Support and Assessment for Fall Emergency Referrals (SAFER) 2: a cluster randomised trial and systematic review of clinical effectiveness and cost-effectiveness of new protocols for emergency ambulance paramedics to assess older people following a fall with referral to community-based care when appropriate

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Scientific summary

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Scientific summary

Background

Emergency calls to ambulance services are frequently made for older people who have fallen, but ambulance crews often leave patients at the scene without any ongoing care. Subsequent falls and emergency episodes of care are common in this group. In the Support and Assessment for Fall Emergency Referrals (SAFER) 2 trial, we evaluated a new clinical protocol that allows paramedics to assess older people who had fallen and refer those who do not need to be taken to the emergency department (ED) to community-based falls services for continuing care.

Aim and objectives

Aim

To assess the benefits and costs of a complex intervention comprising training and clinical protocols enabling paramedics to assess older people who have fallen and refer them to falls services when appropriate.

Objectives

- To compare outcomes, processes and costs of care between intervention and control groups:
  - patient outcomes: rate and pattern of subsequent emergency health-care contacts or deaths; health-related quality of life; falls efficacy (fear of falling); and change in place of residence
  - processes of care: pathway from index incident; subsequent health-care contacts; ambulance service operational indicators and protocol compliance including clinical documentation
  - costs of care to the NHS.
- To understand how patients experience the new intervention.
- To identify factors which facilitate or hinder the use of the intervention.
- To inform the development of methods for falls research.

Methods

We undertook a systematic review of published evidence related to the effectiveness of emergency care interventions by ambulance crews for older people who had fallen. We searched the following electronic databases: The Cochrane Library, Allied and Complementary Medicine Database (AMED), Applied Social Sciences Index and Abstracts (ASSIA), British Nursing Index (BNI), Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus, Internurse, MEDLINE, PsycINFO, PubMed, Scopus, The British Library, UK Institutional Library Search, GreyNet, Conference Proceedings Citation Index (Web of Science), OpenGrey and The British Library's Electronic Table of Contents (Zetoc) between 1990 and July 2013.

The SAFER 2 study was a multicentre, cluster randomised controlled trial with economic evaluation and qualitative component. We undertook the trial in defined areas within three ambulance services in which falls services were set up but direct referral from the ambulance service did not take place. We allocated ambulance stations, and the paramedics who volunteered to take part, to intervention and control groups. We included patients in the trial if they were aged ≥ 65 years, resident in the catchment area of participating falls services, and attended by a study paramedic following an emergency call to the

ambulance service that was coded by a dispatcher as a fall without priority symptoms. Patients were recruited for their first incident within the trial period.

The complex intervention that we evaluated comprised assessment protocol, referral pathway, falls service, and training, clinical and operational support to paramedics. We asked paramedics at control stations to continue their usual practice, comprising routine assessment, initial care, assistance in moving and conveyance to ED unless the patient refused.

The primary outcome comprised subsequent emergency health-care contacts (death, emergency admissions, ED attendances and emergency service calls) at 1 month and 6 months.

Secondary outcomes from routine data:

- referral to falls service or other provider
- compliance with clinical documentation guidelines
- durations of ambulance service job cycle and episode of care
- duration of subsequent inpatient episodes
- subsequent fractures
- costs of care.

Secondary outcomes from patient questionnaires:

- health-related quality of life [Short Form questionnaire-12 items (SF-12)]
- patient satisfaction (Quality of Care Monitor, at 1 month only)
- 'fear of falling' [modified Falls Efficacy Scale (mFES)]
- self-reported falls.

Routine outcomes were retrieved from the ambulance services and matched to central NHS registers by the National Welsh Informatics Service and the Health and Social Care Information Centre (HSCIC) in to link them to NHS and Office for National Statistics data sets. We linked self-reported outcomes from postal questionnaires to the routine data by trial identifiers and analysed them in the Secure Anonymised Information Linkage (SAIL) databank without identifiers.

We collected qualitative data from patients attended by intervention paramedics concerning their experience and satisfaction, and from ambulance service paramedics and managers on their views of implementation of the intervention.

We analysed quantitative data by treatment allocated except for those describing uptake of the intervention. Qualitative data were analysed using a framework approach.

We obtained ethical approvals from the Research Ethics Committee for Wales, the National Information Governance Board and each participating health board, NHS trust and primary care trust. We followed all patients who did not actively decline consent (dissent) through the anonymised route.

Results

Systematic review

Of 5355 papers identified by searches, 138 appeared potentially eligible from title and abstract; we included 13 papers (12 studies) after detailed reading of full text. Studies from the USA, the UK, Australia and New Zealand comprised two randomised controlled trials, nine cohort studies and one qualitative study. These yielded limited and weak evidence of the most effective ways to deliver alternative treatments to older people who fall. A minority identified benefits – reductions in subsequent emergency calls and hospital admissions –

for patients referred to a falls prevention service or attended by a paramedic with additional skills. However, several studies did not explore such outcomes and the quality of most of the studies was low. We concluded that robust evidence from well-designed and rigorous research is needed to inform service delivery.

