Self-management for men surviving prostate cancer: A review of behavioural and psychosocial interventions to understand what strategies can work, for whom and in what circumstances

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Key words: Cancer, Oncology, Prostate, Self-Management, Survivorship

There are no ethical implications associated with this review paper.

There are no conflicts of interests associated with this review paper.

Acknowledgement:

Funding is acknowledged for this study as being provided by the CRUK as part of its small grants programme Ref: CRUK 06/040

ABSTRACT

Objective: In the context of increasing prostate cancer survivorship, evidence of unmet supportive care needs and growing economic healthcare restraints, this review examined and evaluated best approaches for developing self-management programmes to meet men's survivorship needs.

Methods: A search of international literature published in the last twelve years was conducted. Only randomised controlled trials were included in the analysis. Key components of the interventions were evaluated to determine what has been offered, and which elements are most beneficial in improving health outcomes. Methodological issues were also considered.

Results: Targeting participant need and promoting motivation to participate and maintain programme adherence were the most important factors to emerge in ensuring positive health outcomes. Both need and motivation are multi-faceted, the components of which are identified and evaluated. Guidance was also identified in relation to delivery design, theoretical mechanisms for change, modes of delivery and facilitator issues.

Conclusion: Self-management is a viable and appropriate way of providing health care solutions to ameliorate men's functional and emotional problems associated with increased prostate cancer survivorship. Integration into clinical practice will require training, resources and commitment and, in addition, economic viability will be difficult to assess since cost comparison with current provision is not straightforward. Nevertheless, from the psychosocial and behavioural studies reviewed there is convincing evidence that can be used to design, implement and evaluate future self-management programmes for men surviving prostate cancer.

INTRODUCTION

Self-Management

In the last decade, advances in clinical care for prostate cancer have meant that the majority of men diagnosed and treated will live five years or more and many will not die from the disease [1]. Survivorship has therefore become a significant aspect of provision: the Eurocare- 4 report identified a mean adjusted five year survival rate for prostate cancer across 23 European countries of 76% [2]. This is encouraging, but a corollary is that there is a growing population of men who continue to experience functional and emotional side effects of the disease and its treatment [3, 4]. It has also been found that some of these men can be reluctant to talk openly about their problems [5] and physicians may not readily be able to address men's needs when they are raised [6]. Emerging simultaneously is the increasing economic pressure on health care services and the need to find cost-effective ways in which to support men's survivorship needs.

Self-management offers a realistic answer to this dilemma: increasingly recognised as an important support to health management in chronic disease there is good evidence that it can improve health status in a range of conditions [7, 8]. The concept of self-management, however, is often confused with self-care, but there is a difference. Self-care refers to an individual's self-generated actions or behaviour intended to enhance health and well-being, prevent disease, limit illness and restore health [9, 10], usually with minimal involvement from healthcare practitioners. Self-management, in contrast, encompasses an interactive process whereby individual responses and behaviour aimed at managing physical and psychosocial consequences of symptoms and treatment, are guided by a clinician, often involving therapeutic approaches. To be successful Barlow et al [7] determine that self-management needs to convey the *"ability to monitor one's condition and to affect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life."* (p.178).

Self-management interventions aimed at empowering cancer survivors by providing information, education and practical strategies to enhance well-being have been developed and tested over the last decade. Although the number of studies published in this area is relatively limited compared to the wealth of evidence for self-management in chronic disease, they have been influential in formulating UK cancer policy [11, 12]. Nevertheless, the concept of 'self-management' has not been readily applied within interventions for prostate cancer. There is, however, a growing cohort of studies focused on the longstanding psychosocial consequences of prostate cancer survivorship [13]. Some of these are placed in a complex framework delivering skill sets, others are presented more simply as training or educating men [9]. Where these interventions have sought to provide men with ways of coping and empowerment in the management of their illness and treatment side-effects, they are de facto, offering men a self-management approach. There is a need to distil these interventions to understand what they offer, their design, their target audience, their mode of action and their efficacy, in order to shape future development of self-management as a viable health care strategy for men surviving prostate cancer. This review provides the initial steps in that process.

METHODOLOGY

This paper is not a systematic analysis but a comprehensive review of available published papers. This discursive approach, that examines the nature and content of the studies, is a more pragmatic method of advancing understanding of self-management in this area [14].

Publications from medical and psychological literature were surveyed from 1997 to April 2009. The search was limited to randomised controlled trials on the basis that they offer the most robust evidence for translation into clinical practice. Databases utilised were Medline, Cinahl, ISI Web of Science, Psych Info and Cochrane Review. Search terms and derivations were as follows: prostate cancer/neoplasms/carcinoma and psychosocial intervention or rehabilitation or self-management or educational intervention or skills training or pelvic floor muscle exercise or biofeedback and research or coping or quality of life or adjustment or adaptation or self-efficacy or support and randomised controlled trial.

Search Results

The initial search criteria were broad as descriptions of psychosocial and behavioural interventions in this area vary widely. 1043 studies were revealed which were then refined by hand. Adequate homogeneity was sought to facilitate interpretation: studies were selected that offered a 'self-management' approach, in line with the definition used by Barlow et al [7], and a working definition for prostate cancer survivorship was designated as 'men who are living with a diagnosis of cancer and/or have completed treatment, but are not in the terminal phases of illness'. Table 1 shows the exclusion criteria used.

(Table 1)

Seventeen studies were identified. This review took into account new MRC guidance on developing and evaluating complex interventions [16] and examined key components of the studies in terms of sampling, outcome measures, follow-up times, and theoretical underpinnings. In addition, intervention components were evaluated to understand what has been offered to men to help them manage the consequences of a prostate cancer diagnosis, and how and where these elements may be most beneficial in effecting health outcomes. Analysis of these components is reported in the Findings section of this review under *Intervention features* and *Study features*. Very few of the studies reported effect size and, coupled with a variation in outcome measures and sampling, comparison of statistical outcome is potentially misleading and has not been included in depth.

FINDINGS

Intervention Features

Identifying needs

The interventions reviewed apply to men's needs across a well-being continuum that emphasises proximal and distal effects of disease, treatment and outcomes [17]. In summary, *proximal* refers to the basic effects of disease or intervention on

functioning, i.e. urinary or sexual dysfunction, and *distal* refers to affective states and life satisfactions that are the psychological and social consequences of proximal effects [18].

There were seven interventions (Table 2) designed to help men *adjust* to diagnosis and lifestyle changes associated with cancer, focusing on distal survivorship issues. Men were targeted at various stages of diagnosis and treatment. The main emphasis in these interventions was to improve general quality of life [19-24], or psychological distress and anxiety [19, 20, 25]. Five studies also looked at mediating variables: seeking to understand social moderators of control, conflict, thinking and support [21]; the ability to respond to challenges [22, 23]; control and uncertainty [25]; and self-efficacy, processes of change and decision making [20]. Three studies found no improvements in terms of quality-of-life, [19, 20, 24], with Berglund et al [19] citing complicated design, lack of power and heterogeneity of sample as a possible reason. However, Carmack Taylor et al [20] and Stiegelis et al [25] found evidence that where distress was elevated at study entry greater benefit could be obtained, and Lepore et al [21] found an improvement in mental health. The greatest impact on distress was found by Penedo et al [22, 23]: participants made significant improvements in health-related quality-of-life and in benefit finding by enhancing their stress management skills.

(Table 2)

The other studies (Table 3), were *problem* focused and aimed their intervention at proximal effects of disease and treatment. They targeted men who would potentially have a recognised need, i.e. participants from an ethnic group [26-29] or those more likely to have symptom distress e.g. those who had recently completed prostate cancer treatment [18, 30-32]. One pilot study (reported across two papers) [33, 34] solely targeted men who were experiencing urinary incontinence six months after surgery, and another [18] used patient-defined problems to guide the intervention content. The needs addressed in these studies were more narrowly defined and measured in terms of urinary, bowel, sexual and depression problems. Individual differences in intervention effect were explored in relation to coping [35], self-efficacy [26, 31, 32, 35], social support [31, 32], depression, anxiety and emotional adjustment [18, 33, 34, 36] interpersonal sensitivity [36] and illness uncertainty [27].

(Table 3)

Outcomes for symptom relief across problem-focused interventions were mixed. Penedo et al [29], in a cognitive-behavioural stress management (CBSM) programme with an ethnic minority group of men, found a positive effect for sexual functioning, together with improved physical and emotional well-being. Molton et al [36], with the same CBSM programme modified to emphasise sexual dysfunction found a three-fold improvement in sexual functioning. Geisler et al [18] also found a sustained increase in sexual functioning, reduced sexual limitation and cancer worry and also that levels of depression mediated response: men with high levels of depression gained benefit in terms of general quality-of-life but were not able to benefit in terms of relief of physical symptoms. Zhang et al [33, 34] found a positive effect on perceived and self-assessed continence levels and on men's preparedness to practice daily exercise, and did find that improved continence was associated with reduced depression and symptom distress overtime. Other studies here found small [26, 31], weak [27, 32, 37] or no [35] effects on symptom bother and/or management,

and the limited benefits found tended not to be sustained over time. Analysis of outcomes used is included later under *Study features*.

Treatment profiles

Overall, most studies offered interventions to men after surgery and radiotherapy mixed within the same sample. Only four focused on a single treatment modality: surgery [33, 34] radiotherapy [25, 32] primary or adjuvant continuous hormone therapy [20]. One targeted men six months after diagnosis resulting in a range of treatments within the sample [19]. Another study [35] targeted men across three stages: diagnosis, recurrence and advanced disease, and included a spread of treatment modalities within their sample. These last two studies were based on the most heterogeneous samples reviewed and neither found an intervention effect for symptom functioning or quality of life.

Timing of intervention

The time between diagnosis or treatment and commencement of the intervention was also a variable factor. Eight interventions targeted men recently out of treatment, ranging from 2-6 months [18, 21, 24, 25, 27, 31-34]. In contrast, five interventions were offered to men a considerable time post-treatment: extending from 10 to 60 months [22, 23, 29, 36, 37]. The remaining interventions were less specific, samples defined as 'on continuous hormone treatment' [20], six months from diagnosis [19], 'beyond the acute phase of diagnosis and treatment' [26] and across stages of prostate cancer diagnosis, treatment and illness [35]. Where men were longer post-treatment they would have had longer-term illness experiences which would contribute to sample diversity, i.e. failure with medication, therapy, or attempts at self-care and increased prevalence of co-morbidity. These added dimensions would affect sample coherence in terms of motivation and adherence, and potentially, attrition rates and outcomes.

Intervention partners

Five studies included spouses, intimate partners or a significant family member in the intervention. Campbell et al [26] and Northouse et al [35] delivered home-based and/or telephone sessions to men and their partners simultaneously, and Lepore et al [21] delivered education and skills training to men and their spouses at the same time but in separate groups. Neither of these studies was designed to evaluate the differential effect of a partner. However, other studies did make a comparison. Mishel et al [27] compared a telephone intervention for men with and without a family member, and Canada et al [37] evaluated sexual rehabilitation counselling sessions for men with and without their partners. In the former study, benefit from having a family member also receiving the intervention was weak, and the latter study found that inclusion of a partner did not affect outcomes. Molton et al [36] later acknowledged this lack of effect and targeted their intervention for improving sexual functioning to men alone.

Ethnic groups

Three interventions addressed ethnicity as a mediator of response: Mishel et al [27] analysed African-American and Caucasian men separately in trying to improve coping with illness uncertainty and treatment side effects; Penedo et al [29] tested

the CBSM intervention on monolingual Spanish speaking men and Campbell et al [26] sought to increase research participation and enhance quality of life amongst African-American men beyond the acute diagnosis and treatment phase. All these studies were based on large samples and showed positive intervention outcomes for the ethnic groups studied. Given the higher incidence of prostate cancer in some ethnic groups, in particular those of African origin [38, 39], these populations are under represented in the majority of studies reviewed.

Intervention design

Interventions offered either psychosocial and/or educational approaches, or cognitive behavioural training (CBT). Psychosocial/educational approaches included education, information and peer discussion to enhance quality of life [21, 31]; lay support within peer dyads [32]; telephone social support to promote adaptation to diagnosis [24]; physical training and education to improve depression and anxiety [19]; pelvic floor muscle exercise and social support to improve symptom management and quality of life [33, 34]; education and support tailored to individual needs [18]; and a family based intervention delivered to men and their partners to improve coping and distress [35].

CBT is based on the theory that the manner in which patients perceive their disease and illness affects their ability to control it, and that by learning relevant skills they can make changes that can improve their perceptions and control and ultimately their illness experience. CBT in these studies included lifestyle and physical activity instruction to improve survivorship experiences [20]; cognitive behavioural stress management to improve benefit finding and/or quality of life [22, 23, 29] or sexual function [36]; telephone problem solving and cognitive reframing to relieve illness uncertainty [27]; skills and coping strategies to reduce illness uncertainty [25] or to facilitate research participation and enhance quality of life [26]; and counselling to improve sexual rehabilitation [37]. CBT intervention has been associated with improved symptom management outcomes for patients with cancer, particularly when patients initially show high levels of distress [40]. Some psychosocial/educational interventions reviewed [35] were unclear as to the method of delivery and could well have contained CBT elements such as problem solving techniques. Whilst relatively weak or poorly sustained effects were present within all the intervention approaches, the most consistent symptom relief was found in interventions based on CBT [22, 23, 29, 36].

Delivery

Mode of delivery was in group or one-to-one sessions, with mailed support the focus of one intervention [25]. Didactic group training sessions and open discussion were used in both psychosocial/educational and CBT approaches [19-23, 29, 31, 36]; peer group discussion was evaluated in the studies by Lepore et al [21, 31] and Zhang et al [33, 34] evaluated the effect of a support group as a supplement to pelvic floor muscle training. Participation in group sessions improves psychosocial parameters [20], and facilitates exchange of social support and information. Group cohesion can be a mechanism for change [41] and both the group dynamic and the collective task can have a positive effect on intervention outcome by enhancing patients' knowledge about cancer, managing side effects and preventing and coping with problems [21, 42]. However, the underlying mechanisms responsible for this still need to be understood [43]. Group discussion can also convey information that one is valued, esteemed and cared for by other group members and can increase self-efficacy. In

particular, studies examining men and women's experience of group sessions, have shown that men report positive experiences from their participation in support groups [44] and their ability to cope with cancer can be significantly improved [45]. Despite this, some men can be reluctant to talk openly about their problems [5] whether to their GP or peers, and in an intervention context would benefit from the opportunity to speak with a facilitator in private. It has also been suggested that tailored one-to-one sessions may improve symptom functioning better than group sessions [31]. There were several interventions focused on one-to-one delivery, including peer support [32], counselling [37] telephone support [18, 24, 26, 27] and home visits [35].

Duration

The majority of interventions were over 4-12 weeks duration. Only four interventions differed and included a one-off mail shot [25] and more extended facilitator-led programmes from 4-12 months [18, 24, 35]. For the longest of these, length of intervention does not appear to be linked to effectiveness: Giesler et al [18] in a six-month, face-to-face and telephone intervention found sustained positive effects up to twelve months later, whereas Scura et al [24] found no effects at the end of a twelve-month intervention of telephone social support. The face-to-face element in the Giesler et al study may have contributed to its effectiveness, but to understand this element more thoroughly, and considering cost effectiveness, further research into optimum intervention duration is required.

Study Features

Contexts

Fifteen of the studies were based in the USA, with one each in Sweden and the Netherlands. Just over half were carried out by health psychology or clinical psychology departments and the remainder by nursing or public health departments. In respect of comparators, nine studies compared one or more forms of an intervention with usual care, the remaining studies compared two or more forms of an intervention without reference to usual care. Where usual care was used as a control it was often not described in full. Description of control group care can highlight potential similarities and overlaps with experimental groups and so aid understanding of the intervention benefit. This should be considered as a standard reporting element.

Theoretical frameworks

Placing an intervention within an explicit theoretical framework can assist cumulative science and thereby serve many functions: it can aid replicability, enable comparison across studies, allow causal links, offer explanation and promote prediction [46, 47]. This research ethos emanates from a psychology discipline and nearly all studies in this review from such a background explicitly incorporated theory in describing mechanisms for change [20-23, 26, 29, 31, 36], although studies from other backgrounds also introduced an explicit theoretical framework [27, 32]. The most consistent framework applied was either cognitive behavioural theory [22, 23, 26, 29, 36, 37], which was often implicitly incorporated within the cognitive behavioural training approach, or social cognitive theory including self-efficacy [20, 21, 26, 31, 32]. Equivocal effects were found with self-efficacy. Lapore et al [21] found favourable outcomes on personal control (a measure of self-efficacy) but of the other

four studies, Lepore et al [31] and Weber et al [32] found only small effects. Lepore et al cited increased self-efficacy brought about by group influences as a reason for lower educated men remaining in employment and this is clearly a way in which self-efficacy could promote intervention effectiveness. Self-efficacy is the confidence an individual has in his or her actions and beliefs and thereby it can play a central role in the process of behaviour change and an individual's ability to manage their illness [46-48]. An individual's successful engagement with a self-management programme is often linked to his or her level of self-efficacy and motivation. Evidence from studies of chronic disease [49-51] and cancer [52] indicate that those who have the belief that changes in behaviour and lifestyle can affect health outcomes will benefit more from intervention. According to social cognitive theory, the CBT approaches in these studies could also link successful intervention outcomes to improved self-efficacy, although it is noted that no studies took this opportunity.

Other theoretical perspectives included Interpersonal Theory [36], Illness Uncertainty [25, 27] and Stages of Motivation Readiness [20]. Stage of motivational readiness was not predictive of mechanisms for change and improvements in illness uncertainty were only short lived. However, Molton et al [36] found that men with higher interpersonal sensitivity were particularly responsive to a CBSM intervention evidenced through improved sexual functioning. They highlight that Interpersonal Theory suggests that the individual is responsible for the quality of his or her own personal networks and that men with high levels of interpersonal sensitivity have more rigid, maladaptive self-concepts for which they seek reinforcement from others, producing poor quality social interactions. They further argue that this is not shown to be true for the therapeutic alliance, where personality dysfunction is associated with better treatment outcome in supportive and cognitive-behavioural interventions, and their CBSM intervention supported this. However, the mechanisms for change across the broader spectrum for prostate cancer symptoms were not discussed. Molton et al [36] also postulated several alternative mechanisms to account for the changes found, including group process variables, and amount of clinician contact. Nevertheless, this is an intuitively relevant use of theoretical variables and potentially augments understanding of how interventions work. Whether or not it can be shown to have explanatory value across the breadth of survivorship needs, as is the case with self-efficacy, needs to be the subject of further research.

Facilitators

A criticism often applied to self-management intervention studies, is the lack of adequate description of facilitator experience and training, which can hinder replication [9]. Nearly all the studies reviewed here described facilitator professions. They were variously, clinical psychologists [21-23, 29, 31, 36, 37], licensed health psychologists [33, 34], medical psychologists [26], oncology nurses, nurses [18, 21, 27, 35], an oncology research assistant [24], a physiotherapist [19]. One study did not report anything about facilitators other than that they were supervised by a licensed clinical psychologist [20]. Crucially, only six studies adequately described the intervention training given to facilitators [21-23, 27, 29, 36]. Another study, Steiglis et al [25], whilst based on a mailed intervention, supplemented that with an evaluative telephone call: there was no mention of who delivered the telephone call and no acknowledgement that this would potentially affect experience of the intervention since it was delivered prior to final assessment and only to men in the intervention group. There was poor transparency in reporting numbers of facilitators

involved. Three interventions were delivered by the same facilitators [21, 24, 31], and the remaining interventions explicitly, or implicitly, used multiple facilitators.

Despite the majority of interventions being conducted by more than one facilitator, only one study [37] analysed the co-variance in efficacy between counsellors, albeit relatively vague in reporting the nature, number and training of those counsellors. Ignoring the effect of clustering as a result of multiple facilitators can potentially lead to incorrect and inappropriate generalisation of conclusions. Self-management programmes in clinical practise are bound to be delivered by many different facilitators. No matter how similar their training, by nature of their personality, demographics, and experiences, they will have a differential effect on the groups they lead. Evaluation of an intervention should therefore take this into account and analysis of group variance should be reported [53].

Sample and Attrition

Of the studies reviewed most were based on large samples (n=120-263) although there were examples of smaller studies (n=17-29) [21, 24, 33, 34]. Very few studies provided a power analysis in relation to their sample size. Smaller samples make it more difficult to analyse for mediating variables and findings from small studies where multiple analysis have been performed should be treated with some caution [33, 34]. Attrition also varied: rates of between 0 and 14%, (mainly below 8%) were apparent in those studies where participants were relatively close to treatment end [18, 21, 24, 25, 27, 31-34], whereas there were much larger attrition rates, from 24 to 54%, for studies where men were further from treatment [23, 26, 29, 37]. Attrition may be affected by many factors including heterogeneity of sample due to different treatment and symptom issues, as well as perceived need. In controlling for attrition effect, intention-to-treat analysis was carried out in only four studies [19, 23, 29, 31] and was notably absent within studies with some of the largest attrition rates [26, 37].

Follow-up

Only two studies extended follow-up times to ten months or more after intervention completion [18, 19, 31]. In extrapolating the overall findings of these studies to a survivorship self-management paradigm, determining long term effectiveness is crucial, and the absence of robust data in this respect is a further limitation that must be borne in mind. Of the three studies that did include longer term follow up, Berglund et al [19] found no intervention effects at any stage; Lepore et al [31] found only relatively small main effects on critical quality of life outcomes not sustained at twelve months; and the twelve-month improvements found by Giesler et al [18] were only evident in a few dimensions of sexual functioning, sexual limitation and cancer worry, but there were no sustained effects for sexual bother or urinary or bowel outcomes.

Outcome measures

The majority of studies that addressed *adjustment* to prostate cancer (Table 2) incorporated general health-related quality of life measures supplemented by measures covering social and psychological mediating variables [19-23]. In addition, one study addressed prostate symptom experience and quality of relationships as well as general quality of life [24], and another study measured psychological distress and theoretical mediating variables of illness uncertainty [25].

Effect on general health-related quality of life was equivocal. Penedo et al [22, 23] found an improvement but for other studies the effect was weak [21] or not present at all [19, 20, 24]. Evidence from cancer research shows that measuring quality of life at the general level is subject to a number of interpretative issues, such as the relevance of constructs used across and within participants [54], and the phenomenon of response shift [55, 56], and so its unreliability across these studies and the apparent lack of effect is not surprising.

