**Title**

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

**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 (Baniel et al., 2000; Ames et al., 2009; McCaughan et al., 2012; Parahoo et al., 2013; Sharp and 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; White et al., 2012; McCaughan et al., 2013). 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).

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, 2004; Ezer et al., 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 and 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 et al., 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 et al., 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 et al., 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 (xxx; xxx), 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.

**Methods**

**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.

**The intervention**

The CONNECT intervention (xxx) was developed based on the literature and previous work by the research team (xxx). The program was also based on some components of a large American intervention study, called FOCUS (Northouse et al., 2007). The FOCUS intervention had been developed for both men with prostate cancer and their partners and it showed promising results when it was tested with a US population.

CONNECT consists of five intervention sessions that are delivered to prostate cancer patients and their partners over a nine-week period of time. The five sessions consist of three 2-hour small group sessions (on weeks 1, 3 and 9) and two telephone sessions (weeks 5 and 7) with men and their partners. The overall aim of this facilitator-led intervention was to enhance the couple’s belief in their ability to manage their cancer and related issues. The sessions consisted mainly of discussions on symptom management, sexual and urinary dysfunction, uncertainty management, positive thinking and healthy lifestyles (xxx). The aim of the group sessions was to empower couples to become skilled in adopting and managing a healthy lifestyle and to help them to navigate their way through the prostate cancer journey effectively. The group sessions were conducted to facilitate personal/couple development and achievement of goals that were relevant to each couple’s needs.

The telephone sessions were conducted with each couple individually and considered booster sessions where content from the previous group sessions was reinforced. These sessions provided the opportunity for the intervention to be individualized, as participants were encouraged to set their own personal targets. A full description of the intervention has been published (xxx).

These sessions were supplemented by information sheets developed for the FOCUS project (Northouse et al., 2007) and adapted for use in Northern Ireland by a team of experts, including facilitators and users. The information sheets provided triggers for group discussion.

**Facilitators**

Facilitators (those who delivered the intervention) were recruited from a national cancer charity. They had a cancer counseling background but limited experience of working with men with prostate cancer and their partners. Although they had experience in leading support groups and one-to-one sessions, they did not have prior experience of delivering a structured group (face-to-face) and telephone psychosocial intervention, such as CONNECT. One of the researchers co-facilitated all the group sessions as a participant observer.

Four facilitators and the co-facilitator received a 5-day training course to familiarize themselves with the program followed by bi-monthly monitoring of facilitators’ performance. Training methods included role play, problem solving and group facilitation exercises. Training content included, among other things, familiarization with the CONNECT protocol, facilitators’ role in the trial, the importance of adherence to rigor, maintaining fidelity of the intervention as well as information on prostate cancer (its physical, psychological and emotional impact, and its treatment and side effects). A protocol manual was produced by the research team (xxx) and used to guide intervention delivery and promote fidelity among facilitators.

**Outcome assessments**

Data were collected from both men and their partners, in both treatment and control groups, at three time-points: prior to the intervention (T1), immediately post-intervention (T2) and at one month post-intervention (T3). The outcomes and outcome measures were:

* *Self-efficacy* was measured by the 17-tem, modified version of the Lewis Cancer Self-Efficacy Scale (Lewis et al., 1996) used in Northouse et al., (2007) [internal consistency alpha coefficient: .97].
* *Quality of life* was measured by the 27-item Functional Assessment of Cancer Therapy (FACT-G). Adequate internal consistency, concurrent validity and sensitivity have been reported (Esper et al., 1997). Partners completed a slightly modified version of the FACT-G that asked them to report on their own quality of life (Northouse et al., 2007).
* *Symptom distress* was measured with the 16-item Symptom Scale of the Omega Screening Questionnaire. Evidence of adequate concurrent validity, internal consistency, and test-retest reliability of the scale have been reported (Northouse et al., 2007).
* *Communication about the illness* (between men and their partner) was measured by the 32-item Lewis Mutuality and Interpersonal Scale. Internal consistency (alpha coefficient .85 - .88) has been reported (Siefer et al., 2008).
* *Uncertainty surrounding the cancer experience* was measured using a 28- item, modified Mishel Uncertainty in Illness Scale. Adequate internal consistency and construct validity of the original scales has been reported for both patients and family members (Mishel and Epstein, 1990).
* *Illness benefits* were measured by the modified Helgeson Benefits of Illness Scale. The scale has shown an internal consistency of .95 (Lepore et al., 2003).
* Social support was measured with a 9-item, brief version of the Social Support Scale that assessed patients’ and caregivers’ perceived support from one another (Northouse et. al, 2007)). Concurrent validity and high internal consistency were reported with the original, longer version of the scale (Northouse, 1988).

**Data Analysis**

Data were analyzed using SPSS version 20 (IBM Corp, 2011). The number of men screened, those eligible and ineligible, and those not willing to participate with reasons for ineligibility and non-participation were documented. Demographic, clinical and baseline data of participants were summarized using descriptive statistics. Analysis of outcome data were done using Mann Whitney tests and focused on testing the changes in outcomes between participants receiving the CONNECT intervention and the control group.

**Ethical approval**

The Northern Ireland Research Ethics Committee granted ethical approval for this study. Written informed consent was obtained from all study participants.

**Results**

**Recruitment**

During a 12- month recruitment period, 87 dyads attending the Northern Ireland Cancer Centre were identified as being potentially eligible participants from their clinical notes. Of this sample, 22 patient-spouse dyads did not meet all eligibility criteria once fully screened by medical staff, and 48 dyads declined to take part in the study when approached by the researcher responsible for recruitment. In total 17 dyads (34 participants) agreed to participate and were enrolled to the study. Due to this small number of participants and the need to learn about the implementation of the intervention and the experience of participants and facilitators, we decided to have four intervention and one control groups.

Of the 22 men who were ineligible to participate, the most common reasons for exclusion were: the partner being too ill to participate and having no partner. Other reasons included: partner not cohabitating and patient not immediately post treatment. Reasons for declining to take part varied. The most significant reasons were: partners not wishing to participate, men not interested in group activities, too busy and too ill to participate. Other reasons included travel issues, people feeling they did not have any issues to require enrolment to the intervention, and other family crises.

The process of recruitment started with doctors asking their patients if they were willing to meet with a researcher who was responsible for recruitment to the study. No reasons were given by doctors about why 28 patients, potentially eligible for the study, declined to take part. We interviewed four couples to find out why they declined to take part in the study. The main reason they gave was that they had not fully understood what the study was about. Some wanted to ‘close the door’ on their cancer (as they had just completed treatment) and move on with their lives.

Overall attendance (in both group and telephone sessions) of patients was 90.8% and partners was 86.2%. Reasons for non-attendance included: withdrawal of one couple after the second group session (reason appeared to be group dynamics and complex emotional problems); sickness, and unexpected hospitalization. With regard to adherence to outcome assessment, at post-intervention (TP 2), completion of outcomes in the intervention group was 92.3% (24/26) and in the control group was 87.5% (7/8). At TP 3 (one month follow-up), the completion rate in the intervention group was 84.6% (22/26), whereas the control group decreased slightly from 62.6 (5/8).

At post-intervention, outcome data were not available from one dyad in the intervention group as the couple withdrew after 1 session, stating that they were ‘uncomfortable with group meetings’. In addition, in another dyad, one partner in the control group did not want to complete outcome assessment. At one-month follow-up, 12 dyads in the intervention group completed the program and outcome assessment and two dyads in the control group completed outcome assessment. Overall attendance (in both group and telephone sessions) of men was 90.8% and partners was 86.2%.

**Description of participants and non-participants at baseline**

At baseline, there were no significant differences between participants and non-participants in age, ethnicity, marital status, occupation or demographic variables. However, quality of life and self efficacy were higher in the experimental group and uncertainty and symptom distress were higher in the control group at baseline.

The mean age of men in the intervention group was 67.5 years (SD= 6.54; Range: 56-79) and in the control group, 63.8 (SD: 6.95; Range: 56-71). The mean age of partners was 64.1 years (SD: 8.8; Range: 54-76) in the intervention group and 60 years (SD = 4.6; range: 50-74) in the control group. Most of the participants had attended further education or University. All participants were Caucasian and the majority were married. All partners were female.

In both the intervention and control groups, the most common treatment men had received was hormone treatment, followed by radiotherapy. Only one participant (control group) reported having had surgery. In both groups the majority of participants (intervention group= 69.2%; control group= 75%) were still receiving hormone therapy. Approximately 25% of the men in the intervention (n=4/17) and 50% in the control groups (n=2/4) reported having other medical problems such as chronic illness.

**Psychosocial Outcomes**

Table 3 provides the men’s mean scores on the outcome measures over time and Table 4 provides partners’ mean scores. The men in the intervention group had higher mean scores than the men in the control group on only two outcomes (communication and social support). ‘Illness benefits’ and ‘Health behavior’ remained more or less the same for both groups. Quality of life increased and uncertainty decreased for both groups.

Partners in the intervention groups fared better than their counterparts in the control group on most of the outcomes (Table 4). These results should be put in context of the small number of participants in the intervention and control groups and the lack of power to detect statistical significance. Due to the small number of participants and the unequal allocation to groups (only 4 dyads in the control group), only the mean scores are presented here; statistical results cannot be meaningfully assessed in this context.

**Economic evaluation**

The costs of training the facilitators and in delivering the intervention to 13 couples were calculated. Two trainers delivered the training at a cost of US $1092 (42 hours over three and a half days at US $26 per hour). Each facilitator was paid US $675 (over three and a half days) for taking part in the training. Hence, the total cost for trainers and training four facilitators was US $3792.

The cost of delivering the intervention to one group (four couples), providing information sheets, making phone calls, hiring venues, providing refreshments, refunding travelling expenses for participants and travelling to venues was recorded at US $1173. This includes US $386 for the facilitators’ time for delivering the intervention for 5 sessions. This amounts to approximately US $294 per couple.

**Discussion**

**Psychosocial outcomes**

This is the first documented psychosocial intervention developed for men with prostate cancer and their partners in the UK. This study was underpinned by the Medical Research Council framework for evaluating complex intervention (Craig et al., 2008) and some components of Bowen et al’s (2009) framework for undertaking feasibility studies of the implementation of intervention. This study has generated a significant amount of data on the effects of the intervention on psychosocial outcomes for these men and their partners, the challenges of recruiting and retaining participants to the trial, and the costs involved in the training of facilitators and in delivering the intervention. Together with previously reported qualitative data on the participants’ and facilitators’ perceptions of the intervention (xxx and xxx), this project has generated useful insights into the complexity of developing, implementing and evaluating psychosocial interventions for this population. These insights would be helpful to researchers and clinicians working in this field.

While the sample size did not allow for statistical significance to be established, the results of this study suggest that men in the intervention group did better than their counterparts in the control group on two outcomes: *communication* and *support*. Communication is related to dyadic adjustment, which in turn affects psychological outcomes (Wooten et al., 2007; Badr and Cormack Taylor, 2009). However, one can only speculate as to the effects that improved communication had on spousal relationship, as this was not assessed in this study. We recommend that future researchers measure this outcome directly as communication can have significant effects on spousal relationship (Zautra et al., 1998).

In a study of a family intervention for men with prostate cancer and their partners (Northouse et al., 2007), men in the intervention group reported more communication about the illnesses with spouses and less uncertainty than their counterparts in the control group. As in Northouse et al., (2007), there was no significant improvement on other psychosocial outcomes such as quality of life or self-efficacy in this study. As the content of the intervention was broadly similar in the two studies, it would be wise to review the components that could directly affect these outcomes and reflect on why they did not work. Elsewhere, we have reported the qualitative data showing that some of the components of CONNECT such as setting healthy lifestyle objectives, were not delivered as expected (xxx).

Another explanation is that the quality of life and the self-efficacy of these men were already at normative levels at baseline and they may not have needed the intervention. Parahoo et al. (2013), following their systematic review of psychosocial interventions for men with prostate cancer, concluded that there is a need to focus more on those men and their partners who most require help and support. As they explained:

The ‘broad brush’ approach of offering the same interventions to well-adjusted, well-educated men who experience the same quality of life as the normal population and to those experiencing urinary, sexual or marital difficulties is unlikely to be effective in terms of desired outcome and cost.

Partners in the intervention group seemed to have benefitted the most as they improved on most outcomes compared to their counterparts in the control group. This is similar to the findings of Northouse et al., (2007). This is a significant finding as partners play a key role in supporting their spouses and often experience stress and poor health. According to Northouse et al., (2007), partners in their study may have benefitted most because they may have had a greater need for the intervention than the men. This could also have been the case in this study. Wittmann et al., (2014) have also highlighted the need to understand the role of partners in supporting the men and the distress that partners experience in this context.

The information that partners obtained from the CONNECT intervention and the opportunities to share and learn from other partners helped them to understand their situation better and provided them with strategies to help them support their partners. The findings of the qualitative interviews showed that partners found the CONNECT intervention to be beneficial in helping them cope with their stress and taught them how to manage their partners’ condition (xxx).

**Recruitment issues**

By far the biggest challenge faced in this feasibility study was the recruitment of eligible participants for this study. Although we expected to recruit 48 couples, only 17 couples agreed to take part in this study. There were a number of obstacles that prevented the recruitment of participants as intended. With hindsight multiple strategies, including recruitment via the media, would have, perhaps, been more successful than just relying on the cancer center where participants were recruited. Organizing public lectures/talks on prostate cancer, for those diagnosed with the disease may help to boost enrolment. One study reported that increasing potential participants' awareness of the health problem being studied and its potential impact on their health appeared to increase recruitment to clinical studies (Caldwell et al., 2010).

A major issue in recruitment is patient understanding of clinical trials and their role in them (National Cancer Research Institute, 2017). In this study, some men and their partners revealed in the interviews that they did not seem to fully understand the purpose of the intervention, although there were opportunities for them to ask for clarifications before giving consent. This supports previous findings showing some clinical trials participants were confused regarding their roles and expectations after enrolling in trials (Joshi et al., 2013). On reflection, we should have had a checklist to ensure that all aspects of the intervention and the participants’ role in the trial were covered. We need to give more opportunities to potential participants to explore the purpose of the intervention. Researchers should also explore participants’ expectations of, and reasons for, consenting to take part in research studies. Too often the focus is on researchers giving information and answering potential participants’ questions.

In a study on research priorities for trials (Tudur-Smith et al., 2014), ‘methods to boost recruitment’ topped the list. Recruiting men for clinical trials can compound this problem, as men are normally reluctant to access services and to recognize they need help. Recruiting both men and their partners for the same study can be even more difficult than recruiting them separately because when one agrees the other may refuse. This was sometimes the case in this study.

It was also observed by the researcher responsible for recruitment, that higher recruitment numbers were obtained when doctors referred patients to the study. In a study of public awareness and perception of clinical trials, Joshi et al., (2013) reported that the main reason for participation was doctor advice. However, doctors have limited time to spend with patients and recruiting patients for trials is not a priority. Ways to involve other relevant health professionals more in recruitment should be explored further. For example, research nurses in the UK do not currently have access to patients’ notes to identify potential participants for clinical trials. The Health Research Authority in the UK (HRA, 2015), after conducting a public dialogue on identifying and recruiting participants for health research, concluded that there was widespread support for research nurses and doctors to have access to patient records to identify participants for health research providing certain conditions are met.

**Unequal allocation to groups**

There was intentional unequal allocation to groups in order to gain more insight into the implementation of the intervention. Hence, there were 4 intervention groups (13 dyads in total) and one control group (4 dyads). Three intervention groups had three dyads each and the fourth had four dyads.

