SWAT 57: Provision of information about a core outcome set and trial questionnaire completion

Objective of this SWAT
To investigate the impact of informing participants of the use of an infant feeding core outcome set (COS) in a pilot trial of a complex intervention for childhood obesity by
1. Examining if informing participants that the trial uses a COS for infant feeding increases questionnaire response rates.
2. Examining if informing participants that the trial uses a COS influences participant attitudes towards questionnaire completion.

Study area: Outcomes, Data Quality
Sample type: Participants
Estimated funding level needed: Medium

Background
Lack of standardised trial outcomes significantly impacts examination of intervention effects and synthesis of trial findings. The use of core outcome sets (COS) enhances outcome evaluation and evidence syntheses, by reducing outcome heterogeneity and reporting bias risk.[1] COS are standardized sets of outcomes representing the minimum that should be measured and reported in trials for a specific health area or population.[1] A patient and public involvement (PPI) approach, including patients, the public, and experts, is often used to achieve consensus on outcomes for COS inclusion. This is followed by selection of valid and feasible outcome measurement instruments (OMIs).[2] PPI in outcome content and questionnaire format development contributes to improved quality of research.[3] While PPI plays a role in COS development, it has yet to be incorporated in evaluating whether COS, and associated OMIs, are perceived as appropriate by trial participants. Similarly, the effect of knowledge about COS development on trial participant buy-in, in terms of questionnaire response rates, has yet to be examined. Previous reviews have identified that participants and the general public have a poor understanding of different aspects of health research.[4] Participants who feel they are better informed are more willing to participate in such research;[4] for instance, participants who receive pre-notification of a health research trial have substantially higher response rates than participants who receive no prior information.[5] Furthermore, personalising questionnaires, in the form of addressing participants by name and including a hand-written signature, can also increase questionnaire response rates.[6] Thus it appears that questionnaire response rates can be improved by increasing information for participants and personalisation of questionnaire material. Informing participants about the processes by which COS used in trials were developed serves a dual purpose. It provides additional information to participants about the outcomes of importance being measured in the trial, and highlights the role of members of the relevant patient and/or public group in determining these outcomes. In line with previous findings, this approach therefore has the potential to increase participant response rates. If a significant increase in response rates is observed following inclusion of a simple informative explanation, this could present a useful mechanism to maximise questionnaire responses and minimise research waste in future trials that incorporate a COS. The quantitative and qualitative findings of this SWAT will contribute significantly to the literature on the appropriateness and usefulness of COS in trial methodology.

Interventions and comparators
Intervention 1: Study questionnaires only.(Participants randomised to this group will receive the short COS information paragraph before completing the open-ended questions that examine their attitudes to COS)
Intervention 2: Short written explanation of the infant feeding COS, in addition to the study questionnaires. The COS information will be presented in a brief paragraph, before the questionnaires, which includes the following:
- Statement that the questionnaires include measurement of an infant feeding COS
- Lay-summary of what a COS is and how they can improve examination of trial outcomes
- Brief description of how the infant feeding COS was developed with experts and parents of infants

Index Type: Method of Follow-up, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Percentage of questionnaire completed
Secondary: Time taken to respond to questionnaire

Analysis plans
Following completion of the study questionnaires, all participants will be invited to complete additional open-ended questions. These questions will evaluate participant attitudes to the outcomes and questionnaire completion in terms of their usefulness and appropriateness. Descriptive statistics will involve calculating the percentage of questionnaire completion per intervention group. Independent samples t-tests will examine differences between the groups for proportion of the questionnaire completed. Potential differences between the groups will be examined at baseline for outcome variables and a range of socio-demographic factors, including age, education, and income level. Multivariate analyses will be used to examine differences in proportion of questionnaire completion between intervention groups while controlling for such potentially confounding variables.

Possible problems in implementing this SWAT
The additional open-ended questions may influence response rates. To minimise any problems that may arise in relation to ensuring accurate randomisation to the intervention groups, a randomisation protocol will be in place throughout the trial and staff involved in randomisation will be made aware of the importance of adherence to this protocol and maintenance of accurate records.

References
1. Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. Trials 2012;13:132.
2. Prinsen CAC, Vohra S, Rose MR, et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. Trials 2016;17:449.
3. Brett J, Staniszewska S, Mockford C, et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. Health Expectations 2014;17(5):637-50.
4. Ellis PM, Butnow PN, Tattersall MHN. Informing breast cancer patients about clinical trials: a randomized clinical trial of an educational booklet. Annals of Oncology 2002;13:1414-23.
5. Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2009;(3):MR000008.
6. Scott P, Edwards P. Personally addressed hand-signed letters increase questionnaire response: a meta-analysis of randomised controlled trials. BMC Health Services Research 2006;6:111-4.

Publications or presentations of this SWAT design
Griffin C, Toomey E, Queally M et al. Influence of providing information to participants about development of trial outcomes on response rates and attitudes to questionnaire completion: Protocol for a study within a trial [version 1; referees: awaiting peer review]. HRB Open Res 2019, 2:2 (https://doi.org/10.12688/hrbopenres.12895.1)

Examples of the implementation of this SWAT

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