

SWAT 123: Seldom heard: Listening to patients and the public during intervention development

Objective of this SWAT

The aim of this SWAT is to examine the impact of involving patients and the public in the development of an intervention to improve uptake of retinopathy screening. This will be achieved through four linked objectives:

1. To describe patient and public involvement (PPI) partners' reasons for and experiences of participating in a consensus process to develop a complex intervention.
2. To explore the impact of involving PPI partners on the group dynamics of a consensus process.
3. To compare the intervention content from consensus groups comprising of PPI partners alone, PPI partners working with healthcare professionals and policy-makers and healthcare professionals and policy-makers alone.
4. To raise the public profile of trial methodology research and PPI in clinical trials by engaging with and involving academic and public audiences in the dissemination of this SWAT's findings.

Study area: Intervention Development, Trial Design

Sample type: Patients, Healthcare Professionals

Estimated funding level needed: Medium

Background

Intervention development is a critical first step when conducting a large-scale definitive trial of a complex intervention. It is increasingly recognised that intervention development should be participatory, evidence- and theory-based and systematic to maximise the effectiveness and acceptability of the resulting intervention. Emerging evidence suggests involving patients and the public in intervention development increases the likelihood of developing interventions which are usable, clinically effective and appropriate to cultural context (1). However, little is known about the contribution and impact of involving patients and the public on intervention development. As funding agencies and researchers increasingly focus on role of PPI, there is an urgent need to develop robust methods to assess the impact of PPI at all stages of clinical trials (2).

Interventions and comparators

Intervention 1: Consensus process exercise with PPI partners only.

Intervention 2: Consensus process exercise with a combination of healthcare professionals, policy makers and PPI partners.

Intervention 3: Consensus process exercise with healthcare professionals and policy makers only.

Index Type:

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Preferences and recommendations for the content and delivery of the proposed intervention from each consensus exercise group.

Secondary: Feasibility of proposed intervention assessed by steering group for the host trial; group dynamics and processes; and reasons for participating and experiences of all consensus process members.

Analysis plans

Consensus process exercises will be audio-recorded and transcribed verbatim. Data will be managed using NVivo software. Content analysis will identify preferences and recommendations for the content and delivery of the intervention from each group. Transcripts and proposals will be analysed to identify areas of convergence and divergence across groups.

The host trial's steering group will determine the impact of involving PPI partners on the feasibility of the proposed intervention by comparing the intervention proposals using the APEASE Criteria (acceptability, practicability, effectiveness/cost-effectiveness, affordability, safety/side-effects,

equity). Field notes will be taken during each NGT exercise with details on group dynamics and processes including the members' behaviours and visual cues (facial expressions, gesture, body language, movement, etc.). Notes will be thematically analysed and themes will be compared across the consensus exercises. Findings will be used to assess the impact of involving PPI partners on group dynamics and processes. Completed surveys from group members will be coded and analysed using descriptive statistics in Stata. Reasons for and experiences of participating will be compared across the three groups to evaluate the impact of involving PPI partners on the experiences of all members.

Possible problems in implementing this SWAT

References

1. Owens C, Farrand P, Darvill R, Emmens T, Hewis E, Aitken P. Involving service users in intervention design: a participatory approach to developing a text messaging intervention to reduce repetition of self harm. *Health Expectations* 2011; 14(3): 285-95.
2. Bagley HJ, Short H, Harman NL, Hickey HR, Gamble CL, Woolfall K, et al. A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials a work in progress. *Research Involvement and Engagement* 2016; 2(1): 15.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of revisions: