



Original article

Evaluating a psychosocial intervention for men with prostate cancer and their partners: Outcomes and lessons learned from a randomized controlled trial



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ABSTRACT

Aim: This study evaluated the process and outcome of a psychosocial intervention for men with prostate cancer and their partners. As more men survive prostate cancer, they and their partners need help and support to help them cope with the physical and psychosocial effects of the disease and treatment. There is a lack of psychosocial interventions for men with prostate cancer and their partners.

Methods: A randomized controlled trial was conducted with 34 participants to measure the effects of the intervention on selected psychosocial outcomes, post-intervention and at one month' follow-up. The nine-week program (CONNECT) consisted of three group and two telephone sessions. It focused on symptom management, sexual dysfunction, uncertainty management, positive thinking and couple communication. The outcomes, measured by validated tools were: self-efficacy, quality of life, symptom distress, communication, uncertainty and illness benefits.

Results: The men in the intervention group did better on two outcomes (communication and support) than controls. Partners in the intervention group did better than controls on most outcomes. Less participants than expected participated in the trial. The reasons for non-participation included partners not wishing to participate, men not interested in group work, and not understanding the core purpose of the intervention. The cost of training facilitators and for delivering the intervention appeared to be low.

Conclusion: The knowledge generated from this study will be beneficial for all those grappling with the challenges of developing, implementing and evaluating complex psychosocial interventions. This study has also highlighted the difficulties in recruiting men and their partners in clinical trials.

1. Introduction

Prostate cancer is the second most common cancer in men and the fifth most common cancer in the world among individuals of both sexes combined (Cancer Research UK, 2013). Incidence rates vary worldwide with the majority of cases diagnosed in economically developed countries, with the highest rates recorded in North America, Australia and Northern Europe (American Cancer Society, 2013). Improved survival rates in the last 25 years (American Cancer Society, 2013) have led to an increasing focus on survivorship issues. A diagnosis of cancer and the treatment that follows can give rise to significant psychosocial

problems, including distress, anxiety, depression, sexual dysfunction, financial strain, uncertainty and reduced quality of life (Ames et al., 2009; Baniel, Israilov, Segenreich, & Livne, 2000; McCaughan et al., 2012; Parahoo et al., 2013; Sharp & Timmons, 2016). Through time, most men with prostate cancer adapt and cope with the disease and its treatment, but a significant minority (almost a third) has ongoing, moderate and severe unmet needs for psychosocial support (Ames et al., 2009; Ernstmann et al., 2009; McCaughan et al., 2013; White, D'Abrew, Katris, O'connor, & Emery, 2012). Partners of men with prostate cancer are an integral part of the cancer journey, because they are often the main support for the men (McCaughan et al., 2013).

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Partners can often be more distressed than the men themselves (Couper et al., 2006), experiencing a lack of information and uncertainty about the future (Mason, 2005; Ezer, Rigol Chachamovich, & Chachamovich, 2011). Men with prostate cancer may experience erectile dysfunction, often resulting in the loss of sexual intimacy with partners and this can affect their relationship. They can also experience different perceptions related to these sexual symptoms (Boehmer & Clarke, 2001). According to Wittmann et al. (2014), “given the prevalence of prostate cancer diagnoses in older men, partners’ distress represents a public health concern” (p. 2509).

Creating an environment that encourages discussion to reduce couples’ distress and uncertainty and improve their relationship is a challenge that health professionals face when addressing the needs of these men and their partners (Manne, Badr, Zaider, Nelson, & Kissane, 2010). Central to this challenge has been the development and evaluation of psychosocial interventions for men with prostate cancer (Parahoo et al., 2013). There are, however, few studies of psychosocial interventions designed for both men with prostate cancer and their partners. A systematic review of psychosocial interventions for couples affected by prostate cancer concluded that further investigation in the area was warranted (Chambers, Pinnock, Lepore, Hughes, & O’Connell, 2011). There is also a paucity of literature determining how best to help couples improve their communication about intimacy, coping strategies, psychosexual functioning, and obtaining information on managing long-term treatment side effects (Galbraith, Fink, & Wilkins, 2011).

