SWAT 46: Participants' perspectives and preferences on clinical trial result dissemination

Objective of this SWAT
To use a Public and Patient Involvement (PPI) strategy to develop participants' preferred method of receiving end-of-trial information.

Study area: Dissemination
Sample type: Patients
Estimated funding level needed: Low

Background
Dissemination of the results from randomised trials has traditionally been limited to three channels: scientific meetings and journals, lay media and groups with a particular health interest (1). In March 2001, the UK Department of Health issued a research governance framework safeguarding that members of the public would have confidence in and ultimately benefit from good quality research. This report asks Principal Investigators to provide feedback to participants promptly and appropriately once research findings are recognised (2). Disclosure of study results to trial participants adds a fourth channel of dissemination and may enhance the accuracy of reporting. It is desirable that results are shared with study participants but there is no consensus on the most appropriate methods of sharing research findings with these important stakeholders (1). Researchers need to be particularly sensitive with regards to dissemination of results for placebo controlled trials, especially in the case of participants who have responded well on inactive treatment. Placebo responders may have higher expectations of their treatment, attributing positive changes to this. In this case, reactions may be negative during feedback and the placebo response may in turn be disrupted (3). Patient and Public involvement (PPI) in research has expanded nationally and internationally over the last decade and recently there has been significant attention given to understanding its role and impact. PPI in research is relatively new to Ireland, however it is gaining significant momentum. This SWAT will be done within the existing TRUST study in subclinical hypothyroidism and will add to existing research on how best to include patients in research and ensure effective end-of-trial result dissemination.

The Thyroid Hormone Replacement for Subclinical Hypothyroidism (TRUST) study is a double blind, placebo controlled, international, phase III clinical trial testing the efficacy of thyroxine replacement in subclinical hypothyroidism (SCH) in older community dwelling adults. The study has collaborating centres in the University of Glasgow (linking with Greater Glasgow Health Board); Leiden University Medical Centre; Netherlands; University College Cork (UCC) Ireland; and University of Berne in Switzerland. It recruited 738 participants with SCH over a 42 month period, with 115 participants in Ireland. TRUST is in the final phase of participant follow up and is due to close out in November 2016. In early 2017, the results of the trial will be disseminated to all participants.

To ensure that the dissemination report is clear, simple and tailored for TRUST participants, a qualitative focus group study is to be conducted with participants to elicit their perspectives, preferences and knowledge requirements. The first step will be a qualitative study with semi-structured focus groups: Three focus groups will be conducted with a maximum of 10 participants in each group. Focus groups will be led by experienced and independent qualitative researchers. A topic guide will be used to structure the groups and ensure key insights are appropriately elicited by the researcher. The Consensus-Oriented-Decision-Making (CODM) model will be used in order to guide the group to reach a consensus, with the following steps: (1) Framing the topic; (2) Open discussion; (3) Identifying underlying concerns; (4) Collaborative proposal building; (5) Choosing a direction; (6) Synthesizing a final proposal; and (7) Closure. Purposive sampling based on geographical location will be used to choose focus group participants. The framework for participant sampling will be based on geographical location. All Cork-based participants (n=38) will be contacted via letter and invited to participate. This letter will then be followed up with a phone-call to confirm participation.

The information collected during the focus group stage will be used to establish and implement a PPI-based method of disseminating end-of-trial results to participants, which will then be tested in a randomised trial.

Interventions and comparators
Intervention 1: The PPI-based method of disseminating end-of-trial results will be used for half the participants in the TRUST study.
Intervention 2: The standard dissemination report will be sent to the other half of the participants in the TRUST study.

Index Type: Method of Dissemination, Method of Dissemination, Questionnaire Format

Method for allocating to intervention or comparator
Random

Outcome measures
Primary: Quantitative survey identifying patient understanding and satisfaction of end-of-trial results. Both groups of participants (recipients of PPI-based method and recipients of standard method) will be asked for feedback on the appropriateness of the dissemination method.
This feedback will be gathered using a validated health literacy questionnaire and a patient satisfaction questionnaire. The feedback will be used to determine the impact participant involvement has on levels of patient satisfaction and understanding of clinical trials.

Analysis plans
Focus group recordings will be transcribed verbatim by the qualitative researcher and entered into NVivo Version 11 for thematic analysis. Thematic analysis has six clearly defined steps as follows: (1) Familiarizing yourself with your data; (2) Generating initial codes; (3) Searching for themes; (4) Reviewing themes; (5) Defining and naming themes; and (6) Producing the report. All transcripts will be coded by the primary researcher and another experienced qualitative researcher. The emerging themes will be used to inform the development of an appropriate end-of-trial result dissemination method for participants.

Possible problems in implementing this SWAT
Possible low response rate for focus group sessions. As the framework for participant sampling will be based on geographical location, all Cork-based participants (n=38) will be invited to attend the focus groups. As the sample size is quite limited, there could be problems with a low response rate. This risk will be mitigated by inviting all Cork-based participants via letter initially, followed by phone-calls to provide more information about the study and confirm attendance. If these efforts do not secure a reasonable response rate, face-to-face interviews could be done to collect the necessary data.

References
1. Fernandez CV, Kodish E, Weijer C. Informing Study Participants of Research Results: An Ethical Imperative. IRB: Ethics and Human Research 2003;25:12-9.
2. Di Blasi Z, Kaptchuk TJ, Weinman J, Kleijnen J. Informing participants of allocation to placebo at trial closure: postal survey. British Medical Journal 2002;325:1-4.
3. Jenkins V, Farewell V, Farewell D, Darmanin J, Wagstaff J, Langridge C, Fallowfield L. Drivers and barriers to patient participation in RCTs. British Journal of Cancer 2013;108:1402-7.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Professor Patricia Kearney
Contact email address: patricia.kearney@ucc.ie
Date of idea: 10/FEB/2016
Revisions made by:
Date of revisions: