SWAT 100: Patient and family co-developed participant information to improve recruitment rates, retention, and patient understanding of a randomised trial

Objective of this SWAT
To examine if participant information co-developed by patients and their families can lead to greater recruitment rates, retention, and participant understanding of the study in comparison to standard participation information leaflets in the Rehabilitation Strategies following Oesophago-gastric and Hepatopancreaticobiliary Cancer (ReStOre II) trial.
Specific objectives are;
• To engage with patients with upper gastrointestinal (UGI) cancer, namely oesophageal/gastric/ pancreatic/liver cancer and their family members to develop participant information for ReStOre II.
• To examine the impact of the patient and family co-developed participant information on ReStORe II recruitment rates.
• To determine the impact of the patient and family co-developed participant information on ReStOre II retention rates.
• To explore the impact of the patient and family co-developed participant information on patient's understanding of the ReStORe II trial.

Study area: Recruitment, Retention, Trial Understanding
Sample type: Patients, Carer/Parent
Estimated funding level needed: Medium

Background
As cancer survival rates continue to improve, optimising survivorship care has become a research priority [1, 2]. Exercise rehabilitation is a care strategy with considerable potential to optimise physical function and quality of life in cancer survivorship [3]. However, recruitment and retention in cancer exercise trials remains a challenge [4], which may be detrimental to the validity of trial results. Accordingly, there is strong rationale to investigate strategies which may aid recruitment and retention to cancer exercise trials.

Public and Patient Involvement (PPI) has been described as research being carried out with or by members of the public rather than to, about, or for them [5, 6, 7]. This approach to research is encouraged as it is felt that those affected by research should have say in how it is carried out [8]. There is also evolving evidence that PPI can increase the rate of recruitment to research and improve its quality and impact [9]. A recent systematic review and meta-analysis by Crocker et al [5] investigated the impact of PPI on patient enrolment and retention in clinical trials. The overall results were supportive of PPI as a method of enhancing enrolment. PPI significantly increased the odds of participant recruitment (odds ratio 1.16, 95% confidence interval and prediction interval 1.01 to 1.34). An example of a PPI strategy to enhance trial enrolment is the inclusion of patients and the public in the design of participant information. Traditional participant information has consistently been criticized for being too lengthy, using technical or difficult language, and for lacking navigability and visual appeal [10]. Furthermore, it is reported that patients with cancer may gain little understanding of the potential harms and benefits of research from the participant information they are given [11]. Therefore, participant information may in fact become a barrier to trial understanding and enrolment, and it is important to investigate this so that trial participant information can be optimised.

ReStORe II (NCT03958019) is a randomised trial of a multidisciplinary rehabilitation programme for survivors of cancer of the oesophagus, stomach, pancreas, and liver. The programme will consist of supervised and self-managed exercise, 1-to-1 dietary counselling, and education sessions. In a previous feasibility randomised trial, this programme led to significant improvements in cardiorespiratory fitness [12], and benefits for on physical, mental and social wellbeing [13]. Furthermore, a patient recruitment rate of 40% was achieved [12]. Whilst this rate is higher than those cited by other cancer rehabilitation programmes (11.1%) [14], given the potential benefits of participation even greater rates of enrolment for ReStOre II would be worthwhile. Importantly, an increased recruitment rate would accelerate the progress, completion and dissemination of the trial. To this end, this study within a trial (SWAT) will engage with patients and their families and

ask them to contribute to the development of participant information, and examine its impact by an embedded randomised trial.

Interventions and comparators
Intervention 1: Patient and family co-developed participant information
Intervention 2: Standard participant information

Index Type: Method of Recruitment, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Recruitment rate
Secondary: Retention rate
Trial Understanding (Decision Making Questionnaire)

Analysis plans
Statistical analysis will comprise evaluation of the impact of the patient and family co-developed participant information on: i) rates of recruitment to the trial (assessed by odds ratios); ii) questionnaire scores, analysed separately for recruited participants and those who refused ReStOre II participation; and iii) rates of retention in ReStOre II (to the first follow-up data collection time point, assessed by odds ratios).

Possible problems in implementing this SWAT
We do not foresee any major problems in implementing this SWAT.

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Publications or presentations of this SWAT design

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Examples of the implementation of this SWAT

People to show as the source of this idea: Linda O'Neill, Peter Knapp, Suzanne Doyle, Emer Guinan, Juliette Hussey et al
Contact email address: oneilll8@tcd.ie
Date of idea: 1/MAY/2018
Revisions made by: Linda O'Neill
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