Title

**A randomised control study of patient satisfaction with Phone consultations compared to in-person consultations amongst urological oncology patients.**

**Sponsor**

**Urology Department, Westmead Hospital**

**PROJECT TEAM ROLES AND RESPONSIBILITIES (Please ensure each investigator is aware of The Australian Code for the Responsible Conduct of Research, 2018 – Responsibilities of researchers)**

**Coordinating Principal Investigator:**

Name: Professor Manish Patel

Position: Urological Oncology Surgeon

Institution: Westmead Hospital

**Principal Investigator:**

Name: Dr David Armany

Position: Resident Medical Officer

Institution: Westmead Hospital

**Principal Investigator:**

Name: Dr Anika Jain

Position: Senior Resident Medical Officer

Institution: Westmead Hospital

1. **SUMMARY**

**Study Title:** A randomised control study of patient satisfaction with phone consultations compared to in-person consultations amongst urological oncology patients.

**Aims/Objectives:**

* **Primary:** To assess the rate of patient satisfaction regarding phone consultations vs face to face consultations in a subset of patients undergoing follow-up for urological oncology.
* **Secondary:** To assess for other outcomes

1. Preference for next consultation
2. Clinician satisfaction by questionnaire
3. Clinician complied list of problems and benefits for each consultation
4. Adverse events experienced in the tele-health arm that could have been avoided with a traditional face to face consultations.

**Study Design:** Randomised control study

**Planned Sample Size:** 126 participants

**Study procedures:** Review of data gained through both online and paper copies of validated questionnaires that will be sent to each individual patient in each group (Phone and face to face), they will be assigned on a point-based system which will quantify patient satisfaction across both groups for comparison.

**Study Duration**: Expected time period for data collection and analysis is 2 months.

1. **BACKGROUND AND RATIONALE**

COVID-19 has had a detrimental effect regarding patient care and has provided many challenges amongst the appropriate follow up and ongoing management amongst urological oncology patients.

Telemedicine and phone consultations have thus been an invaluable tool in delivering patient care and facilitating ongoing urological input. This study aims to determine if patient satisfaction is higher with Phone follow-up consultations in comparison to standard face to face outpatient consultations. In addition, the study will also look at the limitations of either model of care and the clinical consequences associated with these.

Based on the current literature, we hypothesize that there will be a high rate of patient satisfaction with regards to consultations carried out over the phone, as opposed to more traditional face to face consultations. If the study validates the hypothesis, it would suggest that phone consultations have an important role to play in the ongoing management of urological oncology patients and can be further extrapolated to referrals/initial visits, surveillance consultations and post-operative visits on a more consistent basis. If the study’s negative outcome measures reveal statistically insignificant weaknesses with phone consultations, then its widespread adoption in urological oncology could mean better patient clinical outcomes.

1. **STUDY AIMS/OBJECTIVES**

Primary Aim:

This study will aim to assess the rate of patient satisfaction regarding phone consultations vs face-to-face consultations in a subset of patients that are currently linked in with the following Crown-Princess Mary Cancer Centre Clinics:

* Kidney Cancer Clinic
* Bladder Cancer Clinic
* Prostate Cancer Clinic

Our Hypothesis is that there will be a significant high patient satisfaction across each of the above clinics with regards to phone consultations when compared to standard face to face consultations. This will be determined through data obtained through the use of validated questionnaires. In future, this may improve our health service with regards to urological oncology and can see increased rates in patient compliance and understanding of their illness. This can also be further extrapolated to other stages of Urological Oncology management, including initial visits/referrals.

Secondary Aim:

This study will also consider clinician-based satisfaction with each modality of care and the limitations of each model of care will be explored. The following are a list of secondary objectives:

1. Preference for next consultation
2. Clinician satisfaction by questionnaire
3. Clinician complied list of problems and benefits for each consultation
4. Adverse events experienced in the tele-health arm that could have been avoided with a traditional face to face consultations.
5. **PARCTIPATING SITES**
6. Crown Princess Marcy Cancer Centre – Westmead Hospital
7. **STUDY DESGIN** 
   1. **Study Type**

