



The PACT Study: A time series study investigating the feasibility and acceptability of an integrated, patient-centred model for psychosocial assessment, care and treatment of patients with urological and head and neck cancers.

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4 **and acceptability of an integrated, patient-centred model for**
5 **psychosocial assessment, care and treatment of patients with**
6 **urological and head and neck cancers**
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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the feasibility, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test the feasibility, acceptability and cost of the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level change, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are acceptability of the model to patients and health care professionals (HCPs) and impact on the knowledge and confidence of HCPs, assessed via patient and HCP surveys at baseline and at follow-up and HCP interviews at follow-up. The intervention cost (tertiary outcome) will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly, this work has substantial potential for translation into other cancer services, beyond the current study.

Limitations of the study:

- The target population is vulnerable and experiencing an acute stressor that may impact on recruitment.
- As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Consequently, some of the health professionals who complete a survey at twenty-four months may be only minimally exposed to the intervention and have diluted perceptions of impact.
- Other health initiatives may be introduced into hospitals in the study area, which could affect the impact of this intervention.

For peer review only

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3 Emotional distress, pain and fatigue are commonly experienced by the majority of
4 cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed
5 with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience
6 urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck
7 (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including
8 melanoma, thyroid) often experience profound disfigurement and functional disability,
9 changed body image, speech difficulties, nutritional problems, and have higher suicide rates
10 than other people with cancer.[2] Both urological and H&N cancer patients often report
11 negative changes in their intimate and social relationships.[1, 3] Some cancers, including
12 urological and H&N cancers, are more prevalent in rural areas,[4] where people experience
13 major difficulties accessing cancer services, including psychosocial care.[5] There is good
14 evidence of the effectiveness of a variety of interventions and services to prevent and/or
15 relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that
16 much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7]
17 Failure to address these problems can exacerbate suffering and lead to decreased patient
18 satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and
19 mortality outcomes.[8]

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22 Recent cancer patient satisfaction surveys in Australia, the United Kingdom and
23 Canada have highlighted problems in coordination of services and limitations in psychosocial
24 care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of
25 care are important contributing factors.[12] Many health care professionals are not aware of
26 effective evidence-based strategies to address patients' concerns, or underestimate the
27 benefits of attending to psychosocial needs or referring to psychosocial personnel or services.
28 There are few formalised mechanisms for communication between health care providers and
29 systems of care may contribute to patients receiving fragmented and poorly coordinated care;

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3 especially those who reside in rural areas.[8] With well supported stepped care models, the
4 needs of the majority of cancer patients can be met without referral to specialist psychosocial
5 services.[13] Models of care that provide basic psychosocial care delivered by frontline
6 health care providers (eg oncology nurses), with appropriate training and mentorship by
7 psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of
8 the increase in quality-adjusted life-years achieved.[14]

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17 The Institute of Medicine [8] has recommended a model for integrated psychosocial
18 cancer care that comprises: 1) identifying patients' health needs through screening and
19 assessment; 2) linking patients to health services via structured referral, case management
20 and clinical integration of services; 3) supporting patients in illness self-management; 4)
21 coordinating psychosocial and biomedical health care through care coordinators,
22 multidisciplinary team meetings, multidisciplinary care plans and electronic health records;
23 and 5) following up on care delivery by telephone calls or web-based technology to re-
24 evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most
25 specialist oncology services and evaluating its effectiveness represent major challenges.[15-
26 16] These challenges are accentuated in settings where cancer care is integrated into general
27 medical or surgical care, with the absence of dedicated on-site cancer teams. This means that
28 staff may not identify themselves as cancer clinicians and service models are generic to cater
29 for a diverse range of illness groups. Nevertheless this represents the setting in which a
30 significant proportion of cancer patients experience at least part of their treatment. Within this
31 type of care delivery setting, how can effective models of integrated psycho-oncology care be
32 developed, implemented and evaluated? This is one of the key questions this project aims to
33 investigate.

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The Hunter New England Local Health District of New South Wales, Australia,
includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a

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3 major metropolitan centre and several large regional centres, as well as many smaller rural
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5 centres and remote communities. This area has an average of 4,171 new cases of cancer
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7 diagnosed per annum, with over 9,000 inpatient separations per year for cancer related
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9 conditions.[17]
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11 The current model of cancer care at the John Hunter Hospital (JHH), the site for this
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13 study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing
14
15 radiation or chemotherapy are referred to a nearby specialist cancer service and generally
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17 return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124
18
19 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology
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21 service comprises five senior urologists and four dedicated outpatient nursing staff, and the
22
23 H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-
24
25 based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range
26
27 of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team
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29 meetings provide a forum to discuss individuals with complex cancers.
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34 Screening for psychosocial needs is not routine and when it is conducted (using pen-
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36 and-paper Distress Thermometer and Problem Checklist),[18] the Cancer Care Coordinator
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38 discusses the issues with the patient and referrals may be made to allied health care
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40 professionals or other agencies, albeit not based on a specific care pathway. Although each
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42 unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-
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44 oncology services; patients requiring psycho-oncology assessment are either referred to
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46 generic Liaison Psychiatry, which provides a limited role including advice, inpatient
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48 consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service
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50 at the nearby cancer hospital, which is a separate service with no shared records and located
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52 at a different site to patients' routine outpatient care at the JHH.
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Objective

The objective of this study is to develop, implement and assess the feasibility, acceptability and cost of, an integrated, patient-centred model for psychosocial assessment, care and treatment of patients with urological and H&N cancers.

Study Design

A time series research design will be used to test the feasibility and acceptability of the Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [19] and is an acceptable design for inclusion in Cochrane reviews.[20] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[20] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of

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3 NSW, Australia. It provides the main services for a large sector of the state of NSW,
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5 comprising a population of over 850,000 people. It is the main teaching hospital of the
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7 University of Newcastle.
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10 11 **Eligibility criteria**

12 13 **Patients**

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16 Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer
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18 or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH.
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20 21 **Staff**

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23 Staff who are employed through the JHH will be eligible to complete the Knowledge
24
25 and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide
26
27 care for patients who are receiving inpatient or outpatient urological or H&N cancer services
28
29 at this site. Staff will be eligible to participate in interviews to assess the acceptability of the
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31 PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing
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33 or allied health staff member, b) provide care for patients who are receiving inpatient or
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35 outpatient urological or H&N cancer services, and c) have been involved in the PACT care
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37 pathway of one or more patients, either on-site at JHH, or through provision of follow-up
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39 care, following discharge from JHH.
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45 46 **Intervention**

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48 The PACT (**P**sychosocial Assessment, **C**are and **T**reatment) model, targeting patients
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50 with H&N or urological cancers, will be developed as part of this study. This model aims to
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52 systematise the approach to screening for distress and responding to that distress in a
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54 coordinated manner, including facilitating continuity of care for patients who reside some
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3 distance from the acute care setting where they were treated for cancer. The development of
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5 this care model includes the following key components:

- 6
7 1) The implementation for inpatients and outpatients of the two surgical units of
8 routine screening for distress, and associated psychosocial care plans.
- 9
10 2) The identification of intervention options for all levels of need, and pathways to
11 specialist psycho-oncology care if required.
- 12
13 3) The addition of dedicated psycho-oncology clinical services (including
14 psychologist, psychiatrist and mental health nurse).
- 15
16 4) The provision of staff development and support to implement such a model
17 (including training in skilled communication to identify and respond to
18 emotional distress), and structured case review for complex or challenging
19 cases. The latter strategies will incorporate oncology clinical staff and others
20 working with cancer patients within urban, regional and remote communities.
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22 5) Videoconferencing to facilitate case review meetings between clinicians at
23 urban and rural sites.

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39 In order to achieve these intervention goals, the following are intrinsic to the service model:

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41 a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology
42 and adult education, will coordinate the establishment and delivery of the model, with a
43 special focus on development and implementation of a systematic and structured approach to
44 routine assessment, triage and management of cancer patients' individual physical,
45 psychological and social concerns during active treatment and at follow-up.

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51 b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators
52 with experience in communication skills training (AG, BK) will develop and deliver a
53 communication skills-based training program to support frontline clinical staff (mostly
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nursing and allied health care professionals) in implementing the psycho-oncology care model and facilitating within-team communication to enhance continuity of patient care. This training program will be run on numerous occasions to reach as many frontline staff as possible during the intervention period.

c) The CNC and Clinical Psychologist will facilitate the delivery of the care model through the training of frontline staff, provision of clinical assessment and specialised evidence-based care for patients who are referred to the psycho-oncology service, monitoring of progress on psychosocial care plans including with rural clinicians through case reviews, and providing advice as required to rural clinicians to support linking patients to local rural specialised services. Where specialised services are not available, the Clinical Psychologist will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of the program, participate in staff training, and direct clinical evaluation and treatment of patients with the highest level of distress or complexity.

Clinical practice guidelines recommend routine distress screening of cancer patients (with feedback to health care providers) at periods of increased vulnerability to ensure that those at risk are identified promptly and offered appropriate treatment.[18] As part of the newly developed model of care, all inpatient and outpatient urology and H&N cancer patients will be screened at their first diagnostic or treatment visit and at each subsequent follow-up visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which will inform the development of a care plan to address the issues identified through the screening and second-line inquiry. The care plan will facilitate provision of care tailored to the specific needs of patients and promote continuity of care across care settings and providers, including with health care professionals (HCPs) in the rural and regional areas.

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3 The screening and problem checklist will act as a trigger for frontline staff to inquire
4 about, and discuss the cause/s of, distress with patients whose distress levels are above the
5 recommended cut-off of 4 or more out of 10.[21] Training for frontline staff will focus on
6 discussing the cause/s of the distress, developing an evidence-based psychosocial care plan to
7 address identified concerns, providing information and/or basic counselling, or referring
8 patients with significant or persistent distress to the psycho-oncology service, and facilitating
9 continuity of care, including linking patients with hospital and community services as
10 required. Long-term sustainability of these service changes will be promoted through
11 organisational leadership and management support, engagement of cancer clinician leaders in
12 each unit in the design and evaluation of the service model, and development of a model with
13 the aim of adaptability and flexibility to diversity of locations and patient complexity (eg
14 through complex case review and revision of psychosocial care plans and active involvement
15 of clinicians from rural locations in this process).[22]
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34 **Outcomes**

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36 The primary outcome is a system-wide increase in the proportion of eligible patients
37 receiving care at the study facility who complete a DT and accompanying Problem Checklist
38 (see Data Collection Methods) on at least one occasion and have a psychosocial care plan
39 developed which complies with recommended care pathways. This outcome will be assessed
40 at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new
41 model of care – refer to Intervention section).
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49 The secondary outcome is an increase in the proportion of eligible patients receiving
50 care at the study facility who report positive experiences of their cancer care at 12 and 24
51 months post-baseline compared to patients receiving care in this facility at baseline.
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The tertiary outcome is an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline.

The resource use and costs of the intervention will also be monitored, by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	Intervention delivery	Data collection
0 months		Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey
	Development and delivery of communication skills training to health professionals	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
12 months	PACT intervention delivery	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
	On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)	
24 months		Recruitment of Patient Cross-sectional Sample #3

		Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
		Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey
		Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention
		Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)
		Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention

Recruitment

Patients

Three cross-sectional samples of patients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. Patients will be recruited from inpatient wards and the outpatient clinics associated with the JHH. During the study audit periods at baseline, 12 months and 24 months, the Research Officer (RO) will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The RO will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained from Hunter New England Local Health District (HNELHD), a Consent Form for data to be obtained from the Department of Human Services, a Request for Summary of Study Results Form, a copy of

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3 the self-administered Patient Experience Survey and a Paperwork Return Checklist. Patients
4
5 will be asked to take the Information Pack home to consider before completing the survey
6
7 and consent forms and posting them back to the researchers, using a self-addressed reply paid
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9 envelope, within 10 days. Staff at the outpatient clinics and inpatient wards will also be
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11 supplied with Information Packs to distribute to eligible patients who attend the clinic when
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13 the RO is not in attendance.
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18 Staff

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21 *Health Professional Knowledge and Confidence Survey*

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23 Two cross-sectional samples of HCPs involved in the care of patients with H&N or
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25 urological cancers at the study facility will be recruited during the study audit periods at
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27 baseline and at 24 months, to assess the skills development of clinical staff who work at the
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29 parent facility. At each time point, the RO will contact the Managers of the inpatient wards
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31 and outpatient clinics in which care is provided to patients with urological and H&N cancers.
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33 The Managers will be asked to identify the nursing and allied health staff members who
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35 routinely provide care to the patients of their respective wards/clinics, as well as each staff
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37 member's employment status as either permanent or casual. A list of HCPs eligible to receive
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39 an Information Pack will then be generated, and Information Packs sent via internal mail to
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41 the department at which each staff member is based. The Information Pack will contain an
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43 Information Letter and a copy of the self-administered Knowledge and Confidence Survey
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45 for HCPs to complete and post back to the researchers, using a self-addressed reply paid
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47 envelope, within 10 days. A second survey will be mailed to HCPs who do not return a
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49 completed survey within four to six weeks and a third survey will be sent to non-returnees
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51 four to six weeks after that.
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Health Professional receptivity and acceptability interviews

At approximately 24 months (nearing study completion), purposively sampled allied health, nursing and medical staff will be interviewed by the RO about the acceptability of the key aspects of the PACT integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers, clinical case reviews), perceived effectiveness of the model at improving care, and perceived impact of the staff training. The RO will send an Information Pack to those staff members who meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-minute telephone interview at a mutually convenient time.

Data collection methods

The primary outcome of system-level change will be assessed through audit of patient medical records, and through Medicare and PBS claims information for follow-up care sought via referral through the new model of care; the secondary outcomes of acceptability of the model and impact on HCP knowledge and confidence will be assessed via patient and HCP surveys and HCP interviews; and the tertiary outcome of cost of the intervention will be assessed from information collected through Medicare and PBS claims information, as well as information logged pertaining to intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS) claims information

At baseline, 12 months and 24 months, the files of all patients who provide their consent will be reviewed by the RO and an appointed research assistant who is not involved in the intervention delivery, to calculate the proportions of patients a) who have completed a DT and accompanying Problem Checklist at least once, b) who have had a psychosocial care plan developed, and c) whose management, including referrals, complies with recommended care pathways. A checklist will be used to achieve a systematic approach to extraction of these records. The coders (RO and a second research assistant) will initially review one file with the Clinical Psychologist to ensure consistency in understanding of the checklist and 10% of the files will be double-coded by the two coders to calculate inter-rater reliability.

Medicare and PBS claims information will also be extracted by the Department of Human Services for those participants who provide their consent, and will be reviewed by the health economist investigators (MH and RV) to extract information relating to psychosocial care delivered in a hospital or community health setting, by a private provider, or by a general practitioner.

Patient Experience Survey

A 35-item survey will include items assessing patient perceptions of care received, relating to the dimensions of emotional support, information, education and coordination of care. All items are phrased from the first-person perspective (eg “*I had confidence and trust in the staff treating me*”), to be answered using a 5-point Likert-type scale ranging from 1 = ‘strongly disagree’ to 5 = ‘strongly agree’. A patient experience score will be aggregated based on the sum of selected responses.

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3 The survey will also measure key *socio-demographic, disease and medical variables*,
4 including age, residential location, gender, marital status, indigenous identification, languages
5 spoken, country of birth, educational attainment, employment status, private health coverage,
6 income, cancer type, date of diagnosis, treatment received, recurrence status, and number of
7 prior inpatient admissions and outpatient clinic visits.
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13 14 15 16 Health Professional Knowledge and Confidence Survey 17

18 A 65-item survey will include items targeting health professionals' knowledge, skills
19 and confidence pertaining to responding to patients' specific psychosocial concerns. The
20 survey contains 12 items from a *Confidence in Communication Skills and Discussing*
21 *Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[23] The
22 survey also contains a case study and associated Care Planning, Monitoring and Review
23 items from the Client-Centred Care – Training Needs Survey;[24] all adapted such that they
24 refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician
25 Belief Scale is contained in the survey; based on the Physician Belief Scale,[25] it contains
26 all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group
27 of health professionals than doctors, and items will be answered on a 5-point Likert-type
28 scale ranging from 1= 'strongly disagree' to 5= 'strongly agree'. Finally, the survey contains
29 the single-item Clinician Burnout survey, which is the Physician Burnout survey,[26]
30 renamed to apply to a broader group of health professionals than doctors. A
31 knowledge/confidence score will be aggregated based on the sum of selected responses.
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49 The survey will also measure key *socio-demographic, experience and training*
50 *variables*, including age, residential location, gender, occupational specialty, number of years
51 of experience in a) their current specialty and b) in cancer care, number of hours spent
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1
2
3 weekly in direct patient contact, indigenous identification, languages spoken, country of
4
5 birth, and country of training.
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9 10 Health Professional receptivity and acceptability interview

11
12 An interview will be scheduled with consenting participants to assess the acceptability
13
14 of the key aspects of the integrated model of psychosocial care (including screening, triage,
15
16 access to psychosocial services/providers and clinical case reviews), perceived effectiveness
17
18 of the model in improving care, and the perceived impact of training. It is anticipated that the
19
20 interview will take 20 minutes, with an audio recording being made for transcription
21
22 purposes. Examples of questions in the interview guide include: “Have you been aware of
23
24 there being a more systematic approach to the provision of psychosocial care for people with
25
26 H&N or urological cancers over the past year or so compared to previously?” and “What’s
27
28 your impression of patient/family member/caregiver attitudes toward the new model (eg
29
30 acceptance)?”
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36 Intervention costs

37
38 In keeping with the time series design, information about resource use and associated
39
40 costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained
41
42 from the hospital’s databases regarding emergency department (ED) attendance, triage
43
44 category, whether the patient was admitted or discharged from the ED, and their diagnosis.
45
46 Information about use and costs of medical services and pharmaceuticals will be obtained
47
48 from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff
49
50 training, inter-professional case reviews and other communications required to support rural
51
52 and regional providers, will also be monitored.
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Sample size

Patients

Data from twenty-five patient surveys were used to estimate the sample size. The mean patient experience score at baseline was 45 (out of a possible 55). Hence, at least 38 patients will need to be recruited at each time point to achieve a minimum clinically significant improvement of 5 points between baseline and last follow-up (24 months), assuming a standard deviation of 7.58 (derived from current surveys), significance level of 5%, and power of 80%.

Health care professionals

Data from twenty-eight surveys were used to estimate the sample size. The mean score of knowledge/confidence was 61.5 (out of a possible 105). Hence, at least 48 health professionals will need to be recruited at each time point to achieve a minimum clinically significant improvement of 10 points between baseline and follow-up (24 months), assuming a standard deviation of 17.13 (derived from current surveys), significance level of 5%, and power of 80%.

Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the RO. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this

1
2
3 electronically stored data will be maintained in separate, password-protected files, which will
4
5 be stored on a password-protected local area network drive, accessible only by the RO and
6
7 the chief investigators. On completion of data analysis and report writing, computer files will
8
9 be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by
10
11 the RO and the chief investigators.
12

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14 Data in paper format will be stored for seven years, while computer files will be
15
16 stored for 15 years. All will be shredded by a contracted security waste disposal company at
17
18 the conclusion of the storage period.
19

20 21 22 **Statistical methods**

23 24 **Analysis of primary and secondary outcomes**

25
26 In keeping with a focus on evaluating the feasibility of implementing a new service, it
27
28 is essential to proceed in stages, with initial evaluation of a new model being devoted to
29
30 performance monitoring and process studies, before moving on to studies that document
31
32 impact.[27] Therefore, this evaluation will focus on the feasibility and acceptability of the
33
34 new model of care, with system-level outcomes being of primary interest. Data will be
35
36 collected at baseline, 12 months and 24 months on the proportion of patients a) who are
37
38 screened for distress at least once, b) who have a psychosocial care plan developed, and c)
39
40 whose management complied with recommended care pathways.
41
42
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44

45
46 Data on points a) to c) above will be collected at the three time points and analysed
47
48 using Poisson or Negative Binomial regression depending on over-dispersion of the counts of
49
50 each outcome. The Poisson/Negative binomial models will include a time variable (0, 12 and
51
52 24 months), a before and after variable, a term for the interaction of these two variables, and
53
54 an offset variable which is used to adjust for the total number of patients consented at each
55
56 time point. The interaction term will be used to estimate any difference between the two
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1
2
3 periods, which would indicate a slow improvement in the outcome during the intervention
4
5 period. The before and after variable will be used to estimate the change in the outcome that
6
7 may occur immediately after the introduction of the model of care. The models will adjust as
8
9 appropriate for potential confounding variables such as age, gender, residential location,
10
11 indigenous status, cancer type, and time since diagnosis.
12
13

14 15 16 Patient Experience and Health Professional Knowledge and Confidence

17
18 For patient experience surveys, a linear regression will be used to model the patient
19
20 experience scores over the three time points to determine whether there was a significant
21
22 improvement during the study period whilst adjusting for potential confounding variables (eg
23
24 duration of care within the service, other psychosocial support services used, disease and
25
26 treatment characteristics, age, and gender). Similarly, for the health professional knowledge
27
28 and confidence surveys, a linear regression be used to determine if there was a difference in
29
30 the knowledge/confidence scores between the two time points whilst adjusting for potential
31
32 confounding variables (eg other training in psychosocial care received, duration of
33
34 employment in this service, prior experience, work role and time allocation, age, and gender).
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40 41 Economic analysis

42
43 Estimates of resource use and costs will take into account the costs of implementation
44
45 of the new model, but will not include costs of the evaluation/audit. At each time point
46
47 (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence
48
49 intervals will be generated by boot-strapping the data. Benefits will be measured via surveys
50
51 and interviews to ascertain the acceptability of the intervention and how the new model is
52
53 experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes
54
55 will be reported separately at each time point and trends over time will be evaluated.
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Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs of individual cancer patients by (1) systematically identifying patients' physical and psychosocial health needs, (2) developing care pathways and plans to address identified needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating ongoing psychosocial health care. The project has a focus on translating evidence regarding psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff, including those in rural settings, and will promote improved coordination and continuity of care for patients in rural and remote areas. Improving the psychosocial component of routine care, building distress screening into a model of routine care, and developing a psychosocial care plan for patients will enhance the acceptability and appropriateness of psychosocial care.

1
2
3 Specialist services will be active in providing training, advice and support within an inter-
4 professional team, and providing specialist assessment and treatment as a member of this
5 team when needed. Addressing the process and outcome variables will support investigation
6 of the quality of care provided from patient and clinician perspectives.
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10
11 The proposed care model has the potential to address several unmet needs identified in
12 key policy documents and surveys. Specifically, it will provide improved emotional support
13 and information for both cancer inpatients and outpatients,[9] expand psycho-oncology
14 services to improve access to specialised care,[17] and provide timely individualised support
15 to the level and detail required for patients.[28] In addition, this research program directly
16 addresses the priority issue of delivering quality cancer care that addresses patients' physical
17 and psychosocial health needs [6, 8] by bringing together the scientific evidence about the
18 management of cancer patients' psychosocial problems into a model of patient-centred cancer
19 care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of
20 research attention compared to their burden on the Australian community.[29]
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34 The translational capacity of this research program is enhanced through three major
35 strengths. First, it is supported by a very strong collaborative team. Enhancing the role of
36 'frontline' clinical staff, defining pathways of care and promoting integration between major
37 centres and rural clinicians entails a high level of support from clinical staff for objective
38 implementation and evaluation. This project has strong support from the highest level of
39 cancer service governance in our area, senior nursing clinicians and existing on-site
40 psychiatric services. The linkage of the PACT model to Area-level network of psycho-
41 oncology services will promote integration of psychosocial care into routine clinical care,
42 promote continuity of care, and, through its clinician training model, improve the overall
43 quality of care for patients and their families.
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3 Second, the study utilises strong methodology appropriate for health services research.
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5 The evaluation framework and methodology ensures that the evaluation is sensitive to the
6
7 role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and
8
9 informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes
10
11 and changes in these over time; an important consideration as economics is an often
12
13 overlooked element of interventional research. The close engagement of clinicians in the
14
15 planning, implementation and evaluation will ensure maximum relevance of the project to the
16
17 local context of clinical practice, including rural and remote settings. The built-in capacity for
18
19 flexibility in the clinical setting (eg documenting and addressing local barriers to integration
20
21 of psychosocial care) will promote translation to routine care, and potential applicability to
22
23 other settings.[27]
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26

27
28 Third, there is strong support for integration of psychosocial care into routine care, and
29
30 efficient use of specialist services. This project will provide important evidence for the
31
32 effective use of existing resources for nurses and allied health professionals working in
33
34 routine cancer care. If the outcomes of the research are positive, this will provide the basis for
35
36 a model of implementing psycho-oncology services across other clinical services within this
37
38 network. While the project includes the use of routine screening, it does so in a manner that
39
40 builds this into a model of care, so that these tools can support clinical practice within a
41
42 model of integrated care, defined service pathways and support to distant sites. The work has
43
44 substantial potential for translation into other cancer services beyond the research
45
46 collaborators.
47
48

49
50 Despite the strengths, there are also several challenges for the research and evaluation.
51
52 The target population is vulnerable and experiencing an acute stressor that may impact on
53
54 recruitment. As the intervention will continue over a twenty-four month period, changes in
55
56 health professional staff over that time may be substantial. Hence, some of the health
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professionals completing the survey at twenty-four months may have been minimally exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health initiatives introduced more broadly into hospitals in the study location may affect the impact of this intervention, but are beyond the control of the research team.

ETHICS AND DISSEMINATION

Ethics approval

Research ethics approval has been obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of New South Wales. Minor adverse events (eg a participant being tearful and distressed when talking with the RO) will be logged and fed back to the study team by the end of the study. Serious adverse events (eg expressing suicidal thoughts) will be reported immediately to the chief investigators and to the ethics committees. Any protocol amendments will be submitted to the ethics committees before these are implemented, and relevant changes will also be communicated to other relevant organisations (eg trial registry).

Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the RO. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

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2
3 All of the electronically stored personal participant information will be maintained
4 and destroyed in the same manner as all data collected throughout the study. On completion
5 of data analysis and report writing, computer files will be transferred to CD-ROM, which will
6 then be stored in a locked cabinet, accessible only by the RO. These will be stored for fifteen
7 years, then shredded by a contracted security waste disposal company at the conclusion of the
8 storage period.
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19 **Competing interests**

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21 As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John
22 Hunter Hospital and a chief investigator on this project, BK may experience competing
23 interests with respect to reporting the feasibility, cost and acceptability of the new
24 psychosocial care model. These potentially competing interests will be minimised and
25 managed by having the other chief investigator, AG, primarily responsible for the conduct of
26 the research and result reporting.
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38 **Access to data**

39 The study's chief investigators (AG, BK), RO, Biostatistician, and Health Economists
40 will have exclusive access to the final trial dataset.
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46 **Dissemination policy**

47
48 The results will be widely disseminated through peer-reviewed publications as well as
49 relevant health care professional and consumer publications. Oncology health care
50 professionals and administrators within Hunter New England Local Health District will be
51 invited to a face-to-face presentation of the results by the chief investigators. Presentations
52 will be delivered at relevant national oncology and nursing conferences and meetings. The
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3 results will be reported to the funding body and other peak bodies with influence on cancer
4 policy and practice, including Cancer Australia, Clinical Oncology Society of Australia,
5 Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants
6 who request a summary of the study's key findings will be mailed one on completion of the
7 project.
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14 15 16 17 **AUTHORS' CONTRIBUTIONS**

18
19 BK and AG conceived of the study and are the grant holders. AB assisted in the initial
20 study design and AP and DB provided organisational guidance on service model and
21 implementation. BK and AG, along with the newly appointed clinical staff, developed the
22 communication skills training, and HC will oversee the day-to-day study implementation
23 according to the protocol. MH and RV provided guidance on data requirements for the
24 economic analysis and will undertake these analyses. JD provided guidance on sample size
25 requirements and will be conducting the primary statistical analyses. All authors contributed
26 to refinement of the study protocol and approved the final manuscript.
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40 41 **ACKNOWLEDGEMENTS**

42 The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative
43 Research Group (PoCoG), The University of Sydney, Australia. The study protocol and
44 relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and
45 the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central
46 role in facilitating recruitment and implementation of the intervention, and Catherine Adams
47 and Deanna Sue in the communication skills training of health professionals involved in the
48 delivery of the PACT model of care.
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<input checked="" type="checkbox"/>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<input checked="" type="checkbox"/>
	2b	All items from the World Health Organization Trial Registration Data Set	<input checked="" type="checkbox"/>
Protocol version	3	Date and version identifier	<input checked="" type="checkbox"/>
Funding	4	Sources and types of financial, material, and other support	<input checked="" type="checkbox"/>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<input checked="" type="checkbox"/>
	5b	Name and contact information for the trial sponsor	<input checked="" type="checkbox"/>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<input checked="" type="checkbox"/>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<input checked="" type="checkbox"/>
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<input checked="" type="checkbox"/>
	6b	Explanation for choice of comparators	N/A

Objectives	7	Specific objectives or hypotheses	<input checked="" type="checkbox"/>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<input checked="" type="checkbox"/>
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<input checked="" type="checkbox"/>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<input checked="" type="checkbox"/>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<input checked="" type="checkbox"/>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<input checked="" type="checkbox"/>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<input checked="" type="checkbox"/> Table 1

1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<input checked="" type="checkbox"/>
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7	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<input checked="" type="checkbox"/>
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9				
10	Methods: Assignment of interventions (for controlled trials)			
11				
12	Allocation:			
13				
14	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
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23	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
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29	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
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33	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
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38		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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42	Methods: Data collection, management, and analysis			
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44	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<input checked="" type="checkbox"/>
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	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<input checked="" type="checkbox"/>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<input checked="" type="checkbox"/>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<input checked="" type="checkbox"/>
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<input checked="" type="checkbox"/>
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<input checked="" type="checkbox"/>
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<input checked="" type="checkbox"/>
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<input checked="" type="checkbox"/>
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	<input checked="" type="checkbox"/>
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	<input checked="" type="checkbox"/>
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<input checked="" type="checkbox"/>
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	<input checked="" type="checkbox"/>
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<input checked="" type="checkbox"/>
	31b	Authorship eligibility guidelines and any intended use of professional writers	<input checked="" type="checkbox"/>
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<input checked="" type="checkbox"/>

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
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The PACT Study Protocol: A time series study investigating the impact, acceptability and cost of an integrated model for psychosocial screening, care and treatment of patients with urological and head and neck cancers.

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The PACT Study Protocol: A time series study investigating the impact, acceptability and cost of an integrated model for psychosocial screening, care and treatment of patients with urological and head and neck cancers

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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the impact, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level impact, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are impact of the model on patient experience and health care professionals' (HCPs) knowledge and confidence, assessed via patient and HCP surveys at baseline and at follow-up. Acceptability of the intervention will be assessed through HCP interviews at follow-up, and cost will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly, this work has substantial potential for translation into other cancer services, beyond the current study.

Limitations of the study:

- The target population is vulnerable and experiencing an acute stressor that may impact on recruitment.
- As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Consequently, some of the health professionals who complete a survey at twenty-four months may be only minimally exposed to the intervention and have diluted perceptions of impact.
- Other health initiatives may be introduced into hospitals in the study area, which could affect the impact of this intervention.

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3 Emotional distress, pain and fatigue are commonly experienced by the majority of
4 cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed
5 with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience
6 urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck
7 (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including
8 melanoma, thyroid) often experience profound disfigurement and functional disability,
9 changed body image, speech difficulties, nutritional problems, and have higher suicide rates
10 than other people with cancer.[2] Both urological and H&N cancer patients often report
11 negative changes in their intimate and social relationships.[1, 3] Some cancers, including
12 urological and H&N cancers, are more prevalent in rural areas,[4] where people experience
13 major difficulties accessing cancer services, including psychosocial care.[5] There is good
14 evidence of the effectiveness of a variety of interventions and services to prevent and/or
15 relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that
16 much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7]
17 Failure to address these problems can exacerbate suffering and lead to decreased patient
18 satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and
19 mortality outcomes.[8]

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22 Recent cancer patient satisfaction surveys in Australia, the United Kingdom and
23 Canada have highlighted problems in coordination of services and limitations in psychosocial
24 care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of
25 care are important contributing factors.[12] Many health care professionals are not aware of
26 effective evidence-based strategies to address patients' concerns, or underestimate the
27 benefits of attending to psychosocial needs or referring to psychosocial personnel or services.
28 There are few formalised mechanisms for communication between health care providers and
29 systems of care may contribute to patients receiving fragmented and poorly coordinated care;

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3 especially those who reside in rural areas.[8] With well supported stepped care models, the
4 needs of the majority of cancer patients can be met without referral to specialist psychosocial
5 services.[13] Models of care that provide basic psychosocial care delivered by frontline
6 health care providers (eg oncology nurses), with appropriate training and mentorship by
7 psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of
8 the increase in quality-adjusted life-years achieved.[14]

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17 The Institute of Medicine [8] has recommended a model for integrated psychosocial
18 cancer care that comprises: 1) identifying patients' health needs through screening and
19 assessment; 2) linking patients to health services via structured referral, case management
20 and clinical integration of services; 3) supporting patients in illness self-management; 4)
21 coordinating psychosocial and biomedical health care through care coordinators,
22 multidisciplinary team meetings, multidisciplinary care plans and electronic health records;
23 and 5) following up on care delivery by telephone calls or web-based technology to re-
24 evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most
25 specialist oncology services and evaluating its effectiveness represent major challenges.[15-
26 16] These challenges are accentuated in settings where cancer care is integrated into general
27 medical or surgical care, with the absence of dedicated on-site cancer teams. This means that
28 staff may not identify themselves as cancer clinicians and service models are generic to cater
29 for a diverse range of illness groups. Nevertheless this represents the setting in which a
30 significant proportion of cancer patients experience at least part of their treatment. Within this
31 type of care delivery setting, how can effective models of integrated psycho-oncology care be
32 developed, implemented and evaluated? This is one of the key questions this project aims to
33 investigate.
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Objective

The objective of this study is to develop, implement and assess the impact, acceptability and cost of, an integrated, patient-centred model for psychosocial screening, care and treatment of patients with urological and H&N cancers at a large tertiary referral hospital.

Study Design

A time series research design will be utilised to test the Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [17] and is an acceptable design for inclusion in Cochrane reviews.[18] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[18] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of

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3 NSW, Australia. It provides the main services for a large sector of the state of NSW,
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5 comprising a population of over 850,000 people, including a major metropolitan centre and
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7 several large regional centres, as well as many smaller rural centres and remote communities.
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9 This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000
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11 inpatient separations per year for cancer related conditions.[19] It is the main teaching
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13 hospital of the University of Newcastle.
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17 The current model of cancer care at the John Hunter Hospital (JHH), the site for this
18
19 study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing
20
21 radiation or chemotherapy are referred to a nearby specialist cancer service and generally
22
23 return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124
24
25 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology
26
27 service comprises five senior urologists and four dedicated outpatient nursing staff, and the
28
29 H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-
30
31 based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range
32
33 of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team
34
35 meetings provide a forum to discuss individuals with complex cancers. Although each unit is
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37 supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology
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39 services. Patients requiring psycho-oncology assessment are either referred to generic Liaison
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41 Psychiatry, which provides a limited role including advice, inpatient consultation and a
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43 restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby
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45 cancer hospital, which is a separate service with no shared records and located at a different
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47 site to patients' routine outpatient care at the JHH.
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Eligibility criteria

Patients

Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH. Patients from metropolitan and all rural areas served by this hospital are included in the study.

Staff

Staff will be eligible to complete the Knowledge and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services at this site. Staff will be eligible to participate in interviews to assess the acceptability of the PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing or allied health staff member, b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services, and c) have been involved in the PACT care pathway of one or more patients, either on-site at JHH, or through provision of follow-up care, following discharge from JHH.

Intervention

It is important to note that this study focuses on a system-level intervention aimed at modifying provision of service to all patients attending these units, rather than recruiting a sample of patients for the provision of a specific psychosocial intervention. While data are collected periodically from patients attending this hospital and from staff, this is chiefly with the intention of examining the impact of the service changes. The PACT (Psychosocial Assessment, Care and Treatment) model focuses on a system of care for patients with H&N or urological cancers. This model aims to systematise the approach to screening for distress and responding to that distress in a coordinated manner, including facilitating continuity of care for patients who reside some distance from the acute care setting where they were

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3 treated for cancer. In order to address the needs of those patients in rural regions, a specific
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5 component of the innovation introduced to the system of care is extended to this population.
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8 The development of this care model includes the following key components:

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- 1) The implementation for inpatients and outpatients of the two surgical units of routine screening for distress, and associated psychosocial care plans.
 - 2) The identification of intervention options for all levels of need, and pathways to specialist psycho-oncology care if required.
 - 3) The addition of dedicated psycho-oncology clinical services (including psychologist, psychiatrist and mental health nurse).
 - 4) The provision of staff development and support to implement such a model (including training in skilled communication to identify and respond to emotional distress), and structured case review for complex or challenging cases. The latter strategies will incorporate oncology clinical staff and others working with cancer patients within urban, regional and remote communities.
 - 5) Videoconferencing to facilitate case review meetings between clinicians at the hospital base site and those at rural sites who are engaged in the on-going post-discharge care of patients initially treated at the hospital.

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44 In order to achieve these intervention goals, the following are intrinsic to the service model:

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- a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology and adult education, will coordinate the establishment and delivery of the model, with a special focus on development and implementation of a systematic and structured approach to routine screening, triage and management of cancer patients' individual physical, psychological and social concerns during active treatment and at follow-up.

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3 b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators
4 with experience in communication skills training (AG, BK) will develop and deliver a
5 communication skills-based training program to support frontline clinical staff (mostly
6 nursing and allied health care professionals) in implementing the psycho-oncology care
7 model and facilitating within-team communication to enhance continuity of patient care. This
8 training program will be run on numerous occasions to reach as many frontline staff as
9 possible during the intervention period and is based on an evidence-based consultation skills
10 training program previously developed and evaluated by our team. [20-21]
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21 c) The CNC and Clinical Psychologist will facilitate the delivery of the care model
22 through the training of frontline staff, provision of clinical assessment and specialised
23 evidence-based care for patients who are referred to the psycho-oncology service, monitoring
24 of progress on psychosocial care plans including with rural clinicians through case reviews,
25 and providing advice as required to rural clinicians to support linking patients to local rural
26 specialised services. Where specialised services are not available, the Clinical Psychologist
27 will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist
28 assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of
29 the program, participate in staff training, and direct clinical evaluation and treatment of
30 patients with the highest level of distress or complexity.
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43 Clinical practice guidelines recommend routine distress screening of cancer patients
44 (with feedback to health care providers) at periods of increased vulnerability to ensure that
45 those at risk are identified promptly and offered appropriate treatment.[22] As part of the
46 newly developed model of care, all inpatient and outpatient urology and H&N cancer patients
47 will be screened at their first diagnostic or treatment visit and at each subsequent follow-up
48 visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which
49 will inform the development of a care plan to address the issues identified through the
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3 screening and second-line inquiry. The care plan will facilitate provision of care tailored to
4 the specific needs of patients and promote continuity of care across care settings and
5 providers, including with health care professionals (HCPs) in the rural and regional areas.
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10 The screening and problem checklist will act as a trigger for frontline staff to inquire
11 about, and discuss the cause/s of, distress with patients whose distress levels are above the
12 recommended cut-off of 4 or more out of 10.[23] Training for frontline staff will focus on
13 discussing the cause/s of the distress, developing a psychosocial care plan to address
14 identified concerns providing information and/or basic counselling, or referring patients with
15 significant or persistent distress to the psycho-oncology service, and facilitating continuity of
16 care, including linking patients with hospital and community services as required. Staff will
17 also assist patients with access to self-management information on tablets which will be
18 available during their hospital visit. Long-term sustainability of these service changes will be
19 promoted through organisational leadership and management support, engagement of cancer
20 clinician leaders in each unit in the design and evaluation of the service model, and
21 development of a model with the aim of adaptability and flexibility to diversity of locations
22 and patient complexity (eg through complex case review and revision of psychosocial care
23 plans and active involvement of clinicians from rural locations in this process).[24]
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43 **Outcomes**

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45 The primary outcome is a system-wide increase in the proportion of eligible patients
46 receiving care at the study facility who complete a DT and accompanying Problem Checklist
47 (see Data Collection Methods) on at least one occasion and have a psychosocial care plan
48 developed which complies with recommended care pathways. This outcome will be assessed
49 at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new
50 model of care – refer to Intervention section).
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The secondary outcomes are: a) an increase in the proportion of eligible patients receiving care at the study facility who report positive experiences of their cancer care at 12 and 24 months post-baseline compared to patients receiving care in this facility at baseline, and b) an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline. HCP satisfaction with the PACT intervention will also be assessed via interviews at follow-up, and the resource use and costs of the intervention will be monitored by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	Data collection	Intervention delivery
Commencing at 0 months (March 2013)	Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	Development and delivery of communication skills training to health professionals PACT intervention delivery throughout the study period
Commencing at 12 months	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)
Commencing	Recruitment of Patient Cross-sectional	

at 24 months	Sample #3 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
	Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention	
	Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)	
	Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention	

Recruitment

Patients

Three cross-sectional samples of current inpatients and outpatients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. The main purpose of these data collection phases is the evaluation of the impact of system-level changes, rather than recruiting patients who will undertake the intervention. During the study audit periods at baseline, 12 months and 24 months, the Research Officer will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The Research Officer will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained

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3 from Hunter New England Local Health District (HNELHD), a Consent Form for data to be
4
5 obtained from the Department of Human Services, a Request for Summary of Study Results
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7 Form, a copy of the self-administered Patient Experience Survey and a Paperwork Return
8
9 Checklist. Patients will be asked to take the Information Pack home to consider before
10
11 completing the survey and consent forms and posting them back to the researchers, using a
12
13 self-addressed reply paid envelope, within 10 days. Staff at the outpatient clinics and
14
15 inpatient wards will also be supplied with Information Packs to distribute to eligible patients
16
17 who attend the clinic when the Research Officer is not in attendance.
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20 21 22 Staff

23 24 *Health Professional Knowledge and Confidence Survey*

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27 Two cross-sectional samples of HCPs involved in the care of patients with H&N or
28
29 urological cancers at the study facility will be recruited during the study audit periods at
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31 baseline and at 24 months, to assess the skills development of clinical staff who work at the
32
33 parent facility. At each time point, the Research Officer will contact the Managers of the
34
35 inpatient wards and outpatient clinics in which care is provided to patients with urological
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37 and H&N cancers. The Managers will be asked to identify the nursing and allied health staff
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39 members who routinely provide care to the patients of their respective wards/clinics, as well
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41 as each staff member's employment status as either permanent or casual. A list of HCPs
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43 eligible to receive an Information Pack will then be generated, and Information Packs sent via
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45 internal mail to the department at which each staff member is based. The Information Pack
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47 will contain an Information Letter and a copy of the self-administered Knowledge and
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49 Confidence Survey for HCPs to complete and post back to the researchers, using a self-
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51 addressed reply paid envelope, within 10 days. A second survey will be mailed to HCPs who
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3 do not return a completed survey within four to six weeks and a third survey will be sent to
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5 non-returnees four to six weeks after that.
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8 9 *Health Professional receptivity and acceptability interviews*

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11 At approximately 24 months (nearing study completion), purposively sampled allied
12
13 health, nursing and medical staff will be interviewed by the Research Officer about the
14
15 acceptability of the key aspects of the PACT integrated model of psychosocial care
16
17 (including screening, triage, access to psychosocial services/providers, clinical case reviews),
18
19 perceived effectiveness of the model at improving care, and perceived impact of the staff
20
21 training. The Research Officer will send an Information Pack to those staff members who
22
23 meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent
24
25 Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-
26
27 minute telephone interview at a mutually convenient time.
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33 **Data collection methods**

34
35 The primary outcome of system-level change will be assessed through audit of patient
36
37 medical records, and through Medicare and PBS claims information for follow-up care
38
39 sought via referral through the new model of care; the secondary outcomes of impact of the
40
41 model on patient experiences and on HCP knowledge and confidence will be assessed via
42
43 patient and HCP surveys. Acceptability of the intervention will be assessed via HCP
44
45 interviews, and cost of the intervention will be assessed from information collected through
46
47 Medicare and PBS claims information, as well as information logged pertaining to
48
49 intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient
50
51 contact, providing training sessions, engaging in case review) and their associated costs (eg
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1
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3 CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions,
4
5 videoconferencing costs).
6
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8

9
10 Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS)
11 claims information
12

13 At baseline, 12 months and 24 months, the files of all patients who provide their
14 consent will be reviewed by the Research Officer and an appointed research assistant who is
15 not involved in the intervention delivery, to calculate the proportions of patients a) who have
16 completed a DT and accompanying Problem Checklist at least once, b) who have had a
17 psychosocial care plan developed, and c) whose management, including referrals, complies
18 with recommended care pathways. A checklist will be used to achieve a systematic approach
19 to extraction of these records. The coders (Research Officer and a second research assistant)
20 will initially review one file with the Clinical Psychologist to ensure consistency in
21 understanding of the checklist and 10% of the files will be double-coded by the two coders to
22 calculate inter-rater reliability.
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35 Medicare and PBS claims information will also be extracted by the Department of
36 Human Services for those participants who provide their consent, and will be reviewed by the
37 health economist investigators (MH and RV) to extract information relating to psychosocial
38 care delivered in a hospital or community health setting, by a private provider, or by a general
39 practitioner.
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49 Patient Experience Survey
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51 A 35-item survey will include items assessing patient perceptions of care received,
52 relating to the dimensions of emotional support, information, education and coordination of
53 care. All items are phrased from the first-person perspective (eg "*I had confidence and trust*
54 *in the staff treating me*"), to be answered using a 5-point Likert-type scale ranging from 1 =
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2
3 ‘strongly disagree’ to 5 = ‘strongly agree’. A patient experience score will be aggregated
4 based on the sum of selected responses. The survey contains 3 items from the Cancer Care
5 Survey, [25] and 8 items from the Hospital Care – Overnight Patient Survey; [26] all adapted
6 such that they could be answered from the first-person perspective. The survey also contains
7 10 items from the Critical Cancer Care Events Scale; [27] some of which required adaptation
8 so that they referred to a broader group of health professionals than doctors, and all of which
9 were adapted to be answered on a 5-point Likert-type scale (as described above).

