SWAT 215: Effects of remote, web-based data collection on completion of patient-reported outcomes.

Objective of this SWAT
To compare completion of patient-reported outcomes using a face-to-face, paper-based method versus a web-based system.

Study area: Follow-up, Data Quality, Outcomes
Sample type: Participants, Patients
Estimated funding level needed: Low

Background
Poor retention in trials gives rise to missing data, which can undermine the validity, reliability and generalisability of the results of randomised trials [1]. This appears to be particularly problematic in trials gathering patient reported outcomes on the status of a patient's own health conditions [2]. Barriers to face-to-face, paper-based outcome completion include lack of time and burden associated with both administering the outcomes (for researchers and health professionals) and completing the measure (for participants) [3].

Using technology to streamline and maximise the collection of outcome data may mitigate the problem of poor retention [3]. These benefits may be particularly relevant to people with early-onset type-2 diabetes (T2D) given the burden of care experienced by this group and the complex lives they lead (including family planning, careers, and new independent living). Despite this, evidence which could enhance key trial processes such as outcome completion and retention are lacking for this population, partly because they are poorly represented in clinical trials overall [4].

Interventions and comparators
Intervention 1: Data collection with remote collection of appropriate outcomes via a web-based system.
Intervention 2: Face-to-face, paper-based data collection of outcomes during trial visits.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Proportion of participants concordant with outcome completion (defined as providing a fully-completed questionnaire) at the 52-week assessment.
Secondary: Proportion of participants concordant with outcome completion (defined as providing a fully-completed questionnaire) at the 26- (for those questionnaires collected) and 104-week assessment visits; proportion of participants concordant with at least partial completion (defined as providing a partially-completed questionnaire) at the 26- (for those questionnaires collected), 52- and 104-week assessment visits; number and proportion of missing whole measures; and number and proportion of missing data items.

Analysis plans
To compare face-to-face, paper-based, data collection with remote collection via a web-based system, primary and secondary outcomes will be reported descriptively. No formal statistical testing will be performed. An equivalent completion rate between the two methods will be considered beneficial, because of the reduced burden and increased flexibility for participants and staff that is associated with this method [3].

Possible problems in implementing this SWAT
Some participants may have low experience and/or confidence in using electronic devices or web-based systems. To minimise this issue, the 3-item Digital Health Care Literacy Scale [5] will be used to determine participant's confidence, familiarity, and comfort related to digital solutions at screening. Participants with low scores will be supported to access and use the app as required. It is also possible that some participants may not have access to appropriate electronic devices.

Where required, we will provide Wi-Fi-enabled devices to participants wishing to participate if they would otherwise not be able to do so because of limited technology access.

References

1. Gillies K, Kearney A, Keenan C, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032.

2. Food and Drug Administration Unit. Drug Administration: Guidance for industry: Patient-reported outcome measures: Use in medical product development to support labeling claims. Food and Drug Administration, Center for Drug Evaluation and Research 2009;6.

3. Meirte J, Hellemans N, Anthonissen M, et al. Benefits and disadvantages of electronic patient-reported outcome measures: systematic review. JMIR Perioperative Medicine 2020;3(1):e15588.

4. Sargeant JA, Brady EM, Zaccardi F, et al. Adults with early-onset type 2 diabetes (aged 18-39 years) are severely underrepresented in diabetes clinical research trials. Diabetologia 2020;63(8):1516-20.

5. Nelson LA, Pennings JS, Sommer EC, et al. A 3-item measure of digital health care literacy: development and validation study. JMIR Formative Research. 2022;6(4):e36043.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Dr Jack Sargeant and Dr Tommy Slater
Contact email address: tvs2@leicester.ac.uk
Date of idea: 25/JUN/2020
Revisions made by:
Date of revisions: