SWAT 36: Training in obtaining informed consent for clinical trials

Objective of this SWAT
To assess the effects of on-line training versus classroom training in obtaining informed consent for clinical trials

Study area: Patient Selection, Obtaining Informed Consent
Sample type: Trial Team, Healthcare Professionals
Estimated funding level needed: Low

Background
Grounded in the Nuremberg Code, underpinned by the Declaration of Helsinki and outlined in the ICH-GCP guidelines [1], participant consent obtained in conjunction with health research has to be voluntary, competent and informed [2]. However, it is proving increasingly difficult for research teams and healthcare professionals to ensure that consent associated with scientific research is taken in an appropriate manner. This is in part due to rapid technological and medical advancements which are aimed to revolutionise the way in which people are cared for and, in part, due to an acknowledged need to safeguard vulnerable adults. Consequently, robust training and awareness regarding the aspects which need to be taken into consideration before enrolling a prospective participant in a clinical trial is of vital importance, especially because research has shown that 'satisfaction with decision-making and subjective informed consent are both strong predictors of later decisional regret' [3]. And decisional regret, in turn, could lead to withdrawal from the trial and to loss of data.

The manner in which the training pertaining to informed consent is delivered could have an impact on the quality of the informed consent and on the assessment of the eligibility of potential participants in the clinical trial. This can also be considered in a context in which e-learning has become an increasingly preferred method of learning, because it affords time and location flexibility, is learner centred and self-paced, and cost effective. However, some individuals might not be able to use the e-learning tools effectively and therefore, might miss important sections in the course. By contrast, classroom training is more expensive to deliver and poses time and location constraints, but it allows instructor and student interaction and might be a preferred method of learning for individuals who are not computer proficient, but otherwise are highly skilled healthcare professionals [4].

This SWAT will compare the effects of e-learning training versus classroom training in obtaining consent for clinical trials, and will be embedded in the CORDIA Trial (ClinicalTrials.gov Identifier: NCT01891786), which is testing a self-management intervention for type 2 diabetes.

Interventions and comparators
Intervention 1: e-learning training in obtaining informed consent.
Intervention 2: classroom training in obtaining informed consent.

Index Type:

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Performance assessment, measured with a standardised test undertaken by all the SWAT participants to determine their competency in taking informed consent. The test will be marked by an independent assessor blinded to the names and the type of training undertaken by participants. The comparison of the results for the participants in the two randomised groups will show which of the two types of training is more efficient and the proportion of participants who performed well in the two groups.
Secondary: Satisfaction of the clinical trial participants with the informed consent taker, measured with a questionnaire.

Analysis plans

The primary statistical analysis is the analysis of variance of the results of the performance assessment test for SWAT participants allocated to the two different types of training.

Possible problems in implementing this SWAT

This SWAT would use cluster randomization, which means that the SWAT participants would be aware of their random allocation. The tests to measure performance could be independently assessed, in order to ensure an unbiased estimate of the effects of the two types of training. The secondary outcome involves a questionnaire which would measure the satisfaction of the clinical trial participants with the SWAT participants, and the validity and reliability of the questionnaire might need to be tested before using it in this SWAT. In order to minimise bias in study management, the principal investigator for the SWAT will ensure standardised study procedures (e.g. the same e-learning course will be made available to all e-learning consent takers and the same instructor will present the classroom training, ideally at the same time for all the classroom training participants). Those responsible for the SWAT will also need to ensure that the quality of both the e-learning training and classroom training is maintained at a high standard and that the topic of interest is exhausted.

References

1. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice 1996; 15. (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf)
2. Berg JW, Appelbaum PS, Lidz CW, Parker LS. Informed Consent: Legal Theory and Clinical Practice. 2nd Edition, Fair Lawn, NJ, Oxford University Press, 2001.
3. Stryker EJ, Wray JR, Emmons MK, Winer E, Demetri G. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. Patient Education and Counselling 2006; 63: 104-9.
4. Arabasz P, Pirani JA, Fawcett D. Impact and challenges of e-learning. In: Supporting e-learning in higher education. EDUCAUSE Center for Applied Research 2003; 3: 39-47.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

Coronary Heart Disease Risk in Type 2 Diabetes (CORDIA) trial (https://clinicaltrials.gov/ct2/show/NCT01891786)

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Date of idea: 13/MAR/2016
Revisions made by:
Date of revisions: