

PB-PG-0711-25070 – NIHR Research for Patient Benefit Programme – Final report

Project title: Can Ambulance Paramedics use FRAX® (the WHO Fracture Risk Assessment Tool) to help GPs improve Future Fracture Risk in Patients that Fall?

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Plain language summary

Background: Broken bones (fractures) are painful, often disabling, and cost the NHS £2 billion annually. People at high risk can take tablets to reduce the chance of a fracture, but only about a third of them do.

It is difficult to identify patients most at risk before they have a broken bone. Patients with osteoporosis (thin bones) who fall are at risk of fracture.

We wanted to train paramedics to assess a patient's fracture risk (using a short set of questions called FRAX®) when they were called to help after a fall. Telling the patient's GP the FRAX score might lead them to prescribe tablets to those at high risk of fracture, reducing the risk of a broken bone. This small study aimed to find out if such a plan might work.

Findings: We trained 25 paramedics who attended around 1500 patients after a fall. Of these, 175 patients gave verbal consent to take part in the study, but some were not suitable for inclusion and others did not want to, although they had shown initial interest. Patients who said "no thanks" told us they felt too ill, didn't have enough time, or felt too old to be in research. 53 patients signed up for the study.

The patients' ages ranged between 58 and 98; most had fallen 3 times or more in the previous year. One in four needed help filling in the research forms. About half the patients were at moderate/high risk of future fracture, but only 4 taking any tablets to reduce this risk.

Patients, paramedics and GPs generally liked the idea of paramedics asking fracture questions so that GPs could be told about a patient's risk of future fracture. Paramedics were willing and able to ask the fracture questions, but sometimes did not want to ask vulnerable patients to take part in research. GPs said it was useful to know a patient's fracture risk and the number of falls that they had.

Conclusions: Paramedics can assess a patient's fracture risk. Patients who fall are often at high risk of fracture but review of GP records suggests relatively few take tablets to prevent breaks. Patients, paramedics and GPs support the idea of asking people the FRAX questions and sending letters to GPs but there were barriers to study recruitment.

We could take this research forward by training paramedics to assess patients' fracture risk routinely. To avoid asking vulnerable patients to complete research forms we could instead use prescription data (collected anonymously) to find out if this meant that GPs recommended more treatment to patients.

Keywords

Feasibility; Fall; FRAX; Osteoporosis; Paramedic; Randomised Controlled Trial

Summary of research findings

Background: Identification and management of patients at risk of osteoporotic fracture in the UK is sub-optimal. There are effective treatments to reduce the risk of fractures in people with osteoporosis but only a small minority of eligible patients take them. As the majority of patients who fracture have fallen, it follows that people who fall can be targeted to improve treatment rates and reduce osteoporotic fracture.

Paramedics are often called to patients who fall, so may be well placed to assess future fracture risk using the Fracture Risk Assessment Tool (FRAX®). Further, if that information were transmitted to the patient's GP, doctors may prescribe anti-osteoporotic treatment to patients at high risk. In turn, this should reduce future fractures.

Aims and Objectives: This was a feasibility study to collect quantitative and qualitative data to inform the design of a main trial with fracture reduction as the outcome. We set the following objectives:

1. Determine recruitment, eligibility, consent rates, and the proportion of participants that continue to study completion.
2. Establish the proportion of participants at sufficiently high risk of fracture to warrant preventive treatment, and the proportion already taking appropriate medication.
3. Find out if paramedics can ask the necessary questions and gain the right information to reliably calculate fracture risk.
4. Determine if paramedics will collect and submit the information.

5. Determine the acceptability of trial design and intervention to patients (carers where appropriate), paramedics, and GPs.
6. Collect data and information on participants' GP attendances, referral for investigation (DXA scan) and/or treatment in both the intervention and control groups.
7. Identify, measure and value resources required to deliver the intervention.
8. Explore methods of collecting NHS resource use data for the follow-up period, including from patients, GP practices and hospitals.
9. Collect quality of life data using the EQ-5D-5L.

Methods:

The study took the form of a pragmatic, randomised controlled trial comparing usual care with an intervention. The latter comprised calculation of future fracture and fall risk by paramedics using FRAX®, and transmission of that risk to the patient's GP. Patients in the intervention arm at moderate or high risk of fracture were encouraged to attend their GP for investigation or treatment.

Patients (50 years +) who fell, called an ambulance, and were attended by a study paramedic were included. Patients considered clinically stable were asked for verbal consent: (a) for the paramedic to ask questions relating to the patient's fracture (using FRAX®) risk and (b) for a researcher to subsequently contact them with further information about the study.

