Appendix 2 – protocol addendum (added 15/08/2012)

REFORM sub-study: A nested randomised controlled trial of a newsletter and Post-it® note to increase postal questionnaire response rates in REFORM trial participants.

1. Background

Postal questionnaires are widely used in health research to collect outcome data on participants. [1] They are an attractive means of collecting data, because they are easy to administer and may be the only economically viable method of collecting data on large numbers of participants who may be geographically dispersed. However, poor response rates can introduce non-response bias and reduce the statistical power of the study. [2] Studies in the elderly population have shown questionnaire response rates of 60% or less [3, 4]. Therefore, evaluating methods which can be implemented to improve response rates is highly relevant to health services researchers.

A Cochrane systematic review [5] evaluated 110 different strategies to improve response rates to postal questionnaires. This review identified pre-notification as an effective means of increasing response rates. The odds of response were increased by a half when participants were pre-notified (OR 1.45; 95% CI 1.29 to 1.63). Although there have been several studies evaluating different methods of pre-notification (such as letters, postcards or telephone calls to participants) very few of these trials have been conducted in a healthcare setting. As far as we are aware to date, there has only been one randomised controlled trial evaluating the effectiveness of newsletters to increase response rates. This study found a small statistically significant increase in response rates (OR 1.45; 95% CI 1.01 to 2.10) [6].

The Cochrane systematic review [5] also identified that the appearance of the questionnaire can affect response rates. For example the odds of response were increased by a quarter when hand-written labelled questionnaires were used (OR 1.25; 95% CI 1.08 to 1.45). Whilst there have been several studies evaluating the appearance of questionnaires (such as using a more personalised approach and handwritten signatures on cover letters) to date we are aware of only four studies

which evaluated the effectiveness of attaching a Post-it® note to increase response rates to postal questionnaires. These studies [7] were however, undertaken within an academic setting but did report a statistical increase ($p<0.05$) in responses rates when Post-it® notes were used.

2. Aim of the study

The aim of this study is to evaluate the effectiveness of a patient newsletter and a Post-it® note as a means of increasing response rates to the six month postal follow-up questionnaire sent to participants taking part in the REFORM study.

3. Method

3.1 Design

The proposed study is a nested 3 x 2 factorial randomised controlled trial.

3.2 Inclusion/exclusion criteria

All patients who are due to be sent their six month follow-up questionnaire for the REFORM study will be eligible for this sub-study. Patients who have asked to be withdrawn from the REFORM study or did not want to receive a questionnaire at this time point will not be eligible for this study. There are no additional inclusion or exclusion criteria.

3.3 Randomisation

Block randomisation, stratified by REFORM treatment group allocation will be used to allocate participants to one of six groups. An independent data manager or statistician from the York Trials Unit will generate the randomisation sequence by computer and allocate patients to either one of the six arms in a 1:1:1:1:1:1 ratio.

3.4 Intervention groups

Patients will be assigned to one of the following six groups: newsletter plus handwritten Post-it® note; newsletter plus printed Post-it®; newsletter only; handwritten Post-it® note only; printed Post-it® only; no newsletter or Post-it® note .

The newsletter will be sent to participants three weeks prior to the six month follow up questionnaire being sent and will contain information about trial progress, a reminder about the importance of the trial and of completing and returning postal questionnaires and will be treatment group specific i.e. whether or not the patient was allocated to receive the multifaceted podiatry intervention or not. The wording on the Post-it® note will be very similar to the following message “Please take a few minutes to complete this for us. Thank you! ” (Initials of person sending the questionnaire.) Every effort will be made to ensure the format of the message is similar as possible. A note will be made of the amount of time taken to write out the Post-it® notes.

3.5 Control group

Patients allocated to the control group will be sent the REFORM newsletter eight weeks after the six month follow up questionnaire was sent to them but without a printed or handwritten Post-it® note.

3.6 Management of postal questionnaires

Questionnaires returned to the York Trials Unit, will be date stamped on the front page and then logged onto the REFORM data management system. Patients who do not return their follow-up questionnaire within two weeks will be sent the York Trials Unit standard reminders i.e. up to two reminders, two weeks apart either by post, text or email according to the participant’s preference, followed by a telephone reminder one week later.

