An integrated multicomponent care model for men affected by prostate cancer: A feasibility study of TrueNTH Australia

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Abstract
Objective: To evaluate the feasibility of implementing an integrated multicomponent survivorship care model for men affected by prostate cancer.

Methods: Using a single arm prospective cohort study design, men with prostate cancer were recruited from two regional public hospitals in Australia for a 6-months program that provided information and decision support, exercise and nutrition management, specialised clinical support, and practical support through localised and central care coordination. Carers of the men were also invited to the program. Data were collected from multiple sources to evaluate: (1) recruitment capability and participant characteristics; (2) appropriateness and feasibility of delivering the specific intervention components using an electronic care management tool; and (3) suitability of data collection procedures and proposed outcome measures.

Results: Of the 105 eligible men, 51 (consent rate 49%) participated in the program. Of the 31 carers nominated by the men, 13 consented (consent rate 42%). All carers and 50 (98%) men completed the program. Most (92%) men were newly diagnosed
with localised prostate cancer. All men attended initial screening and assessment for supportive care needs; a total of 838 episodes of contact/consultation were made by the intervention team either in person (9%) or remotely (91%). The intervention was implemented as proposed with no adverse events. The proposed outcome measures and evaluation procedures were found to be appropriate.

**Conclusions:** Our results support the feasibility of implementing this integrated multicomponent care model for men affected by prostate cancer.

**KEYWORDS**
cancer, feasibility, model of care, oncology, psycho-oncology, prostate, quality of life, survivorship, urology

### 1 | INTRODUCTION

Approximately 20,000 men are diagnosed with prostate cancer each year in Australia and 95% of them live at least 5 years after diagnosis.\(^1\) The prostate cancer survivorship starts at the time of initial diagnosis and treatment and remains the rest of life,\(^2\) in which men face various challenges associated with complex treatment decisions, treatment-related side effects, psychological distress and the prospect of recurrence or progression of disease. Urinary incontinence and erectile dysfunction are the most common treatment-related side effects following radical prostatectomy that negatively impact quality of life. Other common treatment-related side effects include bowel urgency from radiation therapy, and deterioration in body composition, physical function, cardiometabolic toxicity and loss of libido and physical feminisation from androgen deprivation therapy.\(^3\)–\(^6\) Additionally, men can experience acceleration of comorbid conditions associated with their cancer treatment, such as osteopenia and osteoporosis, cardiovascular disease, diabetes and obesity.\(^6\) The complexity of these disease- and treatment-related effects mean that many men with prostate cancer are at risk of or experience unmet supportive care needs. Carers of these men report unmet needs in relation to information and health care services,\(^7\) with some studies reporting that carers can experience greater distress than the men.\(^8\)–\(^9\)

To promote comprehensive follow-up care and improve quality of life of men with prostate cancer, the American Cancer Society (ACS) and American Society of Clinical Oncology (ASCO) Prostate Cancer Survivorship Care Guidelines\(^10\)–\(^11\) identify five key domains for action: health promotion, surveillance, physical side effects, psychosocial management, and care coordination. A number of studies have conducted interventions to address these key areas of care. Exercise and psychosocial interventions have been shown to improve men’s health promotion and psychosocial outcomes and reduce physical side effects.\(^12\)–\(^14\) Supported self-management interventions have been shown to be comparable to traditional follow-up care\(^15\) and enhance sexual and urinary function.\(^16\) Nutrition interventions,\(^17\) with or without aerobic exercise, are efficacious in reducing body mass in overweight and obese men with prostate cancer. Studies of family/couple-based interventions also report benefits for carers, such as improved information and psychosocial support, better coping and adjustment to the disease.\(^14\)–\(^18\)

While evidence for prostate cancer survivorship care interventions has grown over the last decade, most studies to date have focused on one area of care, with single intervention approaches that report only on the short-term effects. These studies often fail to recognise that many men and their carers have multiple supportive care needs that can exist over extended periods of time.\(^2\) It is noteworthy to mention that the design and implementation for long-term comprehensive survivorship interventions are sometimes restrained due to issues such as short funding periods and privately insured health care systems.

Recent literature highlights the need to develop comprehensive models of survivorship care that recognise the multiple co-existing and changing requirements that men with prostate cancer experience, and the many service providers that need to be engaged to prevent and manage these needs over time.\(^2\) In Australia, the recent Prostate Cancer Survivorship Essentials Framework\(^19\) supports well-coordinated and responsive survivorship care, in which an integrated, needs-based approach to survivorship care is required. This includes a tailored approach to address the complexity of each individual’s requirements through multi-faceted health care, including psychological, exercise and nutrition support.\(^20\) While the principles inherent in these models have become widely accepted, there is limited literature that reports on the development, implementation and evaluation of integrated multi-component survivorship interventions.

This paper reports the outcomes of a study that assessed the feasibility of an integrated multi-component survivorship intervention (known as TrueNTH, funded by Movember) designed for men with prostate cancer and their partners/carers. Specifically, the aims of this study were to evaluate: (1) recruitment capability and resulting participant characteristics; (2) appropriateness and feasibility of delivering the specific intervention components and using an electronic care management tool to support delivery of the intervention; and (3) suitability of data collection procedures and proposed outcome measures to obtain valid, reliable and complete data over time.
2 | METHODS

2.1 | Study design

This was a single arm prospective cohort study. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615000499583) and received ethical approvals from the lead universities (QUT Approval Number 1400000860) and participating health services.

2.2 | Setting and sample

Based on the capacity and readiness to implement the intervention, two regional public health services from Queensland and New South Wales were selected to participate. Men were eligible if they: (1) were diagnosed with localised prostate cancer within the last 3 months or diagnosed with advanced prostate cancer at least 12 months prior to the recruitment period; (2) were able and willing to participate in the intervention and complete patient reported outcome assessments; and (3) nominated a general practitioner (GP) who agreed to use an online care management tool. Men were excluded from the study if they: (1) were too unwell (as determined by their treating specialists); or (2) had physical, psychological or cognitive difficulties that would prevent them from participating in the intervention or completing self-report outcome measures. The treating specialist (e.g., urologist, radiation or medical oncologist) introduced the study to the potential participants when they attended clinic appointments at the site. Men who expressed interest were referred to an on-site research nurse (who operated independently from nurses delivering the intervention) for further study information and written consent. Upon consenting, men were asked to nominate a GP who was subsequently sent written information about the study. Verbal consent to participate was obtained from the GP via a follow-up telephone conversation with the research nurse.

All consented men were asked to nominate one partner/carer, who was also invited to participate. Partners/carers were required to be: (1) aged 18 years or older; (2) competent to give informed consent; and (3) able to complete questionnaires. Participation of the partner/carer was not a requirement for the man to participate in the study.

2.3 | Intervention

The TrueNTH intervention was a multi-component integrated model of care for men with prostate cancer. Components of the program and care pathway are illustrated in Figure 1. An experienced urology nurse with demonstrated capabilities in clinical assessment and care planning, supportive care, advanced communication, teamwork, and organisational skills was based at each site to coordinate the health care needs of the participant. This nurse was nominated to be the local care coordinator responsible to deliver or facilitate the intervention components for approximately three months via face-to-face consultation, video or telephone support, or email communication.

After three-months, men who were on active surveillance or had completed treatment and no longer required for specialised treatment service (i.e., surgery, radiation) were referred to a Movember employed central care coordinator who was independent to the participating sites. The central care coordinator provided ongoing information and support on an as needed basis and facilitated referral to relevant clinical or supportive care services to meet ongoing and newly emergent needs of men using telephone or video conferencing support as required.

At enrolment, all men received a structured face-to-face consultation with the local care coordinator who comprehensively assessed their needs related to prostate health, general and psychological health, nutritional status, and supportive care needs. Men were provided with an evidence-based education package relevant to their stage of disease and treatment and decision support material (e.g., the online P3P Decision Support Program\(^\text{21}\)) if they were newly diagnosed with prostate cancer and not yet received treatment. Partners/carers were encouraged to attend the session with the man.

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![Figure 1](https://example.com/image.png)

**Figure 1** Components of the TrueNTH program and care pathway for men with prostate cancer
and were provided with support as appropriate, which included the provision of relevant information.

The outcome of the initial assessment was communicated to the man’s treating specialist/team and GP via email or postal mail. This information was used as the basis for development of a care plan and referral to appropriate specialist support services according to the man’s health needs and preferences, preference of treating specialist/team and the availability of local resources. The local care coordinator liaised with the man’s GP to facilitate additional assessments for risks or comorbidities. Based on the assessment, the GP liaised with the treating team to facilitate the management of any identified risk factors and conditions.

All men were referred to an accredited exercise physiologist and an accredited practising dietitian either locally or through a centralised service to receive an evidence-based exercise prescription and individualised dietetic services, respectively. They were provided with information about local peer support programs and were referred to relevant support services to address their needs relating to transport, accommodation, finance, legal, employment and respite services for carers, as required.

The above services were offered to all men regardless their stage of prostate cancer and treatment received. The needs for specific prostate cancer related services (as shown in Figure 1) varied by men’s stage of disease and treatment received and thereby the specialised services were by referral at any point during the intervention according to needs. These services were delivered locally where available or remotely by a central specialist service engaged for the purposes of this project. Not all men needed all specialised services.

To ensure the intervention fidelity, a detailed intervention manual was provided to the care coordinators. All staff involved in the intervention delivery attended an orientation and skill development program, ongoing education and training as required, and regular team meetings. An online care management tool (cdmNet) was used to manage and support care planning, delivery, and review of the services by the intervention team. Men were provided with this tool at the initial consultation, which enabled them to access the individualised care plan and undertake ongoing self-monitoring of their symptoms and needs on a 3 monthly basis or when new symptoms emerged. An alert was sent to the local care coordinator and GP when assessments were completed. If the man did not want to use cdmNet to communicate with the care team or access information, hard copies of information and the care plan were provided with telephone support.

2.4 | Data collection and measurements

2.4.1 | Recruitment capability and resulting participant characteristics

The primary outcome for this study was feasibility measured by the number of eligible patients in the targeted population, number of consents, reasons for declining participation, and retention rate. These measures were documented by the research nurse responsible for recruitment using structured forms.

2.5 | Appropriateness and feasibility of delivering intervention components

Information on intervention delivery and attendance were captured by cdmNet. After each initial consultation, the local care coordinators also completed a log to record the extent to which they delivered intervention activities and the length of the session. Seven sessions were audio-recorded with permission from the participants to enable assessment of the fidelity of the intervention delivery to protocol.

Suitability of data collection procedures and proposed outcome measures.

Surveys were conducted with participants at enrolment (T1), and at 3 months (T2) and 6 months (T3) after enrolment. A range of validated questionnaires (Appendix S1) was used to measure patient-reported health outcomes, including prostate cancer-specific quality of life (EPIC-26),22 psychological well-being (GHQ-12),23,24 experience of care (PPE-15),25 supportive care needs (SCNS-SF34),26 and decisional conflict (regret).28 The proposed economic outcome measures, including three health-related quality of life measures (i.e., EQ-5D-5L,29 AQoL-8D30 and FACT-P,31), self-reported health service usage and cost data were also collected via the survey. The T3 survey was completed by participants at the clinic on the day of the initial consultation and follow-up questionnaires were posted to the participants with pre-paid return envelopes. The research nurse would aid participants if required. Participants were informed that their responses were confidential and not supplied to their care providers.

2.6 | Data analysis

All quantitative analyses were performed using SPSS for Windows (Version 23.0). Descriptive statistics were used to summarise data relating to the primary feasibility outcomes (i.e., recruitment, retention, characteristics of participants) and the uptake of the intervention components. The tape recordings of the initial consultation sessions were reviewed using a checklist that included key intervention components to describe what topics were addressed and to what extent.

While the study was not powered to assess clinical significance, one-way ANOVA was employed to undertake exploratory comparisons on the proposed outcome measures over the study period. Only participants who provided data at all three time points were included in the test. An alpha level of $p \leq 0.05$ was considered statistically significant. The internal consistency of these outcome measures was estimated by using Cronbach’s alpha coefficient with a level of 0.70 considered suitable.
3 | RESULTS

3.1 | Recruitment capability and participant characteristics

During the recruitment period between 2015 and 2016 (one site recruited for 6 months and another site recruited for 12 months), a total of 183 men with prostate cancer were referred to the study (see Figure 2). Of the 105 eligible men, 51 consented (consent rate 49%); of the 31 nominated carers, 13 consented (consent rate 42%). Baseline demographic characteristics of participants are presented in Table 1. Most men \( n = 47 \), 92% were newly diagnosed with localised prostate cancer at enrolment; among them 70% \( n = 33 \) received surgery, 13% \( n = 6 \) received radiotherapy, 6% \( n = 3 \) received multiple treatments, and 11% \( n = 5 \) were undergoing active surveillance during the study. Of the four men with advanced prostate cancer, three were undergoing hormone treatment and one had completed surgery at enrolment.

3.2 | Intervention delivery

3.2.1 | Local care coordinator interventions

All men attended the initial consultation with the local care coordinators at enrolment. The themes identified from these sessions are presented in Table 2. The extent to which various components of the intervention were addressed in these sessions is reported in Appendix S2. During the session, information and education components of the intervention were explained to the men in great detail. For approximately one in five men, intervention components relating to decision support and technology supported monitoring were addressed a little or not at all. Referrals to sexual counselling, continence and psychological services were addressed to a lesser extent than other support services. The average length of the session was 141 min \( (SD = 33) \). The coordinators also spent on average 134 min \( (SD = 41) \) organising and/or following-up the session. Partners/carers were present at 67% of the sessions \( n = 34 \); and of these partners/carers, 89% \( n = 30 \) were involved completely to at a great extent in the sessions. Excluding the initial consultation, local care coordinators made a total of 350 episodes of contact/consultation with the men to provide ongoing monitoring and support; and the average length of each contact/consultation was 16 min \( (SD = 16) \).

3.2.2 | Number and delivery mode of intervention components

A total of 838 episodes of contact/consultation were made with the intervention team, including 401 contacts made by the local care coordinators, 80 by the central care coordinators, 180 by dietitians, 122 by exercise physiologists, 53 by psychiatrists, one by a sexual health specialist and one by a continence consultant. Each man

![Flow diagram of the study procedure](image)

* including 15 consented but later found to be ineligible.
| Characteristics                        | Men                                      | Partners/Carers                        |
|--------------------------------------|------------------------------------------|----------------------------------------|
| Age (years)                          | Mean 62.9 (SD = 6.9, range 49–76)        | Mean 58.5 (SD = 7.6, range 46–69)      |
|                                       | n (%)                                     | n (%)                                  |
| Age groups (years)                   |                                          |                                        |
| 40–49                                | 1 (2)                                    | 2 (15)                                 |
| 50–59                                | 15 (29)                                  | 3 (23)                                 |
| 60–69                                | 28 (55)                                  | 8 (62)                                 |
| 70–79                                | 7 (14)                                   | 0 (0)                                  |
| Area of residence                    |                                          |                                        |
| Major cities                         | 11 (22)                                  | 0 (0)                                  |
| Inner regional                       | 39 (77)                                  | 12 (92)                                |
| Outer regional                       | 1 (2)                                    | 1 (8)                                  |
| Remote                               | 0 (0)                                    | 0 (0)                                  |
| Very remote                          | 0 (0)                                    | 0 (0)                                  |
| Marital status                       |                                          |                                        |
| Married/de facto                     | 38 (75)                                  | 12 (100)                               |
| Widowed                              | 1 (2)                                    | 0 (0)                                  |
| Divorced/separated                   | 9 (18)                                   | 0 (0)                                  |
| Never married                        | 3 (6)                                    | 0 (0)                                  |
| Education level                      |                                          |                                        |
| No formal schooling/Primary school   | 2 (4)                                    | 0 (0)                                  |
| Secondary school                     | 21 (41)                                  | 4 (31)                                 |
| Trade apprenticeship                 | 8 (16)                                   | 0 (0)                                  |
| TAFE college                         | 11 (22)                                  | 3 (23)                                 |
| University degree or higher          | 9 (18)                                   | 4 (31)                                 |
| Other                                | 0 (0)                                    | 2 (15)                                 |
| Employment status                    |                                          |                                        |
| Working full/part-time               | 21 (41)                                  | 7 (54)                                 |
| Retired                              | 22 (43)                                  | 5 (38)                                 |
| Home duties                          | 0 (0)                                    | 1 (8)                                  |
| Unemployed                           | 7 (14)                                   | 0 (0)                                  |
| Sick/on leave/disability             | 1 (2)                                    | 0 (0)                                  |
| Annual gross income (individual)     |                                          |                                        |
| < $20,000                            | 16 (31)                                  | 5 (42)                                 |
| $20,000-$39,999                      | 11 (22)                                  | 1 (8)                                  |
| $40,000-$59,999                      | 10 (20)                                  | 1 (8)                                  |
| $60,000-$79,999                      | 7 (14)                                   | 3 (25)                                 |
| ≥ $80,000                            | 2 (4)                                    | 0 (0)                                  |
| No information provided              | 5 (10)                                   | 2 (17)                                 |
| Being a carer to dependents          |                                          |                                        |
| Dependent child                      | 10 (20)                                  | 1 (8)                                  |
| Aged spouse/relative/friend          | 1 (2)                                    | 2 (17)                                 |
| Person with a disability             | 2 (4)                                    | 0 (0)                                  |
| No dependents                        | 37 (72)                                  | 9 (75)                                 |
| Other                                | 1 (2)                                    | 0 (0)                                  |
| Health concession card holder         | 29 (58)                                  | 6 (46)                                 |
| Eligible for IPTAA                    | 15 (33)                                  | Not applicable                         |
received a median of 16 contacts. Approximately 9% of the contacts were conducted in person, 76% were made via phone, and 15% via email or online teleconference or other modes.

### 3.2.3 Completion rates

Nearly all men (98%) and all carers completed the full 6-months intervention, with only one man withdrawing after two months due to personal and family issues. No adverse health events were experienced or reported by participants as a result of the intervention.

### 3.2.4 Use of technology

Data captured by cdmNet showed that it was used for supporting the delivery of the intervention in a variety of ways. The local care coordinators used it to assess key patient-reported outcomes (i.e., prostate cancer specific symptoms, distress level and initial nutrition

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**TABLE 1** (Continued)

| Characteristics                              | Men   | Partners/Carers |
|----------------------------------------------|-------|-----------------|
| Willingness to provide consent for collection of medicare data | 49 (96) | 13 (100) |

Abbreviations: IPTAAS, isolated patients travel & accommodation assistance scheme; SD, standard deviation.

*For people on a low income or who have reached qualifying age for Age Pension to access to Pharmaceutical Benefits Scheme prescription items, and certain Medicare services, at a cheaper rate.

| IPTAAS is a subsidy program which provides financial assistance to help with travel and accommodation costs for people who need to travel long distances to access specialist medical services not available locally.

| Medicare data are health related statistics administered by the Australian government which provide information on general practitioner, specialist, diagnostic test and prescription pharmaceutical use.

**TABLE 2** Topics addressed by local care coordinators in initial consultations

| Themes                          | Examples                                                                                                                                                                                                 |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Screening and assessment        | - Assessment of prostate cancer specific symptoms, distress and nutrition screening using the tools as per protocol.                                                                                       |
|                                 | - Assessment of prostate cancer stage, treatments received or treatment intention, medication, and comorbidities.                                                                                           |
| Navigation and referral         | - Informing men about the TrueNTH program and central care coordination, e.g., what support and services would be available, who would contact the man and how the services would be delivered; role of the general practitioner (GP); communication between care coordinators, treating specialists and other care providers. |
|                                 | - Introduction of care plan and multidisciplinary approach.                                                                                                                                               |
| Information provision and education | - Introduction of reliable online information resources and provision of TrueNTH education package, e.g., (PCFA), Andrology Australia, cancer Council online fact sheets and booklets.                        |
|                                 | - Explanation about stage of disease, treatment options, prognosis, and test results etc.                                                                                                                                 |
|                                 | - Discussion of post treatment issues, such as side effects of treatment on sexual function and penile rehabilitation, continence; activities that enhance the recovery.                                     |
| Decision support                | - Introduction of the personal patient profile (P3P).                                                                                                                                                   |
| Self-management support         | - Providing access to and demonstrating the use of cdmNet.                                                                                                                                              |
| Practical and peer support      | - Introduction of local prostate cancer support groups.                                                                                                                                                 |
|                                 | - Discussion of financial issues related to cancer treatment.                                                                                                                                             |
|                                 | - Discussion of carer and family support.                                                                                                                                                               |
| Advanced prostate cancer comorbidities management | - Explanation about the role of GP.                                                                                                                                                                      |
|                                 | - Introduction of the exercise and nutrition components of the TrueNTH program.                                                                                                                         |

Note: Based on the recordings of seven initial consultation sessions. 
Abbreviation: PCFA, prostate cancer Foundation of Australia.
screening), identify individual needs, and refer men to relevant services. The intervention team used it for communication and to manage and support care planning, care delivery and review. There was no record that the tool was used by referring specialists or by GPs. Men’s progress was updated with their specialists and GPs via telephone conversations, emails or letters prepared by care coordinators.

### 3.3 Data collection procedures and outcome measures

All participants completed T₀ survey, 35 men and 12 partners/carer returned T₁, and 36 men and all partners/carer returned T₂ survey. Participants appeared to have no difficulty completing the health-related outcome measures independently as there was little missing data (<3%). The internal consistency reliability of these measures (as shown in Appendix S3) was satisfactory (Cronbach’s α = 0.67-0.90) except for the urinary obstructive subscale (Cronbach’s α = 0.51) of the EPIC questionnaire.

Some participants needed assistance from the research assistant to complete the health service usage questionnaire as they had difficulty spelling drug names, recalling all of the services and medicines used, and the relevant costs over the preceding three months. As a result, 2% of men and 5% of partner/carer responses were missing on the health services usage questions. However, men often provided more data regarding their use of pharmaceuticals than was requested. In addition, 96% men and all partners/carers indicated a willingness to consent to the researchers accessing their Medicare data for health services usage data. The three health-related quality of life measures (i.e. EQ-5D-5L, AQoL-8D and FACT-P) showed high completion rates (missing data <2%).

Scores from key patient-reported health outcome measures collected at each time point are summarised in Appendix S3. Symptom severity was highest for sexual dysfunction at all time points. Men reported a significant improvement regarding urinary obstruction (p = 0.03), but worse sexual health (p < 0.001) and urinary incontinence (p < 0.01) over time. Levels of psychological distress in men did not change (p = 0.73) over time with 57% (n = 29) at T₀, 54% (n = 19) at T₁ and 63% (n = 22) at T₂ reporting that they did not have any psychological distress. Around 18% of the men (n = 6) at T₁ and 27% (n = 9) at T₂ reported that they did not experience any problems with their care. However, this change was not statistically significant (p = 0.30). There were no statistically significant changes over time in terms of supportive care needs (p = 0.06-0.64) and decision regret (p = 0.39) for men.

### 4 DISCUSSION

This study assessed the feasibility of implementing an integrated, multicomponent care model designed to address critical areas of care for men and their partners/carers affected by prostate cancer in Australia. Our findings are that the program was accepted by men, was largely implemented as per protocol with high completion rates and no adverse events. The proposed evaluation procedures were appropriate. However, some important issues were raised in this study that have implications for future studies involving multicomponent interventions.

Interest in the program by the treating team was high and use of existing clinical networks as referral sources was effective. Over 180 referrals were received from the two regional settings during the recruitment period. Of note, around 40% of the referrals did not meet the inclusion criteria relating to time since diagnosis. The strict inclusion criteria in the present study were chosen to enhance homogeneity of the sample and enable testing of the full intervention pathway from the beginning of their cancer journey. The high number of ineligible referrals due to duration of diagnosis highlights the clinician’s and/or the man’s desire to access supportive care.

The main reason that eligible men declined participation in this study was ‘lack of interest’ or ‘not being in need of supportive care’ (50%), ‘feeling overwhelmed/perceived burden’ (20%) and ‘no desire to use computers or smart devices’ (17%). Such concerns highlight the need for active strategies to enhance men’s participation in the program, such as providing additional written information to explain the purpose and procedures of the program, as well as possible benefits and risks; offering hands-on support for using computers/smart devices; and offering alternative modes of service and communication. Post Covid-19 pandemic it is likely that the ‘no desire to use computers or smart devices’ sentiment will be much reduced since all age groups of Australians have embraced computer-based forms of communication in much greater numbers than previously.

The recruitment resulted in a sample of men who were of a similar age range to men affected by prostate cancer in Australia. Most men were from a regional area and one third of them had to travel long distances (eligible for government subsidy) for treatment and specialist appointments. Around 40% took time off work to participate in the face-to-face services. Therefore, interventions that are delivered remotely via telephone or digital health were appropriate and acceptable for the current sample. We suggest that while some men were reluctant to participate in the study due to concerns about use of technology, most intervention activities (91%) were carried out remotely via telephone or digital health.

In terms of the data collection procedures and outcome measures, participants had no difficulty independently completing questions related to their health and responded with minimal missing data. The internal consistency of the key patient-reported health outcome measures with our sample was similar to that reported in the previous studies. The four quality of life measures that were tested in the study showed equally high acceptability and response rates over time. Two of them (AQoL-8D, FACT-P) contain 35 and 40 items respectively, one contains 26 items (EPIC-26), and one (EQ-5D-5L) contains 5 items. The measures with most concise items would be more acceptable for the larger trial. The advantage
of the EQ-5D-5L and the AQoL-8D is that generic health utility scores can be generated for comparative economic evaluation purposes (i.e., both instruments are multi-attribute utility instruments (MAUIs) usable in a variety of settings). The AQoL-8D has more sensitivity to change than the EQ-5D-5L but is considerably longer. Both have been extensively used in trials to describe the self-rated health, but the EQ-5D-5L has had greater application in prostate cancer patients. As a result, the EQ-5D-5L would be recommended for a larger study as the preferred economic instrument. The two measures (FACT-P and EPIC-26) were tested as patient relevant outcome measures and as the comparison cancer specific quality of life measure for the generic economic instruments. On balance the two shorter quality of life measures would be chosen for a larger study—the EPIC-26 (disease specific) and the EQ-5D-5L (generic).

4.1 Clinical implications

Overall, the uptake of intervention components was high, and the intervention was implemented as proposed. This included uptake of the referral to remotely provided nutrition and exercise management services, and other support following treatment completion. Smaller numbers of referrals were made to specialised services including sexual counselling, continence, and psychological services. These lower referral rates could reflect that such referrals were seen to be necessary only for severe cases or reflect reluctance on the part of local care coordinators to share care with others. It might also reflect reluctance on the part of patients to accept help for these concerns. A previous study of a nurse-led prostate cancer survivorship service in UK reported that 22% of men who initially declined to attend a supportive care program asked for a supportive care clinic appointment after attending education sessions. Our finding highlights the need to develop clear protocols to facilitate needs-based referrals, and to actively work with patients to manage concerns about referrals to these services.

Partners/carers of the men were also actively involved in the program. Although only a quarter of partners/carers (13 out of 51) participated in the study, the two thirds of the initial consultation sessions (34 out of 51) included partners/carers and these sessions were well accepted.

We suggest that the online care management tool supported the implementation of the intervention in multiple ways, including facilitating the team communication. Even though the participating GPs agreed to use the tool, none of them actually accessed it during the study, nor did the treating specialists. For this reason, the men’s medical team received progress updates via telephone and letters written by care coordinators. It was also challenging to monitor and obtain data on the services provided by the local service providers outside of the public health system. The barriers to using the tool for these health professionals need to be explored as effective communication within the patients’ care team and care coordination across service providers and settings are key to the successful management of patient care.

4.2 Study limitations

This study was designed to assess the feasibility and acceptability, but not the effectiveness of the intervention. Nonetheless, some preliminary observations can be made regarding the validity and sensitivity of the tools. The changes regarding prostate cancer specific quality of life, while not designed to be evaluated for statistical significance, were in line with other patient-reported outcome studies, in which urinary obstructive symptoms improved with treatment over the time. Urinary continence and sexual functioning declined initially and improved with time after treatment. Other limitations of the study include the use of convenience study sites and that most patients were newly diagnosed and were undertaking or had just finished their treatment. While not all men needed all services provided by the intervention during the study period, participation in the study likely increased men’s knowledge of disease and treatment effects and promoted awareness of such support which could benefit these men in the long-term. Moreover, while referral to specialist services for side-effects of treatment such as urinary and sexual function was not high, the use of experienced nurses with expertise in these areas likely has important benefits as some men would prefer that such sensitive topics are addressed by known health professionals.

5 CONCLUSIONS

In this study we have demonstrated the feasibility of implementing an integrated multicomponent care model for men affected by prostate cancer. Future studies need to focus on how to engage with men and their partners/carers to ensure similar interventions take into account their concerns and to reduce burden. Consideration of health literacy and tailoring of the intervention to personal circumstances are integral to success of long-term interventions such as TrueNTH. Additional strategies to encourage the involvement of GPs, if they are to take on a more active role in follow up care, are needed. Clear protocols that guide when referrals should be made to specialist support services will be required to ensure appropriate use of these services.

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CONFLICT OF INTEREST
Donna Cowan (DC) and Cyril Dixon (CD) were employees of Movember during the study. CD was the Project Manager and DC was a central care coordinator of the TrueNTH program. Nicholas Dennis was a private practitioner who provided dietetic service in the program. All other authors declare that they have no conflicts of interests.

AUTHOR CONTRIBUTIONS
Patsy Yates and Rob Carter obtained funding from Movember to conduct the study. Patsy Yates and Wei-Hong Liu drafted the manuscript. All authors have made contributions to conception and design, or acquisition of data, or analysis and interpretation of data. All authors contributed to critical revision of the manuscript for important intellectual content.

DATA AVAILABILITY STATEMENT
The datasets used and/or analysed in this study are available from the corresponding author on reasonable request.

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ENDNOTE
1 It is now called Inca.

