**A randomised controlled trial evaluating the use of a multimedia video to improve consent in patients undergoing total laparoscopic hysterectomy**

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**Introduction**

Consent is a vital component in healthcare and has ethical, legal and practical implications.1 It is imperative to the delivery of safe, patient-centred care. Despite the well-documented benefits and legal requirements for adequate and thorough consent, it is frequently poorly performed, leaving patients and clinicians vulnerable to significant sequelae.2

Surgical procedures have become increasingly complex while time constraints in outpatient clinics have continued to increase.3 Additionally, in the current coronavirus pandemic many patients have had fewer visits to their gynaecologist, longer intervals from initial consent to surgery, and more appointments via video or telephone instead of in-person. All these factors may risk the quality of informed consent leading to increased patient anxiety and confusion, and potentially medicolegal consequences.

Pre-operative surgical informed consent requires that procedures are sufficiently explained. The patient must properly understand the procedure and the risks inherent to the procedure.4 Unfortunately patients’ recollection of the details of their informed consent is often low.5 The use of multimedia material has been shown to increase patient recollection and their understanding of the procedure.5

Multimedia videos have been demonstrated to improve informed consent by increasing knowledge recall without increasing patient anxiety.6-8 Several studies examining the use of multimedia videos have consistently shown superior knowledge levels and a high degree of patient acceptability.8-13

To our knowledge, there is only one study looking at the use of a multimedia video in patients undergoing any form of hysterectomy which showed improved patient comprehension and consent with less clinician counselling time required.14 We were unable to find any studies looking specifically at the use of multimedia for informed consent in patients undergoing a total laparoscopic hysterectomy.

Informed consent is a critical component of high-quality surgical care. We believe our patients undergoing a total laparoscopy hysterectomy should have a good understanding of the procedure and risks involved, as well as what to expect post-operatively. The multimedia video that has been developed provides comprehensive education on the procedure whilst using plain language to ensure that it is easy to understand.

It is hypothesized that patients who are randomised to watch the multimedia video will have a better insight into their procedure and recall of information, without any negative impact on their anxiety rates. Given the shift in the way healthcare is delivered due to advancing technology and the pandemic, we hope that the use of a supplementary multimedia video will alleviate patient anxiety and provide an additional source of patient education to improve understanding.

**Study Design**

**1. SUMMARY**

This is a randomised controlled trial. Participants will be patients currently on the waitlist for a total laparoscopic hysterectomy at the Mercy Hospital for Women who have already received routine consent with their doctor. Participants will be assessed on their baseline understanding of the procedure and have their baseline anxiety levels and health literacy evaluated. They will be randomised into two groups. Group 1 will receive additional routine verbal consent. Group 2 will receive additional routine verbal consent and then watch an 11 minute multimedia video. Both groups will complete a questionnaire afterwards to evaluate their understanding of their procedure, anxiety and satisfaction levels.

Our hypothesis is that patients who watch the multimedia video will have a better understanding of their procedure which will be reflected in a higher score in the questionnaire about their procedure, without a negative impact on their anxiety level.

**2. STUDY AIMS**

* **Primary Aim:** 
  + To assess whether use of a supplementary multimedia video is useful in improving the informed consent process for patients undergoing a total laparoscopy hysterectomy which will be demonstrated in improved knowledge scores without increasing anxiety
* **Secondary Aims:**
  + To assess patients’ baseline understanding of their planned procedure after routine consent
  + To evaluate patient satisfaction with the use of a multimedia video as supplementary consent

**3. PROJECT TIMELINE**

* Participants who consent to be in the study will complete an initial questionnaire which should take 5-10 minutes to complete.
* Group 1 (verbal consent only) will then receive routine consent via telephone by a doctor and Group 2 (verbal consent PLUS multimedia video) will receive routine consent via telephone and watch an 11 minute video.
* Both groups will then repeat the questionnaire to assess knowledge, and evaluate their level of anxiety and satisfaction which should take 5-10 minutes to complete.
* 4 weeks following the initial questionnaire, both groups will repeat the knowledge questionnaire.
* When recently checked there were approximately 80 patients currently on the surgical waitlist who may be appropriate study participants. This should provide an adequate sample size, even allowing for patients who decline or are excluded from the study for other reasons. Given an expected 40% uptake rate, the target numbers are expected to be reached within 12 months.
* The upper limit of the duration of the project is expected to be 12 months to provide ample time for recruitment, completion of surveys and follow up.

**4. PATIENT ELIGIBILITY:**

**Summary:** The study population will include patients on the waitlist for a total laparoscopic hysterectomy at the Mercy Hospital for Women

* **Inclusion criteria:** 
  + **Age:** Adult, 18 years or above
  + **Procedure:** Planned Total laparoscopic hysterectomy. Procedures may include other components such as salpingectomy, treatment of endometriosis etc
* **Exclusion criteria:** 
  + **Procedures:** hysterectomy for malignant indications, or under the gynae-oncology team
  + **Consent:** unable to give informed consent, non-english speaking

**5. RECRUITMENT**

* **Number:** The expected number of participants is 34
  + The required sample size has been calculated using the two sample t test and based on a power test of 0.8 an assumed knowledge difference between groups of 5 and 10% the recommended sample size is 17 per group.
  + This is in keeping with previous studies published by Dr Beischer which have shown statistically significant differences with sample sizes of 6015,5616 and 3117.
* **Method:** The eligible cohort will be contacted by a member of the research team via telephone. The patient information consent forms will be either mailed or emailed to the patients via an encrypted secure link (Docusign).
* **Randomisation:** Will be computer generated

**6. MULTIMEDIA VIDEO**

* **Description:** The multimedia video is an 11 minute video which uses animations to depict and describe the relevant anatomy and indications for surgery, an explanation of the surgery, and the post-operative recovery. There is one multimedia video for total laparoscopic hysterectomy and one for total laparoscopy hysterectomy with bilateral salpingo-oophrectomy.
* **Presentation:** Patients will receive an emailed link to view the video

**7. QUESTIONNAIRES**

* Patients will receive the questionnaires via a secure link to be completed online

**Data Handling**

* **Confidentiality:** Data will be stored on paper and kept in a folder in a locked office in the Endosurgery Unit. When the data is ready to be written up in a peer reviewed journal the data will be entered into a statistics software package. The participants will no longer be represented by name but by a trial number.
* **Duration:** The data will be kept for 7 years
* **Disposal:** The data will be incinerated at this time

**Conflict of interest**

None

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