It is not unusual for pilot trials to adopt ratios other than the usual 1:1 for not well established interventions if the aim is to gain experience in delivering the intervention (Eldridge et al., (2016). The initial aim in this study was to have an equal number of intervention and control groups with equal or near equal number of participants and an overall sample size to allow for power calculations. The recruitment plan was to obtain informed consent from as many participants as required to enable block randomization to groups, with the aim of facilitating participants to access the intervention near their place of residence. With hindsight this was too ambitious. It became obvious that we would have to wait a long time for this strategy to be successful. With the additional problem of fewer people willing to participate than we expected, we were faced with a choice of focusing on testing the ‘limited efficacy’ or on ‘acceptability, demand, implementation and practicability’ (Bowen et al., 2009). On this occasion, we sacrificed the integrity of the randomized controlled trial, in favour of learning about the process of implementing the intervention and what it means to participants and facilitators rather than on the outcome.

On reflection we believe we made the right decision as we were able to obtain valuable insight into how participants experienced the intervention, their views of its benefits and how it can be improved (xxx). We learnt about the process of implementing the intervention, the challenges faced by facilitators and their perceptions of what worked and what did not (xxx). Future researchers should also consider other evaluation designs than the randomized controlled trial when it is not feasible to recruit sufficient sample sizes within a limited period of time.

**Costs**

Although the figures provided earlier are only an estimate of the costs of training facilitators and delivering the intervention, it shows that once the intervention is developed and training is provided, the cost was US $294 per couple. This should be compared with the cost of providing one-to-one advice or counseling for couples experiencing the effects of the disease and its treatment in a future study.

This cost of the intervention in this study can be compared with two similar previous studies in the US. Badger et al. (2013) costed their 8-week interpersonal counseling intervention breast cancer patients and their partners at about US $164 per dyad. The interventions were delivered via telephone while the intervention in this study consisted of three, face-to-face and two telephone sessions. In Titler et al., (2017) study, the cost of five, face-to-face, dyadic psycho-educational interventions for patients and family caregivers was US $168 per dyad. These two studies (Badger et al., 2013; Titler et al., 2017) primarily assessed the time and wages of those who oversaw and delivered the interventions. This may explain why the cost of delivering the CONNECT intervention was higher. This may explain why the cost of delivering the CONNECT intervention was higher.

Researchers often develop interventions that are not subsequently adopted in practice, in spite of evidence showing that they are effective. This is probably because once the project is over, there is no more funds to continue to offer the service. Clinicians are often faced with the challenge of competing demands on their resources. Their priorities may not be the same as researchers. It is important to involve clinicians at the start of the project to ensure that new interventions are what they need.

In this study, we collaborated with a national charity to deliver the intervention. This voluntary organization was already offering counseling services to people with cancer. It is likely that evidence-based interventions, such as CONNECT, could become part of the portfolio of support that they provide.

**Limitations**

The main limitation is the smaller number of participants than were anticipated. Therefore it was not possible to establish statistical significance of the findings. As feasibility studies are designed to test an intervention, albeit in a limited way (Bowen et al., 2009), a convenience sample with shorter follow-up periods (i.e. one month post intervention), or with limited statistical power, was conducted. There were significant differences in baseline scores between these two groups which made it difficult to draw firm conclusions about the effectiveness of the intervention. However, the lesson learnt relates to the need to recruit adequate samples and to focus on those who have low self-esteem, and low quality of life and those with high uncertainty and symptom distress.

There was unequal allocation to groups resulting in one control and four intervention groups and the reason for this has been explained above. However, this compromised the integrity of the randomized controlled trial. The high attrition rate (50%) in the control group skewed the findings further.

We interviewed only four people who declined to take part in the study. With hindsight, we realized that we should have interviewed more of them in order to get a fuller picture of why people were unwilling to participate. Interviews with participants and facilitators in this study revealed that sexual issues related to prostate cancer was a topic that some of them (participants and facilitators) were reluctant to discuss (xxx and xxx). It is possible that those who refused to participate were not prepared to discuss problems related to sex and other intimate issues with other participants in a group format. Future researchers should balance the benefits of block randomization (aimed at facilitating access to the intervention by grouping participants from the same geographical area) with the embarrassment that participants may face when discussing personal issues with others who may be their neighbors or known to them.

All partners in this study were female. While there was no exclusion criteria regarding the sexual orientation of partners, only female partners volunteered to take part. With hindsight we should have made more efforts to recruit a range of partners by exploring the potential of lesbian, gay, bisexual and transgender groups to refer participants to the study.

While we kept a record of the costs involved in this project, we did not carry out a cost-effectiveness exercise, which is crucial for making decisions in the context of scare resources. One reason why successful interventions may not be adopted in routine practice is because there may be a lack of data on their cost-effectiveness (Dieng et al., 2016).

**Conclusions**

There is some indication that the CONNECT intervention can produce positive benefits to men with prostate cancer. Their partners seem to have benefitted even more from their participation in the intervention than the men. This is encouraging since there is a lack of studies on how, and to what extent, partners are affected when the men are diagnosed with cancer.

We have encountered difficulties in recruiting participants to the trial and we learnt some of the reasons why we were not as successful as we anticipated. On the other hand, the high retention rate in the trial is encouraging. This is supported by the findings from the qualitative interviews that both men and their partners reported that they benefitted greatly from taking part in the intervention.

This study has provided critical insights to enable us to make some changes to the intervention before undertaking a larger, multi-site study. The knowledge generated from this feasibility study will also be useful for all those grappling with the challenges of developing, implementing and evaluating complex interventions.

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Figure 1 Recruitment and attrition flow chart

**Referrals** (n=87 dyads)

Not included: 70 dyads

* Not eligible: 22 dyads
* Declined to participate::48 dyads

Randomized: 17 dyads (34 participants)

One month follow-up

2 dyads and one man completed assessment

1 dyad did not complete assessment

Post-intervention

3 dyads and 1 man completed the assessment

1 partner did not complete assessment

Baseline

Allocated to control: 4 dyads (8 participants)

Baseline

Allocated to intervention: 13 dyads (26 participants)

 Did not receive allocated intervention (n=2)

Post-intervention

12 dyads completed

1 dyad withdrew

One month follow-up

12 dyads completed

**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.  |

Table 2 Key areas of focus for feasibility studies and possible outcomes

|  |  |
| --- | --- |
| **Acceptability** | To what extent is a new idea, program, process or measure judged as suitable, satisfying, or attractive to program deliverers? To program recipients? |
| **Demand** | To what extent is a new idea, program, process, or measure likely to be used (i.e., how much demand is likely to exist?) |
| **Implementation** | To what extent can a new idea, program, process, or measure be successfully delivered to intended participants in some defined, but not fully controlled, context? |
| **Practicality** | To what extent can an idea, program, process, or measure be carried out with intended participants using existing means, resources, and circumstances and without outside intervention? |
| **Adaptation** | To what extent does an existing idea, program, process, or measure perform when changes are made for a new format or with a different population? |
| **Integration** | To what extent can a new idea, program, process, or measure be integrated within an existing system? |
| **Expansion** | To what extent can a previously tested program, process, approach, or system be expanded to provide a new program or service? |
| **Limited efficacy** | Does the a new idea, program, process, or measure show promise of being successful with the intended population, even in a highly controlled setting? |

From: Bowen et al., (2009)

**Table 3: Comparison of intervention and control participants (men)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Baseline** | **Post-intervention** | **1-Month follow-up** |
|  |  | **Mean (SD)** | **Mean (SD)** | **Mean (SD)** |
| **Variable** | **Score Range****(Upper quartile)** | **Intervention group** **(N=13)** | **Control group** **(N=4)** | **Intervention group****(N= 12)** | **Control group** **(N=4)** | **Intervention group** **(N=12)** | **Control group** **(N= 2)** |
| **Quality of Life** |  |  |  |  |  |  |  |
| FACT-G | 0-105 (>78.75) | 85.83 (14.10) | 76.88 (22.04) | 86.82 (13.87) | 76.67 (26.08) | 85.76 (17.07) | 80.22 (22.75) |
| **Appraisal variables** |  |  |  |  |  |  |  |
| Uncertainty a | 36-9 (<15.75) | 15.85 (3.16) | 22.25 (0.96) | 13.92 (3.37) | 17.91 (5.78) | 12.64 (3.53) | 16.33 (6.51) |
| Benefits of illness | 11-44 (>35.75) | 34.31 (7.89) | 32.25 (9.36) | 36.36 (5.87) | 31.50 (12.26) | 34.09 (7.34) | 34.33 (12.66) |
| **Coping resources** |  |  |  |  |  |  |  |
| Self-efficacy | 0-170 (>127.5) | 142.73 (31.58) | 118.25 (54.14) | 150.33 (22.25) | 120.00 (37.21) | 149.36 (19.96) | 130.67 (52.54) |
| Communication | 23-115 (>92) | 83.54 (18.79) | 81.55 (19.91) | 91.92 (10.84) | 71.38 (19.65) | 87.09 (13.99) | 74.36 (11.36) |
| Social Support | 7-35 (>28) | 31.23 (4.62) | 30.50 (3.32) | 32.67 (2.39) | 28.00 (5.77) | 33.00 (2.19) | 29.67 (2.52) |
| Health behaviours | 0-48 (>36) | 27.62 (6.78) | 26.33 (12.66) | 27.67 (7.13) | 29.00 (12.52) | 28.91 (6.09) | 35.36 (3.81) |
| **Symptoms** |  |  |  |  |  |  |  |
| Symptom distress a | 32-0 (<8) | 7.31 (3.38) | 10.25 (6.99) | 7.69 (4.58) | 10.02 (6.51) | 8.04 (5.19) | 7.16 (5.01) |

A indicates that a lower score denotes improvement; (.) SD missing as only one participant completed outcomes

**Table 4 Comparison of intervention and control participants (partners)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Baseline** | **Post-intervention** | **1-Month follow-up** |
|  |  | **Mean (SD)** | **Mean (SD)** | **Mean (SD)** |
| **Variable** | **Score Range****(Upper quartile)** | **Intervention group****(N=13)** | **Control group****(N=4)** | **Intervention group** **(N=12)** | **Control group** **(N= 3)** | **Intervention group****(N=12)** | **Control group** **(N=2)** |
| **Quality of Life** |  |  |  |  |  |  |  |
| FACT-G | 0-105 (>78.75) | 83.82 (18.96) | 74.78 (10.35) | 83.23 (17.09) | 67.61 (1.21) | 83.01 (13.65) | 66.33 (12.73) |
| **Appraisal variables** |  |  |  |  |  |  |  |
| Uncertainty a | 36-9 (<15.75) | 16.67 (5.21) | 14.00 (2.00) | 16.50 (5.02) | 14.33 (4.04) | 15.64 (4.32) | 17.00 (2.83) |
| Benefits of illness | 11-44 (>35.75) | 29.53 (7.40) | 28.19 (7.63) | 30.50 (5.55) | 27.33 (2.52) | 32.96 (6.52) | 21.00 (6.52) |
| Caregiver assessment a | 80-16 (<32) | 21.19 (5.66) | 24.33 (10.21) | 21.63 (6.51) | 29.00 (7.55) | 22.66 (6.74) | 32.50 (7.78) |
| **Coping resources** |  |  |  |  |  |  |  |
| Self-efficacy | 0-170 (>127.5) | 147.67 (20.44) | 141.05 (27.99) | 146.42 (14.99) | 118.67 (30.89) | 146.62 (10.44) | 106.50 (13.44) |
| Communication | 23-115 (>92) | 79.15 (13.74) | 84.82 (15.23) | 79.83 (14.24) | 64.00 (2.65) | 79.69 (12.88) | 60.50 (0.71) |
| Social Support | 7-35 (>28) | 26.92 (5.58) | 26.00 (5.57) | 28.00 (5.17) | 20.00 (3.46) | 29.55 (4.76) | 21.50 (0.71) |
| Health behaviours | 0-48 (>36) | 25.62 (6.61) | 14.97 (10.55) | 24.58 (7.05) | 19.33 (14.19) | 26.47 (6.00) | 18.50 (6.36) |
| **Symptoms** |  |  |  |  |  |  |  |
| Symptom distress a | 32-0 (<8) | 8.23 (6.12) | 10.33 (4.93) | 7.42 (4.54) | 7.11 (1.54) | 7.57 (4.29) | 16.00 (11.31) |

A indicates that a lower score denotes improvement; (.) SD missing as only one participant completed outcomes