REFERENCES
1. Australian Institute of Health and Welfare. Cancer in Australia 2017. Cancer Series no.101. Cat. No. CAN 100. Canberra, Australia: AIHW; 2017.
2. Narayan V, Harrison M, Cheng H, et al. Improving research for prostate cancer survivorship: a statement from the Survivorship Research in Prostate Cancer (SuRECaP) working group. Urologic Oncol Seminars Orig Investigations. 2020;38(3):83-93.
3. Emanu JC, Avildsen IK, Nelson CJ. Erectile dysfunction after radical prostatectomy. Curr Opin Support Palliat Care. 2016;10(1):102-107.
4. Carlsson S, Drevin L, Loeb S, et al. Population-based study of long-term functional outcomes after prostate cancer treatment. BJU Int. 2016;117(6B):E36-E45.
5. Donovan JL, Hamdy FC, Lane JA, et al. Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer. N Engl J Med. 2016;375(15):1425-1437.
6. Heidenreich A, Bastian PJ, Bellmunt J, et al. EAU guidelines on prostate cancer. Part II: treatment of advanced, relapsing, and castration-resistant prostate cancer. Eur Urol. 2014;65(2):467-479.
7. Girgis A, Lambert S, Lecathelinais C. The supportive care needs survey for partners and caregivers of cancer survivors: development and psychometric evaluation. Psycho-Oncology. 2011;20(4):387-393.
8. Resendes LA, McCorkle R. Spousal responses to prostate cancer: an integrative review. Canc Invest. 2006;24(2):192-198.
9. Couper J, Bloch S, Love A, Macvean M, Duchesne GM, Kissane D. Psychosocial adjustment of female partners of men with prostate cancer: a review of the literature. Psycho-Oncology. 2006;15(11):937-953.
10. Skolarus TA, Wolf AMD, Erb NL, et al. American Cancer Society prostate cancer survivorship care guidelines. CA A Cancer J Clin. 2014;64:225-249.
11. Resnick MJ, Lacchetti C, Bergman J, et al. Prostate cancer survivorship care guideline: American Society of Clinical Oncology clinical practice guideline endorsement. J Clin Oncol. 2015;33(9):1078-1085.
12. Crawford-Williams F, March S, Goodwin BC, et al. Interventions for prostate cancer survivorship: a systematic review of reviews. Psycho-oncology. 2018;27(10):2339-2348.
13. Bourke L, Smith D, Steed L, et al. Exercise for men with prostate cancer: a systematic review and meta-analysis. Eur Urol. 2016;69(4):693-703.
14. Chambers SK, Hyde MK, Smith DP, et al. New Challenges in Psycho-Oncology Research III: a systematic review of psychological interventions for prostate cancer survivors and their partners: clinical and research implications. Psycho-Oncology. 2017;26(7):873-913.
15. Frankland J, Brodie H, Cooke D, et al. Follow-up care after treatment for prostate cancer: evaluation of a supported self-management and remote surveillance programme. BMC Canc. 2019;19(1):368.
16. Skolarus TA, Metreger T, Wittmann D, et al. Self-management in long-term prostate cancer survivors: a randomized, controlled trial. Jco. 2019;37(15):1326-1335.
17. Mohamad H, McNeill G, Haseen F, N’Dow J, Craig LCA, Heys SD. The effect of dietary and exercise interventions on body weight in prostate cancer patients: a systematic review. Nutr Cancer. 2015;67(1):43-60.
18. Wittmann D, Koontz BF. Evidence supporting couple-based interventions for the recovery of sexual intimacy after prostate cancer treatment. Curr Sex Health Rep. 2017;9(1):32-41.
19. Dunn J, Green A, Ralph N, et al. Prostate cancer survivorship essentials framework: guidelines for practitioners. BJU Int. 2020. https://doi.org/10.1111/bju.15159
20. Clinical Oncology Society of Australia Model of Survivorship Care Working Group. Model of Survivorship Care: Critical Components of Cancer Survivorship Care in Australia Position Statement. Sydney, NSW: Clinical Oncology Society of Australia; 2016.
21. Berry DL, Halpeny B, Wolpin S, et al. Development and evaluation of the personal patient profile—prostate (P3P), a Web-based decision support system for men newly diagnosed with localized prostate cancer. J Med Internet Res. 2010;12(4):e67.
22. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the expanded prostate cancer index composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. Urology. 2000;56(6):899-905.
23. Goldberg DP, Gater R, Sartorius N, et al. The validity of two versions of the GHQ in the WHO study of mental illness in general health care. Psychol Med. 1997;27(1):191-197.
24. Goldberg D, Williams P. A User’s Guide to the General Health Questionnaire (GHQ). London, UK: GL Assessment; 2006.
25. Jenkinson C, Coulter A, Bruster S. The Picker Patient Experience Questionnaire development and validation using data from in-patient surveys in five countries. Int J Qual Health Care. 2002;14(5):353-358.
26. Boyes A, Girgis A, Lecathelinais C. Brief assessment of adult cancer patients’ perceived needs: development and validation of the 34-item Supportive Care Needs Survey (SCNS-SF34). J Evol Clin Pract. 2009;15(4):602-606.
27. O’Connor AM. Validation of a decisional conflict scale. Med Decis Mak. 1995;15(1):25-30.

28. Brehaut JC, O’Connor AM, Wood TJ, et al. Validation of a decision regret scale. Med Decis Mak. 2003;23(4):281-292.

29. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727-1736.

30. Richardson J, Iezzi A, Khan MA, Maxwell A. Validity and reliability of the Assessment of Quality of Life (AQoL)-8D multi-attribute utility instrument. Patient. 2014;7(1):85-96.

31. Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. Jco. 1993;11(3):570-579.

32. Magnus A, Isaranuwatchai W, Mihalopoulos C, Brown V, Carter R. A systematic review and meta-analysis of prostate cancer utility values of patients and partners between 2007 and 2016. MDM P P. 2019;4(1):1-19.

33. Torvinen S, Bergius S, Roine R, Lodenius L, Sintonen H, Taari K. Use of patient Assessed health-related quality of life instruments in prostate cancer research: a systematic review of the literature 2002-15. Int J Technol Assess Health Care. 2016;32(3):97-106.

34. Ferguson J, Aning J. Prostate cancer survivorship: a nurse-led service model. Br J Nurs. 2015;24(Sup18):S14-S21.

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