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Rantell A[1], Srikrishna S[1], Cardozo L[1], Robinson D[1]
1. *Kings College Hospital, London*

HOW CAN WE IMPROVE PERSISTENCE IN CLINICAL TRIALS?

Hypothesis / Aims of study

Pelvic organ prolapse (POP) and urinary incontinence are common and distressing problem that can affect patients quality of life. It has been estimated that women have a lifetime risk of 11% of undergoing surgery for urinary incontinence or prolapse and 7% for prolapse alone[1]. For women who have had surgery they will have a 30% chance of needing repeat surgery for their prolapse at a later date[1]. As surgery remains the definitive treatment for a large percentage of women there is a need for good quality long-term prospective studies looking into post operative outcomes. However, one of the common problems that research units encounter is patients withdrawing from the trial or not attending appointments. If these rates are high the outcomes of research may not be valid. The primary aim of this study was to assess the number of patients who failed to attend or withdrew from the trial and examine contributing factors. The secondary aim was to identify any key changes in our practice to improve patient persistence in clinical trials.

Study design, materials and methods

This was a prospective longitudinal observational study conducted at a tertiary referral centre. Women were recruited from the waiting list for pelvic reconstructive or continence surgery. They were seen 6 times in total (once pre operatively and the post operatively at 6 weeks, 3 months, 6months, 1 year and 2 years). At each visit they were examined and assessed using the Pelvic Organ Prolapse Quantification (POPQ) and completed 3 validated Quality of Life Questionnaires. They also completed a Patient Global Impression of Improvement (PGI-I) at each review and urodynamics were performed pre operatively and at 6 month post operative. Each patient recruited was seen by the same research fellow who fully explained the protocol. Any non English speaking patients were excluded as per the trial exclusion criteria. Patients gave informed consent prior to participation and were given information leaflets. As all questionnaires were also filled out pre operatively women, were aware of what would be involved at each visit.

Results

In total 201 women were recruited into the trial. Complete data were available for 112 (55.71%) women at the 2 year review. 54 (26.86%) women missed at least one appointment during the 2 years however, these data are not included in this analysis. 35 (17.41%) women were lost to follow up or withdrew from the trial. Of these women 10 had no follow up in the trial at all, 6 were lost at the 6week stage, 9 at 3 months and 10 at 6 months. All women who attended at 1 year completed the trial. 1 patient was removed from the trial as following examination under anaesthetic she did not have prolapse or incontinence surgery. 17 women (48.57%) chose not to attend appointments or to withdraw from the trial. 4 women (11.43%) needed repeat surgery or were referred to other specialities for investigation of co-morbidities. 13 women (37.14%) were lost due to administrative issues by hospital staff. This is demonstrated in Figure 1. Figure 2 shows the breakdown of these reasons at each visit.

