

## Lifestyle interventions to improve the quality of life of men with prostate cancer: A systematic review of randomized controlled trials



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### Contents

1. Introduction .....	14
2. Methods .....	14
2.1. Literature search .....	14
2.2. Inclusion and exclusion criteria .....	14
2.3. Data extraction .....	14
2.4. Data analysis .....	15
2.5. Quality assessment .....	15
3. Results .....	15
3.1. Risk of bias .....	15
3.2. Characteristics of included studies .....	15
3.3. Quality of life outcomes .....	15
3.4. Quality of life results .....	15
3.4.1. Physical exercise interventions .....	15
3.4.2. Dietary interventions .....	18
3.4.3. Combined interventions .....	19
4. Discussion and conclusion .....	19
Conflict of interest statement .....	20
Acknowledgment .....	20
References .....	20
Biography .....	20

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### ABSTRACT

Improving quality of life is a key issue for patients with prostate cancer (PCa). Lifestyle interventions could positively impact the quality of life of patients. However, there is no clear-cut understanding of the role of diet, exercise and risky behaviour reduction in improving the quality of life of men with PCa. The aim of this review was to systematically summarize randomized controlled trials on lifestyle in PCa patients with quality of life as main outcome.

17 trials were included. Most of them referred to exercise interventions (71%) and involved men undergoing androgen deprivation therapy (47%). Exercise studies yielded the greater amount of positive results on quality of life outcomes (67%), followed by dietary interventions (50%) and combined lifestyle interventions (33%). In particular, supervised exercise programs with resistance training sessions were

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the ones producing greater convincing evidence for benefits on quality of life. Further studies with high methodological quality providing adequate information to develop evidence-based, personalized lifestyle interventions that can effectively ameliorate PCa-related quality of life are needed.

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## 1. Introduction

Prostate cancer (PCa) is one of the “big four” most common cancers occurring worldwide (International Agency for Research on Cancer, WHO, 2014). In Europe, PCa incidence rates are among the highest, largely due to the widespread practice of prostate specific antigen testing (Ferlay et al., 2015), and are expected to rise worldwide within the next decades (International Agency for Research on Cancer, WHO, 2014). Health trajectories of PCa patients differ substantially based on disease clinical features. Most of the times, patients become long-term survivors. As such, they develop over time multiple medical and psychological needs, also consequent to ageing-related issues, that can lead to physical morbidity, poor symptom control, high perceived fatigue, and low quality of life outcomes (Davis et al., 2014). Consequently, the quality of life issues have been recognized as highly important and have become one of the most relevant aspects to consider (Penson et al., 2003; Bellardita et al., 2013). Lifestyle changes have received great attention in the last years, as they can make the difference for preventing health complaints and improving the quality of life of patients (Ornish et al., 2005; Mosher et al., 2009; Bourke et al., 2015; Magné et al., 2011). Maintaining a healthy weight, reducing alcohol and tobacco, taking regular physical activity are all actions that are able to impact on patients' overall health and wellness (Ornish et al., 2005; Mosher et al., 2009). Intervention programs for lifestyle change have proved to have beneficial effects on the quality of life of patients with different cancers (Ferrer et al., 2011; Mishra et al., 2014), and also on mortality rates of healthy subjects (Farahmand et al., 2009). In particular, different studies particularly focused on women treated for breast cancer and provided consistent evidences for a benefit of healthy lifestyles in this population (Magné et al., 2011; Daley et al., 2007; Kellen et al., 2009; Spark et al., 2013). Looking at PCa patients, although different descriptive studies highlighted the importance of healthy lifestyles for improving the quality of life of PCa patients (Ornish et al., 2005; Blanchard et al., 2008; Thorsen et al., 2008), solutions to effectively engage men with PCa in regular healthy habits are still warranted (Blanchard et al., 2008). Increasing age, time since diagnosis, treatment side effects and comorbid conditions can prevent engagement in healthy lifestyles. Furthermore, literature reported a strong gender-based dimension to lifestyle choices, with men being more likely to engage in risky behaviours than women (Von Bothmer and Fridlund, 2005). Considering these assumptions, lifestyle studies on PCa patients deserve a particular attention and reviews of scientific literature are warranted. Reviews are warranted to provide adequate information to develop evidence-based interventions effective in improving the quality of life of patients. However, literature reviews in the field mostly focused on patients not specifically affected by PCa (Fong et al., 2012) or only considered singular lifestyle aspects (Fong et al., 2012; Hasenoehrl et al., 2015; Ma and Chapman, 2009; Keogh and MacLeod, 2012; Gardner et al., 2014; Baumann et al., 2012). The few reviews broadly considering interventions for lifestyle for PCa patients examined the effects of such interventions on the disease course (Hackshaw-McGeagh et al., 2015; Mohamad et al., 2015), and not on quality of life outcomes. To the best of our knowledge, there are no literature reviews examining the impact of

high-quality (randomized controlled trials) lifestyle interventions on quality of life outcomes of patients with PCa.

Following these premises, the purpose of the present study was to systematically review studies on lifestyle interventions aimed at improving quality of life of men with PCa.

## 2. Methods

### 2.1. Literature search

PubMed, CINAHL, Scopus, and PsycINFO databases were systematically searched the 13th of October 2015 for peer-reviewed relevant articles using the following combination of terms: (exercise OR physical activity OR weight loss OR diet\* OR nutrition OR alcohol OR lifestyle OR smok\*) AND “prostate cancer”. The set of databases for literature search was selected after discussion among the authors to cover psychological, medical, and nursing literature fields. Scopus was included for its broad literature coverage. Literature search was not restricted to language or year of publication. Reference lists of relevant review articles were also manually searched to include additional studies.

### 2.2. Inclusion and exclusion criteria

To be eligible, studies had to be randomized controlled trials (RCTs) on lifestyle in PCa patients with quality of life outcomes measures. Lifestyle interventions were defined as intervention that included any dietary, exercise or behavioural component (e.g., smoking cessation, alcohol reduction) (Moran et al., 2011). To be considered for this review, trials needed to report a quality of life previously validated and published indicator as an outcome measure. Studies principally working with PCa patients and additionally including familiars, caregivers, or spouses were considered eligible. Commentaries, replies to other articles and other related documents were excluded.

### 2.3. Data extraction

Data extraction followed three subsequent steps of revisions following the PRISMA statements (see Fig. 1) (Moher et al., 2009). One researcher (JM) performed study selection and data extraction of all publications. A second researcher (LB) was consulted in case of uncertainty. 10% of the publications was screened twice by two researchers (JM and SV) in order to maximize inter-rater agreement and ensure a solid categorization procedure (Broekhuizen et al., 2015). Disagreements were solved through discussion.

In the first step, titles of search results were screened. In the second step, articles were screened at abstract level. At this stage, relevant literature reviews were analyzed at full text level to extract relevant articles. From this supplementary search, 1 article not included in our database was retrieved (Park et al., 2012).

In the third step, the remaining articles were screened at full-text level. In particular, full-texts were analyzed to exclude protocol articles, studies with on-going results, or not RCTs (n = 2). Multiple publications reporting data of the same intervention were further screened and data were only extracted once. In details, two studies of Carmody et al. (2008, 2012) with the same study design

were retrieved; the last publication was excluded because mainly focused on discussing a new outcome measure. Five studies reporting the effects of the same intervention were retrieved (Galvão et al., 2009, 2011; Galvão et al., 2014; Buffart et al., 2014, 2015) and only the most detailed and recent article was included (Galvão et al., 2014). Among the three trials of Cormie et al. (2013a,b, 2015), only the study reporting the quality of life outcomes was included (Cormie et al., 2013a). Only the last study of Pettersson et al. (2014) was included because it also reported the long-term outcomes of the intervention. Two studies describing the same intervention were retrieved (Daubenmier et al., 2006; Frattaroli et al., 2008), and only the most recent study by Frattaroli et al. (2008) was included because with a greater sample. Finally, two studies of Segal et al. (2003, 2009) were retrieved, and both were included because of the advisable differences in the proposed intervention (i.e., number of exercises, intervention length) and because of the different methodological structure of the trials (i.e., number of arms, number and type of participants, type of control group).

#### 2.4. Data analysis

Due to substantial heterogeneity across the studies in relation to intervention design and outcomes reported, pooling of the data by meta-analysis was not possible. Therefore, a qualitative synthesis of all studies was undertaken. The PRISMA statement was followed and adhered to (Moher et al., 2009).

#### 2.5. Quality assessment

The quality of included RCTs was assessed using the Cochrane collaboration risk of bias tool (Higgins et al., 2011). This is reported as the best available tool for assessing quality of RCTs (Zeng et al., 2015). Sequence generation, allocation concealment, blinding of participants and outcome assessors, outcome data, selective-outcome reporting, and other potential threats to validity were appraised. Cases with “yes” in the first three questions were classified as having a low risk of bias (–), cases with “unclear” or “no” in  $\leq 2$  domains were classified as having a moderate risk of bias (+), cases assessed with “unclear” or “no” in  $\geq 3$  domains were classified as having a high risk of bias (++)

### 3. Results

The search strategy yielded 2219 publications. After screening titles and abstracts, deleting duplicates, and searching articles' references, 38 publications were retained (Fig. 1). Most studies were excluded because they did not have a RCT design ( $n=420$ ), were not focused on lifestyle aspects ( $n=239$ ), or did not contain quality of life outcomes ( $n=171$ ). After final analysis of full texts to exclude on-going, duplicate or not RCTs studies, 17 articles were included in qualitative synthesis. Table 1 summarizes the included studies.

#### 3.1. Risk of bias

Quality scores of included RCTs are shown in Table 2. Only three of the RCTs achieved a maximum overall quality score (Carmody et al., 2008; Segal et al., 2009; Bourke et al., 2014), and two of these were physical activity interventions (Cormie et al., 2013a; Segal et al., 2009). The most common source of methodological bias identified by the scoring system was a lack of proper blinding procedures, with 12/17 studies failing to fulfil on this criterion.

#### 3.2. Characteristics of included studies

The 17 RCTs that were eligible for inclusion were published between 2003 and 2015 and involved a total of 1989 participants

from 7 countries: Canada ( $n=5$ ), USA ( $n=4$ ), Australia ( $n=4$ ), UK ( $n=2$ ), New Zealand ( $n=1$ ), Sweden ( $n=1$ ), and Korea ( $n=1$ ). The median sample size was 111 (range 21–423) and duration of intervention ranged from 4 to 96 weeks with a median of 12 weeks. In all the studies, participants were in average in the “young-old” (65–74 years) age group. Participants involved in RCTs underwent a variety of therapies. Most of the studies included participants following a specific treatment option. Eight studies (47%) involved patients undergoing androgen deprivation therapy (ADT), three (18%) involved patients undergoing radiotherapy (RT), and a minority of studies involved patients on active surveillance (AS) (6%), undergoing radical prostatectomy (6%), or undergoing RT plus ADT (6%). A minority of studies included patients from multiple treatment options: two studies (12%) included patients following different active treatments and one study (6%) included patients from a wide range of treatment conditions. Only a minority of studies were multi-centric ( $n=2$ ; 12%). Most of the studies were parallel group RCTs, with one ( $n=14$ ; 82%) or two intervention arms ( $n=3$ ; 18%) versus standard care ( $n=11$ ; 65%), active attention control ( $n=2$ ; 12%), or waiting-list ( $n=3$ ; 18%).

#### 3.3. Quality of life outcomes

All the included studies adopted validated quality of life measures. However, different tools were used within the 17 studies. In detail, five different tools were adopted: Functional Assessment of Cancer Therapy-Prostate scale (FACT-P); European Organization for the Research and Treatment of Cancer, Quality of Life Questionnaire (EORTC QLQ-C30); European Organization for the Research and Treatment of Cancer, prostate tumour – specific module (EORTC QLQ-PR25); Expanded prostate cancer index composite (EPIC); Short Form 36 Health Survey (SF-36). Most of the studies used the SF-36 ( $n=7$ ) or the FACT-P ( $n=7$ ) measure, some of them ( $n=4$ ) used the EORTC QLQ-C30 or the EORTC QLQ-PR25 tool, and 1 of them included the EPIC measure. Generally, the studies included only one tool to measure quality of life ( $n=12$ ); five articles included more than one tool for this aim.

#### 3.4. Quality of life results

The majority of the interventions observed significant effects on quality of life outcomes (59%), six interventions (35%) did not have significant effect on quality of life, and one study (6%) obtained a partial significant effect – only for the cognitive subscales of quality of life.

Results were analyzed considering the different type of interventions: lifestyle interventions with a combination of elements (3 studies; 18%), physical exercise training (12 studies; 71%), or dietary support (2 studies; 12%). Exercise studies yielded the greater amount of positive results on quality of life outcomes (67%), followed by dietary interventions (50%) and mixed lifestyle interventions (33%).

##### 3.4.1. Physical exercise interventions

Among the eight studies that yielded positive quality of life results after physical trainings, two had high methodological quality (Cormie et al., 2013a; Segal et al., 2009). In most of these studies, trainings with resistance exercises (e.g., weightlifting) of 12 or 24 weeks significantly improved patients' quality of life (Segal et al., 2003; Courneya et al., 2004), together with other health and psychological outcomes such as sexual functioning (Cormie et al., 2013a), fatigue (Segal et al., 2009; Higgins et al., 2011), or physical functioning (Park et al., 2012; Galvão et al., 2014; Segal et al., 2003; Galvão et al., 2010). In particular, Segal et al. (2009) compared resistance with aerobic training (e.g., walking, jogging, or cycling) and found greater long-term effects for resistance training.

**Table 1**  
Summary of study results.

Study, country	Study type	Population (and number of arms)	N° of participants in arm(s)	Intervention category and type (duration in weeks), Control	QoL measure	Effect
<a href="#">Courneya et al. (2004)</a> Canada	Mc RCT	PCa patients undergoing ADT (2)	(EG) 82, (CG) 73	PA: supervised resistance exercise (repetitions of 9 exercises) individual training (12) CG: usual care	FACT-P	Significant effect
<a href="#">Carmack Tayloret al. (2006)</a> USA	Sc RCT	PCa patients undergoing ADT (3)	(EG1) 46, (EG2) 51, (CG) 37	PA: cognitive-behavioural PA skills training + monitoring techniques (24) Lifestyle: Educational PA Support (24) CG: usual care	SF-36	No significant effect
<a href="#">Monga et al. (2007)</a> USA	Sc RCT	Localized PCa patients undergoing RT (2)	(EG) 11, (CG) 10	PA: aerobic (walking on a treadmill) exercise program (8) CG: usual care	FACT-P	Significant effect
<a href="#">Segal et al. (2009)</a> Canada	Sc RCT	PCa patients undergoing RT (3)	(EG1) 40, (EG2) 40, (CG) 41	PA: resistance training (repetitions of 10 exercises) (24) PA: aerobic training (on a cycle ergometer, treadmill, or elliptical trainer) (24) CG: usual care	FACT-P; FACT-G	Significant effect
<a href="#">Culos-Reed et al. (2010)</a> Canada	Sc RCT	PCa patients undergoing ADT (2)	(EG) 53, (CG) 47	PA: combined light resistance and aerobic (walking, stretching) group training with at-home exercises and educational booster sessions (16) CG: wait-list	EORTC QLQ-C30; EPIC	No significant effect
<a href="#">Park et al. (2012)</a> Korea	Sc RCT	PCa patients > 65 years undergoing RP (2)	(EG) 33, (CG) 33	PA: resistance, pelvic flexibility, and Kegel exercises (12) CG: Kegel exercises	SF-36	Significant effect
<a href="#">Galvão et al. (2010)</a> Australia	Sc RCT	PCa patients undergoing ADT (2)	(EG) 29, (CG) 28	PA: combined resistance (repetition of 2–4 set of exercises) and cardiovascular aerobic (walking, jogging or cycling) group training (3) CG: usual care	SF-36 QLQ-C30	Significant effect
<a href="#">Segal et al. (2003)</a> Canada	Mc RCT	PCa patients undergoing ADT (2)	(EG) 82, (CG) 73	PA: resistance training (repetition of 9 exercises) (12) CG: wait-list	FACT-P	Significant effect
<a href="#">Cormie et al. (2013b)</a> Australia	Sc RCT	PCa patients undergoing ADT (2)	(EG) 29, (CG) 28	PA: combined resistance (repetition of 8 standard exercises) and cardiovascular aerobic (walking, jogging or cycling) group training with at-home aerobic exercises (12) CG: usual care	QLQ-PR25 SF-36	Significant effect
<a href="#">McGowan et al. (2013)</a> Canada	Sc RCT	PCa patients (3)	(EG1) 141, (EG2) 141, (CG) 141	PA: fact sheet with PA information + self-administered PA implementation intention group with goal-setting and encouragement + individual telephone counseling (4) PA2: fact sheet with PA information + self-administered PA implementation intention group with goal-setting and encouragement (4) CG: fact sheet with PA information	SF-36	No significant effect

Table 1 (Continued)

Study, country	Study type	Population (and number of arms)	N° of participants in arm(s)	Intervention category and type (duration in weeks), Control	QoL measure	Effect
Galvao et al. (2014) Australia	Mc RCT	PCa patients treated with ADT and RT (2)	(EG) 50, (CG) 50	PA: combined resistance (repetition of 2–4 set of exercises) and cardiovascular aerobic (walking, jogging or cycling) group training (24) CG: printed educational material	SF-36	Significant effect
Livingston et al. (2015) Australia	Mc RCT	PCa patients treated with active treatment (PT, RT, ADT) (2)	(EG) 54, (CG) 93	PA: supervised exercise group program following guidelines for cancer patients with at-home exercises (12) CG: usual care	EORTC QLQ-C30 EORTC QLQ-PR25	Partial significant effect (+for cognitive subscale)
Petterson et al. (2014) Sweden	Sc RCT	Localized PCa patients undergoing RT (2)	(EG) 64, (CG) 66	Diet: standardized dietary individual counseling (96) CG: usual care	EORTC QLQ-C30 EORTC QLQ-PR25	No significant effect
Carmody et al. (2008) USA	Sc RCT	PCa patients undergoing a primary treatment (PT, RT, brachytherapy) (2)	(EG) 17, (CG) 19	Diet: didactic and experiential dietary and cooking group classes + mindfulness practice (11) CG: wait-list	FACT-P	Significant effect
Frattaroli et al. (2008) USA	Sc RCT	PCa patients in AS (2)	(EG) 44, (CG) 49	Combined: supplemented vegan diet prescription + aerobic exercise + stress management + adherence support group (48) CG: usual care	SF-36	No significant effect
Bourke et al. (2014) UK	Sc RCT	Advanced/metastatic PCa patients undergoing ADT (2)	(EG) 50, (CG) 50	Combined: combined aerobic and resistance exercise + healthy eating seminars + integrated behaviour change support sessions (24) CG: usual care	FACT-P	Significant effect
O'Neill et al. (2015) UK	Sc RCT	PCa patients undergoing ADT (2)	(EG) 47, (CG) 47	Combined: walking encouragement with pedometer support + individually tailored dietary counseling with dietary guidebook (24) CG: usual care	FACT-P	No significant effect

Abbreviations: Sc = Single center; Mc = multicenter; EG = experimental group; CG = control group; RCT = randomized controlled trial; PCa = prostate cancer; PA = physical activity; CG = control group; ADT = androgen-deprivation therapy; RT = radiotherapy; RP = radical prostatectomy; FACT-P = Functional Assessment of Cancer Therapy-Prostate scale; EORTC QLQ-C30 = European Organization for the Research and Treatment of Cancer, Quality of Life Questionnaire; EORTC QLQ-PR25 = European Organization for the Research and Treatment of Cancer, prostate tumor – specific module; EPIC = Expanded prostate cancer index composite; SF-36 = Short Form 36 Health Survey.



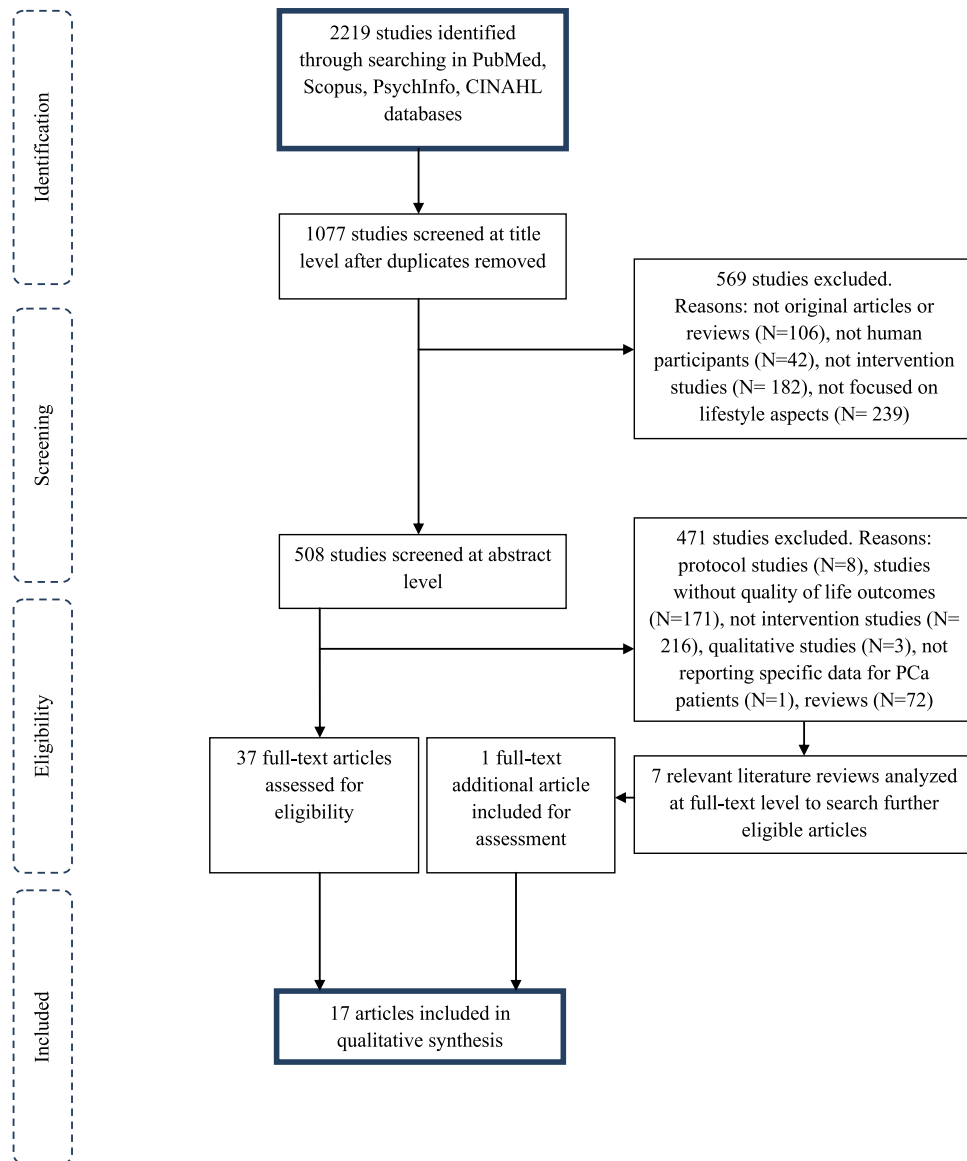


Fig. 1. PRISMA Flow chart.

On the other hand, [Monga et al. \(2007\)](#) tested an aerobic intervention and demonstrated that an 8-week cardiovascular exercise program in patients with localized PCa undergoing radiotherapy improved cardiovascular fitness, flexibility, muscle strength, overall quality of life and prevented fatigue. In the study of [Galvao et al. \(2014\)](#) a 6 months program of supervised exercise followed by 6 months of home-based maintenance produced improvements in physical functioning and physical performance at both 6 and 12 months compared to patients receiving printed educational material about physical activity. Also the study of [Galvão et al. \(2010\)](#) reported improvements in quality of life scores (i.e., general and physical health, role, cognitive health, fatigue, nausea, dyspnea) among patients completing a supervised group resistance and aerobic training of 3 months compared to patients following standard care. Finally, a study testing a generic exercise intervention following guidelines for cancer patients found significant positive results only for cognitive subscales of quality of life scores ([Livingston et al., 2015](#)). Generally, exercise programs delivered by these studies were supervised by exercise physiologists ([Cormie et al., 2013a; Galvao et al., 2014; Galvão et al., 2010; Livingston et al., 2015](#)), by exercise specialists ([Segal et al., 2003, 2009; Courneya et al.,](#)

[2004](#)), or by a kinesiotherapist supervised by a physician ([Monga et al., 2007](#)). Nonetheless, the quality check revealed that the study had a moderate risk of bias. Finally, three studies reported no significant results on quality of life outcomes after non-supervised interventions aimed at motivating and supporting goal-planning for physical activity ([Carmack Taylor et al., 2006; McGowan et al., 2013](#)), or after a combined resistance-aerobic tailored intervention with home-based portion and weekly group sessions ([Culos-Reed et al., 2010](#)). Yet, these results did not emerge from studies that fit the quality criteria.

#### 3.4.2. Dietary interventions

Results of research on nutritional interventions were mixed. Only one study testing dietary and cooking classes together with mindfulness practice for patients and their spouses reported positive quality of life results (together with improvements in healthy food consumption) ([Carmody et al., 2008](#)). Individual advises to reduce insoluble dietary fibre and lactose intake were otherwise not effective in improving quality of life of patients ([Pettersson et al., 2014](#)). Both studies had very high risk of bias.

**Table 2**  
Risk of bias assessment of the selected studies.

Reference	Quality classifications						
	Random sequence generation	Concealment of allocation	Blinding	Incomplete outcome data	Selective outcome reporting	Other potential threats	Overall judgment of quality
Courneya et al. (2004)	yes	unclear	unclear	no	yes	yes	++
Carmack Taylor et al. (2006)	no	unclear	yes	yes	yes	yes	+
Monga et al. (2007)	unclear	unclear	no	no	yes	yes	++
Carmody et al. (2008)	unclear	unclear	unclear	no	unclear	unclear	++
Segal et al. (2003)	unclear	unclear	yes	no	yes	yes	++
Higgins et al. (2011)	yes	yes	yes	yes	yes	yes	–
Culos-Reed et al. (2010)	unclear	unclear	unclear	no	no	yes	++
Moran et al. (2011)	yes	yes	unclear	no	yes	yes	++
Galvão et al. (2010)	yes	yes	no	yes	yes	yes	+
Segal et al. (2003)	yes	no	no	yes	yes	yes	+
Cormie et al. (2013b)	yes	yes	yes	yes	yes	yes	–
McGowan et al. (2013)	yes	unclear	unclear	yes	yes	yes	++
Buffart et al. (2014)	yes	yes	no	yes	yes	yes	+
Daubenmier et al. (2006)	yes	unclear	no	yes	unclear	unclear	++
Courneya et al. (2004)	yes	yes	yes	yes	yes	yes	–
O'Neill et al. (2015)	yes	yes	no	yes	yes	yes	+
Livingston et al. (2015)	yes	yes	no	yes	yes	yes	+

Each trial was given a low (no), high (yes), or unclear (unclear) risk of bias score for each dimension. Articles were scored with – if they had an overall judgment of low risk of bias (>3 dimensions scored with “yes”), with + if they had a moderate overall risk of bias ( $\leq 2$  dimensions scored with “no” or “unclear”), and ++ if they had an high overall risk of bias ( $\geq 3$  dimensions scored with “no” or “unclear”).

### 3.4.3. Combined interventions

Three interventions combined different lifestyle practices (generally exercise sessions plus dietary advice). Results of these studies were mixed. Improvements in the quality of life scores were reported only in the study of Bourke et al. (Bourke et al., 2014) (with low risk of bias), promoting a supervised exercise training program with concurrent healthy eating advice. However, changes were not sustained after six months. For the other two studies, neither the home-based intervention encouraging healthy dietary and physical activity behaviours (O'Neill et al., 2015) nor the intensive lifestyle program with vegan dietary, aerobic exercise, stress management and support group components (Frattaroli et al., 2008) improved quality of life of patients.

## 4. Discussion and conclusion

This review is the first to focus on lifestyle interventions with a RCT design looking specifically at quality of life outcomes. 17 papers were found to report on RCTs that explored the impact of nutritional, physical activity, or combined lifestyle interventions on quality of life of men with PCa. These studies showed a large degree of heterogeneity with regard to intervention types, methods of implementation and quality of life outcome measures. Moreover, few studies met the requirements to be considered methodologically sound. This lack of methodological quality had been already reported by previously published reviews (Hackshaw-McGeagh et al., 2015). In particular, the main reason for the high risk of bias was the lack of blinding of participants and personnel. Blinding participants and researcher is often difficult to do in trials with reduced arms or where the experimental condition is evident. Indeed, most of the included studies used usual care and not attention-control interventions as control group, so masking experimental condition was often impossible.

Regarding the outcome measures used to assess quality of life, these varied substantially across the studies from disease-specific tools to generic quality of life scales. The lack of a common tool to measure quality of life makes studies difficult to compare, and studies are divided between the choice of a generic quality of life scale (SF-36) and a PCa-specific tool (FACT-P). Both the choices have advantages; disease-specific tools can be better framed to the features and needs of the targeted population whereas generic tools can allow researchers to compare outcome results among

different clinical populations. However, the usefulness of the generic instruments may be limited as they can be not able to detect small changes in health status within cancer patients, and the usefulness of disease-specific measures may be limited by lack of comparable data.

Furthermore, rarely lifestyle intervention studies for PCa patients adopted both generic and specific measures of health-related quality of life in parallel. As a means to compare outcomes of lifestyle interventions for PCa patients and to quantitatively analyze the effectiveness of lifestyle interventions on quality of life, shared guidelines about the best set of quality of life measures are needed (Jacobsen and Jim, 2011; Bellardita et al., 2015).

Looking at participants targeted by the included RCTs, patients undergoing ADT were the main targets of the interventions. This can be due to the well-known possible adverse effects on physical, functional, cardiovascular and metabolic functioning of ADT, which have a consequent impact on quality of life of patients (Sountoulides and Rountos, 2013). Physical exercise and other lifestyle interventions are then recommended to fight the adverse effects of ADT and to minimize their impact on patient quality of life (Keogh and MacLeod, 2012; Gardner et al., 2014; Baumann et al., 2012). Average age of patients included in the RCTs was between 65 and 74 years, putting patients in the “young-old” category. However, none of the retrieved interventions took into account age-related issues when delivering lifestyle programs for PCa patients.

Concerning the intervention contents, the findings from this review show that physical exercise training was the most frequently implemented lifestyle intervention. This is consistent with literature evidences that highlight the importance of physical exercise for improving the health status and wellbeing of patients (Hasenoehrl et al., 2015; Keogh and MacLeod, 2012; Gardner et al., 2014; Baumann et al., 2012; Kenfield et al., 2011). In particular, findings suggest that exercise interventions, and in particular supervised resistance training programs, had beneficial effects on quality of life of PCa patients. Similarly, also the reviews specifically focused on exercise interventions suggested that exercises where the body's musculature has to work against some type of resistance should be particularly proposed for PCa patients (Keogh and MacLeod, 2012; Kenfield et al., 2011). Resistance training based on improving muscles strengths was also shown to have positive effects on mood and physical functioning of healthy older men (Hunter et al., 2004). Looking at the other intervention's

type, results for dietary and combined lifestyle interventions were inconsistent and partial in the present review. However, dietary interventions, contrary to exercise only interventions, can have the advantages of reducing weight or BMI as suggested by the review of Mohamad et al. (2015). Surprisingly, despite evidences concerning the role of smoke and alcohol consumption on PCa risk and quality of life (Blanchard et al., 2008; Plaskon et al., 2003; Schoonen et al., 2005), interventions focused on reducing these risky behaviours to improve the quality of life of PCa patients were withheld.

Furthermore, our review mainly retrieved interventions focused on the behavioural component and on single aspects of lifestyle change. Very few articles – and additionally these had low methodological quality and poor results – concurrently worked on different lifestyle modules and considered the importance of motivating patients in implementing lifestyle changes in their daily life. However, in order to help patients maintaining long-term healthy behaviours, working on the attitude of patients towards healthy lifestyle changes is pivotal. Lifestyle programs have to realize that patients should be firstly motivated and fully engaged in adopting a healthy lifestyle in their daily life (Menichetti et al., 2015). One-shot and partial interventions that do not focus on how to sustain patients in becoming the main actors of a process of change, where healthy lifestyle behaviours are a key component, are at risk of producing temporary results. Acting on a successful process of engagement in healthy lifestyle behaviours can boost the effects of interventions and allow long-term results (Graffigna et al., 2014; Barello and Graffigna, 2015). Studies are needed to understand how to work on a whole process of engagement in healthy lifestyle trajectories among PCa patients.

The major limitation of the review was that the number of trials with similar quality of life measures was small, not allowing to verify the effectiveness of trials to be verified through a meta-analysis process. The quality of the trials also varied, and the generally low methodological quality of included RCTs makes definitive conclusions restricted.

The retrieved studies reported a wide range of benefits for lifestyle – and particularly for exercise programs –, on quality of life outcomes and also on other health outcomes. For example, Frattaroli et al. (2008) revealed that patients in AS engaged in a lifestyle program, less frequently shifted over time to conventional active treatment compared to patients in AS not participating in a lifestyle program. Additional large-scale RCTs with high methodological quality are necessary to better understand the benefits of lifestyle in ameliorating the quality of life of PCa patients. Furthermore, additional studies are needed to test lifestyle programs addressing the specific age-based needs of PCa patients. As suggested by recently developed scientific disciplines investigating the connection between lifestyle factors and the ageing process, deepening the role of evidence-based long-term lifestyle interventions on diseases occurring during ageing could “not only improve the quality of life and health of many people, but would also reduce aging-related healthcare costs, increase potential working span, and strengthen economical competitiveness” (Verburgh, 2015).

Improving quality of life is a key issue for PCa patients, and, as lifestyle has the potential to improve both quality of life and health status of patients, understanding which lifestyle intervention is effective might lead to a successful program implementation in clinical practice.

**Conflict of interest statement**

None.

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