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Support and Assessment for Fall Emergency Referrals (SAFER 2) research protocol: cluster randomised trial of the clinical and cost effectiveness of new protocols for emergency ambulance paramedics to assess and refer to appropriate community based care

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Support and Assessment for Fall Emergency Referrals (SAFER 2) research protocol: cluster randomised trial of the clinical and cost effectiveness of new protocols for emergency ambulance paramedics to assess and refer to appropriate community based care

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Abstract

Introduction

Emergency calls to ambulance services are frequently for older people who have fallen, but ambulance crews often leave patients at the scene without ongoing care. Evidence shows that when left at home with no further support older people often experience subsequent falls which result in injury and emergency department attendances. SAFER 2 is an evaluation of a new clinical protocol which allows paramedics to assess and refer older people who have fallen and do not need hospital care to community based falls services. In this protocol paper we report methods and progress during trial implementation. SAFER 2 is recruiting patients through three ambulance services. A successful trial will provide robust evidence about the value of this new model of care, and enable ambulance services to use resources efficiently.

Design

Pragmatic cluster randomised trial.

Methods and Analysis

We randomly allocated 25 participating ambulance stations (clusters) in three services to intervention or control group. Intervention paramedics received training and clinical protocols for assessing and referring older people who have fallen to community-based falls services when appropriate, whilst control paramedics deliver care as usual.

Patients are eligible for the trial if they are: aged 65 or over; resident in a participating falls service catchment area; and attended by a trial paramedic following an emergency call coded as a fall without priority symptoms. The principal outcome is the rate of further emergency contacts (or death), for any cause and for falls. Secondary outcomes include further falls, health-related quality of life, 'fear of falling', patient satisfaction reported by participants through postal questionnaires at one and six months, and quality and pathways of care at the index incident. We shall compare NHS and patient/carer costs between intervention and control groups and estimate Quality Adjusted Life Years (QALYs) gained from the intervention and thus incremental cost per QALY. We shall estimate wider system effects on key performance indicators. We shall interview 60 intervention patients, and conduct focus groups with contributing NHS staff to explore their experiences of the assessment and referral service. We shall analyse quantitative trial data by 'treatment allocated'; and qualitative data using content analysis.

Ethics and Dissemination

The Research Ethics Committee for Wales gave ethical approval and each participating centre gave NHS Research & Development (R&D) approval. We shall disseminate study findings through peer-reviewed publications and conference presentations.

Trial Registration ISRCTN 60481756

INTRODUCTION

We have written this protocol paper during trial implementation and include information about study progress. We have made several minor amendments to the protocol since the original version. We highlight key differences between the original and current protocol, including sample size calculations and consent processes.

Background

Falls in older people are recognised as an important issue internationally,[1,2] with high human and organisational costs. Reduction in quality of life and physical activity lead to social isolation and functional deterioration with a high risk of resultant dependency and institutionalisation[3-5]. In the UK falls account for 3% (about £980 million) of total National Health Service expenditure,[6] and the prevention of falls in older people has been highlighted as a priority[7,8].

Although prevention appears effective,[8] reducing falls and associated morbidity depends on early identification of people at high risk and delivery of interventions across traditional service boundaries[9] – priorities now reflected in national and international guidelines[10-12]. A recent systematic review and meta-analysis found limited evidence of benefit from multifactorial risk assessment and targeted intervention for falls in primary, community or emergency care. However, none of these trials reported quantitative outcome data on Health Related Quality of Life (HRQoL) and although six had been undertaken in emergency care, none were conducted in prehospital care.

Older people taken to Emergency Departments following a fall are highly likely to fall again in the following year, with a 30% chance of sustaining fracture or dislocation[13]. Multidisciplinary interventions have increased uptake of preventative advice,[14,15] and reduced subsequent falls, length of hospital stay and disability[13]. Older people commonly call an emergency ambulance (999) following a fall. In London (UK) this group accounts for about 60,000 attendances (8% of emergency ambulance responses) each year. This is very similar to the proportion reported in an urban Emergency Medical Service system in the US[16]. Non-conveyance to Emergency Departments (EDs) is high in this group – close to 40% in London,[17] elsewhere in the UK,[18,19] and US[16]. Most (90%) falls not conveyed to ED occur in the home[20]. Non-conveyance of patients is recognised internationally as a safety and litigation risk[21].