However, there was evidence of a consistent effect on *distress*, either through specific measures or via emotional adjustment constructs within the quality of life measures used. The broader cancer literature indicates that the most elevated psychological response to a diagnosis of cancer is that of distress, anxiety and depression [57], and so in developing and measuring interventions to aid adjustment, evaluation of these psychological constructs directly is most useful. The studies reviewed here confirm that where distress is addressed and measured, an intervention effect can be evident. Lepore et al [21] found a marked improvement in mental health and Carmack Taylor et al [20] showed that both lifestyle and education intervention delivered in groups benefited those with greater distress and more limited social support. Stiegelis et al [25] found that provision of information was associated with less tension, anger and depression, albeit, the researchers acknowledged that they did not measure psychological distress prior to the intervention and so could not indicate whether this actually reduced over the period. However, the positive effect on quality of life found by Penedo et al [22, 23] was mediated via teaching men the skills to handle their stress, supporting the notion that distress is the dominant psychological response in managing *adjustment* to prostate cancer.

For *problem* specific approaches (Table 3) there was a very broad range of primary outcomes used across and within studies: these included a range of quality of life measures, and measures of mediating variables such as illness uncertainty and uncertainty management [27]; self efficacy [26, 31, 32, 35]; social support or functioning [32-34]; psychological distress and/or depression [18, 32-34, 37]; prostate cancer knowledge and health behaviours [31]; relationship functioning [18, 35]; illness intrusiveness [33, 34]; and interpersonal sensitivity [36]. Five studies also looked at general quality-of-life, but as with *adjustment* studies, found small [29, 31], weak [18] or no effects [26, 35]. All the studies consistently based part of their primary evaluation on subjective symptom measures of function or distress in relation to urinary, bowel and/or sexual symptoms. The different focus of the interventions again makes it difficult to compare effectiveness across these symptom measures but of the seven interventions that were aimed broadly at physical symptoms, six reported a positive effect on sexual functioning or both [18, 26, 27, 29, 31, 32] and only two [26, 27] found a positive effect for urinary measures. Studies aimed solely at sexual or urinary problems also found improvement on respective symptom measures [33, 34, 36, 37].

It has been argued that to evaluate the effectiveness of behaviour change techniques it is essential that the main endpoints are objective behaviours rather than subjective health or emotional outcomes. [58] In extrapolating to self-management interventions aimed at reducing both physical and emotional symptom effects for prostate cancer, researchers need to ensure that the primary outcome contains both objective and subjective symptom measurement. This controls for the over-

estimation effect that subjective measures used in non-blinded randomisation can generate (*I have been through an intervention therefore I must feel better*) and provides a more consistent and reliable comparison across research studies. Only one study reviewed accomplished this [33, 34] finding an intervention effect for perceived and self-reported continence using a visual analogue scale for men who had had pelvic floor muscle training followed by support group sessions. For urinary or bowel symptoms this would be relatively straightforward to incorporate into studies but for sexual and emotional issues assessment would be more complex. Nevertheless, the limitations of studies without objective measurement should be acknowledged.

WHAT HAVE WE LEARNED?

This review of psychosocial and cognitive behavioural interventions for men surviving prostate cancer was conducted in order to understand how to develop and test relevant and sustainable self-management programmes in support of the growing survivorship agenda. Whilst there are few studies that describe their programmes as 'self-management', all the studies in this review offered men coping and empowerment techniques so that they could potentially manage their conditions by themselves in the longer term. A consistent finding in the studies was the lack of intervention effect sustained over time, yet for self-management to be deemed successful there should be long term sustainability and benefit. A range of intervention and study elements have emerged that are defining features of a self-management programme and which are crucial to address if programmes are going to be successful.

Targeting programmes to men's needs is one of the most important issues to be considered. Recruitment based on broad targeting is in danger of including men with dissimilar needs, which can affect intervention adherence, promote study attrition and dilute effect. Men's needs differ in emphasis across the disease trajectory, distress being most apparent in relation to diagnosis and adjustment, and symptom problems being particularly salient after treatment. Targeting men with homogenous levels and types of need within a sample is of greater relevance to participants and promotes intervention effectiveness; alternatively, this can be achieved by tailoring an intervention to identify individual needs and address each participant's requirements individually. Needs also differ in relation to treatment modality [59], and individual differences in terms of education, economic status, social support and ethnicity: these factors should also be taken into account explicitly in targeting and evaluating programmes. Additionally, measuring outcome effectiveness should mirror the needs that are being addressed at both subjective and objective levels.

Motivation is a key component of any self-management intervention. For successful self-management, not only should participants feel that an intervention is relevant to the problems they are experiencing, they should be motivated to engage with the intervention in practice and over time. The factors to emerge from this review that encourage motivation are located in participant characteristics and theoretical constructs. Participants are more motivated when they embark on an intervention at a time when they are receptive and determined. This 'teachable-moment' [60] is likely to be as close to diagnosis and treatment as possible. The evidence for the influence of other participant characteristics is more equivocal. Presence of a partner can aid involvement and long-term adherence in relation to distress and urinary or bowel symptoms [18] but, in the studies reviewed here, it was not

consistently linked to an advantage when addressing sexual functioning [18, 27, 37]. This is surprising, since evidence from the broader literature suggests that dyadic intervention for sexual issues is essential. It has also been suggested, in a protocol report [61], that in order to enhance sexual function for men, their partner's sexual function and satisfaction should be equally addressed as well as the couple relationship per se. When available, the results of this on-going trial may be able to clarify the inconsistencies in the current literature under review. In addition to these issues, the relationship between depression and symptom relief remains unclear with high study entry depression being related to emotional and physical benefits but not symptom benefits [18], and symptom improvement being associated with reduced depression [33, 34]. There is a requirement to clarify these relationships in further research amongst prostate cancer survivors.