10
11 The survey will also measure key *socio-demographic, disease and medical variables*,
12 including age, residential location, gender, marital status, indigenous identification, languages
13 spoken, country of birth, educational attainment, employment status, private health coverage,
14 income, cancer type, date of diagnosis, treatment received, recurrence status, and number of
15 prior inpatient admissions and outpatient clinic visits.

16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 Health Professional Knowledge and Confidence Survey

33
34 A 65-item survey will include items targeting health professionals’ knowledge, skills
35 and confidence pertaining to responding to patients’ specific psychosocial concerns. The
36 survey contains 12 items from a *Confidence in Communication Skills and Discussing*
37 *Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[28] The
38 survey also contains a case study and associated Care Planning, Monitoring and Review
39 items from the Client-Centred Care – Training Needs Survey;[29] all adapted such that they
40 refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician
41 Belief Scale is contained in the survey; based on the Physician Belief Scale,[30] it contains
42 all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group
43 of health professionals than doctors, and items will be answered on a 5-point Likert-type
44 scale ranging from 1= ‘strongly disagree’ to 5= ‘strongly agree’. Finally, the survey contains
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3 the single-item Clinician Burnout survey, which is the Physician Burnout survey,[31]
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5 renamed to apply to a broader group of health professionals than doctors. A
6
7 knowledge/confidence score will be aggregated based on the sum of selected responses.
8

9
10 The survey will also measure key *socio-demographic, experience and training*
11 *variables*, including age, residential location, gender, occupational specialty, number of years
12 of experience in a) their current specialty and b) in cancer care, number of hours spent
13 weekly in direct patient contact, indigenous identification, languages spoken, country of
14 birth, and country of training.
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20 21 22 23 Health Professional receptivity and acceptability interview

24
25 An interview will be scheduled with consenting participants to assess the acceptability
26 of the key aspects of the integrated model of psychosocial care (including screening, triage,
27 access to psychosocial services/providers and clinical case reviews), perceived effectiveness
28 of the model in improving care, and the perceived impact of training. It is anticipated that the
29 interview will take 20 minutes, with an audio recording being made for transcription
30 purposes. An interview schedule previously developed by our team has been adapted for use
31 in the present study, and examples of questions in the interview guide include: “Have you
32 been aware of there being a more systematic approach to the provision of psychosocial care
33 for people with H&N or urological cancers over the past year or so compared to previously?”
34 and “What’s your impression of patient/family member/caregiver attitudes toward the new
35 model (eg acceptance)?”
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50 51 52 Intervention costs

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54 In keeping with the time series design, information about resource use and associated
55 costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained
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1
2
3 from the hospital's databases regarding emergency department (ED) attendance, triage
4 category, whether the patient was admitted or discharged from the ED, and their diagnosis.
5
6 Information about use and costs of medical services and pharmaceuticals will be obtained
7
8 from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff
9
10 training, inter-professional case reviews and other communications required to support rural
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12 and regional providers, will also be monitored.
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19 **Sample size**

20 **Patients**

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22 Data from the initial twenty-five patient surveys completed were used to estimate the
23 required patient sample size. The mean patient experience score at baseline was rated highly
24 at 45 out of a possible 55. Hence, the research team determined that a 5-point improvement
25 between baseline and the last follow-up (24 months) would be a meaningful change,
26 assuming a standard deviation of 7.58 (derived from current surveys), significance level of
27 5%, and power of 80%, with at least 38 patients needing to be recruited at each time point to
28 detect this change over time.
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41 **Health care professionals**

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43 Data from the first 28 surveys completed were used to estimate the required sample
44 size. The mean score of knowledge/confidence was moderate at 61.5 out of a possible 105.
45 Hence, it was determined that at least 48 health professionals were required to be recruited at
46 each time point to achieve a significant improvement of 10 points between baseline and
47 follow-up (24 months), assuming a standard deviation of 17.13 (derived from current
48 surveys), significance level of 5%, and power of 80%.
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Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the Research Officer. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this electronically stored data will be maintained in separate, password-protected files, which will be stored on a password-protected local area network drive, accessible only by the Research Officer and the chief investigators. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the Research Officer and the chief investigators.

Data in paper format will be stored for seven years, while computer files will be stored for 15 years. All will be shredded by a contracted security waste disposal company at the conclusion of the storage period.

Statistical methods

Analysis of primary and secondary outcomes

This evaluation will focus on the impact and acceptability of the new model of care, with system-level outcomes being of primary interest. Cross-sectional data will be collected at baseline, 12 months and 24 months on the proportion of patients a) who are screened for distress at least once and b) who have a psychosocial care plan developed.

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2
3 Data will be collected at the three time points and analysed using Poisson or Negative
4 Binomial regression depending on over-dispersion of the counts of each outcome. The
5 Poisson/Negative binomial models will include a time variable (0, 12 and 24 months), a
6 before and after variable, a term for the interaction of these two variables, and an offset
7 variable which is used to adjust for the total number of patients consented at each time point.
8 The interaction term will be used to estimate any difference between the two periods, which
9 would indicate a slow improvement in the outcome during the intervention period. The before
10 and after variable will be used to estimate the change in the outcome that may occur
11 immediately after the introduction of the model of care. The models will adjust as appropriate
12 for potential confounding variables such as age, gender, residential location, indigenous
13 status, cancer type, and time since diagnosis.
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29 Patient Experience and Health Professional Knowledge and Confidence

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31 For patient experience surveys, a linear regression will be used to model the patient
32 experience scores over the three time points to determine whether there was a significant
33 improvement during the study period whilst adjusting for potential confounding variables (eg
34 duration of care within the service, other psychosocial support services used, disease and
35 treatment characteristics, age, and gender). Similarly, for the health professional knowledge
36 and confidence surveys, a linear regression will be used to determine if there was a difference
37 in the knowledge/confidence scores between the two time points whilst adjusting for potential
38 confounding variables (eg other training in psychosocial care received, duration of
39 employment in this service, prior experience, work role and time allocation, age, and gender).
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Economic analysis

Estimates of resource use and costs will take into account the costs of implementation of the new model, but will not include costs of the evaluation/audit. At each time point (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data. Benefits will be measured via surveys and interviews to ascertain the acceptability of the intervention and how the new model is experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes will be reported separately at each time point and trends over time will be evaluated.

Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs

1
2
3 of individual cancer patients by (1) systematically identifying patients' physical and
4
5 psychosocial health needs, (2) developing care pathways and plans to address identified
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7 needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating on-
8
9 going psychosocial health care. The project has a focus on translating evidence regarding
10
11 psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff,
12
13 including those in rural settings, and will promote improved coordination and continuity of
14
15 care for patients in rural and remote areas. Improving the psychosocial component of routine
16
17 care, building distress screening into a model of routine care, and developing a psychosocial
18
19 care plan for patients will enhance the acceptability and appropriateness of psychosocial care.
20
21 Specialist services will be active in providing training, advice and support within an inter-
22
23 professional team, and providing specialist assessment and treatment as a member of this
24
25 team when needed. Addressing the process and outcome variables will support investigation
26
27 of the quality of care provided from patient and clinician perspectives.
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32 The proposed care model has the potential to address several unmet needs identified in
33
34 key policy documents and surveys. Specifically, it will provide improved emotional support
35
36 and information for both cancer inpatients and outpatients,[9] expand psycho-oncology
37
38 services to improve access to specialised care,[19] and provide timely individualised support
39
40 to the level and detail required for patients.[32] In addition, this research program directly
41
42 addresses the priority issue of delivering quality cancer care that addresses patients' physical
43
44 and psychosocial health needs [6, 8] by bringing together the scientific evidence about the
45
46 management of cancer patients' psychosocial problems into a model of patient-centred cancer
47
48 care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of
49
50 research attention compared to their burden on the Australian community.[33]
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53

54 The translational capacity of this research program is enhanced through three major
55
56 strengths. First, it is supported by a very strong collaborative team. Enhancing the role of
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1
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3 'frontline' clinical staff, defining pathways of care and promoting integration between major
4
5 centres and rural clinicians entails a high level of support from clinical staff for objective
6
7 implementation and evaluation. This project has strong support from the highest level of
8
9 cancer service governance in our area, senior nursing clinicians and existing on-site
10
11 psychiatric services. The linkage of the PACT model to Area-level network of psycho-
12
13 oncology services will promote integration of psychosocial care into routine clinical care,
14
15 promote continuity of care, and, through its clinician training model, improve the overall
16
17 quality of care for patients and their families.
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19

20
21 Second, the study utilises strong methodology appropriate for health services research.
22
23 The evaluation framework and methodology ensures that the evaluation is sensitive to the
24
25 role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and
26
27 informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes
28
29 and changes in these over time; an important consideration as economics is an often
30
31 overlooked element of interventional research. The close engagement of clinicians in the
32
33 planning, implementation and evaluation will ensure maximum relevance of the project to the
34
35 local context of clinical practice, including rural and remote settings. The built-in capacity for
36
37 flexibility in the clinical setting (eg documenting and addressing local barriers to integration
38
39 of psychosocial care) will promote translation to routine care, and potential applicability to
40
41 other settings.[34]
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45
46 Third, there is strong support for integration of psychosocial care into routine care, and
47
48 efficient use of specialist services. This project will provide important evidence for the
49
50 effective use of existing resources for nurses and allied health professionals working in
51
52 routine cancer care. If the outcomes of the research are positive, this will provide the basis for
53
54 a model of implementing psycho-oncology services across other clinical services within this
55
56 network. While the project includes the use of routine screening, it does so in a manner that
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3 builds this into a model of care, so that these tools can support clinical practice within a
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5 model of integrated care, defined service pathways and support to distant sites. The work has
6
7 substantial potential for translation into other cancer services beyond the research
8
9 collaborators.
10

11 Despite the strengths, there are also several challenges for the research and evaluation.
12
13 The target population is vulnerable and experiencing an acute stressor that may impact on
14
15 recruitment. As the intervention will continue over a twenty-four month period, changes in
16
17 health professional staff over that time may be substantial. Hence, some of the health
18
19 professionals completing the survey at twenty-four months may have been minimally
20
21 exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health
22
23 initiatives introduced more broadly into hospitals in the study location may affect the impact
24
25 of this intervention, but are beyond the control of the research team.
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32 **ETHICS AND DISSEMINATION**

33 **Ethics approval**

34
35 Research ethics approval has been obtained from the Human Research Ethics
36
37 Committees of Hunter New England Local Health District and the University of New South
38
39 Wales. Minor adverse events (eg a participant being tearful and distressed when talking with
40
41 the Research Officer) will be logged and fed back to the study team by the end of the study.
42
43 Serious adverse events (eg expressing suicidal thoughts) will be reported immediately to the
44
45 chief investigators and to the ethics committees. Any protocol amendments will be submitted
46
47 to the ethics committees before these are implemented, and relevant changes will also be
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49 communicated to other relevant organisations (eg trial registry).
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Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the Research Officer. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

All of the electronically stored personal participant information will be maintained and destroyed in the same manner as all data collected throughout the study. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the Research Officer. These will be stored for fifteen years, then shredded by a contracted security waste disposal company at the conclusion of the storage period.