Support and Assessment for Fall Emergency Referrals 2 cluster randomised controlled trial

Recruitment

Between March 2011 and June 2012, across the three study sites, 3073 eligible patients were attended by 105 paramedics based at 14 ambulance stations randomly allocated to the intervention group, and 2841 eligible patients were attended by 110 paramedics based at 11 stations allocated to the control group. After excluding dissenting and unmatched patients, we included 2391 from the intervention group and 2264 from the control group in primary outcome analyses at 1 and 6 months.

Baseline data

Recruitment of patients was higher at site 1 than at the other sites. There was little difference in age, sex, time of call, distance to ED or time to recruitment between trial arms. There was one more intervention station at each site, but fewer paramedics per station.

Missing data

We retrieved a number of routine data for all 4704 eligible patients who did not dissent. However, neither the SAIL database nor HSCIC enabled us to match 49 of these, or to retrieve data on their ED attendances, hospital admissions and death. Questionnaire response rates at 1 month varied between sites from 30% to 51%, with 1307 questionnaires returned; and at 6 months from 53% to 74%, with 678 questionnaires returned.

Outcomes and estimation

Clinical effectiveness

One-third of patients had suffered a further emergency episode or death by 1 month [870 out of 2391 (36.4%) intervention group patients and 843 out of 2264 (37.2%) control group patients; odds ratio (OR) 0.96, 95% confidence interval (CI) 0.85 to 1.08]. By 6 months this had risen to two-thirds [1701 out of 2391 (71.1%) intervention group patients and 1592 out of 2264 (70.3%) control group patients; OR 1.02, 95% CI 0.89 to 1.16].

We found evidence of fewer emergency service calls by 1 month [442 out of 2391 (18.5%) intervention group patients called vs. 493 out of 2264 (21.8%) control group patients; OR 0.82, 95% CI 0.70 to 0.94]; thus, the mean number of further calls per patient per day at risk was 0.020 and 0.025, respectively (difference –0.004, 95% CI –0.008 to 0.000). By 6 months, 1046 out of 2391 (43.7%) intervention group patients had called the emergency services, compared with 1046 out of 2264 (46.2%) control group patients (OR 0.90, 95% CI 0.80 to 1.01); the mean number of further calls per patient per day at risk was 0.013 and 0.017, respectively (difference –0.005, 95% CI –0.007 to –0.002). These differences were largely consistent across sites, and there was some evidence of fewer ED attendances at 6 months (mean number of further attendances per patient: intervention group, 0.84; control group, 0.91; event ratio 0.81, 95% CI 0.72 to 0.91).

The proportion of patients transported to the ED at the time of index incident was similar in the two groups [1579 out of 2420 (65.2%) patients in the intervention group compared with 1431 out of 2284 (62.7%) patients in the control group; OR 1.08, 95% CI 0.96 to 1.22]. However, this proportion varied considerably by site, from < 60% at site 1 to nearly 80% at site 2. Intervention paramedics referred 8% of patients to falls services, ranging from 7.5% at site 1 to 9.7% at site 3. Control paramedics referred only 1.1% of patients to falls services, with some variation between sites. The number of patients left at the

scene without any referral for further care was lower in the intervention group (547 out of 2420; 22.6%) than in the control group (692 out of 2284; 30.3%) (OR 0.69, 95% CI 0.60 to 0.78).

Completion of clinical documentation was high (> 90% on all key physiological indicators recorded on-scene) across sites, with no clear difference between trial groups. We also found no differences in operational indicators [the mean duration of episodes of care, from emergency service call until patient's emergency episode was complete, was 196.8 minutes in the intervention group and 192.8 minutes in the control group (difference 2.05 minutes, 95% CI –6.68 to 10.77 minutes); and the mean duration of the job cycle, from emergency service call until the ambulance was free, was 99.9 minutes in the intervention group and 97.8 minutes in the control group (difference 1.69 minutes, 95% CI –0.75 to 4.12 minutes)].

We did not find differences in the following measures:

Duration (mean) of inpatient stay, which at 1 month was 2.25 days in the intervention group versus 2.10 days in the control group (difference 0.14 days, 95% CI –0.21 to 0.49 days) and at 6 months was 11.18 days in the intervention group versus 11.62 days in the control group (difference –0.56 days, 95% CI –1.88 to 0.76 days).

SF-12 mental health component (mean score), which at 1 month was 39.80 in the intervention group versus 38.89 in the control group (difference 0.90, 95% CI –0.74 to 2.55) and at 6 months was 43.21 in the intervention group versus 42.82 in the control group (difference 0.46, 95% CI –1.72 to 2.64).

SF-12 physical health component (mean score), which at at 1 month was 29.07 in the intervention group versus 29.40 in the control group (difference –0.50, 95% CI –1.85 to 0.86) and at 6 months was 30.44 in the intervention group versus 31.88 in the control group (difference –1.30, 95% CI –3.28 to 0.68).