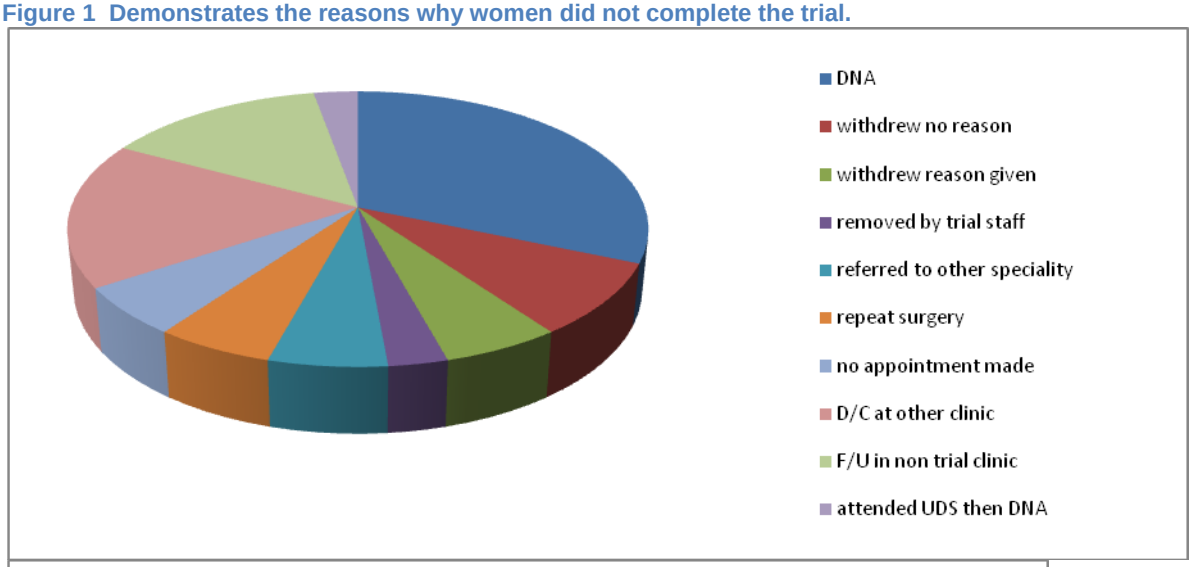
Interpretation of results

The most common reason as to why patients did not complete the trial was that women chose to withdraw or not attend the appointments. To overcome this it is important to ensure that when we counsel the women to participate, our expectations of their role in the trial should be fully explained and specific emphasis should be placed on identifying patients who travel long distances to attend. However, there is a limit on how much pressure we place on patients to participate in clinical trials as this can also be a reason for them to withdraw or not attend. Some women may not attend as they feel they have achieved cure and no longer need to attend the hospital. The importance of long term data should be stressed to these women. For those women who require referral to other specialities for co-morbidities they may find that they have too many appointments to attend and rate the trial appointment as the least important of these. Alternatively, if they require repeat surgery for their condition every effort should be made to encourage participation in the trial. The main area where we need to improve our practice is in the way we manage the administrative needs in our trials. 37% of women were lost due to poor clerical practice. Some did not receive appointments for follow up and others were booked in the general outpatient clinic. Although all sets of notes for trial patients were marked, some of the general team who were not part of the core research staff reviewed the patients and were not aware of the trial or the patient's involvement. This led to some women being discharged from the hospital or booked for further follow up in general clinics. This highlights the need to improve clinical staff education as well as administrative staff about ongoing trials and ways to highlight trial patients on clinic lists or running separate clinics for their follow up appointments. However, this may incur extra costs in the trial and would need to be set up at the beginning of the trial for full impact.

Concluding message

To ensure that we obtain valid results from our research we need to collect as much data as possible. Maximising completion and participation in trials will help to achieve this aim. All staff should be advised of the trials in progress and easy identification of patients should be a priority.

Figure 1 Demonstrates the reasons why women did not complete the trial.



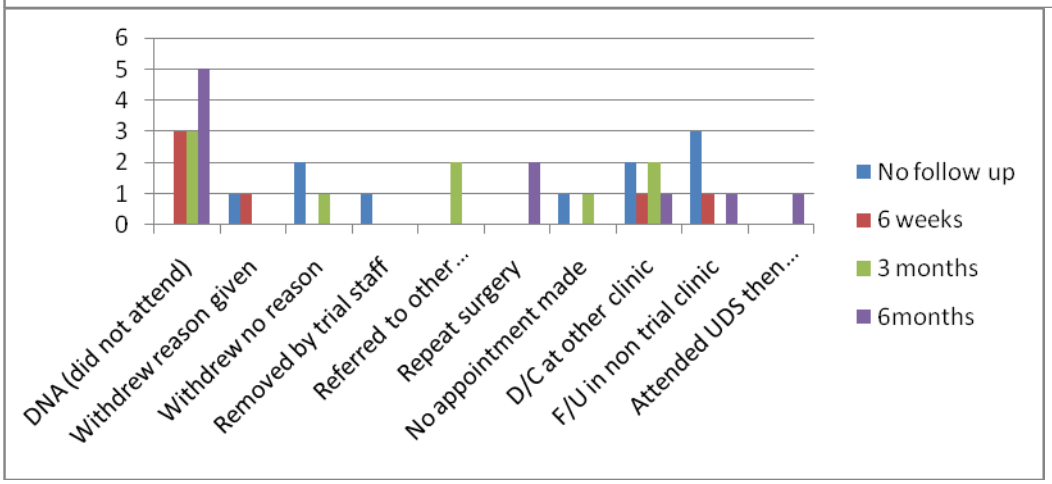


Figure 2 Shows the breakdown of these reasons at each visit.

References

1. Obstetrics & Gynecology 1997; 89(4):501-506

Specify source of funding or grant	**None**
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	**King's College Hospital Research and Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**