Competing interests

As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John Hunter Hospital and a chief investigator on this project, BK may experience competing interests with respect to reporting the impact, cost and acceptability of the new psychosocial care model. These potentially competing interests will be minimised and managed by having the other chief investigator, AG, primarily responsible for the conduct of the research and result reporting.

Access to data

The study's chief investigators (AG, BK), Research Officer, Biostatistician, and Health Economists will have exclusive access to the final trial dataset.

Dissemination policy

The results will be widely disseminated through peer-reviewed publications as well as relevant health care professional and consumer publications. Oncology health care professionals and administrators within Hunter New England Local Health District will be invited to a face-to-face presentation of the results by the chief investigators. Presentations will be delivered at relevant national oncology and nursing conferences and meetings. The results will be reported to the funding body and other peak bodies with influence on cancer policy and practice, including Cancer Australia, Clinical Oncology Society of Australia, Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants who request a summary of the study's key findings will be mailed one on completion of the project.

AUTHORS' CONTRIBUTIONS

BK and AG conceived of the study and are the grant holders. AB assisted in the initial study design and AP and DB provided organisational guidance on service model and implementation. BK and AG, along with the newly appointed clinical staff, developed the communication skills training, and HC will oversee the day-to-day study implementation according to the protocol. MH and RV provided guidance on data requirements for the economic analysis and will undertake these analyses. JD provided guidance on sample size requirements and will be conducting the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

ACKNOWLEDGEMENTS

The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia. The study protocol and relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central role in facilitating recruitment and implementation of the intervention, and Catherine Adams and Deanna Sue in the communication skills training of health professionals involved in the delivery of the PACT model of care.

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The PACT Study Protocol: A time series study investigating the feasibility-impact, and acceptability and cost of an integrated, patient-centred model for psychosocial assessmentscreening, care and treatment of patients with urological and head and neck cancers

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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the ~~feasibility~~impact, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test ~~the feasibility, acceptability and cost of~~ the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level ~~impact~~change, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are ~~acceptability~~impact of the model ~~to-on~~ patient experiences and health care professionals' (HCPs) ~~and impact on the~~ knowledge and confidence ~~of HCPs~~, assessed via patient and HCP surveys at baseline and at follow-up. ~~and Acceptability of the intervention will be assessed through~~ HCP interviews at follow-up. ~~and -The intervention cost (tertiary outcome)-~~ will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly,

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2
3 this work has substantial potential for translation into other cancer services, beyond
4 the current study.

5 **Limitations of the study:**

- 6
7 • The target population is vulnerable and experiencing an acute stressor that may
8 impact on recruitment.
9
10 • As the intervention will continue over a twenty-four month period, changes in health
11 professional staff over that time may be substantial. Consequently, some of the health
12 professionals who complete a survey at twenty-four months may be only minimally
13 exposed to the intervention and have diluted perceptions of impact.
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15 • Other health initiatives may be introduced into hospitals in the study area, which
16 could affect the impact of this intervention.
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Emotional distress, pain and fatigue are commonly experienced by the majority of cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including melanoma, thyroid) often experience profound disfigurement and functional disability, changed body image, speech difficulties, nutritional problems, and have higher suicide rates than other people with cancer.[2] Both urological and H&N cancer patients often report negative changes in their intimate and social relationships.[1, 3] Some cancers, including urological and H&N cancers, are more prevalent in rural areas,[4] where people experience major difficulties accessing cancer services, including psychosocial care.[5] There is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7] Failure to address these problems can exacerbate suffering and lead to decreased patient satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and mortality outcomes.[8]

Recent cancer patient satisfaction surveys in Australia, the United Kingdom and Canada have highlighted problems in coordination of services and limitations in psychosocial care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of care are important contributing factors.[12] Many health care professionals are not aware of effective evidence-based strategies to address patients' concerns, or underestimate the benefits of attending to psychosocial needs or referring to psychosocial personnel or services. There are few formalised mechanisms for communication between health care providers and systems of care may contribute to patients receiving fragmented and poorly coordinated care;

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3 especially those who reside in rural areas.[8] With well supported stepped care models, the
4
5 needs of the majority of cancer patients can be met without referral to specialist psychosocial
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7 services.[13] Models of care that provide basic psychosocial care delivered by frontline
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9 health care providers (eg oncology nurses), with appropriate training and mentorship by
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11 psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of
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13 the increase in quality-adjusted life-years achieved.[14]
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16 The Institute of Medicine [8] has recommended a model for integrated psychosocial
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18 cancer care that comprises: 1) identifying patients' health needs through screening and
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20 assessment; 2) linking patients to health services via structured referral, case management
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22 and clinical integration of services; 3) supporting patients in illness self-management; 4)
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24 coordinating psychosocial and biomedical health care through care coordinators,
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26 multidisciplinary team meetings, multidisciplinary care plans and electronic health records;
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28 and 5) following up on care delivery by telephone calls or web-based technology to re-
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30 evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most
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32 specialist oncology services and evaluating its effectiveness represent major challenges.[15-
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34 16] These challenges are accentuated in settings where cancer care is integrated into general
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36 medical or surgical care, with the absence of dedicated on-site cancer teams. This means that
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38 staff may not identify themselves as cancer clinicians and service models are generic to cater
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40 for a diverse range of illness groups. Nevertheless this represents the setting in which a
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42 significant proportion of cancer patients experience at least part of their treatment. Within this
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44 type of care delivery setting, how can effective models of integrated psycho-oncology care be
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46 developed, implemented and evaluated? This is one of the key questions this project aims to
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48 investigate.
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54 ~~The Hunter New England Local Health District of New South Wales, Australia,~~
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56 ~~includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a~~
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major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[17]

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers.

Screening for psychosocial needs is not routine and when it is conducted (using pen and paper Distress Thermometer and Problem Checklist),[18] the Cancer Care Coordinator discusses the issues with the patient and referrals may be made to allied health care professionals or other agencies, albeit not based on a specific care pathway. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology services; patients requiring psycho-oncology assessment are either referred to generic Liaison Psychiatry, which provides a limited role including advice, inpatient consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby cancer hospital, which is a separate service with no shared records and located at a different site to patients' routine outpatient care at the JHH.

Objective

The objective of this study is to develop, implement and assess the [feasibility](#) [impact](#), acceptability and cost of, an integrated, patient-centred model for psychosocial [assessments](#) [screening](#), care and treatment of patients with urological and H&N cancers [at a large tertiary referral hospital](#).

Study Design

A time series research design will be [used](#) [utilised](#) to test the [feasibility](#) [and](#) [acceptability](#) [of the](#) Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [197] and is an acceptable design for inclusion in Cochrane reviews.[2018] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[2018] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of NSW, Australia. It provides the main services for a large sector of the state of NSW, comprising a population of over 850,000 people, including a major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions. [197] It is the main teaching hospital of the University of Newcastle. The Hunter New England Local Health District of New South Wales, Australia, includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions. [17]

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology

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4 Psychiatry, which provides a limited role including advice, inpatient consultation and a
5 restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby
6 cancer hospital, which is a separate service with no shared records and located at a different
7 site to patients' routine outpatient care at the JHH.
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14 15 16 **Eligibility criteria**

17 18 19 **Patients**

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21 Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer
22 or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH. Patients from
23 metropolitan and all rural areas served by this hospital are included in the study.
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27 28 29 **Staff**

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31 Staff who are employed through the JHH will be eligible to complete the Knowledge
32 and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide
33 care for patients who are receiving inpatient or outpatient urological or H&N cancer services
34 at this site. Staff will be eligible to participate in interviews to assess the acceptability of the
35 PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing
36 or allied health staff member, b) provide care for patients who are receiving inpatient or
37 outpatient urological or H&N cancer services, and c) have been involved in the PACT care
38 pathway of one or more patients, either on-site at JHH, or through provision of follow-up
39 care, following discharge from JHH.
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52 53 54 **Intervention**

55 It is important to note that this study focuses on a ~~system-level~~ system-level
56 intervention aimed at modifying provision of service to all patients attending these units.
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3 rather than recruiting a sample of patients for the provision of a specific psychosocial
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5 intervention. -While data are collected periodically from patients attending this hospital and
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7 from staff, this is chiefly with the intention of examining the impact of the service changes.
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10 The PACT (Psychosocial Assessment, Care and Treatment) model focuses on a system of
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12 care for, ~~targeting~~ patients with H&N or urological cancers, ~~will be developed as part of this~~
13
14 study. This model aims to systematise the approach to screening for distress and responding
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16 to that distress in a coordinated manner, including facilitating continuity of care for patients
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18 who reside some distance from the acute care setting where they were treated for cancer. In
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20 order to address the needs of those patients in rural regions, a specific component of the
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22 innovation introduced to the system of care is extended to this population. The development
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24 of this care model includes the following key components:
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- 27 1) The implementation for inpatients and outpatients of the two surgical units of
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29 routine screening for distress, and associated psychosocial care plans.
- 30 2) The identification of intervention options for all levels of need, and pathways to
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32 specialist psycho-oncology care if required.
- 33 3) The addition of dedicated psycho-oncology clinical services (including
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35 psychologist, psychiatrist and mental health nurse).
- 36 4) The provision of staff development and support to implement such a model
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38 (including training in skilled communication to identify and respond to
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40 emotional distress), and structured case review for complex or challenging
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42 cases. The latter strategies will incorporate oncology clinical staff and others
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44 working with cancer patients within urban, regional and remote communities.
- 45 5) Videoconferencing to facilitate case review meetings between clinicians at the
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47 hospital base site and those at urban and rural sites who are engaged in the on-
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49 going post-discharge care of patients initially treated at the hospital.
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In order to achieve these intervention goals, the following are intrinsic to the service model:

a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology and adult education, will coordinate the establishment and delivery of the model, with a special focus on development and implementation of a systematic and structured approach to routine assessmentscreening, triage and management of cancer patients' individual physical, psychological and social concerns during active treatment and at follow-up.

b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators with experience in communication skills training (AG, BK) will develop and deliver a communication skills-based training program to support frontline clinical staff (mostly nursing and allied health care professionals) in implementing the psycho-oncology care model and facilitating within-team communication to enhance continuity of patient care. This training program will be run on numerous occasions to reach as many frontline staff as possible during the intervention period and is based on an evidence-based consultation skills training program previously developed and evaluated by our team. [20-21]

c) The CNC and Clinical Psychologist will facilitate the delivery of the care model through the training of frontline staff, provision of clinical assessment and specialised evidence-based care for patients who are referred to the psycho-oncology service, monitoring of progress on psychosocial care plans including with rural clinicians through case reviews, and providing advice as required to rural clinicians to support linking patients to local rural specialised services. Where specialised services are not available, the Clinical Psychologist will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of the program, participate in staff training, and direct clinical evaluation and treatment of patients with the highest level of distress or complexity.