More widely, in most UK ambulance services, treatment protocols advise conveying patients to ED unless they refuse to travel to hospital. In practice, however, ambulance services allow their staff to decide who can be safely left at home. Little is known about how, in the absence of specific protocols or training to leave older people who fall at home, paramedics make these decisions. A US study acknowledged the pragmatic nature of negotiation with patients whether to go to hospital or not[22]. A UK study identified factors affecting these decisions including: experience and confidence of ambulance staff, time into the shift, presence of carers, quality of the accommodation, waiting times at the local ED, and prior knowledge of the patient[23]. There have been few established referral pathways, or even encouragement to inform patients' GPs, or other services of the emergency call. However, recent policy changes in the UK have encouraged the development and implementation of alternative models of care for delivery by the ambulance service, including enhanced training for paramedics, and community-based referral pathways for patients who do not need the ED[24,25].

The National Service Framework for Older People[7] advocates that ambulance crews refer older people who have fallen to community-based care, although this reflects consensus rather than research evidence. A recent study found that referring elderly patients, who had fallen and been left at home by their attending ambulance crew, to a community-based falls prevention service reduced further falls and improved clinical outcomes[26]. Previous studies in this setting have found that change in practice is difficult to achieve and new pathways of care are difficult to exploit[27]. Furthermore there is little evidence about the safety of non-conveyance decisions by paramedics[28].

The SAFER 2 trial has followed the MRC framework for developing and evaluating complex interventions[29]. Logan[26] has since reinforced the case for a multi-centre trial of an intervention in which attending ambulance crews assess patients who have fallen and refer them to community-based falls services from the scene[30-34]. We hypothesise that the intervention works by improving the decision-making of paramedics to use falls services to best effect. If so, we expect better outcomes and reduced costs, both for patients now referred to falls services and for those not now taken to ED unnecessarily. Achieving these improved outcomes for patients requires participating paramedics to change their practice in relation to assessment, conveyance and referral of patients. Hence we have designed SAFER 2 to gather data about each of the elements of the pathway and to assess both processes and outcomes.

Aim and objectives

Aim

To assess the benefits and costs to patients and the National Health Service (NHS) of a complex intervention comprising education, clinical protocols and pathways enabling paramedics to assess older people who have fallen and refer them to community-based falls services when appropriate.

Objectives:

1. To compare outcomes, processes and costs of care between intervention and control groups:
   - A. patient outcomes: rate and pattern of subsequent emergency health care contacts or deaths, for any reason and for falls; health-related quality of life (HRQoL); psychological status, especially fear of falling; and change in place of residence;
   - B. processes of care: pathway of care at index fall; subsequent healthcare contacts; ambulance service operational indicators; and protocol compliance including clinical documentation; and
   - C. costs of care: provided by NHS and personal social services; incurred by patients or carers in seeking care.
2. To estimate wider system effects of the introduction of the intervention on ambulance service performance and costs.
3. To understand how patients experience the new health technology.
4. To identify factors which facilitate or hinder the use of the intervention.
5. To inform the development of methods for falls research especially outcome measures recommended for trials of interventions for older people who fall[2].

METHODS AND ANALYSIS

Trial design and management

This is a cluster randomised trial (CRT), with economic and qualitative components. We have randomly allocated ambulance stations between trial groups, both to enable us to support change of practice in the intervention group and to minimise contamination between groups in evaluating patient outcomes. The economic component addresses Objectives 1 and 2 by valuing the benefits and costs of the intervention.

The qualitative component addresses Objectives 2 and 3 through two methods: semi-structured interviews with participants (or their carers) attended by intervention paramedics; and focus groups with intervention paramedics and NHS service providers.

Following the MRC guidelines for good practice in clinical trials[35] the management structure comprises external Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC); and internal Trial Management Group (TMG), Local Implementation Team (LIT) in each area, and core team. The TSC oversees the trial and provides advice to the Chief Investigator (CI), the HTA and the Sponsor on all aspects. The DMEC has access to unblinded comparative data to monitor the data and make recommendations to the TSC whether there are ethical or safety reasons why the trial should not continue. The TMG manages the trial from day to day. The LITs deal with issues emerging at each trial site and provide opportunities to share progress. The core team is smaller, including the CI and research team.

Setting and site selection

We are undertaking the trial in pre-hospital emergency care, with paramedics delivering the intervention in partnership with community-based falls services. We have selected three ambulance services in England and Wales, covering a mixture of urban and rural areas where a falls service was available, but no process in place for paramedics to make direct referrals from the scene of 999 attendances.

