

SWAT 56: Patient decision aid to reduce decisional conflict in patients considering entry into a prospective cohort study

Objective of this SWAT

To determine the effect of the introduction of a patient decision aid on decisional conflict in patients considering entry into a prospective cohort study.

Study area:

Sample type: Participants

Estimated funding level needed: Medium

Background

This SWAT will be embedded in the PRIMETIME study, which is a prospective biomarker directed cohort study aiming to identify a subgroup of breast cancer patients who can safely avoid adjuvant breast radiotherapy following breast conserving surgery.[1] This subgroup is deemed to be at such a low risk of local relapse that the potential benefits of radiotherapy are unlikely to outweigh the known risks. The current uncertainty regarding the absolute benefit of adjuvant radiotherapy (in this group), the concept of avoiding treatment, and the offer of entry into a clinical trial can be overwhelming and challenging for patients to cope with. The uncertainty patients face regarding healthcare decisions is known as 'decisional conflict'. We would like to optimise the decision making process for patients facing this uncertainty. Decision aids are 'interventions designed to help people make specific and deliberative choices among options by providing information about the options and outcomes relevant to a person's health status'.[2] Evidence suggests decision aids reduce decisional conflict.[3] This SWAT will investigate the effect of a decision aid in addition to standard patient information documentation on patients' decisional conflict regarding their decision of whether to enter the PRIMETIME study. If decision aids reduce decisional conflict this may justify putting more resources into the development of decision aids.

The SWAT will use a cluster stepped-wedge trial design to introduce the decision aid. The cluster stepped-wedge trial design is being used because the decision aid is likely to reduce decisional conflict and the stepped-wedge trial design ensures that by the end of the SWAT all centres will have use of the decision aid. Furthermore, in a stepped-wedge trial each cluster acts as its own control, increasing the statistical power of the study. Each cluster will consist of a radiotherapy centre and peripheral centres referring patients into that radiotherapy centre. Decisional conflict will be assessed using a validated decisional conflict scale [2] in centres before and after implementation of the decision aid. All centres will receive the standard patient information sheets and be randomised (using minimisation) to receive the decision aid video at 2, 4, or 6 months from when the first patient enters the PRIMETIME SWAT. Based on experience with existing breast radiotherapy trials (IMPORT HIGH and FAST FORWARD), centres included in the SWAT will be stratified into high versus low recruiters according to average number of patients recruited per month in the IMPORT HIGH and FAST FORWARD trials.

Interventions and comparators

Intervention 1: Decision aid, which will be in video format, along with standard patient information documentation.

Intervention 2: Standard patient information documentation alone.

Index Type: Recruitment

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: The primary outcome is a measure of patients' decisional conflict. Decisional conflict will be assessed using the validated decisional conflict scale.[2] The scale comprises 16 items and each is measured on a five-point Likert scale (1= strongly agree to 5=strongly disagree) and scored from 0-4. The 16 items (items 1-16 inclusive) are summed, divided by 16 and then multiplied by 25. Scores range from 0 (no decisional conflict) to 100 (extremely high decisional

conflict). Decisional conflict scores will be recorded for patients who do and do not consent to join PRIMETIME.

Secondary: The secondary outcome is acceptance of entry into PRIMETIME. The proportion of patients eligible for PRIMETIME will be recorded and compared with the proportion of patients who consent to participate.

Analysis plans

There is limited literature on what is a clinically significant reduction in decisional conflict (the primary outcome for this SWAT). A reduction of 7 points has been identified from two studies.[4,5] Both studies were in similar populations to PRIMETIME but they were small single centre studies. This SWAT is powered for a larger reduction in decisional conflict, in order to obtain a sample size that is feasible within the constraints of this study. The power calculation used a mean for the control group of 25.43 [4,5] and a mean for the intervention group of 15.93 (9.5 point reduction), with a standard deviation of 17.76 in both groups,[4, 5] and alpha of 0.05, intra class correlation varying between 0-1. This gave a sample size for three steps in the stepped-wedge design (at 2, 4 and 6,months) of 33 clusters (11 per step), number of observations (questionnaires returned) per cluster per 2-month period of 2 and a sample size of 264 patients, with power of at least 80% for all values of the intra class correlation.

The data will be analysed on the intention to treat analysis principle such that clusters will be analysed according to randomised decision aid start time, regardless of the period the centre actually uses the decision aid. Only patients who return questionnaires will be analysed, regardless of whether they choose to participate in the main PRIMETIME study.

The mean decisional conflict score pre- and post-implementation of the decisional aid will be calculated (with 95% confidence interval) as a paired analysis using each cluster as their own control. Appropriate methods for the primary analysis such as multi-level models, which take into account the clustered element of the study will be selected to make comparisons between the mean decisional conflict pre- and post-implementation of the decisional aid. Calendar time is a possible confounder and will be adjusted for in the analysis.

The secondary outcome of acceptance of entry into PRIMETIME will be measured by the proportion of patients who are recruited into PRIMETIME out of the total number of eligible patients approached to enter PRIMETIME. Similar analyses comparing pre and post use of decision aid as detailed above will be performed but for binary data (not continuous data).

Possible problems in implementing this SWAT

The decision aid will require development and ethical approval. As of April 2017, the decision aid is currently being developed by members of the PRIMETIME Trial Management Group in close collaboration with patient advocates, an expert in psychosocial oncology and a film production company. Ethical approval has already been obtained for the main PRIMETIME Study. The Ethics committee has been contacted regarding ethical approval for this PRIMETIME SWAT and has advised that the content of the decision aid may be submitted as a substantial amendment for approval prior to proceeding to production of the video/ graphics. Following production of the video, a further substantial amendment will be submitted for approval of the decision aid and SWAT.

Feasibility of recruitment to PRIMETIME has been assessed by questionnaire to UK Breast Intergroup where clinicians from 80 UK hospitals expressed interest in participation. Based on anticipated recruitment figures from centres that have shown interest we have been able to estimate an anticipated sample size required for the study.

References

1. Kirwan CC, Coles CE, Bliss J. It's PRIMETIME. Postoperative avoidance of radiotherapy: biomarker selection of women at very low risk of local recurrence. *Clinical Oncology* 2016;28(9):594-6.
2. O'Connor AM. Validation of a decisional conflict scale. *Medical decision making: an international journal of the Society for Medical Decision Making* 1995;15(1):25-30.
3. O'Connor AM, Stacey D, Entwistle V, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2003;(2):CD001431.

4. Juraskova I, Butow P, Bonner C, et al. Improving decision making about clinical trial participation - a randomised controlled trial of a decision aid for women considering participation in the IBIS-II breast cancer prevention trial. *British Journal of Cancer* 2014;111(1):1-7.
5. Wong J, D'Alimonte L, Angus J, et al. Development of patients' decision aid for older women with stage I breast cancer considering radiotherapy after lumpectomy. *International Journal of Radiation Oncology, Biology, Physics* 2012;84(1):30-8.

Publications or presentations of this SWAT design

Bhattacharya I, Coles C E, Bliss J M, et al. Planned implementation of a study within a trial using a stepped wedge trial design evaluating the introduction of a patient decision aid on decisional conflict in patients considering entry into the PRIMETIME study. *Trials* 2017; 18:P180 (Presented at the 4th International Clinical Trials Methodology Conference 2017, 7-10 May 2017, Liverpool)

Examples of the implementation of this SWAT

People to show as the source of this idea: PRIMETIME Trialists

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