SWAT 212: Cluster randomised SWAT to investigate whether a video link in the participant information sheet (PIS) increases recruitment and retention, compared to a PIS without this link

Objective of this SWAT
This SWAT is embedded within the MOOSE trial IRAS1006576 ISRCTN 14403521, with the objective of determining whether inclusion of a video link in the participant information sheet (PIS) with trial information including an explanation of what the methotrexate injection would comprise of, increases recruitment and retention compared to a PIS without the link.

Study area: Recruitment, Retention
Sample type: Participants
Estimated funding level needed: Low

Background
Our patient and public involvement (PPI) group suggested using a video to explain the methotrexate injection to better inform potential participants before consent might increase recruitment to the MOOSE trial. However, there is insufficient evidence that such an intervention improves recruitment and SWAT 106 is testing the use of a video clip alongside a standard PIS. This Study Within a Trial (SWAT) will randomise sites to use one or other PIS.

Interventions and comparators
Intervention 1: PIS that includes a link to a video clip explaining the trial and showing the subcutaneous injection process and associated activities (such as safe disposal of sharps and storage of medicines).
Intervention 2: Standard PIS without the link to the video clip.

Index Type: Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Proportion of patients who consent to take part in the host trial.
Secondary: Proportion of participants providing primary outcome data (at 24 weeks) and proportion of participants remaining in the host trial at 52 weeks.

Analysis plans
It is planned that interim analyses comparing the proportions of participants consenting in the two intervention groups (those with PISs with the QR code to the information video and those with PISs which do not have the QR code) will be performed at 9 and then potentially at 15 months after the first participant is randomised to determine whether there is a greater proportion consenting in either of the intervention groups.

Possible problems in implementing this SWAT
It may be difficult to ensure that all approached patients at the sites randomised to the PIS with the video link watch the video before being consented and it is possible that some consented patients at these sites will not have watched the video. Some data about this might be captured on the screening log and on the video viewing platform, but this might not provide an accurate picture of whether a complete viewing of the video has taken place.

References
1. Stoffer MA, Schoels MM, Smolen JS, et al. Evidence for treating rheumatoid arthritis to target: results of a systematic literature search update. Annals of the Rheumatic Diseases 2016;75(1):16-22.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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