PREVENTION OF FALL INJURY TRIAL:

PROTOCOL SUMMARY

Title:	Prevention of Fall Injury Trial (PreFIT).
Chief Investigator:	Professor Sallie Lamb, with Warwick Clinical Trials Unit co-ordinating research activities across the regional centres.
Trial support:	The trial is funded by the NHS through the NIHR HTA programme. It has received ethical approval and been adopted by the Primary Care Research Network.
Background:	Falls are common among older people and can result in injury, disability and dependence. The NHS currently commits substantial funding to multi-factorial fall prevention programmes (MFFP), conservatively estimated at £34 million per annum (Lamb et al. 2007). However, there has been no direct evaluation with robust economic appraisal of alternative fall prevention strategies. The main driver of cost-effectiveness would be prevention of falls that result in serious injury and disability, but these outcomes have not been included within most trials owing to the large sample needed. Instead, reducing falls has been the focus, but not all falls result in injury, and it is possible that minor falls can be prevented, but more serious falls cannot. Uptake of falls prevention strategies will also be a key driver of cost effectiveness (Eldridge et al. 2005), and we know that increasing the reach of any intervention into the population at risk will be essential. Reach of current services into the UK population is estimated to be 2% of those at risk (Lamb et al. 2007). There is also considerable uncertainty over the value of targeting interventions to higher risk groups. The most important information in this respect, which is lacking to date, are pre-specified sub-group analyses of simple screening criteria that would be able to distinguish responsiveness to treatment.
Rational:	The trial is designed to reflect the significant and contemporary dilemma in UK health policy, which is whether to introduce systematic screening and linked interventions from primary care. We will compare three fall prevention strategies and investigate if (and how) more intensive treatments should be targeted to those most likely to benefit, and whether fall prevention should be expanded to include primary preventive strategies. PreFIT is consistent with the most important research priorities identified by national and international guideline panels (NICE 2004; AGS / BGS 2008), and will provide evidence to inform UK health practitioners on the options for preventing falls and fractures among peolpe living in the community.

Trial design:	A multi-centre, 3-arm, cluster randomised controlled trial and economic evaluation, with general practice as the unit of randomisation.
Trial interventions:	Practices will be randomised to deliver: (1) *advice* - Age UK leaflet, (2) *exercise* - Otago programme, or (3) *MFFP* - consistent with NICE and AGS / BGS guidance.
Primary objective:	To estimate the comparative effectiveness and relative cost-effectiveness of three, primary care fall prevention strategies: advice, exercise and MFFP.
Secondary objectives:	To estimate the relative effectiveness of fall prevention strategies among sub-groups of participants stratified by age (≥81 years), gender, and falls history.
Primary outcome:	Peripheral fracture at 12 months, for which data will be collected from hospital episode statistics, and validated against primary care records and self-report.
Secondary outcomes:	Falls, generic health-related quality of life, physical and emotional function, and mortality, as well as reasource use (economic) and time to first fracture (safety).
Target population:	People aged over 70 years living in the community, including those living in supported housing but excluding those in residential care or nursing homes.
Sample size:	PreFIT will recruit 9,000 participants from 60 practices, with a target of 150 participants per practice, about a third of whom will be at-risk of falling.
Participant recruitment:	Practices will identify potential participants from practice records, and post a study pack to 300 selected at random. Consent forms will be returned to the study team.
Recruitment period:	For each practice, we anticipate two months to identify, approach and recruit 150 participants, and 21 months to achieve the trial's overall recruitment target.
Participant involvement:	Participants will be asked to complete questionnaires at four monthly time points, as well as four months of falls diaries at one point during the 12-month follow-up period.
Practice involvement:	Practices will be asked to support recruitment procedures, adhere to the allocated intervention and, at 12 months, allow outcome collection from participants' records.
Practice support:	Research nurses will help practices to identify potential participants, mail out invitations to participate and collect 12-month outcomes from medical records.
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TRIAL FLOW DIAGRAM