SWAT 219: Video information given at the point of discharge to improve participant follow-up rates

Objective of this SWAT

To assess the effects of follow-up information presented in an animated video format at the point of discharge on 3- and 6-month follow-up rates. The animated video will include information about how the follow-ups are organised and undertaken, and prompt discussion around practicalities.

Study area: Follow-up, Retention, Outcomes

Sample type: Participants

Estimated funding level needed: Unfunded

Background

Attrition in the PLACEMENT feasibility trial (ISRCTN85710690) was high; less than 40% of alive participants provided outcome data at six months.[1] Research on how to improve follow-up, particularly in this cohort of participants, is essential given the importance the that the patient and public involvement (PPI) focus group, and the team who developed the amputation core outcome set, placed on long-term outcomes.[2] Assessing tools aimed at improving follow-up aligns with the Prioritising Recruitment in Randomised Trials study (PrioRiTy II) priorities, including research question number 4: "what are the best ways to encourage trial participants to complete the tasks (e.g., attend follow-up visits, complete questionnaires) required by the trial?".[3] Participants in the main PLACEMENT trial (ISRCTN72547749) who consent to participate in this optional follow-up SWAT will be randomised 1:1 to the intervention or control arm. The first UK sites were activated in October 2023 and first participant was randomised on 31 October 2023.

Interventions and comparators

Intervention 1: Participants will be provided with written information and shown information about the PLACEMENT follow-up visits in an animated video format at the point of discharge. The animated video will include information about how the follow-ups are organised and undertaken, and prompt discussion around practicalities. They will also be provided with written information about the follow-up visits.

Intervention 2: Written information only.

Index Type: Participant Information

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Successful completion of 6-month follow-up data capture. Secondary: Successful completion of 3-month follow-up data capture.

Analysis plans

Completion rates will be presented as point estimates of the difference in rates and the associated 95% confidence intervals.

Possible problems in implementing this SWAT

Sites will be provided with iPads to show participants the follow-up SWAT video. There is a potential for contamination between intervention and control groups if the video is accidentally shown to wrong participant.

References

- 1) Bosanquet D, et al. Perineural local anaesthetic catheter after major lower limb amputation trial (PLACEMENT): Results from a randomised controlled feasibility trial. BMJ Open 2019;9(11):e029233.
- 2) Ambler GK, et al. Development of Core Outcome Sets for People Undergoing Major Lower Limb Amputation for Complications of Peripheral Vascular Disease. European Journal of Vascular and Endovascular Surgery 2020;60(5):730–8.

3) Brunsdon D, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: The PRioRiTy II (Prioritising Retention in Randomised Trials) study. Trials 2019;20:593.

Publications or presentations of this SWAT design

Perineural Local Anaesthetic Catheter After Major Lower Limb Amputation Trial (Placement) Clinical Trial Protocol, Version: 1.1, Date: 14 July 2023.

Examples of the implementation of this SWAT

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