Participants

We invited paramedics based at ambulance stations that normally attend patients within the catchment area of participating falls services, to participate in the trial before allocating those stations randomly between groups.

Patients are eligible for the trial if they: are aged 65 years or over; live in the catchment area of participating falls services; and are attended by a study paramedic following an emergency call to the ambulance service which is coded by a dispatcher as a fall without priority symptoms [Advanced Medical Priority Dispatch System (AMPDS) code 17]. We exclude patients attended by an Emergency Care Practitioner unless their attendance was at the request of a trial paramedic. We recruit patients to the trial only once, since subsequent falls constitute patient outcomes.

Interventions

The core of the health technology we are evaluating is a clinical protocol for the care of older people who have fallen, enabling emergency ambulance paramedics to assess and refer them to community-based falls services. Development of the intervention built on previous studies in this field. This complex intervention comprises: training; referral pathways to falls services; individual outcome reports to referring paramedics from falls

services; and clinical and operational support to change practice including a feedback loop between paramedics and ambulance service managers. Specialist sub-groups developed specific components of the intervention for SAFER 2, while modelling and stakeholder feedback facilitated testing of economic viability and expected affects. Sites agreed common minimum standards for core elements of the intervention at the outset, while permitting local differences in processes like referral and documentation.

In accordance with the NICE guidelines for the assessment and prevention of falls,[12] the multi-disciplinary falls services team includes nursing, physiotherapy, occupational therapy and rehabilitation provision. They provide risk assessment and treatment including: postural stability and balance training; home hazard advice; equipment and adaptations; medical review including osteoporosis risk; advice on fear of falls; social care; benefit advice; and referral to other community services.

Control intervention: we have asked paramedics based at control stations to continue their usual practice. Although we know that conveyance rates vary considerably among services, stations and paramedics, we have not sought standardisation of practice, as we do not know what is best. Current practice in the control group is therefore care as usual comprising: assessment of injury or other condition requiring immediate care; assistance in moving from where they have fallen; and conveyance to ED unless the patient refuses.

Outcomes

Outcome measures at one and six months after patients' index calls are consistent with recommendations of Prevention of Falls Network Europe (PrOFaNE)[36].

Principal outcomes

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:

- Proportion of patients who suffer these events
- Interval to first event
- Event rate

Secondary outcomes

- Duration of inpatient episodes
- Fractures arising from further falls
- Self-reported further falls
- Health-related quality of life, as measured by the SF12[37]
- 'Fear of falling' as measured by the Modified Falls Efficacy Scale[38]
- Patient satisfaction as measured by the (Quality of Care Monitor)[39]
- Change in place of residence
- Pathway of care as measured by routine ambulance service data on proportions conveyed to ED, referred to falls service, referred to other providers, or left at scene without further care
- Durations of: ambulance service job cycle; episode of care; time to falls service response
- Compliance with guidelines for ambulance service clinical documentation; referrals; and falls services follow up

- Costs of care to NHS and personal social services, estimated by routine data from participating services
- Self-reported costs incurred by patients and carers
- Views of ambulance service paramedics, managers and partners on implementation of the intervention
- Experience and satisfaction of patients receiving the intervention

Data collection methods

This CRT does not approach participants at the point of treatment, because they may be in distress and cannot give informed consent. Instead we seek retrospective consent to follow up through routine medical records and by postal questionnaire. Following experience in several earlier experimental studies, we originally proposed an 'opt-out' procedure, and gained provisional ethical approval from a Multicentre Research Ethics Committee. However information governance approval for this approach was not forthcoming. We therefore designed an active consent process, in which we contact patients to seek consent to follow up first by post, and then if necessary by telephone or home visit, and gained the necessary approvals. We also include a £5 voucher with each invitation pack to thank participants for their time. We are also undertaking anonymised follow up through linked records – in Wales using the Secure Anonymised Information Linkage (SAIL) databank,[40] and in England using similar centralised records – again with information governance approval.

