

The Navigate Trial: A decision aid for treatment selection

By Kalli Spencer

Approximately 25% of Australian prostate cancer patients are diagnosed with low-risk prostate cancer (LRPC): approximately 5500 per year. They may be offered curative treatment options such as a radical prostatectomy (RP), radiotherapy (RT) and brachytherapy (BT), or may be managed with routine monitoring called active surveillance (AS). It is postulated that up to 50% of all prostate cancer cases do not require curative treatment up to 12 years after diagnosis, with evidence suggesting no survival benefit in providing curative treatments for LRPC up to 10 years after diagnosis. Some of the curative options are associated with short and long-term side effects such as urinary and bowel incontinence, erectile dysfunction, and reduced quality of life. This highlights the importance of patient involvement in decision-making regarding the initiation of curative treatment during early-stage disease. AS, as discussed in a recent blog is a proactive approach delaying or avoiding radical treatments through close monitoring of the tumour. It is also the least costly option to the health system. Ten-year prostate cancer-specific mortality rates have been shown to be similar regardless of whether men undergo AS, RT or RP.

Decision making is difficult for men with LRPC. Decision-related distress and confusion are high due to the multitude of treatment options with no clear “best” choice because of individual preference and lifestyle. For those who select AS, anxiety about not receiving curative (radical) treatment is common. It has been noted that many don’t consider all treatment options, nor do they make decisions which match their personal preferences and values. Partners also experience high decisional distress and confusion and may pressure their partners towards curative treatment.

Besides doctors, the internet is the main source of information for men with prostate cancer. This can often overwhelm patients and their carers. Decision aids “improve knowledge of available treatment options and outcomes, and accuracy of risk perceptions, increase decisional satisfaction, decrease decisional conflict, increase congruency between treatment choice and patient values and improve patient-clinician communication.” Accessed from home it promotes rapid and widespread reach, enabling easy updates to content to remain current. Decision aids guide patients through “a deliberative process of actively weighing-up the benefits/costs of available treatment options, thus enabling decision-making that is both evidence-based and considerate of patient preferences and life circumstances”. They may reduce the proportion of those who choose surgery in favour of less invasive management options.

An Australian research team made up of consumers and a multidisciplinary team have developed the Navigate online decision aid which presents up-to-date, unbiased information tailored to Australian men with LRPC in written, graphical, and video formats. It is backed by a qualitative study which explored the experiences of 21 men with LRPC who had been on AS for at least 3 months, and 14 of their partners. The findings confirmed that partners were highly involved in treatment decision-making and highlighted the need for a consistent and accurate process for LRPC diagnosis and management. Men and their partners

emphasised the need for balanced information to facilitate informed and values-based treatment decisions.

The researchers hypothesize that a higher proportion of participants randomised to Navigate will select AS as a first-line management option; will feel better prepared for decision-making; experience lower levels of decisional conflict and regret; have higher levels of decisional satisfaction and report better quality of illness communication and better prostate cancer-specific quality of life when compared to men randomised to the control group.

This is a list of some of the study questions the team aims to answer:

- Do men randomised to Navigate report higher or lower levels of anxiety than men in the control group?
- Do the partners of men randomised to Navigate experience lower levels of decisional conflict and regret, and higher levels of decisional satisfaction when compared with the partners of men randomised to the control group?
- What is the cost-effectiveness of the decision-aid intervention compared with usual care for men newly diagnosed with prostate cancer?
- What are the general patterns of use of the website; are there any identifiable areas for improvement from a user experience perspective?
- Do men diagnosed with prostate cancer use the website differently compared with partners of these men?

Eligibility criteria

Australian patients will be eligible to participate regardless of whether their partners participate, whereas partners are not eligible without a participating patient.

Patients will be eligible to participate in the trial if:

- they are 18 years or older;
- they have been diagnosed with LRPC in the past 3 months and are yet to make a treatment decision;
- they have been deemed eligible for AS by their treating clinician;
- they have Internet access
- they have sufficient English language skills to complete study requirements and use the Navigate website.

The following patients will be excluded:

- Known to have a severe psychiatric or cognitive disorder
- Too unwell to participate as deemed by their treating clinician, self-report, or the research team at the time of approach.

Partners will be eligible to participate in the trial if:

- they are 18 years or older;
- they are the designated partner identified by the consenting patient
- they have Internet access
- they have sufficient English language skills to complete study requirements and use the Navigate website.

Participating sites include five Australian treatment centres within Victoria (Peter MacCallum Cancer Centre, Western Hospital, Cabrini Hospital, Alfred Hospital, Austin Hospital) and two in Queensland (Royal Brisbane and Women's Hospital, Redcliffe Hospital). Patients with LRPC and their partners from either public or private health care settings are also able to self-refer online to the trial.

The participant's information will be collected through a series of online questionnaires with email or telephone follow up.

The following information will be collected (data is confidential and de-identified):

- Demographics
- Clinical information (Gleason Score and PSA)
- Treatment decision
- Preparedness for decision-making
- Decisional conflict
- Decisional satisfaction
- Decisional regret
- Patient and partner communication regarding illness
- Anxiety
- Quality of life related to diagnosis

Sub studies will also be conducted to investigate the financial burden and cost-effectiveness of the online decision aid. Website analytics will be used to indicate preferred modes of interaction; which aspects users (participants) find most engaging; and how users prefer to access information on the Navigate website.

Navigate has the potential to increase the choice of AS to manage LRPC, thereby avoiding or delaying radical treatments. In addition, it has the potential to reduce patients' and partners' confusion and distress in management decision making, reduce decisional regret, increase decision making preparedness and satisfaction and improve prostate cancer-specific quality of life. Navigate will be made available to all Australian men diagnosed with LRPC to support their management decision making. If this intervention is successful in achieving the minimal expected difference of 15%, which represents 825 men selecting AS in preference to the most common curative treatment approach (radical prostatectomy), this could present an annual cost saving of at least AU\$6.1 million to Australians (difference in average cost per patient of AU\$1400 for government and AU\$2300 for out of pocket).

The trial is in the recruitment phase, and it will be interesting to see whether the outcomes of this study will make the Navigate decision aid part of future practice.

Reference

Schofield P, Gough K, Hyatt A, White A, Frydenberg M, Chambers S, Gordon LG, Gardiner R, Murphy DG, Cavedon L, Richards N, Murphy B, Quinn S, Juraskova I. Navigate: a study protocol for a randomised controlled trial of an online treatment decision aid for men with low-risk prostate cancer and their partners. *Trials* 2021; 22:49.



About the Author

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Kalli is an internationally renowned Urological Surgeon, specialising in oncology and robotic surgery. He trained and worked in South Africa, before relocating to Australia where he has worked at Macquarie University Hospital and Westmead Hospital. His passion for what he does extends beyond the operating room, through public health advocacy, education and community awareness of men's health, cancer and sexuality.

Kalli has been involved with the Prostate Cancer Foundation of Australia for many years, advocating for improved cancer care and facilitating community prostate cancer support groups.