Following verbal consent, patients were sent study information packs. Patients who lacked capacity were not excluded, but could take part with the help of a consultee. Patients were asked to complete the consent form and return it; the 'written consent' stage of the study process.

Participants (or their consultee) who provided written consent were randomised to control (usual care) or intervention group.

Participants (except those who opted out of questionnaires – see changes to study plan) completed an EQ-5D-5L at baseline and at 3 month follow up, when they also completed a resource use questionnaire.

Data about prescriptions and primary care consultations were obtained from GP records, and about secondary care resource use from local hospital trusts.

A qualitative study explored acceptability and study design with patients, their GPs (interviews) and paramedics (interviews, field observations and a focus group).

Reasons for declining trial participation were explored by telephone.

Key Findings:

Recruitment and consent (objective 1) – see CONSORT flow diagram in appendix 1.

Over a 12 month recruiting period, paramedics were dispatched to 1447 calls categorised as “falls” (see “denominator” appendix 2). 175 patients gave verbal consent to participation (the number of patients invited to participate was not recorded). Of these, 33 were ineligible (admitted to hospital for >24 hours), 1 died before providing written consent and 1 excluded before randomisation as the FRAX® was not completed.

Of the 140 remaining eligible patients, 87 either declined or did not respond. 53 provided written consent, 34 (64%) of which agreed to complete study questionnaires. 49 (92%) patients continued to study completion.

Proportion of patients at risk (2, 6) Participants’ mean age was 81 years (range 57 to 98) and 27/53 (51%) were women. 23/53 (43%) of patients reported prior fracture. The median number of falls reported in the previous 12 months was 3.0 and median risk of hip fracture 7.6% (risk >5% in 37/53 (70%)).

28/53 (53%) patients were judged to be at intermediate/high risk of fracture. Of these, 9 had ever taken bone protection medication, and 4 were currently doing so. This suggests 19/53 (36% - CI 23.1%, 50.2%) have potential to benefit from bone protection.

Paramedics (3,4) 25 of about 100 paramedics working at an ambulance station volunteered to take part in the study. They received training covering osteoporosis and falls, in consent processes and in administering the FRAX®. Feedback from the sessions was positive.

Acceptability (4,5)

Patient Interviews: Of 33 trial participants who were sent information about qualitative interviews, 14 patients and 6 consultees agreed to take part after completion of the primary outcome data collection (11 from the intervention group; 9 from the control group). Although interviewees who could recall the consent process found it acceptable and considered the research important, 6 interviewees (including 1 consultee) were unable to recall giving verbal consent to take part. The 11 interviewees who recalled answering the FRAX® questions and the study questionnaires found them acceptable.

Paramedic data: Among the 25 paramedics involved, there was considerable variation in the number of falls that each attended and in the proportion of patients they recruited (appendix 2). Of the 25, 14 paramedics agreed to an interview, and we conducted 8 field observations and 1 focus group (n=4). Paramedics identified the potential benefit of intervention for patients and expressed interest in calculating patient fracture risk. They also felt that the intervention was simple, low risk and straightforward to implement. Paramedics identified several challenges to recruitment of patients, including complex cases, patients' vulnerability, the roles of care home staff and family members, and in attending falls at night.

GP interviews: Of 25 approached, 8 GPs agreed to a qualitative interview. Interviewed GPs thought that the research was important and valued receipt of the fracture risk information. GPs made suggestions for improvements to the intervention letters. They liked receiving fracture risk and falls information, and DXA referral forms. GPs used this information to supplement their assessment of patients' needs. They also highlighted the challenges in providing care for patients with complex health needs, adherence to medication and time constraints.

Patients who did not provide written consent: Of 87 patients who gave verbal but not subsequently written consent, we asked 26 of them why. Patients reported feeling too unwell, have insufficient time or feel too old. Some did not specify a reason. Analysis of their demographic data did not reveal differences between them and those who opted to take part.

Investigation and treatment (6)

Participants attended their GP an average of 1.34 occasions over the follow up period (2.42 intervention vs. 0.61 control group $p=0.004$). 8 patients had ever had a DXA scan, of which 3 in the intervention group and 0 in the control group during the study. 7 patients (4/20 intervention) were newly recommended/prescribed vitamin D supplements or bisphosphonate during 3 month follow up. 7/46 patients were referred to a falls clinic (6 in the intervention arm).

Costs (7)

Identified costs included those linked to paramedic training to deliver the FRAX (estimated to be £352 per head), the additional time they spent asking (FRAX) questions (estimated at 5 minutes per call), and those incurred by GPs (administrative, additional investigation and/or treatment).

