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Research Information Sheet for Practices

The Project

Project title:	Prevention of Fall Injury Trial (PreFIT)
Purpose:	To determine the comparative effectiveness, cost-effectiveness and acceptability of three primary care fall prevention strategies (advice, exercise, and a multi-factorial programme) for older people living in the community.
Chief Investigator:	Professor Sallie Lamb
Host institution:	Warwick Clinical Trials Unit
Funder:	NHS Health Technology Assessment Programme
Registration:	ISRCTN 71002650
Approval status:	Ethical and R&D approvals for the project have been obtained

Practice Involvement

The practice will:

- facilitate the identification of patients who can be approached about study participation;
- facilitate the approach to patients via a mailed study information pack;
- be randomised to one of three, primary care fall prevention strategies;
- initiate the allocated strategy among patients who have been recruited;
- provide a report of fractures among the recruited population;
- report to the study team the death of study participants.

Data will be collected from:			(Approx No.)
Practice records (aggregated)	Yes	~~No~~	300
Practice records (individual)	Yes	~~No~~	150
Patients	Yes	~~No~~	150

Period of data collection:	12 months.
Suggested start date in this practice:	September 2011
Reimbursement of practice costs:	Funding is available for the administrative costs of the research (£2,000). An additional payment of upto £1,250 is available for practices allocated to MFFP, if they opt to be trained to assess risk in relevant participants approximately 35 over the duration of the trial.

Processes for Practice Involvement

The researcher will:

- support the practice in meeting the requirements of the trial protocol;
- produce study materials to be mailed to patients approved for approach;
- inform the practice of patients who consent to participation;
- conduct follow-up data collection for patients who have provided consent.

To undertake this research, the researcher will request access to the following personal information, records and / or facilities:

- individual patient records for patients who have consented to participation;
- practice database to extract anonymous, aggregated data for the approached cohort;
- facilities appropriate for accessing sensitive data.

Practice personnel will be asked to:

- adhere to the trial protocol, research processes and data reporting requirements;
- facilitate a search of the practice database to identify potential participants, n=300;
- screen the list of potential participants for exclusions;
- facilitate the approach of potential participants with a mailed study information pack;
- initiate the treatment protocol among patients who have been recruited;
- support data collection from individual patient records for study participants.

How will consent and confidentiality be handled?

- The process for obtaining consent will be in accordance with GCP, and meet the requirements specified in PCRN SOP 13(1.0).
- Practices will facilitate the approach to patients using a mailed study pack, which will include the consent form to be completed and returned by post to the researcher.
- Handling of personal data, in paper or electronic form, will at all times be compliant with the Data Protection Act (1988) and the PCRN SOP 16(1.1).
- Appropriate technical and organisational measures shall be taken to prevent unauthorised access, unlawful processing and accidental disclosure of personal data.
- Data will have restricted access, secure storage in both paper and electronic formats, and be stripped of all personally identifiable information.

Practice feedback:

- during the trial, feedback will be provided by the research team directly to the practice and via updates posted to the trial website.
- at trial completion, a summary of the results will be mailed to practices and made available for download on the trial website.

Thank you for taking the time to read this information sheet.
Do please contact us if you require further information or clarification,
or if you are interested in participating in this important trial.