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3 Clinical practice guidelines recommend routine distress screening of cancer patients
4 (with feedback to health care providers) at periods of increased vulnerability to ensure that
5 those at risk are identified promptly and offered appropriate treatment.[1822] As part of the
6 newly developed model of care, all inpatient and outpatient urology and H&N cancer patients
7 will be screened at their first diagnostic or treatment visit and at each subsequent follow-up
8 visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which
9 will inform the development of a care plan to address the issues identified through the
10 screening and second-line inquiry. The care plan will facilitate provision of care tailored to
11 the specific needs of patients and promote continuity of care across care settings and
12 providers, including with health care professionals (HCPs) in the rural and regional areas.
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25 The screening and problem checklist will act as a trigger for frontline staff to inquire
26 about, and discuss the cause/s of, distress with patients whose distress levels are above the
27 recommended cut-off of 4 or more out of 10.[234] Training for frontline staff will focus on
28 discussing the cause/s of the distress, developing ~~a an evidence-based~~ psychosocial care plan
29 to address identified concerns, providing information and/or basic counselling, or referring
30 patients with significant or persistent distress to the psycho-oncology service, and facilitating
31 continuity of care, including linking patients with hospital and community services as
32 required. Staff will also assist patients with access to self-management information on
33 tablets which will be available during their hospital visit. Long-term sustainability of these
34 service changes will be promoted through organisational leadership and management support,
35 engagement of cancer clinician leaders in each unit in the design and evaluation of the service
36 model, and development of a model with the aim of adaptability and flexibility to diversity of
37 locations and patient complexity (eg through complex case review and revision of
38 psychosocial care plans and active involvement of clinicians from rural locations in this
39 process).[224]
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Outcomes

The primary outcome is a system-wide increase in the proportion of eligible patients receiving care at the study facility who complete a DT and accompanying Problem Checklist (see Data Collection Methods) on at least one occasion and have a psychosocial care plan developed which complies with recommended care pathways. This outcome will be assessed at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new model of care – refer to Intervention section).

The secondary outcomes ~~are: is-a)~~ an increase in the proportion of eligible patients receiving care at the study facility who report positive experiences of their cancer care at 12 and 24 months post-baseline compared to patients receiving care in this facility at baseline, ~~and b)-~~

~~The tertiary outcome is~~ an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline. HCP satisfaction with the PACT intervention will also be assessed via interviews at follow-up, and

~~The~~ resource use and costs of the intervention will ~~also~~ be monitored, by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	Data collection	<u>Intervention delivery</u>
<u>Commencing at 0 months (March 2013)</u>	Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	<u>Development and delivery of communication skills training to health professionals</u> <u>PACT intervention delivery throughout the study period</u>
<u>Commencing at 12 months</u>	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	<u>On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)</u>
<u>Commencing at 24 months</u>	Recruitment of Patient Cross-sectional Sample #3 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
	Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention	
	Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)	
	Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention	

Recruitment

Patients

Three cross-sectional samples of current inpatients and outpatients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. The main purpose of these data collection phases is the evaluation of the impact of system level system-level changes, rather than recruiting patients who will undertake the intervention. ~~Patients will be recruited from inpatient wards and the outpatient clinics associated with the JHH.~~ During the study audit periods at baseline, 12 months and 24 months, the Research Officer (~~RO~~) will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The ~~RO~~ Research Officer will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained from Hunter New England Local Health District (HNELHD), a Consent Form for data to be obtained from the Department of Human Services, a Request for Summary of Study Results Form, a copy of the self-administered Patient Experience Survey and a Paperwork Return Checklist. Patients will be asked to take the Information Pack home to consider before completing the survey and consent forms and posting them back to the researchers, using a self-addressed reply paid envelope, within 10 days. Staff at the outpatient clinics and inpatient wards will also be supplied with Information Packs to distribute to eligible patients who attend the clinic when the ~~RO~~ Research Officer is not in attendance.

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3 Staff

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5 *Health Professional Knowledge and Confidence Survey*

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7 Two cross-sectional samples of HCPs involved in the care of patients with H&N or
8 urological cancers at the study facility will be recruited during the study audit periods at
9
10 baseline and at 24 months, to assess the skills development of clinical staff who work at the
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12 parent facility. At each time point, the ~~R~~Research Officer will contact the Managers of the
13
14 inpatient wards and outpatient clinics in which care is provided to patients with urological
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16 and H&N cancers. The Managers will be asked to identify the nursing and allied health staff
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18 members who routinely provide care to the patients of their respective wards/clinics, as well
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20 as each staff member's employment status as either permanent or casual. A list of HCPs
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22 eligible to receive an Information Pack will then be generated, and Information Packs sent via
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24 internal mail to the department at which each staff member is based. The Information Pack
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26 will contain an Information Letter and a copy of the self-administered Knowledge and
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28 Confidence Survey for HCPs to complete and post back to the researchers, using a self-
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30 addressed reply paid envelope, within 10 days. A second survey will be mailed to HCPs who
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32 do not return a completed survey within four to six weeks and a third survey will be sent to
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34 non-returnees four to six weeks after that.

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42 *Health Professional receptivity and acceptability interviews*

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44 At approximately 24 months (nearing study completion), purposively sampled allied
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46 health, nursing and medical staff will be interviewed by the ~~R~~Research Officer about the
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48 acceptability of the key aspects of the PACT integrated model of psychosocial care
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50 (including screening, triage, access to psychosocial services/providers, clinical case reviews),
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52 perceived effectiveness of the model at improving care, and perceived impact of the staff
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54 training. The ~~R~~Research Officer will send an Information Pack to those staff members who
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3 meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent
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5 Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-
6
7 minute telephone interview at a mutually convenient time.
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10 11 **Data collection methods**

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14 The primary outcome of system-level change will be assessed through audit of patient
15
16 medical records, and through Medicare and PBS claims information for follow-up care
17
18 sought via referral through the new model of care; the secondary outcomes of ~~acceptability of~~
19
20 ~~the model and~~ impact of the model on patient experiences and on HCP knowledge and
21
22 confidence will be assessed via patient and HCP surveys. Acceptability of the intervention
23
24 will be assessed via ~~and~~ HCP interviews, and ~~the tertiary outcome of~~ cost of the intervention
25
26 will be assessed from information collected through Medicare and PBS claims information,
27
28 as well as information logged pertaining to intervention activities (eg time spent by the CNC
29
30 and Clinical Psychologist in direct patient contact, providing training sessions, engaging in
31
32 case review) and their associated costs (eg CNC and Clinical Psychologist salaries and on-
33
34 costs, materials used in training sessions, videoconferencing costs).
35
36
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40

41 Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS) 42 claims information

43
44 At baseline, 12 months and 24 months, the files of all patients who provide their
45
46 consent will be reviewed by the ~~RO~~ Research Officer and an appointed research assistant who
47
48 is not involved in the intervention delivery, to calculate the proportions of patients a) who
49
50 have completed a DT and accompanying Problem Checklist at least once, b) who have had a
51
52 psychosocial care plan developed, and c) whose management, including referrals, complies
53
54 with recommended care pathways. A checklist will be used to achieve a systematic approach
55
56 to extraction of these records. The coders (~~RO~~ Research Officer and a second research
57
58
59
60

1
2
3 assistant) will initially review one file with the Clinical Psychologist to ensure consistency in
4
5 understanding of the checklist and 10% of the files will be double-coded by the two coders to
6
7 calculate inter-rater reliability.
8

9
10 Medicare and PBS claims information will also be extracted by the Department of
11
12 Human Services for those participants who provide their consent, and will be reviewed by the
13
14 health economist investigators (MH and RV) to extract information relating to psychosocial
15
16 care delivered in a hospital or community health setting, by a private provider, or by a general
17
18 practitioner.
19

20 21 22 Patient Experience Survey

23
24 A 35-item survey will include items assessing patient perceptions of care received,
25
26 relating to the dimensions of emotional support, information, education and coordination of
27
28 care. All items are phrased from the first-person perspective (eg “*I had confidence and trust*
29
30 *in the staff treating me*”), to be answered using a 5-point Likert-type scale ranging from 1 =
31
32 ‘strongly disagree’ to 5 = ‘strongly agree’. A patient experience score will be aggregated
33
34 based on the sum of selected responses. [The survey contains 3 items from the Cancer Care](#)
35
36 [Survey, \[25\] and 8 items from the Hospital Care – Overnight Patient Survey; \[26\] all adapted](#)
37
38 [such that they could be answered from the first-person perspective. The survey also contains](#)
39
40 [10 items from the Critical Cancer Care Events Scale; \[27\] some of which required adaptation](#)
41
42 [so that they referred to a broader group of health professionals than doctors, and all of which](#)
43
44 [were adapted to be answered on a 5-point Likert-type scale \(as described above\).](#)
45
46
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48
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50
51

52 The survey will also measure key *socio-demographic, disease and medical variables*,
53
54 including age, residential location, gender, marital status, indigenous identification, languages
55
56 spoken, country of birth, educational attainment, employment status, private health coverage,
57
58
59
60

1
2
3 income, cancer type, date of diagnosis, treatment received, recurrence status, and number of
4
5 prior inpatient admissions and outpatient clinic visits.
6
7
8

9 10 Health Professional Knowledge and Confidence Survey

11
12 A 65-item survey will include items targeting health professionals' knowledge, skills
13
14 and confidence pertaining to responding to patients' specific psychosocial concerns. The
15
16 survey contains 12 items from a *Confidence in Communication Skills and Discussing*
17
18 *Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[283] The
19
20 survey also contains a case study and associated Care Planning, Monitoring and Review
21
22 items from the Client-Centred Care – Training Needs Survey;[294] all adapted such that they
23
24 refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician
25
26 Belief Scale is contained in the survey; based on the Physician Belief Scale,[3025] it contains
27
28 all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group
29
30 of health professionals than doctors, and items will be answered on a 5-point Likert-type
31
32 scale ranging from 1= 'strongly disagree' to 5= 'strongly agree'. Finally, the survey contains
33
34 the single-item Clinician Burnout survey, which is the Physician Burnout survey,[3126]
35
36 renamed to apply to a broader group of health professionals than doctors. A
37
38 knowledge/confidence score will be aggregated based on the sum of selected responses.
39
40
41
42

43 The survey will also measure key *socio-demographic, experience and training*
44
45 *variables*, including age, residential location, gender, occupational specialty, number of years
46
47 of experience in a) their current specialty and b) in cancer care, number of hours spent
48
49 weekly in direct patient contact, indigenous identification, languages spoken, country of
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51 birth, and country of training.
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Health Professional receptivity and acceptability interview

An interview will be scheduled with consenting participants to assess the acceptability of the key aspects of the integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers and clinical case reviews), perceived effectiveness of the model in improving care, and the perceived impact of training. It is anticipated that the interview will take 20 minutes, with an audio recording being made for transcription purposes. [An interview schedule previously developed by our team has been adapted for use in the present study, and](#) Examples of questions in the interview guide include: “Have you been aware of there being a more systematic approach to the provision of psychosocial care for people with H&N or urological cancers over the past year or so compared to previously?” and “What’s your impression of patient/family member/caregiver attitudes toward the new model (eg acceptance)?”

Intervention costs

In keeping with the time series design, information about resource use and associated costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained from the hospital’s databases regarding emergency department (ED) attendance, triage category, whether the patient was admitted or discharged from the ED, and their diagnosis. Information about use and costs of medical services and pharmaceuticals will be obtained from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff training, inter-professional case reviews and other communications required to support rural and regional providers, will also be monitored.

Sample size

Patients

Data from the initial twenty-five patient surveys completed were used to estimate the required patient sample size. The mean patient experience score at baseline was rated highly at 45 (out of a possible 55). Hence, the research team determined that a 5-point improvement between baseline and the last follow-up (24 months) would be a meaningful change~~Hence, at least 38 patients will need to be recruited at each time point to achieve a minimum clinically significant improvement of 5 points between baseline and last follow-up (24 months),~~ assuming a standard deviation of 7.58 (derived from current surveys), significance level of 5%, and power of 80%. with at least 38 patients needing to be recruited at each time point to detect this change over time.