3.7 Primary outcome

The primary outcome is the questionnaire response rate which is defined as the proportion of patients returning their six month postal follow-up questionnaire or reminder questionnaire to the York Trials Unit.

3.7 Secondary outcomes

The secondary outcomes on this study are:

- Time to response. This is defined as the number of days which elapsed between the questionnaire being mailed out to participants and the questionnaire recorded as being returned to York Trials Unit.
- The proportion of participants requiring a reminder.

4. Statistical considerations

4.1 Statistical power

The REFORM Trial is designed to detect a 10% point reduction in falls over 12 months. Assuming this high risk group have an underlying risk of 50% (the incidence observed in our recent trial of occupational therapy for falls reduction) then in order to observe a reduction to 40% with 80% power and a two-sided 5% significance level would require 890 participants (445 in each group, allowing for a 10% loss to follow up). The sample size for this nested study is limited by the number of participants in the REFORM study. Nevertheless, our target sample size of 890 would give us 80% power to observe a difference of 5% assuming a control response rate of 90%.

4.2 Analysis

All analyses will be conducted on an intention to treat basis, including all randomised participates in the groups to which they were randomised. Analyses will be conducted in SAS or other statistical package used within the York Trials Unit using 2-sided significance tests at the 5% significance level. The statistician conducting the analysis will remain blind to treatment group and data will only be unblinded once all data summaries and analyses are completed.

The primary outcome is proportion of patients who return their six month follow up questionnaire or reminder. The primary analysis will be of the *margins* which assumes that the effect of each intervention is uninfluenced by the presence or absence of the other – that is, there is no interaction between them [8]. The primary logistic regression model will include a variable for each intervention group (Post-it® and newsletter), trial treatment group and other important covariates. Odd ratios and corresponding 95% confidence intervals will be obtained from this model. A summary table will be presented as outlined below:

Table 1: Presentation of the results of the primary analysis

Group	Response rate	Adjusted OR (95% CI)	p-value
Handwritten Post-it®	x/X	X.XX (X.XX to X.XX)	X.XX
Printed Post-it®	x/X	X.XX (X.XX to X.XX)	X.XX
No Post-it®	x/X		
Newsletter	x/X	X.XX (X.XX to X.XX)	X.XX
Delayed newsletter	x/X		

OR=Odds Ratio; 95% CI=95% Confidence Interval

A secondary analysis will be undertaken to explore the interactions between the interventions. The primary logistic regression model (described above) will be extended to include an interaction term between the Post-it® and newsletter groups. As this study has not been powered to detect an interaction, a statistical significance level of 10% ($p<0.10$) will be used. Odd ratios and corresponding 95% confidence intervals for the interaction will be obtained from this model. A summary table will be presented as outlined below:

Table 2: Presentation of the results of the secondary analysis

Group	Handwritten Post-it®	Printed Post-it®	No Post-it®	Total
Newsletter	x/X	x/X	x/X	x/X
Delayed newsletter	x/X	x/X	x/X	x/X
Total	x/X	x/X	x/X	x/X

The time to return the questionnaire will be derived as the number of days from the date the follow-up questionnaire was sent out to the date the follow up questionnaire was returned to the York Trials Unit. A Cox's proportional hazards model for time-to-return the questionnaire will be used to compare the treatment groups the model will include a variable for each intervention group (Post-it® and newsletter), trial treatment group and other important covariates.

The proportion of participants who are sent a reminder will be compared using the same model as the primary outcome.

5. Ethical issues

NRES approval has been received to conduct the REFORM study and to send out a newsletter to all participants at six and twelve months. Within this nested sub-study, patients will not have the opportunity to give informed consent to enter into this sub-study. However, we do not consider this to be a major ethical issue, since these patients have already consented to take part in the REFORM study, receive further REFORM questionnaires and approval has already been given to send out a newsletter. Patients will be made aware that if they wish, they may withdraw from the study.

6. Financial and Insurance issues

The trial is funded as part of the main REFORM study which is funded by the NIHR HTA and sponsored by the University of York. Normal NHS indemnity procedures will apply. The University of York will also provide cover.

7. Dissemination of research

The results of this trial will be published in a peer-reviewed journal.

8. References

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