pragmatic trial, any other rehabilitation input beyond the written physiotherapy advice (including a formal referral to physiotherapy) will be left to the discretion of the treating clinicians. However, a record of any rehabilitation input (type and number of additional appointments) as well as other investigations/interventions will be requested as part of the 8 week, 3 month, 6 month and 9 month follow-up questionnaires.

4.8 Study Within A Trial (SWAT)

4.8.1 Background

Reminders are generally an effective way of increasing response rates to questionnaires and there is some evidence that pre-notification (contacting a participant to say that the trial team will be sending a questionnaire out soon) also has some evidence of benefit, although it is not high certainty evidence [29 30]. This SWAT will attempt to establish whether, for a subset of UKSTAR participants, an email pre-notification enhances retention.

4.8.2 Intervention

The SWAT intervention is a combined thank you and pre-notification email (called: "pre-notification email") sent around 2 weeks after a participant has completed a 3 month or a 6 month questionnaire. Emails are sent to participants who are randomised to receive the intervention and who have supplied an email address. The SWAT will be implemented during the period of follow-up of UKSTAR participants.

4.8.3 Participants

Participants will be included if they have not yet been sent their 6 month or 9 month questionnaire at the time this SWAT is implemented. With a July implementation date, approximately 197 participants will be included.

4.8.4 Randomisation

The allocation to the treatment arm will be random and performed centrally to ensure that participants, investigators enrolling participants, and study office staff who administer follow-ups, cannot foresee allocation. Participants will be randomised on a 1:1 basis to either receiving a combined thank you and pre-notification email or not receiving a pre-notification email.

4.8.5 Outcome measure and analysis

Primary outcome: Proportion of participants contacted who respond by electronic means (email or mobile link). The primary analysis for the SWAT is the difference in response rate by electronic means (email or mobile link) between those receiving the pre-notification email and those receiving no incentive.

The outcome of the SWAT will be for internal trial purposes only and will not form part of the main trial report.

4.8 Adverse event management

Adverse events (AE) are defined as *any untoward medical occurrence in a clinical trial subject and which do not necessarily have a causal relationship with the treatment*. All AEs will be listed on the appropriate Case Report Form for routine return to the 'UKSTAR' central office.

Serious adverse events are defined as any *untoward and unexpected medical occurrence that:*

1. *Results in death*,
2. *Is life-threatening,*
3. *Requires hospitalisation or prolongation of existing inpatients´ hospitalisation*,
4. *Results in persistent or significant disability or incapacity*,
5. *Is a congenital anomaly or birth defect,*