* *Randomised Control Study* 
  1. **Expected Study Duration**
* *Validated questionnaires will be sent out to each patient over a two-week period. They will have one month to respond to questionnaires with text message prompts for reminders.*
* *After which data will be collected and analysed for a period of a further one month.* 
  1. **Date Source and Population**
* *All participants in this study will be selected by coordinating with bookings team at Westmead Hospital.*
* *They will all be patients who are currently linked into the Crown Princess Mary Cancer Centre (Limited to Urological Oncology Patients). 63 participants will be placed in each group with a total of 126 participants. One group will contain patients who regularly follow up via standard face-to-face consultations and the other group will contain patients who follow up via phone consultations.*
* *Randomisation and sampling of patients will only occur after ethics approval.*
* *Information regarding participants will be obtained through their electronic medical records with their expressed written consent upon agreeing to participate.* 
  1. **Recruitment and Screening**
* Patients’ details will be collected via Aria from the respective Prostate, Kidney, and bladder cancer clinics. Each patient that meets the inclusion criteria will be contact and the study will be explained to them, they will be advised that they will have a 50/50 chance of being randomized to either a telephone consultation or face-to-face consultation for their upcoming appointment a PICF will also be sent to them. After 48 hours, the patient will be recontacted and if patient verbally consents to the study, they will be asked to sign the consent form and send back. They will then be randomised to face-to-face or telehealth via a web-based generator: <https://www.randomizer.org>
* This will be done on an individual patient basis until the research team reaches 126 recruited randomized patients.
  1. **Inclusion Criteria**
* *Patients with an adequate command of the English language.*
* *Must be a current patient at the Crown Princess Mary Cancer Centre: Kidney, bladder and prostate cancer clinics.*
* *Must be involved in routine follow up only.* 
  1. **Exclusion Criteria**
* *Patients with follow up scheduled for outside the above time frame.*
* Patients not previously known to the Clinic; i.e. new referrals
* Patients awaiting any histology results
* Patients who need to be clinically examined during active surveillance protocol milestones.
  1. **Consent Process**
* *Patient consent forms will follow the PICF framework and will be delivered to each participant prior to any method of data collection has commenced*
* *For the face-to-face patients, consent forms will be given to patients on date of appointment and if written consent is obtained, will also receive validated questionnaire to fill out.*
* *For the phone consultation patients, after random selection, patients will be contacted, informed of the study and a consent form posted out to them with return envelopes.* 
  1. **Study Procedures**
* Population: Patients involved in the Kidney, Prostate, and bladder clinics at the Crown Princess Mary Cancer Centre – Westmead Hospital
* Intervention: Phone consultations
* Comparison: Standard Face-to-face consultations
* Outcome: Expected high rates of satisfaction with phone consultations.
  1. **Randomisation (if applicable)**
* Patients will be randomised by a web based generator: https://www.randomizer.org

1. **TISSUE COLLECTION / BIOBANKING (IF APPLICABLE)**

* Not applicable

1. **ETHICAL CONSIDERATIONS** 
   1. **Study procedure benefits**

* This study better allows us to evaluate the current service and model of care we provide with a specific focus on urological oncology patients. Given the nature of their pathology, these patients require constant follow up and surveillance with often surgical intervention and post-operative management and lifestyle counselling.
* Directly compares patient satisfaction rates between traditional face to face consultations and telephone consultations through the use of a validated questionnaire.
* High patient satisfaction with phone consultations can further expand the service we provide and may lead to improved clinical outcomes and non-clinical outcomes as we aim to show.
  1. **Study Procedure Risks**
* Minor risk in accidental disclosure of personal or health information. This risk is accounted for by de-identifying all data and containing on a secure storage system with password-encrypted files.
* Administration issues including loss of imaging referrals, inability to access radiology images and or reports, providing patients with copies of histology reports. Patients not receiving pathology request forms in time to ensure results are available prior ot next appointment.
* Clinical Examination difficulties. For example, inability to perform a DRE on patients on active surveillance. The exclusion criteria have also been updated to help minimise this risk
  1. **Confidentiality and Privacy**
* All the data will be de-identified, and data will only be used by members of the research team listed on this protocol.
  1. **Data Storage and Record Retention**
* The data will be stored on a desktop WSLHD computer in the urology office as a password encrypted file. Only members of the research team (i.e. the investigators) will only be able to access this file.
* This data will be kept for a maximum of 5 years then securely destroyed.

1. **SAFETY REPORTING (IF APPLICABLE)**

Not applicable

1. **DATA SAFETY AND MONITORING BOARD (CLINICAL TRIALS ONLY)**

Not applicable

**10. EARLY TERMINATION (IF APPLICABLE)**

If any unexpected or serious adverse effects are seen in the tele-health conference group over the face to face, we will terminate the study.

**11. BLINDING AND UNBLINDING (IF APPLICABLE)**

*Not applicable*

**12. CONFLICT OF INTEREST**

*The investigators have no conflicts of interest relevant to this study*

**13. FUNDING**

*There is no funding required for the study*

**14. RESEARCH OUTCOMES**

We will share the results of this study with all the patients who have been involved. As this is seeking patient satisfaction trends across two models of care, sharing the results with patient will be beneficial and if the study proves to have no significant adverse clinical outcomes, patients can choose their method of ongoing follow up and thus make an even greater contribution to their management.