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Sample size and power

We estimated the sample size for the trial from our principal outcome – the proportion of participants who, within six months, die or contact emergency services (999 service or ED). From previous trials of interventions for older people who have sustained a fall and presented for emergency treatment, summarised in a recent systematic review,[41] we make the conservative estimate that trial patients have about 50% chance of making another emergency contact within six months. As the intervention appears cheap a priori, we judge that a change of 5% in this proportion may be clinically and economically important. In the absence of clustering, a sample size of 4190 evaluable participants would yield 90% power to detect a change of at least 5% (from 50% to ≤ 45% or ≥ 55%) when using two-sided 5% significance level. As participants come from 25 clusters (ambulance stations), we need to adjust this sample size to allow for intra-cluster correlation (ICC). We estimate this ICC from the findings of the SAFER 1 trial,[41] which evaluated the clinical and cost effectiveness of Computerised Clinical Decision Support (CCDS) software for use by paramedics when attending older adults who had a fall. SAFER 1 estimated the ICC for the same outcome, but over one month rather than six, as zero when clustering participants by station (as in SAFER 2) but 0.005 when clustering participants by paramedic (as in SAFER 1)[42]. To be conservative, we allow for an ICC of 0.002. Solving a simple algebraic equation then yields: a target of 251.6 evaluable participants per station; a variance inflation factor of [1 + (251.6 - 1) x 0.002] viz 1.5012; and a total evaluable sample of 4190 x 1.5012 = 6290 viz 25 x 251.6. This sample will also have more than 90% power to detect a change of 0.18 in the estimated mean of 1.8 emergency contacts per participant over six months, given an estimated standard deviation of 1.5. Hence SAFER 2 can detect a difference of 1 emergency contact in 10 avoided (or induced) by the intervention.

We had originally postulated that patients recruited to the study would have a 40% chance of making an emergency contact within 6 months; and that the ICC could be as high as 0.03. Under those assumptions our target sample of about 6300 would have yielded 80%

power to detect a change of at least 10% (i.e. from 40% to ≤ 30% or ≥ 50%) when using a two sided 5% significance level. When SAFER1 showed that the assumed ICC was unduly pessimistic, recruitment was progressing well. Rather than finish the trial early, therefore, we decided with the approval of both TSC and DMEC to be less conservative in assuming a worst ICC of 0.02, thus yielding enough power to detect a change of only 5% in the emergency contact rate, still a clinically important difference in the view of our advisers.

Early in SAFER 2, approximately one in ten recruited participants consented to complete questionnaires, confidential but not anonymised. This has now increased to one in four for the one-month questionnaire. The trial is on target to achieve a sample size of 6290, and the resulting sample of 800 returned questionnaires at 6 months would yield 90% power of detecting an effect size of 0.25 (equivalent to one quarter of the population standard deviation) in each of the questionnaire outcomes. Such a low response rate requires that analysis include rigorous non-response analysis to test whether findings extrapolate to the entire population of interest.

Loss to follow up

We monitor routine outcomes in two forms: anonymised linked data from central NHS databanks for all patients that we can match to NHS administrative records, which needs information governance approvals but no consent; and identifiable data from NHS providers for patients who consent for us to do this. Our experience in the recently completed SAFER 1 trial in a similar population in Wales suggests we can achieve 90% follow-up through anonymised linked data. Though this will reduce statistical power below the 90% postulated in our calculations, it will still exceed the traditional 80%.

Randomisation

An independent statistician randomised the 25 participating ambulance stations between intervention and control groups after the paramedics had volunteered to participate, thus minimising selection bias; the stratifying variables were the receiving falls service and the number of paramedics participating in each station.

Blinding

Though the trial managers and fieldworkers need to know the allocation of all participating ambulance stations for operational reasons, we keep the trial statistician blind to these allocations.

Statistical analysis

Primary analysis will be by 'treatment allocated'. Analyses will include: logistic regression for binary outcomes; cross-tabulations and risk ratios for categorical outcomes; and survival analysis including Cox's proportional hazards models for times to events. We shall use multi-level modelling to estimate (random) station effects and (fixed) group effects and analyse repeated observations as such.

Our principal outcomes comprise a hierarchy, and will undergo analysis incrementally: first deaths; second emergency admissions plus deaths; then ED attendances plus admissions and deaths; and finally 999 calls plus attendances, admissions and deaths. Analysis at one and six months will cover, for all such events, and those coded as a fall: the proportion of patients that call 999, attend ED, get admitted or die; survival analysis of the time to the first subsequent emergency contact; the mean number of further emergency contacts adjusted for time at risk, excluding days in hospital or after death; and recurrent event

analysis where feasible. As patients' decision to call 999 after later events could reflect the care they received at the index call, we shall check whether these later calls reflect valid need rather than health seeking behaviour, by comparing them with self-reported falls and health-related quality of life. We will also examine the effect of the intervention on patient satisfaction, health related quality of life and costs (as described separately, below).