Quality of life data collection (8, 9)

92% of those who opted to complete questionnaires (29 baseline /28 follow-up) provided complete EQ5D-5L data. The intervention group utility scores increased from 0.3499 to 0.3823 but in the control group decreased from 0.3703 to 0.3413, a QALY difference (controlling for baseline) of 0.008 over 3 months, 95% CI [-0.014, 0.029].

74% of GP resource data was returned by post and the remainder collected by the research fellow. Hospital resource use collection was straightforward with appropriate permissions.

Expected impact

Despite difficulties in patient recruitment, health professionals and patients see the intervention as valuable. It is possible that people who fall and are attended by paramedics could benefit from focused intervention to reduce future fracture risk. The study provides novel insights into the fracture risk of people who fall, and the challenges of completing this type of research.

Conclusions

Patients, paramedics and GPs see potential benefit in fracture risk assessment. Paramedics attend a group of patients at relatively high risk of fracture, of whom few are taking treatment. Recruitment was, however, challenging, and an alternative future approach could be to train paramedics to assess fracture risk routinely. Instead of asking patients to complete research forms, anonymous prescription and medical records data could be used to evaluate any impact on treatment in primary care, and ultimately on fracture rates.

Patient and public involvement

We worked with the project's patient advisory group in producing this part of the report. The group has reviewed, and commented upon, the whole document.

The project team's collaboration with patients began during the development of the study design before submission of the grant application. Applicants held a "Falls Forum", attended by seven members of the public (and carers), with direct experience of falling. Those at the forum were willing to consider participation in the study as presented, and also felt they would be able to give meaningful answers to all except one of the FRAX® questions if asked by ambulance paramedics. The forum considered the question about rheumatoid arthritis confusing. The study team excluded this question from the risk questions paramedics asked.

Great Western Ambulance Service previously convened an External Reference Group (ERG). Members of that group were asked about our proposed study design. In particular, we were interested in their thoughts about the ethical implications of approaching potentially vulnerable patients (who had fallen) to be in a research study. The 5 group members felt the study to be ethical and reasonable, but were concerned that fracture information might result in more work for overstretched GPs. Their comments prompted us to change the study design so a research fellow calculated the FRAX scores, rather than the patient's GP.

Forum members also suggested that the researcher, at first contact, should be clear about their link with the ambulance paramedics to avoid an older person mistaking them for a "nuisance caller". The group also explored how best to conduct telephone interviews with people living with hearing loss.

We consulted with two local branches of the National Osteoporosis Society (NOS) and with officers working at NOS headquarters about the study design and literature. We received feedback that helped us improve the readability of our information and consent sheets.

Members of the project's patient advisory group were approached through widespread advertisement of our project.

Members of the advisory group, who named themselves the "Oak Leaves", volunteered from the ERG, from local branches of the NOS, and from among the patient base in the hospital osteoporosis and care of the elderly clinics. We have been supported by 6 Oak Leaves.

Oak Leaves attended 2 training sessions held by the principal investigator and supported by the project's research fellow. The sessions covered general training in osteoporosis, falls and fracture risk, but also information about the study and its conduct. Specifically, we explained the patient advisory group role, undertakings and support available. The Oak Leaves were invited to meet the project team in person and were given a tour of the department and visited the DXA scanner. All group members were provided with study contact information and support.

The project team reported to Oak Leaf meetings, held twice annually. The Oak Leaves provided representation at Project Steering Group Meetings (PSC) and attendees reported back to the other group members. Unfortunately, some of the group members have been unwell at times during the course of the project and not all members have been able to attend on all occasions.

The Oak Leaves made valuable contributions to study literature (patient information sheets, consent forms) both in terms of the content, and layout. Oak Leaves attended paramedic training sessions where they role played to provide formative assessment.

The Oak Leaves shared our concern about relatively low patient recruitment and were a part of the decision-making process involved in altering our protocol to allow patients to opt out of questionnaires, and to introduce face-to-face recruitment.

We consulted the Oak Leaves about ongoing slow recruitment and they made recommendations to the project team about the best time to stop.

In addition to the work documented above, the group feels it is important for research projects to collaborate with patient representatives. They commented that there appears to be a considerable administrative burden (red tape) attached to a research study, and that the patient body can provide a “down to earth” (grounded) link.

In addition, the group felt the training and experience they gained within the present study might help them in performing a similar role in any future project with which they might become involved.

The project team were pleased to hear that Oak Leaf members have volunteered to continue to work with the research team, pending clarification of the direction in which the study moves.

Data sharing statement

See link

[<https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253>] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This project was carried out between 01 January 2013 and 31 December 2014. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.