NHMRC Centre of Research Excellence
PROSTATE CANCER SURVIVORSHIP

Scurvy, Economics and the Element of Surprise

Professor Suzanne Chambers AO, Dean, Faculty of Health, University Technology Sydney

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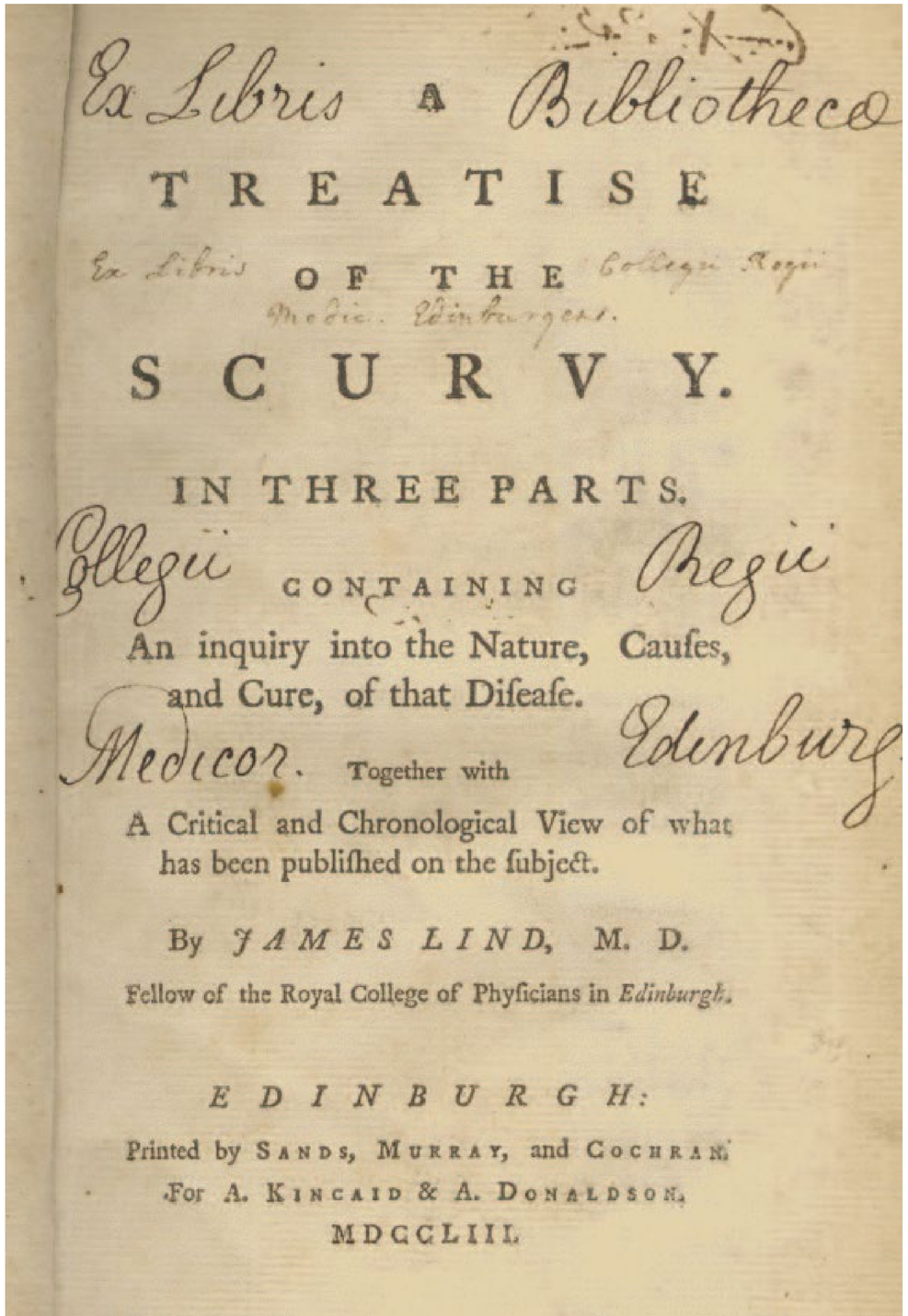
Ex Libris A Bibliotheca

TREATISE

Ex Libris OF THE Collegii Regii Medic. Edinburgen.

SCURVY.

IN THREE PARTS.

Collegii CONTAINING Regii

An inquiry into the Nature, Cauſes, and Cure, of that Diſeaſe.

Medicor. Together with Edinburg.

A Critical and Chronological View of what has been publiſhed on the ſubject.

By *JAMES LIND*, M. D.

Fellow of the Royal College of Phyſicians in *Edinburgh*.

EDINBURGH:

Printed by SANDS, MURRAY, and COCHRAN.

For A. KINCAID & A. DONALDSON.

MDCCLIII.

Lind J. Treatise of the scurvy. 1753. Edinburgh

Value in Health

Health Economics as Rhetoric: The Limited Impact of Health Economics on Funding Decisions in Four European Countries

Franken M, Heintz E, Gerber-Grote A, Raftery J

Volume 19, Issue 8, December 2016, Pages 951-956
https://doi.org/10.1016/j.jval.2016.08.001

Background: A response to the challenge of high-cost treatments in health care has been economic evaluation. Cost-effectiveness analysis presented as cost per quality-adjusted life-years gained has been controversial, raising heated support and opposition. **Objectives:** To assess the impact of economic evaluation in decisions on what to fund in four European countries and discuss the implications of our findings. **Methods:** We used a protocol to review the key features of the application of economic evaluation in reimbursement decision making in England, Germany, the Netherlands, and Sweden, reporting country-specific highlights. **Results:** Although the institutions and processes vary by country, health economic evaluation has had limited impact on restricting access of controversial high-cost drugs. Even in those countries that have gone the furthest, ways have been found to avoid refusing to fund high-cost drugs for particular diseases including cancer, multiple sclerosis, and orphan diseases. Economic evaluation may, however, have helped some countries to negotiate price reductions for some drugs. It has also extended to the discussion of clinical effectiveness to include cost. **Conclusions:** The differences in approaches but similarities in outcomes suggest that health economic evaluation be viewed largely as rhetoric (in D.N. McCloskey's terms in *The Rhetoric of Economics*, 1985). This is not to imply that economics had no impact: rather that it usually contributed to the discourse in ways that differed by country. The reasons for this no doubt vary by perspective, from political science to ethics. Economic evaluation may have less to do with rationing or denial of medical treatments than to do with expanding the discourse used to discuss such issues.

Keywords: cost-effectiveness, health economics, health policy, reimbursement.

THE LANCET
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Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study

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Summary

Background

The absence of trial data comparing robot-assisted laparoscopic prostatectomy and open radical retropubic prostatectomy is a crucial knowledge gap in uro-oncology. We aimed to compare these two approaches in terms of functional and oncological outcomes and report the early postoperative outcomes at 12 weeks.

Method

In this randomised controlled phase 3 study, men who had newly diagnosed clinically localised prostate cancer and who had chosen surgery as their treatment approach, were able to read and speak English, had no previous history of head injury, dementia, or psychiatric illness or no other concurrent cancer, had an estimated life expectancy of 10 years or more, and were aged between 35 years and 70 years were eligible and recruited from the Royal Brisbane and Women's Hospital (Brisbane, QLD). Participants were randomly assigned (1:1) to receive either robot-assisted laparoscopic prostatectomy or radical retropubic prostatectomy. Randomisation was computer generated and occurred in blocks of ten. This was an open trial; however, study investigators involved in data analysis were masked to each patient's condition. Further, a masked central pathologist reviewed the biopsy and radical prostatectomy specimens. Primary outcomes were urinary function (urinary domain of EPIC) and sexual function (sexual domain of EPIC and IIEF) at 6 weeks, 12 weeks, and 24 months and oncological outcome (positive surgical margin status and biochemical and imaging evidence of progression at 24 months). The trial was powered to assess health-related and domain-specific quality of life outcomes over 24 months. We report here the early outcomes at 6 weeks and 12 weeks. The per-protocol populations were included in the primary and safety analyses. This trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), number ACTRN12611000661976.

Findings

Between Aug 23, 2010, and Nov 25, 2014, 326 men were enrolled, of whom 163 were randomly assigned to radical retropubic prostatectomy and 163 to robot-assisted laparoscopic prostatectomy. 18 withdrew (12 assigned to radical retropubic prostatectomy and six assigned to robot-assisted laparoscopic prostatectomy); thus, 151 in the radical retropubic prostatectomy group proceeded to surgery and 157 in the robot-assisted laparoscopic prostatectomy group. 121 assigned to radical retropubic prostatectomy completed the 12 week questionnaire versus 131 assigned to robot-assisted laparoscopic prostatectomy. Urinary function scores did not differ significantly between the radical retropubic prostatectomy group and robot-assisted laparoscopic prostatectomy group at 6 weeks post-surgery (74·50 *vs* 71·10; p=0·09) or 12 weeks post-surgery (83·80 *vs* 82·50; p=0·48). Sexual function scores did not differ significantly between the radical retropubic prostatectomy group and robot-assisted laparoscopic prostatectomy group at 6 weeks post-surgery (30·70 *vs* 32·70; p=0·45) or 12 weeks post-surgery (35·00 *vs* 38·90; p=0·18). Equivalence testing on the difference between the proportion of positive surgical margins between the two groups (15 [10%] in the radical retropubic prostatectomy group *vs* 23 [15%] in the robot-assisted laparoscopic prostatectomy group) showed that equality between the two techniques could not be established based on a 90% CI with a Δ of 10%. However, a superiority test showed that the two proportions were not significantly different (p=0·21). 14 patients (9%) in the radical retropubic prostatectomy group versus six (4%) in the robot-assisted laparoscopic prostatectomy group had postoperative complications (p=0·052). 12 (8%) men receiving radical retropubic prostatectomy and three (2%) men receiving robot-assisted laparoscopic prostatectomy experienced intraoperative adverse events.

Interpretation

These two techniques yield similar functional outcomes at 12 weeks. Longer term follow-up is needed. In the interim, we encourage patients to choose an experienced surgeon they trust and with whom they have rapport, rather than a specific surgical approach.

The Costs of Mental Health Conditions in Cancer Survivors

- Mental health conditions are associated with increased healthcare costs among cancer survivors across all service types and all phases of care.
- These costs remained significantly high even among patients who are in a terminal phase and died during the study period
- Cancer survivors incur lower prescription drug costs and lower out-of-pocket costs for mental health conditions in the treatment phase compared to individuals without cancer likely due to cancer patients forgoing mental healthcare because of cancer treatment costs.

KHUSHALINI ET AL. SYSTEMATIC REVIEW OF HEALTHCARE COSTS RELATED TO MENTAL HEALTH CONDITIONS AMONG CANCER SURVIVORS. 2018 EXPERT REV PHARMACOECON OUTCOMES RES. DOI: 10.1080/1477167.2018.1485097

JOURNAL OF CLINICAL ONCOLOGY

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Mindfulness-Based Cognitive Therapy in Advanced Prostate Cancer: A Randomized Controlled Trial

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Authors' disclosures of potential conflicts of interest are found in the article online at www.jco.org. Author contributions are found at the end of this article.

Clinical trial information: ACTRN12612000306819.

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0732-183X/16/3499-1/$20.00

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ABSTRACT

Purpose
Advanced prostate cancer (PC) is associated with substantial psychosocial morbidity. We sought to determine whether mindfulness-based cognitive therapy (MBCT) reduces distress in men with advanced PC.

Methods
Men with advanced PC (proven metastatic and/or castration-resistant biochemical progression) were randomly assigned to an 8-week, group-based MBCT intervention delivered by telephone (n = 94) or to minimally enhanced usual care (n = 95). Primary intervention outcomes were psychological distress, cancer-specific distress, and prostate-specific antigen anxiety. Mindfulness skills were assessed as potential mediators of effect. Participants were assessed at baseline and were followed up at 3, 6, and 9 months. Main statistical analyses were conducted on the basis of intention to treat.

Results
Fourteen MBCT groups were conducted in the intervention arm. Facilitator adherence ratings were high (> 93%). Using random-effects mixed-regression models, intention-to-treat analyses indicated no significant changes in intervention outcomes or in engagement with mindfulness for men in MBCT compared with those receiving minimally enhanced usual care. Per-protocol analyses also found no differences between arms in outcomes or engagement, with the exception of the mindfulness skill of observing, which increased over time for men in MBCT compared with usual care ($P = .032$).

Conclusion
MBCT in this format was not more effective than minimally enhanced usual care in reducing distress in men with advanced PC. Future intervention research for these men should consider approaches that map more closely to masculinity.

THE CONVERSATION
Academic rigour, journalistic flair

Mindfulness in cancer treatment: time to stop and think

November 22, 2016 10.21am AEDT

Professor Suzanne Chambers
Professor Jeff Dunn AO

Breathe deeply and focus on the moment: mindfulness now appears everywhere as a technique to improve well-being, including in health care.

Mindfulness training is often suggested for cancer patients to reduce high levels of anxiety and distress associated with diagnosis, treatment and anticipation of possible disease recurrence. But two questions persist: does mindfulness work and, if so, for whom?

A new Australian study of men with advanced prostate cancer, published in the Journal of Clinical Oncology, suggests mindfulness training offers no benefit in this particular setting.

What is mindfulness?

Mindfulness as a meditative practice originally derived from the Buddhist tradition, and refers broadly to a way of paying attention to the present experience from moment to moment.

Moving away from its religious origins, mindfulness has been applied in the secular arena over the past two decades, including in diverse contexts such as health and well-being, employee happiness, school room management and even military training.

Early drivers of the mindfulness wave centred around a desire to enhance the human condition, ease suffering and make the world a better place. Now the practice appears to be increasingly shaped by commercial interests and "naive realism", where clinicians apply intuition rather than evidence to assess effectiveness.

Meditation and mindfulness is now a billion dollar industry with almost a quarter of employers in the US offered mindfulness training. A prominent UK report recently recommended mindfulness training be pioneered as a useful practice in the health, education and criminal justice systems.

Mindfulness and cancer

Mindfulness targeted at improving health and well-being, and helping individuals cope more effectively with chronic illness, has also advanced rapidly. Influential health care organisations have supported this movement, including the National Health Service in the UK, and the National Institutes of Health in the US.

In cancer, mindfulness-based therapies are often suggested as a supportive care option for patients. Mindfulness as the core component of these two approaches centres around teaching open awareness of the present experience and a focus on behaviour.

The behaviour element encourages the individual to conduct self observation of habits, and to become less reactive to difficult or unpleasant experiences. This is proposed to create a sense of calmness and composure – often referred to as equanimity – about the illness experience.

Mindfulness-based cognitive therapy also includes an explicit focus on the link between thoughts and mood. This is important in cancer, where fears about the cancer recurring and uncertainty about the future are often problematic and can drive distress.

While mindfulness approaches intuitively seem well matched to the cancer context, to date the research in this area has been limited by variable study quality and a focus on breast cancer patients.

Mindfulness in advanced prostate cancer

Our group recently conducted the first effectiveness trial of mindfulness-based approaches in men with prostate cancer.

For nine months we followed 189 men with advanced prostate cancer to assess whether mindfulness-based cognitive therapy led to any improvements over time. The men had prostate cancer that had spread, or was resistant to hormone treatment.

Men received their usual medical care, and in addition were randomly allocated to receive self-help booklets, or an eight week telephone mindfulness-based cognitive therapy group program delivered by highly trained and closely supervised mindfulness-based cognitive therapists. On average the patients were 70 to 71 years of age.

We found mindfulness-based cognitive therapy did not improve the men's well-being in comparison to their usual medical management. Men receiving mindfulness-based cognitive therapy reported no reduction in psychological distress, no lessening of anxiety about testing for prostate specific antigen – a measure of tumour progression and response to treatment – and no lowering of distress related to their cancer.

Men receiving therapy also reported no improvement in quality of life nor post-traumatic growth, a term that encompasses positive psychological change as a result of their cancer.

Although well-being did not change, many men did describe the program as helpful in terms of not feeling alone, learning meditation and breathing exercises, understanding the meaning of well-being and perceived control of thoughts and health.

More quality evidence is needed

Mindfulness-based approaches have been shown to be helpful for women with breast cancer. It is not clear why mindfulness-based cognitive therapy did not produce measurable benefits for the men in this study. We speculate the acceptability and usefulness of mindfulness may be strongly influenced by contextual issues, such as gender, age, education, and perhaps even the specific nature of the illness challenge.

Importantly, this new study raises further questions about the widespread application of mindfulness across multiple settings as a therapeutic intervention for all people in all situations. Popular culture and commercial interests have embraced mindfulness, and the advance into divergent aspects of life has been rapid.

We suggest more quality evidence is needed about the potential for mindfulness to do good across multiple settings. In parallel, we support the broader conversation about the application and commercialisation of a practice derived from eastern philosophical tradition outside of its original intent.

A Randomized Trial Comparing Two Low-Intensity Psychological Interventions for Distressed Patients With Cancer and Their Caregivers

ONCOLOGY NURSING FORUM®
Vol. 41, No. 4, July 2014

Suzanne Kathleen Chambers, RN, PhD, Araf Girgis, PhD, Stefano Occhipinti, PhD, Sandy Hutchison, M.Clin.Psych, Jane Turner, PhD, Michelle McDowell, PhD, Cathrine Mihalopoulos, BBSc (Hons), GDEcSt, PGDHth Ec, PhD, Robert Carter, PhD, and Jeffrey Charles Dunn, PhD

Purpose/Objectives: To compare the effectiveness of two low-intensity approaches for distressed patients with cancer and caregivers who had called cancer helplines seeking support. Baseline distress was hypothesized as a moderator of intervention effect.

Design: Randomized trial.

Setting: Community-based cancer helplines in Queensland and New South Wales, Australia.

Sample: 354 patients with cancer and 336 caregivers.

Methods: Participants were randomized to either a single session of nurse-led self-management intervention or a five-session psychologist cognitive behavioral intervention delivered by telephone. Assessments were undertaken at baseline (preintervention) and at 3, 6, and 12 months.

Main Research Variables: Psychological and cancer-specific distress and post-traumatic growth.

Findings: No significant moderation by baseline cancer-specific distress was noted. For low-education patients, only the psychologist intervention was associated with a significant drop in distress. For all other participants, distress decreased over time in both arms with small to large effect sizes (Cohen's ds = 0.05–0.82). Post-traumatic growth increased over time for all participants (Cohen's ds = 0.6–0.64).

Conclusions: Many distressed patients with cancer and their caregivers may benefit significantly from a single session of a nurse psychoeducation intervention that can be delivered remotely by telephone and supported by self-management materials. Research is needed to develop an algorithm that moves beyond the use of distress as the only indicator for referral to specialist psychological services. Survivors and caregivers with low education and low literacy may require more in-depth and targeted support.

Implications for Nursing: Brief nurse psychoeducation and stress management for cancer survivors and caregivers should be considered as part of a tiered approach to psychosocial care.

Psycho-Oncology
Journal of the Psychological, Social and Behavioral Dimensions of Cancer

Economic evaluation of a psychological intervention for high distress cancer patients and carers: costs and quality-adjusted life years

Chatterton ML
Chambers SK
Occhipinti S
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July 2016
Pages 857-864

DOI: 10.1002/pon.4020

Objective: This study compared the cost-effectiveness of a psychologist-led, individualised cognitive behavioural intervention (PI) to a nurse-led, minimal contact self-management condition for highly distressed cancer patients and carers.

Methods: This was an economic evaluation conducted alongside a randomised trial of highly distressed adult cancer patients and carers calling cancer helplines. Services used by participants were measured using a resource use questionnaire, and quality-adjusted life years were measured using the assessment of quality of life – eight-dimension – instrument collected through a computer-assisted telephone interview. The base case analysis stratified participants based on the baseline score on the Brief Symptom Inventory. Incremental cost-effectiveness ratio confidence intervals were calculated with a nonparametric bootstrap to reflect sampling uncertainty. The results were subjected to sensitivity analysis by varying unit costs for resource use and the method for handling missing data.

Results: No significant differences were found in overall total costs or quality-adjusted life years (QALYs) between intervention groups. Bootstrapped data suggest the PI had a higher probability of lower cost and greater QALYs for both carers and patients with high distress at baseline. For patients with low levels of distress at baseline, the PI had a higher probability of greater QALYs but at additional cost. Sensitivity analysis showed the results were robust.

Conclusions: The PI may be cost-effective compared with the nurse-led, minimal contact self-management condition for highly distressed cancer patients and carers. More intensive psychological intervention for patients with greater levels of distress appears warranted.

Psycho-Oncology
Journal of the Psychological, Social and Behavioral Dimensions of Cancer

A Randomised controlled trial of a couples-based sexuality intervention for men with localised prostate cancer and their female partners

Chambers SK
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Gardiner RA
Dunn J

Volume 24, Issue 7
July 2015
Pages 748-756

Objective
The diagnosis and treatment of prostate cancer is followed by substantive sexual morbidity. The optimal approach for intervening remains unclear.
Methods/design
A three-arm randomised control trial was undertaken with 189 heterosexual couples where the man had been diagnosed with prostate cancer and treated surgically. The efficacy of peer-delivered telephone support versus nurse-delivered telephone counselling versus usual care in improving both men's and women's sexual adjustment was investigated. Assessments were undertaken at baseline (pre-test) with follow-up at 3, 6 and 12 months.
Results
At 12 months, men in the peer ($p = 0.016$) and nurse intervention ($p = 0.008$) were more likely to use medical treatments for erectile dysfunction (ED) than men in the usual care arm. Men in the nurse intervention more frequently used oral medication for ED than men in usual care ($p = 0.002$). No significant effects were found for sexual function, sexuality needs, sexual self-confidence, masculine self-esteem, marital satisfaction or intimacy.
Conclusion
Although peer and nurse couples-based interventions can increase use of medical treatments for ED, this may not translate into better sexual or relationship outcomes. More research is needed into the optimal timing of interventions to improve sexual outcomes for men with prostate cancer and to identify the subpopulations that will benefit from them.

DOI: 10.1002/pon.3726

Psycho-Oncology
Journal of the Psychological, Social and Behavioral Dimensions of Cancer

Intervening to improve psychological outcomes for men with prostate cancer

Psycho-Oncology **22**: 1025–1034 (2013)

Chambers SK
Ferguson M
Gardiner RA
Aitken J
Occhipinti S

Background: Prostate cancer is the most common cancer in men in the Western world with well-described negative effects from treatments. However, outcomes are highly heterogeneous. A Phase 3 trial of a psycho-educational intervention was undertaken, aiming to reduce cancer-specific and decision-related distress and improve quality of life for men newly diagnosed with localised prostate cancer.

Methods: Seven hundred forty (81.7%) men were recruited after diagnosis and before treatment and randomised to a tele-based nurse-delivered five-session psycho-educational intervention ($N = 372$) or usual care ($N = 368$). Participants were assessed before treatment and 2, 6, 12 and 24 months post-treatment. Outcome measures included cancer-specific and decision-related distress, cognitive judgmental adjustment, subjective well-being, and domain-specific and health-related quality of life. Social support was assessed as a potential moderator.

Results: No unconditioned effects were found. Classification analyses on pre-randomisation measures distinguished three subgroups: younger, higher education and income men ($N = 290$); younger, lower education and income men ($N = 106$); and older men ($N = 344$). Younger, higher education and income men showed positive intervention effects for cancer-specific distress ($p = 0.008$) and mental health ($p = 0.042$). By contrast, for younger, lower education men, participation in the intervention was associated with decreases in cognitive judgmental adjustment over time ($p = 0.006$).

Conclusions: Response to intervention and adjustment over time varied according to previous sexual functioning, age, educational level and income. How to best intervene with younger, low education, low income men with prostate cancer is a critical future research question.

DOI: 10.1002/pon.3095

Psycho-Oncology
Journal of the Psychological, Social and Behavioral Dimensions of Cancer

New challenges in psycho-oncology: Economic evaluation psychosocial services in cancer: Challenges and best practice recommendations

DOI: 10.1002/pon.4933

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El-Saifi N
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Scuffham P

November 2018

CONCLUSIONS AND RECOMMENDATIONS

There is an increasing need to evaluate the cost-effectiveness of psycho-oncology services in cancer to generate the necessary evidence to guide decision making. Recommendations:

- Engagement with decision makers and stakeholders early in the design of economic evaluation is essential to develop a clear and well-defined health economics question.
- Fit-for-purpose economic evaluation should be designed either using patient level data collected alongside clinical trials, or preferably, synthesizing evidence from various sources and using analytical modeling to estimate the long-term costs and outcomes of alternative options.
- All relevant and important costs should be collected including direct medical and relevant non-medical costs as well as and indirect costs - use standardized forms and instruments.
- Conduct cost-utility analyses whereby incremental benefits are expressed in QALYs gained as a standard measure of the health outcomes.
- Reporting should follow the CHEERS statement and/or the recommendations from the Second Panel on Cost-Effectiveness in Health and Medicine.

Psycho-Oncology
Journal of the Psychological, Social and Behavioral Dimensions of Cancer

INVITED EDITORIAL

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New Challenges in Psycho-Oncology Research III:
A systematic review of psychological interventions for prostate cancer survivors and

Suzanne K. Chambers, Melissa K. Hyde, David P. Smith, Suzanne Hughes, Susan Yuill, Sam Egger, Dianne L. O'Connell, Kevin Stein, Mark Frydenberg, Gary Wittert, Jeff Dunn

Funding information
National Health and Medical Research Council; NHMRC Centre of Research Excellence in Prostate Cancer Survivorship, Grant/Award Number: APP1116334

In conclusion, there is sufficient evidence to recommend multi-modal psychosocial and psychosexual interventions for men with PCa; with distress screening and risk and need assessment built in to tailor support to the individual. As yet, there is insufficient evidence to confirm the optimal approach for female partners and couples.

nature REVIEWS UROLOGY

The psychological toll of prostate cancer

Suzanne K Chambers and Peter Heathcote

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Matta et al. report that men with prostate cancer who underwent surgery or radiotherapy, but not active surveillance, had greater odds of receiving antidepressants than controls. However, methodological limitations preclude the interpretation of a psychological benefit for men on active surveillance. *Screening for distress and referral to evidence-based intervention should be a priority*.

Refers to: Matta, R. et al. Variation and trends in antidepressant prescribing for men undergoing treatment for nonmetastatic prostate cancer: a population-based cohort study. Eur Urol. https://doi.org/10.1016/j.eururo.2018.08.035

Position Statement on Distress Screening and Psychosocial Care for Men with Prostate Cancer - Nov 2018

1. After the diagnosis of prostate cancer and regularly through treatment and surveillance men who have been diagnosed with prostate cancer should be screened for distress and their psychological and quality of life concerns should be explored.
2. Men who have high levels of distress should be further evaluated for anxiety and/or depression and evidence of suicidality.
3. Men who have high distress or need for support should be referred to evidence-based intervention matched to their individual needs and preferences for support.
4. Research is needed to identify effective methods to identify partners of men with prostate cancer with high distress or who are at risk of high distress as well as effective interventions for partners and for couples where the man has a diagnosis of prostate cancer
5. Investment in prostate cancer survivorship research is a national health priority

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