Potential predictors of triage decisions include the distance between the site of the index event and the ED; patients' age, sex and history of previous falls; type of presentation (e.g. out of hours); and time since recruitment, as routine data may be less accessible for patients recruited later in the trial. We shall therefore use these as covariates in the analysis. It is possible that patients in the catchment area of one station may receive care for a subsequent event from another station participating in the study but allocated to a different group. Nevertheless analysis will still be by treatment allocated. Secondary analyses will examine outcomes by treatment received, namely whether participants got referred to falls services.

To identify any wider system effects, we shall compare response times during the trial period across the study catchment area and surrounding areas with pre-trial response times and response times elsewhere. We shall also compare the characteristics of those included and not included through both consented and anonymised routes, to explore whether there are systematic differences between groups and routes that may influence outcomes.

To inform the development of outcome measures for falls research as recommended by Prevention of Falls Network Europe (ProFaNE), we shall compare SF12 and derived SF6D scores with mFES scores to establish their construct validity. We shall also assess their predictive validity by comparing scores with the number of further events and the time to the first subsequent event.

Economic evaluation

We are undertaking economic evaluation alongside the cluster randomised trial from the perspective of the UK NHS and personal social services, and patients and their families. Economic analysis will estimate the costs of providing the intervention, the costs to patients and families, and the consequences of the scheme for the NHS and social services in terms of inpatient admissions, ED attendances, GP consultations, out-of-hours GP contacts, NHS Direct contacts, and use of social services. We shall collect data on participants' use of health service and social services resources from paramedic records, routine hospital records and patient-completed questionnaires. We shall estimate NHS resource use from routine data including duration of ambulance job cycles and episodes of care; records of resource use; and patient records. We shall estimate social services resource costs from discussion with relevant social services departments. We shall calculate the resulting costs using unit costs from published sources. We shall estimate the Quality Adjusted Life Years (QALYs) gained by the intervention from the SF6D. We shall derive an incremental cost-per-QALY and present the resulting cost-effectiveness plane and associated cost-effectiveness acceptability curves. We undertake sensitivity analysis to assess the robustness of the results to changes in the configuration of the scheme and other health service costs.

We recognise that the follow-up period is not long enough to yield evaluation over the lifetime of participants. We shall therefore develop a decision model to extrapolate costs and effects beyond the data generated by the trial – probably from the hazard rates estimated by the trial. We shall construct alternative scenarios from previous studies and

discussions with experts – to judge the extent to which risks will remain constant or change over time, and assess the implications of using a longer time-horizon on the basic analysis of costs and benefits.

Qualitative study

One researcher is undertaking semi-structured interviews with older people who have been recruited to the study and focus groups interviews with intervention paramedics and service providers. We are purposively sampling 20 participants in each site attended by intervention paramedics following a fall, to include patients transferred to the ED, patients referred to the falls service and patients neither transferred or referred. We interview these participants or their carers at a site of their choosing six to eight weeks after their index fall. We developed the interview schedule to gather information in depth about the experience of patients in the intervention group, and we consulted user groups about the content and acceptability of that schedule. In particular we are interested in intervention fidelity and the perceptions of those who received the intervention – for instance whether they feel confident about paramedics' decisions whether they need to go to the ED; and how they feel about the process of referral.

Focus groups are a useful way of understanding organisational change,[43] and exploring the success or failure of particular programmes[44]. At each of the three centres we are undertaking focus groups with intervention paramedics before and after the trial period. Following the trial period we shall hold focus groups with a range of ambulance service participants in each centre, including trainers, operational managers, clinical team leaders and dispatch staff; and with participants from other partner services in each centre including falls services, social services and ED. We include six to eight participants in each focus group, to facilitate discussions within manageable groups[45]. We base the topic guides on previous research in this area and consultation with our Local Implementation Teams. Two researchers lead each focus group, one to facilitate discussion and the other to take notes that link text to speakers and highlight points of consensus or disagreement and issues that draw strong emotional responses such as anger, fear or anxiety.

Systematically comparing and analysing qualitative data in raw form is challenging[46]. So we shall record and transcribe all interviews and focus groups with the permission of participants. A protocol will ensure that we use standard format and conventions throughout the transcription process. We shall analyse all these data by using NVivo software to explore commonalities and differences in topics that emerge from the guides. Two researchers will analyse all these data independently and then meet to discuss and agree final coding and interpretation.