Most psychosocial interventions for men with prostate cancer have been developed in the United States (Parahoo et al., 2013). Health systems, socio-economic and cultural differences between countries mean that generalizing findings to other settings is not always possible, although much can be learnt about the development and implementation of interventions and their effectiveness. To date there is no published account of the development and evaluation of psychosocial interventions for men with prostate cancer and their partners in the United Kingdom (UK).

There is also a lack of in-depth descriptions of psychosocial intervention development and implementation that is hindering the identification of which interventions (or which components of an intervention) work (Aranda, 2008). The Medical Research Council (Craig et al., 2008) recommends that the process of randomized controlled trials of complex interventions be studied because they can provide useful information on practical, logistical and recruitment issues, as well as inform us about the benefits participants experience and how facilitators implement interventions.

In this study, we tested the feasibility of implementing a psychosocial intervention (called CONNECT) that we developed for men with prostate cancer and their partners. CONNECT was delivered in three, small group and two telephone sessions over a period of nine weeks. Table 1 shows how each letter of CONNECT represents a different component of the intervention (couple care, optimistic outlook, navigating the journey, new normality, empowering self, change lifestyle and target setting).

Bowen et al. (2009) identified eight areas that feasibility studies should focus on. These are: acceptability, demand, implementation,

practicability, adaptability, integration, expansion and limited efficacy (see Table 2 for more detail). We used Bowen et al. (2009) framework to underpin the design of this study. All but three areas (adaptability, integration and expansion) were relevant for this study. In previous papers (McCaughan, McKenna, McSorley, & Parahoo, 2015; Parahoo et al., 2017), we explored users’ perception and experience with the intervention (acceptability and demand) and the facilitators’ perception of the delivery of the intervention (implementation and practicality). In this paper, we report on the psychosocial outcomes of the CONNECT intervention (limited efficacy) as well as recruitment issues and program costs (practicality).

The objectives were:

1. To determine selected psychosocial outcomes of the CONNECT intervention.
2. To explore the feasibility of recruiting participants to the study.
3. To examine the costs involved in delivering the intervention.

2. Methods

2.1. Design, sample and procedures

A randomized controlled trial involving two groups (intervention and control), with assessment at baseline (T1), post-intervention (T2) and 1-month follow-up (T3) was conducted to measure the study outcomes.

Men with prostate cancer were recruited from a Northern Ireland Cancer Centre. The inclusion criteria were men aged 18 years and over, diagnosed with localized adenocarcinoma of the prostate, immediately post-surgical or post-radiotherapy treatment (curative intent) with or without hormone treatment, physically and mentally able to participate and provide informed written consent. For men to be eligible to participate, it was necessary that they were co-habiting with their spouse/partner who was residing in Northern Ireland. Couples were excluded if the spouse/partner had been diagnosed with cancer within the past year.

A randomized block design was used in this study, with the participants divided into homogenous subgroups (or blocks) in accordance with geographical location. Allocation to intervention or control groups was concealed with the use of opaque envelopes. As this was a feasibility study, there was no sample size calculation. It was anticipated that there would be six intervention cohorts, with each cohort or small group session comprised of approximately, four men and their partners (24 couples) and the equivalent numbers in the control group. The latter received no other intervention except their usual care. In total we expected to recruit 48 dyads.

2.2. The intervention

The CONNECT intervention (McCaughan et al., 2013) was developed based on the literature and previous work by the research team (McCaughan et al., 2012; McCaughan et al., 2014). The program was also based on some components of a large American intervention study,

Table 1
Description of CONNECT components.

Component	Aim
Couple care	Encourage active involvement of men and their partners in a planned programme of care. Develop mutual support and communication.
Optimistic outlook	Assist men and their partners to maintain a positive outlook as they live with the illness and consider their future.
Navigating the journey	Assist men and their partners to obtain information that will reduce their uncertainty about the illness and/or treatments.
New normality	Teach men and their partner’s ways to manage reactions and side effects associated with the illness, treatment and adjustment.
Empowering self	Facilitate men and their partners to become effective self-managers. Underpins the intervention.
Change lifestyle	Encourage men and their partners to adopt or maintain healthy living strategies.
Target setting	Assist men and their partners to set personal targets in relation to their illness, treatment and adjustment. Opportunity to tailor/individualise the intervention.

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