trained in the intervention will make decisions that can enable community-based care and avoid hospital attendance and admission for these older patients, without undertaking the lengthy, comprehensive and expensive training that is required to enable them to act as fully autonomous practitioners. Building on research findings from previous studies carried out by members of the research team, the technology will form an integral part of the package to be evaluated. Protocols have been shown to have limited impact, but integrated into on-line decision support software to be used interactively on scene, may allow identification of patients who can be safely left at home. Thus patients may benefit from a more appropriate response in their homes rather than the traditional care of transportation to A&E, or non-conveyance without referral - because they have been left at home outside protocols. The study will be powered to detect differences in processes and outcomes between patients in the intervention and control groups in these two sites.

The paramedics will be trialling the CDS for a period of approximately nine months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patients will be tracked through the 999 system, A&E departments, GPs and coroners to identify further contacts with these services (or death) following a fall within one month. Referrals will be followed up and contacts with other service providers recorded. Quality of life of patients and carers, self-reported falls and independence will be followed up by questionnaire, to be administered by post (or interview, where necessary), including the SF12 , EQ5D and the CGI at 1 month; patient satisfaction will also be followed up at 1 month with the Quality of Care Monitor. Despite using several validated outcome measures, care has been taken to select brief tools and efforts will be made to keep the questionnaire as short as possible in order to minimise the burden on respondents and to maximise response rate. Job cycle times will be recorded for all calls meeting the study inclusion criteria, from routine ambulance records.

Secondary outcome measures
Health economics: The economic analysis will estimate the costs of providing the new intervention, the consequences of the scheme for the wider NHS (eg A&E attendances, inpatient admissions) and the costs to patients and families. Data on the use of the health service resources will be collected for each patient using a combination of paramedic records, routine hospital records (for hospital events) and patient-completed questionnaires. Costs will then be calculated using unit-costs estimated through a micro-costing study within the trial. Direct costs to the NHS will be assessed using data logged as a part of routine practice and from resource utilisation recording sheets, together with reference to patient records and discussions with relevant finance staff. The EQ5D will also be used to estimate the quality adjusted life years (QALYs) gained from the intervention and an incremental cost-per-QALY estimated. These ratios will be presented along with their associated cost-effectiveness acceptability curves. Sensitivity analysis will be undertaken to assess the robustness of the results to changes in the configuration of the scheme and other health service costs.

Qualitative: A subset of 10 older people who fall and are attended by ambulance crews using the new technology at each study site (20 in total) will be interviewed in more depth, using a semi-structured interview schedule to ascertain their views and preferences regarding the service they received. Where possible, to minimise disruption and number of visitors, these interviews will be carried out by the community based providers who visit the older people following referral from the 999 service. The study researchers will train these providers in qualitative interviewing techniques to ensure that standards of data collection are maintained.

Focus groups (n = 6) will be carried out with paramedics from the intervention and control groups following the trial, and with other stakeholders based in other service providers, particularly in the falls services to explore: triage decision-making processes; views concerning the care of older people who fall; issues in implementation of the innovation and referral. Discussions will be taped and transcribed.

Overall study start date
01/08/2006

Completion date
31/03/2011

Eligibility

Key inclusion criteria
999 calls for patients over 65 in Wales and England attended by a study paramedic and classified by them as having fallen

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1440

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
01/08/2006

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea University
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SA2 8PP

Sponsor information

Organisation
Department of Health Information and Communication Research Initiative (UK)

Sponsor details
NIHR-CCF
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Sponsor type
Government

Website
http://www.nihr-ccf.org.uk/site/default.cfm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health Information and Communication Research Initiative (UK) (ref: 0200055)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	26/01/2010		Yes	No

Results article	results	12/09/2014	Yes	No
Results article	results	04/07/2018	Yes	No