Adverse Event reporting

SAFER 2 is following the principles of the Standard Operating Procedure for adverse events developed by the West Wales Organisation for Rigorous Trials in Health (WWORTH). As the study population has high mortality and morbidity, we do not routinely record or report Adverse Events (AE) that are neither serious nor Adverse Reactions (ARs) in the sense of possibly being caused by the new clinical protocol for referring to falls services. The main potential AR is misdiagnosis, which could lead to an inappropriate pathway of care. As misdiagnosis is reliably identifiable only through patient complaints or coroner's inquest, we focus on these, and treat them as Serious Adverse Reactions (SAR). Any patient complaint or coroner's inquest at which the ambulance service is asked to supply information related to non-conveyance of a trial participant from

the index incident will trigger investigation by the local Principal Investigator and, Chief Investigator. We also investigate suspected ARs brought to our attention in any other way.

Death or emergency hospital admission is a Serious Adverse Event (SAE). As these form the primary outcome of this trial, and are not unusual or unexpected in the study population, we shall report them at the end of the trial. In particular imbalance between intervention and control groups in the occurrence of SAEs or SARs, will be the subject of statistical analysis at the end of the trial.

ETHICS AND DISSEMINATION

Ethics and R & D governance

Current practice has been shown to carry risks for patients, as many (up to half) are left at scene without further care, and many of these (about half) make further emergency healthcare contacts within two weeks[19]. Following a recommendation in the National Service Framework for Older People,[9] ambulance services around the UK have begun to implement alternative pathways of care for older people who have fallen, either through Emergency Care Practitioner schemes or direct referral from paramedics. Research is urgently needed to understand the safety, costs and clinical effectiveness of this new model of care. Ethical and consent issues in cluster randomised trials are acknowledged to present their own unique challenges[47]. Against this background we have obtained we have obtained ethical approval has been obtained from the Research Ethics Committee for Wales, information governance approval from the National Information Governance Board, and NHS R&D approval from each participating Health Board, NHS Trust and Primary Care Trust (PCT).

Service users

We include patients and carers as active participants in the research at all stages. As the relevant service users are often frail, we are using innovative methods to facilitate their contributions. They attend TSC, DMEC, TMG and LIT meetings and additional service user groups, where they contribute to the research process and discuss issues affecting older people with a history of falls. We do not expect them to attend full research team meetings, although they may bring their views to the team meetings, following meetings with service users in other forums. Including service users in emergency care research is a particular challenge,[48] but is achievable and brings rewards to the trial and the team.

Dissemination

We shall comply with the CONSORT guidelines[49]. We will present the study results at national and international conferences and publish them in peer-reviewed journals. In accordance with recommendations we have registered SAFER 2 in a public registry (http://www.controlled-trials.com/isrctn/, Identifier: ISRCTN 60481756).

DISCUSSION

Progress so far (April 2012)

The SAFER 2 trial is underway in three ambulance services, in collaboration with eight participating falls services and twelve hospitals with EDs. We have recruited 220 paramedics from 25 ambulance stations (clusters) to the trial. In the first year of the trial we recruited over 4000 patients. Hence we are on target to detect clinically important differences in outcomes at six months, whilst monitoring the safety of the intervention at one month.

Authors Contributions
All authors made a significant contribution to the conception and design of the study protocol. The protocol was written by Professor Helen Snooks, Sarah Gaze, Professor Judith Phillips, Professor Ceri Phillips, Dr Alan Watkins, Professor Ian Russell, and Dr Ivy Cheung and was critically reviewed by Professor Jon Nicholl, Professor Suzanne Mason, Richard Whitfield, Dr Mushtaq Wani, Professor Niroshan Siriwardena, Professor Ronan Lyons, Dr Pip Logan, Mary Halter, Dr Rachel Donohoe, Rebecca Anthony, Marina Koniotou, Lynsey Wilson, Robin Chatters and Professor Jeremy Dale. All authors gave approval for the publication.

Role of funders and sponsors
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme funds this trial as project 07/01/21; it monitors progress and quality through biannual reports. To inform the British National Health Service, NIHR will peer-review the full report and publish it in *Health Technology Assessment*. The NIHR also encourages grant-holders to seek external peer-reviewed publication. As sponsor Swansea University monitors legal and financial probity; it delegates monitoring of progress and quality to the WWORTH, the local Registered Clinical Trials Unit.

Competing Interests
None.

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