Fall-specific mFES (mean score), which at 1 month was 3.71 in the intervention group versus 3.82 in the control group (adjusted difference –0.06, 95% CI –0.39 to 0.28) and at 6 months was 4.55 in the intervention group versus 4.79 in the control group (adjusted difference –0.23, 95% CI –0.73 to 0.27).

Satisfaction with care: technical mean scores at 1 month were 62.82 in the intervention group versus 63.21 in the control group (adjusted difference –0.32, 95% CI –1.27 to 0.63); in contrast, interpersonal mean scores were significantly higher, that is 68.92 in the intervention group versus 68.04 in the control group (adjusted difference 3.13, 95% CI 1.59 to 4.68).

Fewer intervention patients reported further falls by 1 month: 413 out of 621 (66.5%) in the intervention group versus 409 out of 589 (69.4%) in the control group (OR 0.72, 95% CI 0.54 to 0.96). However, there was no significant difference in subsequent fractures by 1 month, being reported by 98 out of 2391 patients in the intervention group (4.1%) versus 91 out of 2264 (4.0%) patients in the control group (OR 1.00, 95% CI 0.74 to 1.35). By 6 months, however, significant interactions between intervention and site masked any generic effect on further falls or subsequent fractures.

Sixty per cent of intervention group paramedics used their protocols to refer patients to falls services (i.e. between one and 11 times). Patients' age, sex and distance to ED did not influence these referrals. However, only 19 of 40 paramedics (48%) at site 3 referred patients to falls services, compared with 26 of 39 (67%) at site 1 and 19 of 26 (73%) at site 2.

Cost-effectiveness

We estimated the mean cost of the SAFER 2 study intervention across the three ambulance services as £17.30 per patient, including generic and local set-up costs such as training package development, training delivery and clinical support for implementation.

We estimated mean resource use by 1 month to be £3740.00 in the intervention group and £3514.00 in the control group (adjusted difference £190.24, 95% CI –£13.83 to £394.31), with the cost of initial hospital stays (£2523.27 and £2329.79, respectively) a major cost driver. Estimated mean resource use by 6 months was £8816.41 in the intervention group and £8661.77 in the control group (adjusted difference £24.20, 95% CI –£468.01 to £516.40), with the cost of subsequent hospital stays (£3982.21 and £4111.10, respectively) a major cost driver.

The imputed Short Form questionnaire-6 Dimensions (health and quality-of-life outcomes) scores showed that mean utilities over 6 months were slightly higher in the control group; however, the adjusted difference of –0.0026 was not statistically significant (95% CI 0.0066 to 0.0014).

Qualitative findings

Almost all of the 58 patients interviewed were very satisfied with the processes of assessment and examination carried out by paramedics. Most of those able to compare their SAFER 2 study encounter with the ambulance service with a previous contact after a fall could see little difference in the assessment and care delivered. Many patients were already accessing a complex network of community-based services, from a range of providers (NHS, social services, third sector).

Twenty-four paramedics participated in focus groups or interviews before implementation, and 25 paramedics and 31 other stakeholders, including ambulance service managers, trainers and falls services staff, participated in focus groups or interviews after the trial.

Before the trial, paramedics reported that they expected making significant use of the intervention. Post trial, paramedics in all sites reported that the intervention had increased their confidence in leaving patients at home. The structured training on the SAFER 2 study was felt to be more helpful than previous and more informal approaches to introducing innovations. They suggested that a 'simpler' intervention would have sufficed, with a less detailed flow chart. Reported barriers to referral included, in all sites, issues relating to patients' social situation and autonomy, and, in one site, a lack of knowledge of the role of the falls team. Some paramedics were concerned about increased times on-scene, but managers did not see this as an issue.

Methodological findings

We compared the performance of the generic SF-12 outcome measure with the falls-specific outcome measure, the mFES, in the study population and found the moderate correlation between them ($r = 0.55$ to 0.63), with significant floor and ceiling effects for the condition-specific measure.

Conclusions

The SAFER 2 study intervention to facilitate referral to community-based falls services was inexpensive and safe. The number of referrals made to falls services was lower than expected, and there was considerable variation between paramedics. The intervention reduced the number of patients left at the scene by attending ambulance crews without ongoing care, but had little effect on other processes of care. Although the numbers of further emergency health-care contacts and deaths were unchanged overall, subsequent emergency service calls were significantly reduced by 1 and 6 months. There was little evidence of impact on self-reported health outcomes or satisfaction.

Retrieval of anonymised linked data outcomes was highly successful in this 'e-trial', and ensured that findings were generalisable to the whole study population. We plan further analysis trial findings to describe fully the benefits and risks of this new approach.

The SAFER 2 trial has shown that ambulance services can introduce this new clinical pathway for patients without risk of harm, at modest cost and with some reductions in further emergency contacts. However, we did not find evidence of improved health outcomes for patients.

Future work recommendations

Further research is necessary to understand ambulance service implementation and paramedic uptake issues related to the falls intervention tested in the SAFER 2 study; costs and benefits of using anonymised linked data outcomes in trials; and performance of the mFES in this population.

Trial registration

This trial is registered as ISRCTN60481756 and as PROSPERO number CRD42013006418.

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