Health care professionals

Data from the first twenty-eight~~28~~ surveys completed were used to estimate the required sample size. The mean score of knowledge/confidence was moderate at 61.5 (out of a possible 105). Hence, it was determined that at least 48 health professionals were required will need to be recruited at each time point to achieve a minimum clinically significant improvement of 10 points between baseline and follow-up (24 months), assuming a standard deviation of 17.13 (derived from current surveys), significance level of 5%, and power of 80%.

Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the RØResearch

Officer. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this electronically stored data will be maintained in separate, password-protected files, which will be stored on a password-protected local area network drive, accessible only by the Research Officer and the chief investigators. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the Research Officer and the chief investigators.

Data in paper format will be stored for seven years, while computer files will be stored for 15 years. All will be shredded by a contracted security waste disposal company at the conclusion of the storage period.

Statistical methods

Analysis of primary and secondary outcomes

~~In keeping with a focus on evaluating the feasibility of implementing a new service, it is essential to proceed in stages, with initial evaluation of a new model being devoted to performance monitoring and process studies, before moving on to studies that document impact.[27] Therefore, t~~This evaluation will focus on the impact feasibility and acceptability of the new model of care, with system-level outcomes being of primary interest. Cross-sectional ~~D~~data will be collected at baseline, 12 months and 24 months on the proportion of patients a) who are screened for distress at least once and, b) who have a psychosocial care plan developed, ~~and c) whose management complied with recommended care pathways.~~

1
2
3 | Data ~~on points a) to e) above~~ will be collected at the three time points and analysed
4
5 using Poisson or Negative Binomial regression depending on over-dispersion of the counts of
6
7 each outcome. The Poisson/Negative binomial models will include a time variable (0, 12 and
8
9 24 months), a before and after variable, a term for the interaction of these two variables, and
10
11 an offset variable which is used to adjust for the total number of patients consented at each
12
13 time point. The interaction term will be used to estimate any difference between the two
14
15 periods, which would indicate a slow improvement in the outcome during the intervention
16
17 period. The before and after variable will be used to estimate the change in the outcome that
18
19 may occur immediately after the introduction of the model of care. The models will adjust as
20
21 appropriate for potential confounding variables such as age, gender, residential location,
22
23 indigenous status, cancer type, and time since diagnosis.
24
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29 Patient Experience and Health Professional Knowledge and Confidence

30
31
32 For patient experience surveys, a linear regression will be used to model the patient
33
34 experience scores over the three time points to determine whether there was a significant
35
36 improvement during the study period whilst adjusting for potential confounding variables (eg
37
38 duration of care within the service, other psychosocial support services used, disease and
39
40 treatment characteristics, age, and gender). Similarly, for the health professional knowledge
41
42 and confidence surveys, a linear regression will be used to determine if there was a difference
43
44 in the knowledge/confidence scores between the two time points whilst adjusting for potential
45
46 confounding variables (eg other training in psychosocial care received, duration of
47
48 employment in this service, prior experience, work role and time allocation, age, and gender).
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Economic analysis

Estimates of resource use and costs will take into account the costs of implementation of the new model, but will not include costs of the evaluation/audit. At each time point (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data. Benefits will be measured via surveys and interviews to ascertain the acceptability of the intervention and how the new model is experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes will be reported separately at each time point and trends over time will be evaluated.

Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs

1
2
3 of individual cancer patients by (1) systematically identifying patients' physical and
4
5 psychosocial health needs, (2) developing care pathways and plans to address identified
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7 needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating on-
8
9 going psychosocial health care. The project has a focus on translating evidence regarding
10
11 psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff,
12
13 including those in rural settings, and will promote improved coordination and continuity of
14
15 care for patients in rural and remote areas. Improving the psychosocial component of routine
16
17 care, building distress screening into a model of routine care, and developing a psychosocial
18
19 care plan for patients will enhance the acceptability and appropriateness of psychosocial care.
20
21 Specialist services will be active in providing training, advice and support within an inter-
22
23 professional team, and providing specialist assessment and treatment as a member of this
24
25 team when needed. Addressing the process and outcome variables will support investigation
26
27 of the quality of care provided from patient and clinician perspectives.
28
29
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31

32 The proposed care model has the potential to address several unmet needs identified in
33
34 key policy documents and surveys. Specifically, it will provide improved emotional support
35
36 and information for both cancer inpatients and outpatients,[9] expand psycho-oncology
37
38 services to improve access to specialised care,[197] and provide timely individualised support
39
40 to the level and detail required for patients.[3228] In addition, this research program directly
41
42 addresses the priority issue of delivering quality cancer care that addresses patients' physical
43
44 and psychosocial health needs [6, 8] by bringing together the scientific evidence about the
45
46 management of cancer patients' psychosocial problems into a model of patient-centred cancer
47
48 care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of
49
50 research attention compared to their burden on the Australian community.[3329]
51
52
53

54 The translational capacity of this research program is enhanced through three major
55
56 strengths. First, it is supported by a very strong collaborative team. Enhancing the role of
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58
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60

1
2
3 'frontline' clinical staff, defining pathways of care and promoting integration between major
4
5 centres and rural clinicians entails a high level of support from clinical staff for objective
6
7 implementation and evaluation. This project has strong support from the highest level of
8
9 cancer service governance in our area, senior nursing clinicians and existing on-site
10
11 psychiatric services. The linkage of the PACT model to Area-level network of psycho-
12
13 oncology services will promote integration of psychosocial care into routine clinical care,
14
15 promote continuity of care, and, through its clinician training model, improve the overall
16
17 quality of care for patients and their families.
18
19

20
21 Second, the study utilises strong methodology appropriate for health services research.
22
23 The evaluation framework and methodology ensures that the evaluation is sensitive to the
24
25 role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and
26
27 informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes
28
29 and changes in these over time; an important consideration as economics is an often
30
31 overlooked element of interventional research. The close engagement of clinicians in the
32
33 planning, implementation and evaluation will ensure maximum relevance of the project to the
34
35 local context of clinical practice, including rural and remote settings. The built-in capacity for
36
37 flexibility in the clinical setting (eg documenting and addressing local barriers to integration
38
39 of psychosocial care) will promote translation to routine care, and potential applicability to
40
41 other settings.[\[3427\]](#)
42
43

44
45 Third, there is strong support for integration of psychosocial care into routine care, and
46
47 efficient use of specialist services. This project will provide important evidence for the
48
49 effective use of existing resources for nurses and allied health professionals working in
50
51 routine cancer care. If the outcomes of the research are positive, this will provide the basis for
52
53 a model of implementing psycho-oncology services across other clinical services within this
54
55 network. While the project includes the use of routine screening, it does so in a manner that
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1
2
3 builds this into a model of care, so that these tools can support clinical practice within a
4
5 model of integrated care, defined service pathways and support to distant sites. The work has
6
7 substantial potential for translation into other cancer services beyond the research
8
9 collaborators.
10

11
12 Despite the strengths, there are also several challenges for the research and evaluation.
13
14 The target population is vulnerable and experiencing an acute stressor that may impact on
15
16 recruitment. As the intervention will continue over a twenty-four month period, changes in
17
18 health professional staff over that time may be substantial. Hence, some of the health
19
20 professionals completing the survey at twenty-four months may have been minimally
21
22 exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health
23
24 initiatives introduced more broadly into hospitals in the study location may affect the impact
25
26 of this intervention, but are beyond the control of the research team.
27
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31

32 ETHICS AND DISSEMINATION

33 34 Ethics approval

35
36
37 Research ethics approval has been obtained from the Human Research Ethics
38
39 Committees of Hunter New England Local Health District and the University of New South
40
41 Wales. Minor adverse events (eg a participant being tearful and distressed when talking with
42
43 the ~~RO~~Research Officer) will be logged and fed back to the study team by the end of the
44
45 study. Serious adverse events (eg expressing suicidal thoughts) will be reported immediately
46
47 to the chief investigators and to the ethics committees. Any protocol amendments will be
48
49 submitted to the ethics committees before these are implemented, and relevant changes will
50
51 also be communicated to other relevant organisations (eg trial registry).
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Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the ~~RO~~ Research Officer. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

All of the electronically stored personal participant information will be maintained and destroyed in the same manner as all data collected throughout the study. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the ~~RO~~ Research Officer. These will be stored for fifteen years, then shredded by a contracted security waste disposal company at the conclusion of the storage period.

Competing interests

As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John Hunter Hospital and a chief investigator on this project, BK may experience competing interests with respect to reporting the feasibility~~impact~~, cost and acceptability of the new psychosocial care model. These potentially competing interests will be minimised and managed by having the other chief investigator, AG, primarily responsible for the conduct of the research and result reporting.

Access to data

The study's chief investigators (AG, BK), ~~R~~Research Officer, Biostatistician, and Health Economists will have exclusive access to the final trial dataset.

Dissemination policy

The results will be widely disseminated through peer-reviewed publications as well as relevant health care professional and consumer publications. Oncology health care professionals and administrators within Hunter New England Local Health District will be invited to a face-to-face presentation of the results by the chief investigators. Presentations will be delivered at relevant national oncology and nursing conferences and meetings. The results will be reported to the funding body and other peak bodies with influence on cancer policy and practice, including Cancer Australia, Clinical Oncology Society of Australia, Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants who request a summary of the study's key findings will be mailed one on completion of the project.

AUTHORS' CONTRIBUTIONS

BK and AG conceived of the study and are the grant holders. AB assisted in the initial study design and AP and DB provided organisational guidance on service model and implementation. BK and AG, along with the newly appointed clinical staff, developed the communication skills training, and HC will oversee the day-to-day study implementation according to the protocol. MH and RV provided guidance on data requirements for the economic analysis and will undertake these analyses. JD provided guidance on sample size requirements and will be conducting the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

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The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia. The study protocol and relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central role in facilitating recruitment and implementation of the intervention, and Catherine Adams and Deanna Sue in the communication skills training of health professionals involved in the delivery of the PACT model of care.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<input checked="" type="checkbox"/>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<input checked="" type="checkbox"/>
	2b	All items from the World Health Organization Trial Registration Data Set	<input checked="" type="checkbox"/>
Protocol version	3	Date and version identifier	<input checked="" type="checkbox"/>
Funding	4	Sources and types of financial, material, and other support	<input checked="" type="checkbox"/>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<input checked="" type="checkbox"/>
	5b	Name and contact information for the trial sponsor	<input checked="" type="checkbox"/>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<input checked="" type="checkbox"/>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<input checked="" type="checkbox"/>
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<input checked="" type="checkbox"/>
	6b	Explanation for choice of comparators	N/A

Objectives	7	Specific objectives or hypotheses	<input checked="" type="checkbox"/>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<input checked="" type="checkbox"/>
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<input checked="" type="checkbox"/>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<input checked="" type="checkbox"/>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<input checked="" type="checkbox"/>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<input checked="" type="checkbox"/>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<input checked="" type="checkbox"/> Table 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<input checked="" type="checkbox"/>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<input checked="" type="checkbox"/>
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<input checked="" type="checkbox"/>

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<input checked="" type="checkbox"/>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<input checked="" type="checkbox"/>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<input checked="" type="checkbox"/>
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<input checked="" type="checkbox"/>
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<input checked="" type="checkbox"/>
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<input checked="" type="checkbox"/>
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<input checked="" type="checkbox"/>
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	<input checked="" type="checkbox"/>
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	<input checked="" type="checkbox"/>
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<input checked="" type="checkbox"/>
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	<input checked="" type="checkbox"/>
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<input checked="" type="checkbox"/>
	31b	Authorship eligibility guidelines and any intended use of professional writers	<input checked="" type="checkbox"/>
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<input checked="" type="checkbox"/>

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
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For peer review only