In terms of theoretical constructs, self-efficacy is the most prevalent construct employed across the studies, but with inconsistent outcomes. Very few studies that incorporated it found that self-efficacy was affected by, or could explain, the intervention effect. The failures of self-efficacy to explain effect in these studies may well have been due to the broad sample targeting, and the high attrition from many of the studies may support this view. Bandura [62] suggests that patients withdraw participation because they doubt their ability to carry out the task required of them, and because they believe that they cannot influence the outcome regardless of their ability. Therefore individuals who perceive they do not have a need at that time may not see benefit in continuing with a programme. Further theoretical constructs that have been tested across these studies also need to be considered and researched in more detail; in particular, interpersonal sensitivity may play an important role in mediating self-management effectiveness.

Cognitive behavioural training used in these studies was positively linked with effectiveness of intervention and suggests a relevant and fruitful approach to delivery. Nevertheless, the evidence is equivocal in relation to how interventions are beneficially delivered. Group sessions have been effective amongst prostate cancer survivors, as indeed they have amongst other populations of male patients, but the personal nature of men's issues in prostate cancer survivorship suggests that many men will benefit from one-to-one involvement within an intervention. An intervention offering both opportunities would be valuable. Where groups are part of the intervention delivery, however, variability in terms of facilitator characteristics needs to be statistically explored and understood..

CLINICAL IMPLICATIONS

The key to successful provision of self-management interventions for men surviving prostate cancer is to offer the elements that work, to the men who need it, at the time they are likely to be most responsive.

Integration of self-management into clinical practice will have to consider a number of factors not discussed or consistently reported in the studies under review. Firstly, *delivery setting*: exploration is required on where best to locate interventions, either within specialist cancer centres or within more generalised community settings. Secondly, *facilitator training*: the logistics and content of programmes to teach the necessary skills and competences required will need greater understanding and description. Thirdly, *economic analysis of provision*: this is a complex area in relation to both the replacement costs of current clinical procedure and the costs of

intervention. For instance, at the clinical level, the cost of hidden sequelae related to non-disclosure of symptoms, and the costs of consultation and referral related to disclosure of symptoms, are not readily available. For economic assessment of an intervention, direct costs borne by the health care system and by the patients need to be considered, as well as the indirect costs born by the community for lost productivity [63]. Historically, in the chronic disease, self-management literature, including cancer, there is a lack of cost effective analysis and methodologies that can generate accurate economic assessment, and the case for cost effectiveness has not to date been evidenced [64]. However, recent studies in breast cancer specifically tailored to measure economic variables have produced evidence that self-management can have cost advantages over conventional care for survivors [63, 65] and standard approaches to evaluate the cost-effectiveness of psychosocial interventions in cancer are now being called for [65]. Promisingly, on-going trials in treatment decision-making and sexuality intervention post-surgery for prostate cancer patients are also examining cost effectiveness [61, 66].

As self-management becomes part of survivorship care, patient participation will grow out of increased awareness alone, and increasing survival rates and an aging population will add to this. Participation is therefore likely to be substantial and it is crucial that research explores all these further issues. Nevertheless, the long-term gain in well-being for men surviving prostate cancer is evident and compelling.

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Table 1: Study Exclusion Criteria

Studies were excluded that:

- Concentrated on issues of screening, palliative and terminal stages.
- Concentrated on treatment decision making since this could be considered a discrete issue with potentially different intervention criteria.
- Targeted only acute effects of treatment.
- Included prostate cancer as part of a multi-cancer site intervention.
- Examined disease progression or medical outcome.
- Offered only physical approaches to improve symptoms, for instance, delivering instruction in pelvic floor muscle exercise or aerobic exercise.
- Evaluated information delivery alone, as this has been shown not to be enough for improved self-management [14, 15].
- Examined participant satisfaction in isolation of other outcomes.
- Offered interventions to couples or spouses where primary outcomes concentrated on emotional relationships or only spouse-related factors.

Table 2: Studies focused on adjustment to prostate cancer diagnosis and illness

Author & Date	Intervention	Sample	Follow-up after intervention	Attrition	Outcomes assessed	Effects found
Lepore 1999 [21]	1) 6-weekly group sessions delivering education and skills training plus facilitated peer discussion. Spouses included in separate groups. 2) Standard care not specified.	24 men after surgery or radiotherapy – median time from treatment to start of intervention 41 days.	2 weeks	None	<u>Primary:</u> Health-related quality of life (QoL). <u>Secondary:</u> Social moderators, and psychosocial variables of interpersonal conflict, perceived personal control (self-efficacy), intrusive and avoidant thoughts and the availability and adequacy of social support. A measure of prostate cancer knowledge as a manipulation check.	QoL showed an improvement in terms of mental health: the intervention group had greater gains over time (SF-36: M = +14.33 versus +0.67) but no other intervention effects for health-related QoL. There were some changes in mediating variables showing more favourable outcomes for the intervention group on social conflict, personal control, distress caused by intrusive thoughts and prostate cancer knowledge. The intervention was found to be beneficial to men with relatively inadequate social support.
Scura 2004 [24]	1) Phased telephone social support sessions over 12 months, starting at weekly calls, moving to fortnightly calls, and finalising with monthly calls plus mailed education resource kits. 2) Education via a mailed resource kit only and no telephone support.	17 men diagnosed within last 4 weeks.	No extended follow-up	None	Health-related QoL, prostate symptom experience, erectile function and quality of relationships.	No significant differences between groups on measures used.
Penedo 2004 [22]	1) 10-weekly group sessions of cognitive behavioural stress-management (CBSM). 2) One stress-management seminar.	92 men who had had radical prostatectomy or radiotherapy in last 18 months.	2-3 weeks	None given	<u>Primary:</u> Health-related QoL. <u>Secondary:</u> Mediating variable of perceived stress-management skill, i.e. the ability to respond to challenges.	Participation in CBSM was associated with significant improvements in general QoL not found in the control group (FACT-G: M = +3.17% versus -0.72%). Acquisition of perceived stress-management skills was found to be positively associated with this change.
Stiegelis 2004 [25]	1) Booklet mailed 2 weeks after treatment delivering information, coping strategies and social comparisons. 2) Standard care.	228 men two weeks after completing radiotherapy treatment.	No extended follow-up	8%	<u>Primary:</u> Psychological distress. <u>Secondary:</u> Beliefs about control and illness uncertainty.	Men who were low in control and high in illness uncertainty prior to their first treatment reported less tension, anger and depression when they received information than when they did not.
Penedo 2006 [23]	1) 10-weekly group sessions of CBSM 2) One stress-management seminar.	191 men who had radical prostatectomy or radiotherapy on average 10 months previously.	2-3 weeks	25%	<u>Primary:</u> Health related QoL and positive contributions (benefit finding). <u>Secondary:</u> Perceived stress management skill.	Intention-to-treat model for all analysis. The intervention group increased in benefit finding, perceived stress-management skills and quality of life. Participation in CBSM was a significant predictor for all three outcomes.
Carmack Taylor 2006 [20]	1) 21 group sessions over 6 months delivering a cognitive behavioural approach focused on increasing physical activity. 2) Discussion groups over 6 months delivering only education. 3) Standard Care.	134 men diagnosis and receiving continuous hormone therapy.	6 months	16%	<u>Primary:</u> Health-related QoL; depression and mood states; pain inventory, objective measures of endurance; objective body measurements. <u>Secondary:</u> Mediating variables were measured via social support and physical activity as well as theoretical mechanisms of self-efficacy, process of change and decision making.	There were no significant differences in QoL at 6 and 12 months, and no significant differences in any of the proposed theoretical mediating variables. Both lifestyle and education intervention delivered in groups benefited those with greater distress or more limited social support.
Berglund 2007 [19]	1) 7-weekly group sessions delivering a programme of physical training. 2) Programme of information over same time. 3) Programme of physical training plus information over same time. 4) Standard care.	194 men within six months of diagnosis. Range of treatments and stage of disease.	10 months	20%	<u>Primary:</u> Anxiety and depression. <u>Secondary:</u> Health-related QoL.	Intention-to-treat model of analysis. No effects found.

Table 3: Studies focused on symptom problems arising from prostate cancer illness and treatment

Author & Date	Intervention	Sample	Follow-up after Intervention	Attrition	Outcomes assessed	Effects found
Mishel 2002 [27]	1) 8-weekly telephone sessions delivering problem assessment, problem solving, cognitive reframing, information and patient provider communication with mailed delivery of support material for managing specific problems. 2) Same intervention supplemented by delivery to a close family member and focusing on the family member's concerns about the patient. 3) Usual care plus printed general health information and four intervention calls.	239 men (African-American and Caucasian – analysed separately) within two weeks of catheter removal after surgery, or within first three weeks, of radiation therapy.	5 months	5%	Uncertainty in illness; uncertainty management (problem solving, cognitive re-framing, prostate cancer knowledge, patient-provider communication); symptom distress.	Effects found on main outcomes but not sustained over time. Uncertainty management, with and without supplement to a close family member significantly promoted cognitive reframing and problem solving, improved self-reported control of urine, and improved satisfaction with sexual function, but none of these were sustained over time. Decrease in symptoms evident across all groups but only sustained over time for African-American participants. No effect found for cancer knowledge, patient-provider communication or erectile functioning. Separate analysis looking at moderators for change indicated that men's levels of education, amount of sources of information and extrinsic religiosity influenced efficacy of the intervention [28].
Lepore 2003 [31]	1) 6-weekly one hour lectures delivering information and education with no peer contact encouraged. 2) The same lecture sessions with an additional 45 minutes of peer discussion. 3) Standard medical care.	250 men who had a range of treatments within the last month.	12 months	10%	<u>Primary:</u> Prostate Cancer knowledge; General QoL; disease-specific QoL; and health behaviours. <u>Secondary:</u> ratings of the lectures, employment status as a measure of role functioning. Self-esteem, self-efficacy related to controlling side effects of prostate cancer.	Intention-to-treat model of analysis. Relatively small main effects on critical outcomes and the education plus peer group intervention was generally more effective than education alone. Peer group discussion was associated with improved sexual bother but both interventions raised prostate cancer knowledge and neither showed an effect on mental functioning, depressive symptoms or urinary, bowel or sexual functioning. Peer discussion benefited men without a college degree in terms of health behaviour and physical functioning but not sustained at 12 months. Men with lower self esteem, low prostate-specific self-efficacy and higher depressive symptoms gained the most benefit from the intervention [30].
Weber 2004 [32]	1) 8 one-to-one support sessions - in informal surroundings over 8 weeks - with a long-term prostate cancer survivor who had experience of surgery and side effects. 2) Usual care.	30 men after radiotherapy, recruited at six week follow up after treatment.	No extended follow-up	6%	<u>Primary:</u> Social support, self-efficacy (cancer patient adjustment), depression, self-reported incontinence and erectile dysfunction . <u>Secondary:</u> Co-morbidity and satisfaction.	Significant effect on depression at 4 weeks into the intervention ($E_s = 0.99$) but not sustained to the end of the intervention. A smaller effect for self-efficacy (0.20) by the end of the intervention. Support group showed significantly less sexual bother at the end of the intervention but there were no significant effects on sexual function or urinary function or bother. No significant effect in terms of social support.
Canada 2005 [37]	1) 4 counselling sessions with couples 2) 4 counselling session with man alone. Men and partners required to do homework in both conditions.	84 men, 3 to 60 months out of surgery or radiation treatment (not on hormone therapy) and their partners.	6 months	54%	<u>Primary:</u> Assessment of erectile functioning, female sexual functioning, evaluation of utilisation of medial treatments, psychological distress (depression, anxiety, hostility, tendency to somatise and other dimensions of emotional adjustment), and assessment of marital satisfaction. <u>Secondary:</u> Urinary and bowel symptoms, menopausal symptoms and health-related QoL.	Attendance by the partner did not affect outcomes. Men improved on emotional distress, sexual function and satisfaction, which maintained to 3 months follow-up but then declined. Only overall sexual satisfaction continued to improve at 6 months. Use of erectile dysfunction treatments improved over time but had stabilised at less than 20% increase by the final assessment. Analysis of co-variance showed no differences in efficacy between counsellors.

Giesler 2005 [18]	1) 6-monthly sessions (2 x face-to-face, 4 x telephone) of a nurse-led computer-assisted identification of problems related to sexual, urinary and bowel dysfunction, cancer worry, dyadic adjustment, depression and other common sequelae of cancer, and tailoring of physical, behavioural and emotional strategies to deal with problems. 2) Standard care.	85 men plus spouse six weeks after the conclusion of active therapy.	12 months	14%	Prostate cancer QoL; depression; relationship functioning; health-related QoL.	Participants in the intervention arm experienced significant long-term improvements sexual functioning (ES = .37 at 12 months), sexual limitation (ES = .50 at 12 months) and cancer worry (ES = .51 at 12 months). No effects found for sexual bother, urinary or bowel outcomes. Baseline depression moderated the impact of the intervention. Participants with low depression improved on urinary bother but significance not sustained at final follow up (ES = .47). High levels of depression indicated no, or worse, effect for urinary bother (ES = -.70). Weak, outcomes for health-related QoL overall but evidence that high depression associated with some gain in emotional (ES = .58) and physical functioning (ES = .81).
Zhang 2006/7 [33,34]	1) 6-fortnightly support sessions over three months offering information, education, behavioural and psychosocial support and continued practice of exercises. 2) Routine care and at home practice of exercises.	29 men experiencing urinary incontinence six months after surgery. All trained in pelvic floor muscle exercise with the aid of biofeedback prior to randomisation.	3 months	7%	Self-assessed urinary continence, measures of perceived urinary problems, symptom distress, physical functioning, illness intrusiveness, social functioning, emotional disturbance.	An effect for practicing exercise daily (I = 86% vs C = 46%) and perceived and self-assessed continence but only weak effects on QoL. Suggestion of fewer limitations for vigorous activity and ability to walk more than a mile and less illness intrusiveness. Improved continence associated with reduced depression and symptom distress over time.
Penedo 2007 [29]	1) 10-weekly group sessions of CBSM. 2) Half-day psycho-educational stress management seminar in same form as the intervention.	1) 93 monolingual Spanish speaking men who had undergone surgery or radiotherapy in past 18 months.	2-3 weeks	24%	Health-related QoL and sexual functioning.	Intention-to-treat model of analysis. Relatively small effects for QoL. The experimental group when compared to the control group increased in physical well-being (*FACT-G: M = +1.53 versus -1.84) and emotional well-being (FACT-G: M = +1.49 versus -0.43). More significant effect for sexual functioning, the experimental group made more improvements than the control group (**EPIC: M = +2.17 versus +0.5).
Campbell 2007 [26]	1) 6-weekly 1-hour telephone sessions with patients and their intimate partners simultaneously delivering information and coping skills training based on cognitive behavioural techniques. 2) Usual care.	30 African American men beyond the acute diagnosis and treatment phase, and their intimate partners.	No extended follow-up	25%	Health-related QoL, disease-specific QoL and self-efficacy.	Men in the intervention group reported higher disease-related QoL versus the control group, i.e. moderate effect size in relation to bowel bother (EPIC: es = 0.471), urinary bother (es = 0.33), sexual bother (es = 0.45) and for hormonal function (es = 0.39). No effects found for health-related QoL or for self-efficacy.
Northouse 2007 [35]	1) 3 home visits and 2 telephone sessions, all 2 weeks apart delivered between baseline and four months plus standard clinic care. Consisted of 5 core areas: family involvement, optimistic attitude, coping effectiveness, uncertainty reduction and symptom management. 2) Standard clinic care	263 patient-spouse dyads	8 months	17%	Health-related QoL; appraisal of illness and care-giving; coping assessment; cancer self-efficacy; interpersonal communication; general symptom distress and prostate-specific symptoms.	The intervention group reported less uncertainty about their illness (ES = -.22) and more communication with their spouse (ES = .22) immediately after completion of the intervention, but there were no other significant effects at that time or at four or eight months.
Molton 2008 [36]	1) 10-weekly CBSM group sessions of 90 minutes didactic instruction and discussion and 30 minutes of relaxation training. 2) 1 seminar in same format as the intervention – care not specified.	121 men who had had treatment within the past 18 months.	2-3 weeks	17%	Assessment of sexual functioning; concerns about sexual functioning and interpersonal sensitivity.	The intervention had a significant effect on sexual functioning. The experimental group improved by 37.4% versus 11.5% for the control group. Men with higher interpersonal sensitivity were particularly responsive to the intervention: mean scores increased from 19.4 to 43.4 but with low interpersonal sensitivity from 31.1 to 33.6 only. In the control group, interpersonal sensitivity was not related to improvement in sexual functioning.