

EXPLORING FACTORS AFFECTING WOMEN'S DECISION TO PARTICIPATE IN RANDOMISED CONTROLLED TRIALS ASSESSING SURGICAL TREATMENT FOR STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

Randomised controlled trials (RCT) are widely accepted as the most appropriate research method for minimising bias when evaluating health technologies. An informed understanding of women's motivations to participate in RCTs is most likely to increase the rate of recruitment. In this study we aim to evaluate the factors affecting women's decision to accept or decline participating in RCT for surgical management of stress urinary incontinence (SUI) through a purpose-developed questionnaire.

Study design, materials and methods

SIMS is an RCT comparing two surgical methods for treatment of female SUI. The methodology of the RCT is described in details in our published protocol on www.clinicaltrials.gov. The study was approved by the Grampian research ethics committee including administration of the "refusal/ acceptance questionnaire". The questionnaire was designed following a review of the relevant literature and identifying the most commonly reported factors affecting participants' decision whether or not to enrol in research projects. Our literature review was comprehensive and was not restricted to RCTs participants. The questionnaire was designed of 2 sections listing various possible factors that may influence the decision for acceptance (n=6), or declining (n=5) to participate in the RCT. For each factor women were asked to report its degree of relevance/ importance, in affecting their decision on a 6-point scale (ranging from 0 = highly irrelevant to 6 = highly relevant). Finally, an open-end question was given where women were asked to express any other relevant factors. Each factor was given a final score representing the number of women answering that question (n) multiplied by the grade of relevance; so the maximum score will be (nx5) while minimum score is zero; each factor was then given a "percentage of relevance (POR) value" representing its final score/ maximum potential score.

The questionnaire was piloted among the first 27 recruited women and we found minimal missing data, and no incidents of incomprehensible questions. Furthermore no other relevant factors were identified from the open-end question. The questionnaire was completed at women's privacy after taking their informed consent. Women who declined to participate in the RCT and to complete the questionnaire were not approached again according to ethics approval.

181 women were eligible and were invited to participate in the SIMS RCT (October 2009 - October 2010). Out of the 44 women who declined to participate; 31 (70.5%) completed the refusal section. While, 137 women accepted to participate and 135 (98.5%) completed the acceptance section. Data was analysed using SPSS 18.0 (Chicago, Illinois). Descriptive analyses were given for women responses to each potentially influencing factor and the POR value.

Results

135 & 31 women completed the acceptance and refusal sections of the questionnaire respectively with no missing data; therefore the range of scores for each acceptance and refusal factors were 0-675 and 0-155 respectively with higher scores indicating a more relevant factor in affecting women's decision. Figure 1 & 2 summarise the relevance of each factor for women's decision to have accepted or refused participation; the most relevant factor in acceptance was the "interest in less postoperative pain/ rapid recovery in the study arm" (score 620/675; POR 91.9%), followed by "to help research and improve medical inventions" (score 592/675; POR 87.7%). The most relevant factor in refusal of participation was "no enough time for follow up" (score 88/155; POR 56.8%), followed by the "dislike of randomisation process" (score of 85/155; POR 54.4%).

Interpretation of results

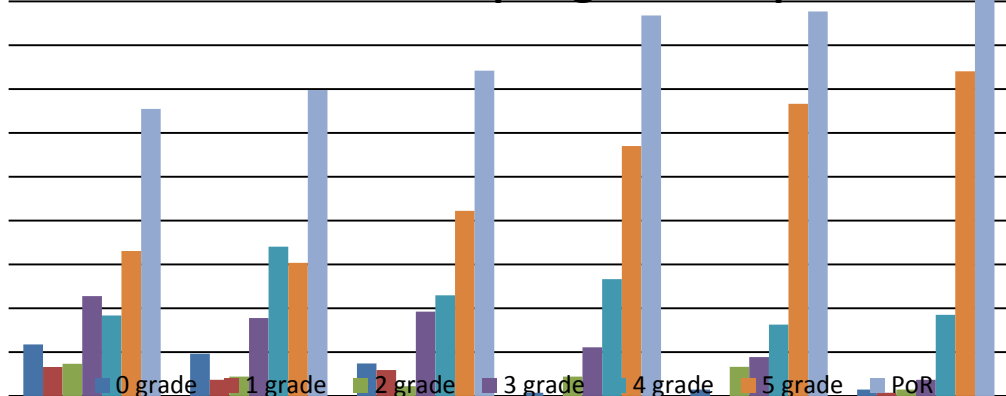
This study shows that "potential personal gain" (expressed in this study as interest in less postoperative pain/ early recovery in the study arm) was the most relevant factor in women's decision to accept participating in the RCT; this was in agreement with similar studies in the literature(1,2). "Interest for helping the research" and altruism was the second highly relevant factor in acceptance which confirm the finding of McCann et al (2) that it is conditional altruism which should be accompanied with patient's personal benefit. In our study, the minimal presumed differences between study and control arms and the acceptable follow-up plan that would minimally limit women's life style/ work commitments were graded as highly relevant factors in women's decision to accept enrolment into the RCT.

In our study, there were 3 highly relevant influencing factors in women's "refusal to participate" decision in this RCT: "the lack of time for follow-up", "unaccepted randomisation concept" and the "lack of long-term results in the study arm". Previous studies, primarily on non-surgical RCTs, have shown similar results (3) however "lack of follow-up time" seems to be unique for our study indicating a possible extra dimension when women decide whether to participate in a surgical RCT for SUI.

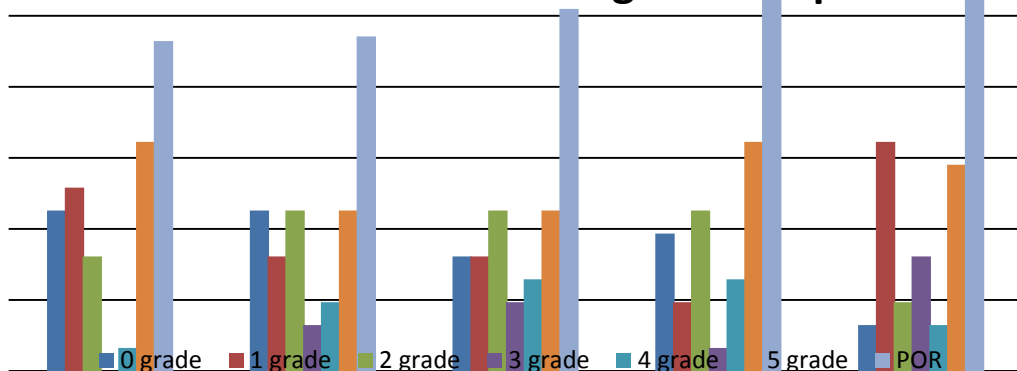
Concluding message

This study shows that potential personal benefit and good explanation of the study are highly relevant in women's decision to help research and participate in surgical RCTs for treatment of SUI while inconvenient follow-up plan seems to be the most relevant and most correctable factor in refusal.

% Reasons for Accepting to Participate



% Reasons for Refusing to Participate



References

1. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. *Ann Intern Med* 1980; 92: 832-6.
2. McCann S, Campbell M, Entwistle V. Reason for participation in randomised controlled trials: conditional altruism and considerations for self. *Trials* 2010; 11:31.
3. Joseph RR. Viewpoints and concerns of a clinical trial participant. *Cancer* 1994; 74: 2692-3.

Specify source of funding or grant	Hinary Smith Charity
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	North of Scotland Research Ethics Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes