

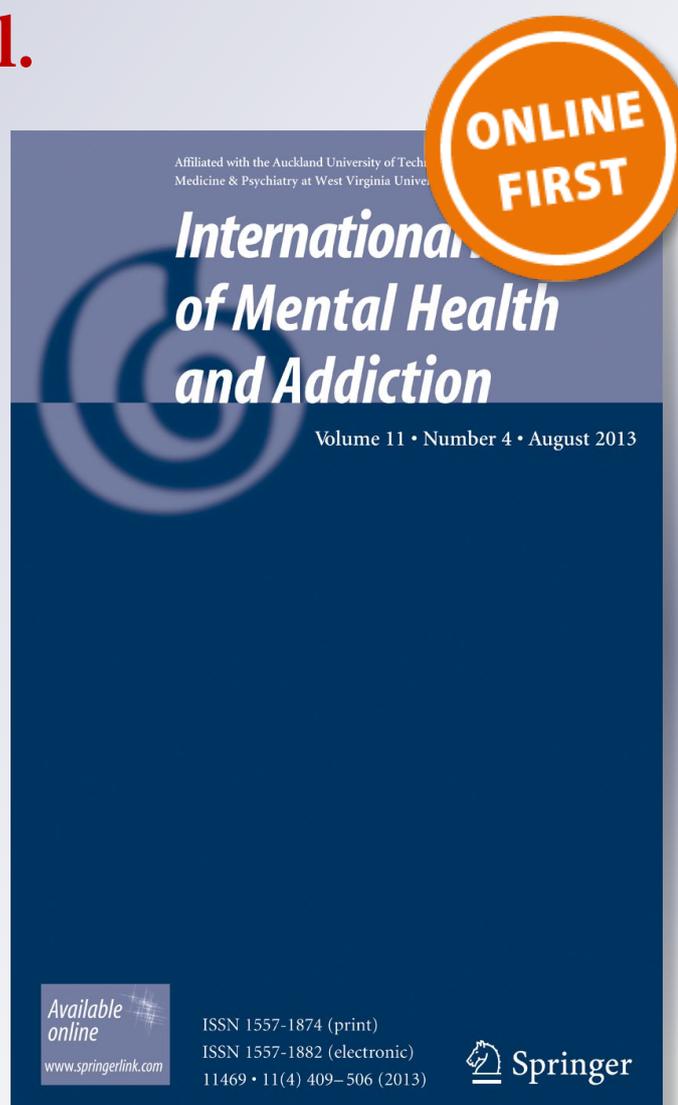
Development and Initial Evaluation of a Multifaceted Intervention to Improve Mental Health and Quality of Life Among Prostate Cancer Survivors

Gabriela Ilie, Ross Mason, David Bell, Greg Bailly, Ricardo A. Rendon, Robert Mann, Joseph G. Lawen, David Bowes, Derek Wilke, et al.

International Journal of Mental Health and Addiction

ISSN 1557-1874

Int J Ment Health Addiction
DOI 10.1007/s11469-019-00108-y



Your article is protected by copyright and all rights are held exclusively by Springer Science+Business Media, LLC, part of Springer Nature. This e-offprint is for personal use only and shall not be self-archived in electronic repositories. If you wish to self-archive your article, please use the accepted manuscript version for posting on your own website. You may further deposit the accepted manuscript version in any repository, provided it is only made publicly available 12 months after official publication or later and provided acknowledgement is given to the original source of publication and a link is inserted to the published article on Springer's website. The link must be accompanied by the following text: "The final publication is available at link.springer.com".



Development and Initial Evaluation of a Multifaceted Intervention to Improve Mental Health and Quality of Life Among Prostate Cancer Survivors

Gabriela Ilie^{1,2,3,4}  · Ross Mason² · David Bell² · Greg Bailly² · Ricardo A. Rendon² · Robert Mann^{5,6} · Joseph G. Lawen² · David Bowes⁴ · Derek Wilke⁴ · Nikhilesh Patil⁴ · Robert D. H. Rutledge⁴

Published online: 03 July 2019

© Springer Science+Business Media, LLC, part of Springer Nature 2019

Abstract

Mental health issues affect a third of prostate cancer (PCa) survivors. Here, we describe the development and preliminary evaluation of a unique multifaceted intervention, the Prostate Cancer–Patient Empowerment Program (PC-PEP), designed to improve mental health and quality of life among survivors. The 28-day pilot PC-PEP Intervention was developed following the engagement of patients, survivors, caregivers and health care professionals in identifying survivorship needs and well-being resources for improved mental health. The pilot intervention was implemented with a group of 30 PCa survivors in Halifax, Canada. Measures collected over the 28-day program included psychological distress and physical health indicators, as well as program compliance. Participation in PC-PEP resulted in significant improvement in measures of mental and physical health over the 28-day program. Very good to excellent compliance with all five components of PC-PEP was observed. This evaluation provides strong initial support for a multifaceted program to improve mental health outcomes in prostate cancer survivors.

Keywords Prostate cancer · Survivorship · Mental health · Fitness · Patient education and empowerment program

Prostate cancer is the most common cancer malignancy affecting Canadian men with more than 21,300 new cases each year (Canadian Cancer Statistics 2017). Prostate cancer accounts for about one-fifth (21%) of all new cancer cases in men and remains the third leading cause of cancer death (behind lung and colorectal cancers) in men in Canada (Ellison 2016). By 2036, because of the aging trend in our population and an expected doubling in the number of adults over 65, the incidence of prostate cancer cases is also expected to double (Statistics Canada 2010). Advances in detection, diagnosis, and effective active forms of treatment have

✉ Gabriela Ilie
Gabriela.Ilie@dal.ca

improved our ability to customize recommendations based on the stage of the disease, prognosis, and patient preferences (Litwin and Tan 2017) leading to defining PCa as a long-term condition. Survival rates for early-stage prostate cancer 10 years after diagnosis are as high as 99%, regardless of whether men undergo surgery, radiation, or are actively monitored (Hamdy et al. 2016), but are often accompanied by compounding short- and long-term side effects (e.g., especially issues related to urinary, bowel, sexual function) (Donovan et al. 2016). Less focus, however, has been placed on trying to understand the mental health implications of the PCa diagnosis and treatments.

Recent reviews of the literature reveal that prevalence of depression and anxiety in men with prostate cancer, across the treatment spectrum, is about 1 in 6 for depression and 1 in 5 for anxiety (Fervaha et al. 2019; Watts et al. 2014), that is three times higher than in the general population (Linden et al. 2012). Past-year prevalence rates for depression in the general population are 5% and 7%, respectively (Pitman et al. 2018), and 9% for depression and 6% for anxiety, for men over 65 (Watts et al. 2014). Pre-treatment prevalence rates of depression and anxiety among men diagnosed with PCa are 17% and 27%, respectively, while among cancer patients they are 20% and 10%, respectively (Pitman et al. 2018). However, unlike other forms of cancer where rates of depression 5 years following diagnosis tend to decrease around 4%, and become more comparable with those of the broader public (Boyes et al. 2009), the prevalence of depression among PCa survivors 5-years post-treatment is considerably higher, at 22%, (Korfage et al. 2006; Ravi et al. 2014; Sharpley et al. 2008). Interestingly, anxiety is found to be less prevalent in older patients compared with younger patients, while the reverse is observed for depression (Nelson et al. 2009). This is not surprising as this is a trend that is also observed among older men without the diagnosis (Korfage et al. 2006; Llorente et al. 2005). However, much remains to be learned about the needs of prostate cancer survivors during their cancer journey and how these needs impact mental health, and little is being done to address mental health issues among PCa survivorship.

Yet, poor mental health among PCa survivors is associated with poor oncological outcomes and mortality, as well as poor sexual health, intimacy, and desire for connection (Bhojani et al. 2008; DiMatteo et al. 2000; Jayadevappa et al. 2012). These adverse health associations are just as detrimental as they are when observed among cardiovascular disease and diabetes patients (Bhojani et al. 2008). As incidence of PCa will likely increase in the years to come, compounded by increased limited health care resources for our aging population, it is essential to identify effective survivorship interventions to alleviate the burden of mental health issues among PCa survivors and their families.

In a comprehensive online quality-of-life survey which we conducted between May 2017 and March 2018, involving 154 PCa survivors from Nova Scotia, New Brunswick, and Prince Edward Island, we found that a high percentage of survivors reported mental health problems, urinary symptoms, intimacy concerns, isolation, insomnia, and many other health concerns (Ilie 2018). However, fewer than 20% reported having ever attended a prostate cancer support group (Ilie 2018), consistent with other Canadian data (Chahine and Urquhart 2019; King et al. 2015; McLeod et al. 2014; Oliffe et al. 2015). In April 2018, we convened a Maritime-wide prostate cancer integrative care conference in Halifax, attended by patients, survivors, caregivers, and health care professionals, and based on these discussions, clinical experience and a comprehensive review of the scientific evidence, we developed the Prostate Cancer–Patient Empowerment Program (PC-PEP), a comprehensive patient empowerment program aimed at educating and teaching the men life skills/habits to improve their mental health, fitness levels, and overall

quality of life, and to decrease treatment-related side effects. The program encouraged changes in four lifestyle areas: stress reduction through meditation and mindfulness; intimacy and connection exercises; strength, aerobic, and pelvic floor exercises; and social connection. Here, we describe the implementation and initial evaluation of the PC-PEP.

Methods

Thirty men with a history of non-metastatic prostate cancer participated in the initial PC-PEP which was offered from January 12 to February 10, 2019 in Halifax, Nova Scotia. Inclusion criteria consisted of having a history of PCa diagnosis in the past or currently, non-metastatic PCa, speaking English, having access to an email address and a cell phone that can receive texts, and being able to come to Halifax for three visits. The program was advertised through posters placed in the Urology and Radiation Oncology Clinics at Queen Elizabeth II Health Sciences Centre, Halifax, and through prostate cancer support groups. Participants were first screened by a physician to assess whether they were fit and safe to enroll in the program. Men enrolled in the program came to Dalhousie University for three visits. Prior to the first visit (pre-intervention) and on the last visit (post-intervention) participants took an online survey assessing mental health, in addition to other physical and functional measures of quality of life. The first study visit took place between January 4 and January 10 and consisted in meeting with a physiologist who took physical measurements of the patients and made strength training and aerobic routine recommendations based on each participant's level of health and fitness. The second visit took place on January 11 and introduced the PC-PEP program and its components which we describe below. The third visit occurred on February 10. At that time, all participants also took the post-survey which assessed the same measures assessed at pre-test. Participants also completed a weekly compliance survey assessing physical and pelvic floor fitness, meditation, and intimacy and connection-prescribed exercises compliance. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients being included in the study. No adverse events occurred during this study.

PC-PEP Description

The Mindfulness-based stress reduction component of PC-PEP consisted of a 1-h Mindfulness-based stress reduction session and meditation training provided by a trained psychologist and was supplemented by a 10-min video with instructions on how to perform meditation once a day for 10 min. The intimacy and connection component of PC-PEP consisted in a 1-h intimacy and connection training session by a psychology professor with experience in teaching healthy aging and intimacy that outlined various forms of intimacy and connection including physical (e.g., touch, kissing, caressing, hugging, sexual intercourse), emotional (e.g., sharing feelings, talking about your innermost thoughts, being emotionally vulnerable in front of your partner), intellectual (e.g., exchanging ideas and thoughts about things you think and care about, life, places you traveled, ideas that you have), recreational (e.g., being active together: hiking, biking, going to the movies, dancing), self (e.g., being aware of your own feelings, caring about those feelings, and sharing them with your partner) intimacy. The participants were

encouraged daily through a video message delivered via email to engage everyday in anyone of these aspects of intimacy, by, for example, calling an old friend “you haven’t called in a long time”. The inclusion of this component was based on a review of the literature that shows the importance of focusing attention onto the survivor’s relationships, particularly, close relationships with others, and engaging in communication behaviors aimed at sustaining or enhancing the relationship during stressful times (Manne and Badr 2008). The buddy system feature of PC-PEP consisted of assigning two buddies to each participant, which the participant was encouraged to call at least once a week and check on how adherence to the program was going and chat about any of the aspects of the program. Daily reminders for meditation and intimacy/connection exercises, as well as an overview of the activities for the next day (including reminders towards the end of the week to contact each other’s buddies), were sent via a 2-min video made available online to all participants.

The aerobic component of the program consisted in adherence to any form of aerobic exercise (e.g., biking, dancing, aerobic-class, ice-skating, tennis, swimming) 5 times a week for a minimum of 30 min. The physiologist made individualized aerobic exercise recommendations based on the individual level of health and fitness of each participant. The strength component of PC-PEP consisted of customized exercises using an elastic band (provided to participants for free) based on the level of health and physical fitness of the patient as assessed by a registered physiologist. The strength exercises were 10-min long and were assigned to be performed 3 times a day, two times a week (Tuesdays and Thursdays). The elastic band strength exercises were supplemented by a video exemplifying how the exercises should be performed based on different strength levels. The videos were made available online to all participants in the program and the links to the videos were sent to participants through email. Participants were given the choice between receiving text reminders on their phone during these days (morning 9 am, afternoon 2 pm, and evening, 6 pm) or setting up a free app which was specifically designed for PC-PEP on Android and iPhone to remind them. Together, between the strength and aerobic exercises, the exercise component of PC-PEP consisted of 150 min of moderate to strenuous physical activity a week, which is in line with the recommendations of the World Health Organization for healthy adults (Oja and Titze 2011; Piercy et al. 2018). The inclusion of the aerobic and strength components of PC-PEP was also based on several systematic reviews and meta-analyses which have suggested that exercise when adopted during and after treatment leads to better oncological and psychological outcomes (Campos et al. 2018; Hart et al. 2017; Santa Mina et al. 2014; Singh et al. 2017; Whittemore et al. 1995).

The pelvic floor component of PC-PEP consisted of a 1-h information and training session provided by a trained physiotherapist in pelvic floor exercises (January 11) and supplemented by an 8 min video (made available online to all participants) with instructions on how to perform the pelvic floor exercises three times a day (8 min each session). Reminders for the pelvic floor exercises (3 times a day: 9 am, 2 pm, 6 pm) were also either sent via text messaging or via the PC-PEP reminders app. In a recent systematic review looking at preoperative and postoperative pelvic floor muscle exercise, it was shown that preoperative exercises improved early (3 months but not 6 month) postoperative urinary incontinence following PCa surgery (Burgio et al. 2006). Overall pelvic floor programs have been shown to improve sexual function and urinary continence post-prostate surgery compared with “usual care” void of this training (Aydın Sayılan and Özbaş 2018; Burgio et al. 2006; Singh et al. 2017).

Measures

Our primary outcome was psychological distress as measured by the Kessler Psychological Distress scale (K10), a 10-item scale that measures symptoms of psychological distress, such as depression and anxiety, within the past 30 days (Andrews and Slade 2001). Scores ranged from 10 to 50, with scores between 20 and 24 indicating mild distress, between 25 and 29 indicating moderate distress, and 30 and above indicating severe distress. Having no indication of psychological distress was coded 0 (a score below 20), and screening positive for psychological distress was coded 1 (a score of 20 or greater). This screening instrument is employed by practitioners in making clinical judgments as to whether individuals need treatment for mental distress (Kessler et al. 2002). The K10 has been widely implemented and is considered one of the best tools for screening for internalizing disorders among adults (Enticott et al. 2018; Cairney et al. 2007; Sampasa-Kanyinga et al. 2018; Anderson et al. 2013).

Demographic measures obtained included education (secondary/some college or trade school; or university and higher), relationship status (married, living with partner, dating), employment status (working full or part time, retired, unemployed), time between diagnosis and survey, and level of physical activity prior at the time the participant was enrolled in the program (less than 30 min a week, 30 min up to 150 min a week, and 150 or more a week of moderate physical activity). Physical measurements of weight, height, and body mass index were taken at pre- and post-test by the physiologist.

Weekly compliance with the PC-PEP was monitored by recording the number of days, minutes per day, and intensity of engagement (for the strength and aerobic components only) in all aspects of the program (except the buddy aspect of the program). These were measured with a weekly self-report online survey. Adherence to the recommendation of calling each buddy at least once a week was assessed during the exit focus groups, and most participants (90%) reported in front of their buddies that they called their assigned buddies at least once a week. All 30 men completed the pre- and post-intervention assessments. No participants dropped out from the program.

PC-PEP Evaluation

At the end of the 28-day program, on February 10, participants were asked to rate their interest in the program overall, rate how important/beneficial PC-PEP would be, in their opinion, to be provided to patients from day 1 of diagnosis, the usefulness of the program to them personally, the usefulness of each of the program's components, the competency of the research team, and their likelihood to recommend such program to men who have been diagnosed with PCa on a Likert scale (0—not helpful at all to 10—extremely helpful).

Statistical Analysis

A McNemar test was used to assess differences in rates of psychological distress from pre- to post-intervention. Repeated measure ANOVA evaluated changes in weight from pre- to post-intervention as well as weekly average number of days, and minutes participants were compliant with the various aspects of the program. No missing values were present.

Table 1 Demographic characteristics of the group of men who participated in the PC-PEP feasibility study, *n* = 30

Age	Mean 68.93 years, Range 56–83 years old
Ethnicity	White/Caucasian: <i>n</i> = 28 (93.4%) Black/African: <i>n</i> = 1 (3.3%)
Education	Middle Eastern/Arab/Indian: <i>n</i> = 1 (3.3%) Secondary/some College or a trade school degree: <i>n</i> = 10 (33.3%) University: <i>n</i> = 20 (66.7%)
Relationship status	Married: <i>n</i> = 27 (90%) Living with a partner: <i>n</i> = 2 (6.7%) Dating: <i>n</i> = 1 (3.3%)
Employment status	Retired: <i>n</i> = 20 (66.7%) Unemployed: <i>n</i> = 1 (3.3%)
Household income	Part- or full-time employment: <i>n</i> = 9 (30%) Between 30K and 79K: <i>n</i> = 8 (26.7%) Between 80K and 100 K: <i>n</i> = 9 (30%) More than 100K = 12 (40%)
Time between diagnosis and survey	Prefer not to say: <i>n</i> = 1, (3.3%) Less than 7 months: <i>n</i> = 4 (14.4%) Between 7 and 12 months: <i>n</i> = 4 (12.3) Between 25 and 166 months: <i>n</i> = 22 (73.3)
Type of treatment for PCa	Active surveillance: <i>n</i> = 4 (13.4%) Radical prostatectomy: <i>n</i> = 10 (33.3%) Radiation (beam, brachy, or seed): <i>n</i> = 1 (3.3%) Androgen deprivation therapy: <i>n</i> = 2 (6.7%) Radiation and hormones: <i>n</i> = 5 (16.7%) Radical prostatectomy and hormones: <i>n</i> = 4 (13.3%) Radical prostatectomy, radiation, and hormones: <i>n</i> = 4 (13.3%)
Current level of physical activity at work or leisure	Not very active (less than 30 min of moderate aerobic or strength exercise a week): <i>n</i> = 10 (33.3%) Moderately active (30 min up to 150 min of moderate aerobic or strength exercise a week): <i>n</i> = 13 (43.3%) Very active (150 min or more of moderate aerobic or strength exercise a week): <i>n</i> = 7 (23.3%) No: <i>n</i> = 20 (66.7%) Yes: <i>n</i> = 10 (33.3%)
Current attendance to support groups	Pre-intervention: mean 91.5 kg, range 59–154 kg Post-intervention: mean 89.9 kg, range 59–152 kg
Weight (Pre and Post)*	Pre-intervention mean 29.5, range 20.40–49.20 Post-intervention mean 28.9, range 20.40–48.80
Body mass index*	

**p* < 0.05

Results

We report evaluation data on 30 participants who completed the program between January 11 and February 12, 2018. Demographic characteristics of the participants are presented in Table 1.

Program Compliance

Overall, the rates of compliance with the various aspects of the program were high. Average number of days, minutes per day, and intensity of engagement (for the strength and aerobic components only) in all aspects of the program are reported in Table 2. Compliance was consistent among the 4 weeks with little variation noted. Overall, participants engaged in an average of 4.11 days a week (5 days a week prescribed) for aerobic exercises, 2.77 days a week (2 days a week prescribed) for strength exercises, 5.33 days a week (7 days a week prescribed) for pelvic floor exercises, 5 days a week (7 days a week prescribed) for meditation, and 4 days a week (7 days a week prescribed) for intimacy and connection exercises. Participants reported that their strenuous level of working out for the aerobic and strength exercises was above the mid-point, 4.07 and 4.08 out of 7, respectively. With an average of 6.88 days a week participation in physical exercise (aerobic and strength), or an average of 198.13 min per week for aerobic and 81.80 min per week for strength exercises (279.93 min per week average total), the participants in this intervention had better than prescribed adherence to the physical exercise component of the program. The average number of days for strength exercises was statistically significantly higher in week 2 compared with week 4 showing a peak in engagement in week 2 compared with the last week of the program; however, this effect is not reflected in the average number of minutes participants were engaged in the activity for each of the 4 weeks, suggesting the time (4 weeks) effect on strength compliance measured by the participants' engagement in strength exercises measured as average number of days a week they engaged in this activity, may reflect participants' level of availability throughout the week to engage in the activity rather than an increase in the amount of time spent overall every week in the activity.

With an average of 5.33 days a week engagement in pelvic floor exercises, or 114.65 min a week (16.38 min a day for each week, on average; compared with 24 min a day prescribed), the participants had 68% compliance, on average, per week for the pelvic floor component of the program. Looking at the average number of minutes per day that participants engaged in pelvic floor exercises and the average number of minutes per week spent on this activity, we notice that although the participants' average number of days per week in which they engaged in the pelvic floor exercises was statistically significantly lower in week 4 compared with week 2, the overall number of minutes engaging in these exercises went up from week 1 to week 4 (marginal statistical significance for average number of minutes per day engaging in pelvic floor exercises), showing better adherence to this aspect of the program as time went by. We also note that by week 4, on average, participants had attained better than recommended adherence to the pelvic floor exercises per day (25.53 min a day), on average.

While participants only engaged in 5 days a week (7 days a week prescribed), on average, in mindful stress reduction meditation, we observed an increase (although not statistically significant) in the number of minutes spent per day, on average, in meditation between week 1 (9.90 min a day) and week 4 (14.80 min a day). On average, participants spent 66.23 min per

Table 2 Repeated measures ANOVA and applicable post hoc comparisons assessing weekly participants' compliance to PC-PEP (weeks 1 through 4), *n* = 30

Compliance measure	Average weeks 1–4 (SE)	Average week 1 (SE)	Average week 2 (SE)	Average week 3 (SE)	Average week 4 (SE)	<i>P</i>
Aerobic exercises						
N. of days/week engaging in aerobic exercises as prescribed by the physiologist	4.11 days (0.25)	4.23 days (0.26)	4.40 days (0.27)	4.07 days (0.28)	3.73 days (0.35)	0.57
Total min./day engaging in aerobic exercises	44.57 min (5.11)	42.83 min (6.18)	42.03 min (5.32)	50.80 min (9.15)	42.60 min (4.85)	0.45
Total min./week engaging in aerobic exercises	198.13 min (29.56)	192.17 min (34.79)	198.23 min (30.74)	218.83 min (47.45)	183.30 min (28.21)	0.61
Describe your exertion (how hard you worked out) on a scale from 0 (rest, no feeling of exertion) to 7 (very, very hard)—aerobic exercises	4.07 (0.15)	4.17 (0.19)	4.07 (0.15)	4.17 (0.13)	3.87 (0.20)	0.10
Strength exercises						
N. days/week engaging in strength exercises as prescribed by the physiologist	2.77 days (0.23)	2.83 days (0.27)	3.13* days (0.27)	2.70 days (0.26)	2.40* days (0.31)	0.04
Total min./day engaging in strength exercises	29.42 min (2.17)	30.83 min (2.45)	30.20 min (2.91)	28.52 min (2.31)	28.12 min (2.54)	0.51
Total min./week engaging in strength exercises	81.80 min (9.00)	85.00 min (10.50)	92.43 min (11.75)	80.28 min (11.16)	69.47 min (9.71)	0.14
Describe your exertion (how hard you worked out) on a scale from 0 (rest, no feeling of exertion) to 7 (very, very hard)	4.08 (0.09)	4.00 (0.08)	4.10 (0.54)	4.20 (0.07)	4.00 (0.16)	0.38
Pelvic floor exercises						
N. days/week engaging in pelvic floor exercises as prescribed by the physiotherapist	5.33 days (0.33)	5.43 days (0.32)	5.57* days (0.31)	5.43 days (0.39)	4.87* days (0.40)	0.02
Total min./day engaging in pelvic floor exercises	19.81 min (2.09)	16.93 min (1.67)	18.61 min (1.67)	18.17 min (2.28)	25.53 min (4.36)	0.05
Total min./week engaging in pelvic floor exercises	114.65 min (15.74)	97.00 min (12.21)	110.90 min (12.94)	108.67 min (17.86)	142.03 min (28.63)	0.12
N. days/week engaging in meditation as prescribed by the psychotherapist	5.00 days (0.34)	5.27 days (0.35)	5.10 days (0.39)	4.83 days (0.41)	4.83 days (0.43)	0.46
Meditation						
Total min./day spend meditating	12.32 min (1.68)	9.90 min (1.16)	10.06 min (1.16)	14.50 min (2.92)	14.80 min (2.76)	0.08
Total min./week spend meditating	66.23 min (11.64)	52.23 min (5.65)	55.30 min (7.34)	76.93 min (18.99)	80.43 min (18.26)	0.11
Intimacy and connection exercises						
N. days/week practiced emotional intimacy	4.05 days (0.38)	4.00 days (0.44)	4.03 days (0.43)	4.23 days (0.44)	3.93 days (0.40)	0.78
N. days/week practiced intellectual intimacy	4.43 days (0.31)	4.53 days (0.36)	4.27 days (0.36)	4.63 days (0.35)	4.27 days (0.37)	0.48
N. days/week practiced physical intimacy	4.84 days (0.40)	5.03 days (0.43)	5.00 days (0.39)	4.77 days (0.46)	4.57 days (0.46)	0.34
N. days/week practiced recreational intimacy	3.09 days (0.25)	2.93 days (0.30)	3.33 days (0.32)	2.9 days (0.31)	3.20 days (0.32)	0.44
N. days/week practiced self-intimacy	3.45 days (0.36)	3.00 days (0.36)	3.50 days (0.46)	3.80 days (0.39)	3.50 days (0.40)	0.09
N. days/week practiced other types of intimacy	4.13 days (0.35)	4.67 days (0.44)	4.03 days (0.43)	3.83 days (0.47)	3.97 days (0.45)	0.26

**p* < 0.05

week meditating (70 min a week was the recommended amount), which is almost 95% average compliance per week.

Intimacy and connection compliance exceeded the recommended engagement in one type of intimacy event per day, as, instead, participants engaged in several forms of intimacy each day, with physical intimacy being the most practiced form of intimacy (average of 4.84 days a week) and recreational intimacy (average of 3.09 days a week) the least.

Mental Health Assessment

At pretest, 27% of participants screened positive for mild to severe psychological distress, and by post-test, this proportion had declined to 7%. The McNemar test revealed that this decline in the proportion reporting psychological distress was statistically significant, $p = 0.031$ (2 sided).

PC-PEP Evaluations

Post-test evaluations of the program indicated that participants' perception of the program were very positive. Overall, participants found the program to be very useful with average evaluations ranging from $M = 8.00$ to $M = 9.61$ (out of 10) for each aspect of the program. The participants' interest in the program was very high ($M = 8.89$). All aspects of the program were perceived as very (meditation and intimacy/connection training) to extremely useful (science behind PC-PEP, pelvic floor, and physical activity training). The meditation component of the program received the lowest rating ($M = 7.46$) compared with all other aspects of the program (ranging from $M = 8.00$ to 8.75). The overall average evaluation of the program was very high ($M = 9.61$, $SD = 0.57$). The usefulness of daily video messages reminding participants the schedule for the next day was perceived extremely high ($M = 9.15$, $SD = 1.75$). The competence of the research team and lead investigators was perceived similarly ($M = 9.79$). On average, participants indicated that their likelihood to recommend the program to someone who had a PCa diagnosis was extremely high ($M = 9.79$, $SD = 0.42$).

Conclusion

This paper describes the development and preliminary evaluation of a 70 min a day, 28-day PC-PEP intervention including mindful meditation stress reduction practice, intimacy and connection exercises, social support engagement, moderately intense physical exercise, and pelvic floor daily routines, in a volunteer sample of patients and survivors of PCa from Eastern Canada. Participants in the study, who showed very good to excellent compliance with all components of the program, were more fit and had less psychological distress post-intervention.

Previous studies have shown that providing psychological support to men with prostate cancer is critical to ensuring that those experiencing distress after treatment do not fall into a cycle of lack of social support, negative thinking and isolation behaviors, which can escalate symptoms and worsening mental health (Nelson et al. 2009; Sharpley et al. 2008, 2010). Our recent PCa survivors Canadian Maritimes online survey (Ilie 2018) showed that very few survivors had participated in a PCa support group or had drawn on ongoing support which is consistent with other reports of prostate cancer support group attendance practices (Chahine

and Urquhart 2019; King et al. 2015; McLeod et al. 2014; Oliffe et al. 2015). One reason for this may be lack of interest in the traditional support group by the survivors. However, our observations, while preliminary, suggest that there may be substantial interest in an intensive program reinforced by social support for PCa survivors. In our study, all 30 men completed the program and the compliance rates and satisfaction for all aspects of our program activities were very high.

Our results indicate statistically significant improvements in mental health outcomes, as well as significant weight loss and body mass index reduction from pre- to post-intervention assessment. Overall, the group reported better mental health and was more fit. Asked whether they would recommend this program for all new PCa patients, the men gave an average score of 9.8 out of 10. While the pelvic floor exercises had the lowest level of compliance, we note that performance and engagement in these exercises showed a trend of improvement from week 1 to week 4, leading to a level exceeding the recommendation by the end of the program.

Although the findings of this preliminary study are very encouraging, important limitations must be recognized. The group of participants was self-selected and may not be representative of the general population of PCa patients or survivors (mostly Caucasian, highly educated, married, and high household income). Our participants may have been highly self-motivated to change their life style, and therefore eager to engage in a program that had the potential to help them improve their quality of life (e.g., help urinary function, weight loss, feeling more connected to partners, friends, and family). Future studies may want to assess the role of self-motivation to changes in mental health outcomes following patient empowerment programs.

A related factor to motivation that may have been responsible for the high adherence to PC-PEP and improved mental health outcomes may have been participant's perceived level of empowerment during the program. Schulz and Nakamoto (2011) have defined patient empowerment as a motivational construct (with two dimensions: self-efficacy and health locus of control) and proposed that patients and survivors participate in decisions regarding their care as self-driven individuals who take increased responsibility for medical care decisions that directly affect their life. We are now seeing that patients are playing an increasingly important role in healthcare and clinical research (Fitzgibbon et al. 2014; Sacristán et al. 2016). Given that PC-PEP was an intervention that educated and empowered patients/survivors to lead life styles that are promoting good health and good quality of life, it is possible that the results we observed here may have been affected by the participants' perception of their own capacity for disease management and belief about how much control they have over their own health outcomes. Future studies should consider incorporating patient empowerment measures in their patient education and empowerment interventions and evaluate their contribution to the observed outcomes.

PC-PEP was built following three stages: (1) reviewing the literature and understanding which aspects of quality of life are affected by a PCa diagnosis and treatment(s) (top down evidence); (2) surveying the population of men with a history of PCa in the Canadian Maritimes provinces in order to understand what the needs of the patients are from their perspective bottom up evidence); (3) holding an annual conference in order to engage the patients, survivors and their partners, clinicians, residents, administrators, and researchers in deciding what type of patient education and empowerment program is needed, in light of the evidence, to address the multifaceted needs of PCa patients and survivors. Transparency, shared goals, accountability, and respect were essential principles that guided the patient and partner engagement and collaboration process (Pushparajah 2018). Thus, it can be said that

PC-PEP emerged from patients' engagement in this research and from a meaningful collaboration between patients, clinicians, researchers, and other stakeholders. Given that the PCa patients and survivors we engaged in this research were people who have actually lived with the PCa condition, they were able to share their personal experiences, concerns, and hopes with our research team during the patient engagement stage of program development. This information, in turn, informed the program and the study, making it more relevant to the participants in the study and the things that really matter to them, and may be responsible, at least in part for the results we obtained. It is not unusual for participants to self-select studies that are more relevant to their lives, needs, and experiences. For example, in a study assessing preference in diabetes research participation, researchers found that three quarters of individuals with diabetes in their sample reported that they would prefer participating in clinical trials that directly measure how the treatment can impact the onset of diabetes-related kidney failure or sight problems (things that actually mattered to diabetic patients), rather than just measuring the effect on their blood sugar levels (Sacristán et al. 2016). Thus, a randomized clinical trial is needed to assess the effectiveness of PC-PEP in reducing negative mental health outcomes associated with PCa diagnosis, treatment, and survivorship issues, in a rigorous methodological setting. An assessment of the clinical and cost effectiveness of PC-PEP is warranted, along with evaluation of a lengthier PC-PEP program. It is possible that attrition and noncompliance rates may be higher in a longer program. Another limitation of the feasibility study is the lack of formal weekly compliance assessment of the social support component of the program (the "buddy" system). Future studies should attempt to measure the compliance to this aspect of the program.

Nonetheless, this feasibility study was able to demonstrate that PCa survivors are likely to enroll in a multidimensional well-being program aimed at improving mental health. The multifaceted aspect of the program along with the critical social component element (buddy system) seemed important to the retention of participants for the duration of the program, as expressed by participants during the exit focus groups.

The goals of PC-PEP were built on three principles: (1) wanting to address the specific needs of survivors at risk of mental health distress (e.g., urinary incontinence, feeling disconnected); (2) aiming to produce a multidimensional intervention that addresses the needs of patients and survivors as identified by them; (3) facilitating social connection among participants to maximize program compliance. This same approach may be used for other types of cancer survivorship in the development of their patient education and empowerment programs. With PC-PEP, we have demonstrated a structure through which a program of this type could be administered and also demonstrated important short-term beneficial effects on mental health and quality-of-life measures. The program was strongly endorsed by participants and has the potential to positively affect the mental health and well-being of men at various stages of their prostate cancer journey. Further evaluation of the PC-PEP is needed, and a randomized clinical trial assessing the program is in preparation. We believe the patients and survivors' involvement in this type of research can make clinical studies more valuable and more relevant to the lives of the people who are ultimately meant to benefit from them.

Acknowledgements We gratefully acknowledge all the men who participated in the study, Halifax Prostate Cancer Support Group, the Urology Department at QEII (special thanks to Liette Connor, Susan Marsh and Emmi Champion), and Prostate Cancer Canada-Nova Scotia site for their help in disseminating the recruitment poster for PC-PEP to support groups; Helen Wong, research coordinator, students, and medical residents volunteers who helped collect the data: Brooklyn Lyons, Lauren Boyce, Louise Moodie, Chloe Blackman,

Amy Prescott, Cody McDonald, Hanna Dahn, and others; Jeff Zahavich, the study's physiologist, and Erika Burger, the study's physiotherapist.

Funding This research was supported by the Dalhousie Medical Research Foundation, through the Soillse Research Fund. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Compliance with Ethical Standards

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients being included in the study. **Conflict of Interest** The authors declare that they have no conflict of interest.

References

- Anderson, T. M., Sunderland, M., Andrews, G., Titov, N., Dear, B. F., & Sachdev, P. S. (2013). The 10-item Kessler psychological distress scale (K10) as a screening instrument in older individuals. *The American Journal of Geriatric Psychiatry*, *21*(7), 596–606.
- Andrews, G., & Slade, T. (2001). Interpreting scores on the Kessler psychological distress scale (K10). *Australian and New Zealand Journal of Public Health*, *25*, 494–497.
- Aydin Sayilan, A., & Özbaş, A. (2018). The effect of pelvic floor muscle training on incontinence problems after radical prostatectomy. *American Journal of Men's Health*, *12*(4), 1007–1015.
- Bhojani, N., Perrotte, P., Jeldres, C., Suardi, N., Hutterer, G., Shariat, S. F., & Karakiewicz, P. I. (2008). The effect of comorbidities and socioeconomic status on sexual and urinary function in men undergoing prostate cancer screening. *Journal of Sex Medicine*, *5*(9), 668–676.
- Boyes, A. W., Girgis, A., Zucca, A. C., & Lecathelinais, C. (2009). Anxiety and depression among long-term survivors of cancer in Australia: results of a population-based survey. *The Medical Journal Australia*, *190*, S94–S98.
- Burgio, K. L., Goode, P. S., Urban, D. A., Umlauf, M. G., Laucher, J. L., Bueschen, A., & Redden, D. T. (2006). Preoperative biofeedback assisted behavioral training to decrease post-prostatectomy incontinence: a randomized, controlled trial. *Journal of Urology*, *175*(1), 196–201.
- Cairney, J., Veldhuizen, S., Wade, T. J., Kurdyak, P., & Streiner, D. L. (2007). Evaluation of 2 measures of psychological distress as screeners for depression in the general population. *Canadian Journal of Psychiatry*, *52*, 111–120.
- Campos, C., Sotomayor, P., Jerez, D., González, J., Schmidt, C. B., Schmidt, K., ... Godoy, A. (2018). Review: exercise and prostate cancer: from basic science to clinical applications. *Prostate*, *78*, 639–645.
- Canadian Cancer Society's Advisory Committee on Cancer Statistics. (2017). *Canadian cancer statistics 2017*. Toronto: Canadian Cancer Society.
- Chahine, S., & Urquhart, R. (2019). A cross-sectional population-based survey looking at the impact of cancer survivorship care plans on meeting the needs of cancer survivors in the posttreatment stage. *Support Care Cancer* advance online publication. <https://doi.org/10.1007/s00520-019-04685-5>.
- DiMatteo, M. R., Lepper, H. S., & Crogham, T. W. (2000). Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. *Archives of Internal Medicine*, *160*, 2101–2107.
- Donovan, J. L., Hamdy, F., Lane, J. A., Mason, M., Metcalfe, C., Walsh, E., ... Neal, D.E. (2016). Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer. *The New England Journal of Medicine*, *375*(15), 1425–1437.
- Ellison, L. (2016). Prostate cancer trends in Canada, 1995 to 2012. *Health at a Glance*. Statistics Canada Catalogue no. 82-624-X.
- Enticott, J. C., Lin, E., Shawyer, F., Russell, G., Inder, B., Patten, S., & Meadows, G. (2018). Prevalence of psychological distress: how do Australia and Canada compare? *Australian & New Zealand Journal of Psychiatry*, *52*(3), 227–238.
- Fervaha, G., Izard, J. P., Tripp, D. A., Rajan, S., Leong, D. P., & Siemens, D. R. (2019). Depression and prostate cancer: a focused review for the clinician. *Urologic Oncology*, *37*(4), 282–288.
- Fitzgibbon, J., Baillie, J., Simon, N., & Nelson, A. (2014). The role of the public in developing interventions: a reflection and critique of a cancer clinical trials unit's model. *Patients Prefer Adherence*, *8*, 1527–1535.

- Hamdy, F. C., Donovan, J. L., Lane, J. A., Mason, M., Metcalfe, C., Holding, P., ... Neal, D. E. (2016) 10-year outcomes after monitoring, surgery, or radiotherapy for localized prostate cancer. *New England Journal of Medicine*, 375(15), 1415–1424.
- Hart, N. H., Galvão, D. A., & Newton, R. U. (2017). Exercise medicine for advanced prostate cancer. *Current Opinion in Supportive and Palliative Care*, 11(3), 247–257.
- Ilie, (2018). A prostate cancer quality of life pilot project testing the feasibility of PROs data collection using an on-line survey infrastructure throughout the Maritimes. Interim Report, April 2018. Soillse scientist research working document series no.1/ April 2018, Halifax, Canada.
- Jayadevappa, R., Malkowicz, S. B., Chhatre, S., Johnson, J. C., & Gallo, J. J. (2012). The burden of depression in prostate cancer. *Psycho-Oncology*, 21(12), 1338–1345.
- Kessler, R. C., Andrews, G., Colpe, L. J., Hiripi, E., Mroczek D. K., Normand, S. L., ... Zaslavsky, A. M. (2002) Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological Medicine*, 32, 959–956.
- King, A. J., Evans, M., Moore, T. H., Paterson, C., Sharp, D., & Huntley, A. L. (2015). Prostate cancer and supportive care: a systematic review and qualitative synthesis of men's experiences and unmet needs. *European Journal of Cancer Care*, 24(5), 618–634.
- Korfage, I. J., Essink-Bot, M. L., Janssens, A. C., Schroder, F. H., & de Koning, H. J. (2006). Anxiety and depression after prostate cancer diagnosis and treatment: 5-year follow-up. *British Journal of Cancer*, 94, 1093–1108.
- Linden, W., Vodermaier, A., Mackenzie, R., & Greig, D. (2012). Anxiety and depression after cancer diagnosis: prevalence rates by cancer type, gender, and age. *Journal of Affective Disorders*, 141, 343–351.
- Litwin, M. S., & Tan, H. (2017). The diagnosis and treatment of prostate Cancer: a review. *Journal of American Medical Association*, 317(24), 2532–2542.
- Llorente, M. D., Burke, M., Gregory, G. R., Bosworth, H. B., Grambow, S. C., Horner, R. D., et al. (2005). Prostate cancer: a significant risk factor for late-life suicide. *American Journal of Geriatric Psychiatry*, 13, 195–201.
- Manne, S., & Badr, H. (2008). Intimacy and relationship processes in couples' psychosocial adaptation to cancer. *Cancer*, 112(11 Suppl), 2541–2555.
- McLeod, D. L., Walker, L. M., Wassersug, R. J., Matthew, A., & Robinson, J. W. (2014). The sexual and other supportive care needs of Canadian prostate cancer patients and their partners: defining the problem and developing interventions. *Canadian Oncology Nursing Journal*, 24(4), 272–278.
- Nelson, C. J., Weinberger, M. I., Balk, E., Holland, J., Breitbart, W., & Roth, A. J. (2009). The chronology of distress, anxiety, and depression in older prostate cancer patients. *Oncologist*, 14, 891–899.
- Oja, P., & Titze, S. (2011). Physical activity recommendations for public health: development and policy context. *The EPMA Journal*, 2(3), 253–259.
- Oliffe, J. L., Chambers, S., Garrett, B., Bottorff, J. L., McKenzie, M., Han, C. S., & Ogrodniczuk, J. S. (2015). Prostate cancer support groups: Canada-based specialists' perspectives. *American Journal of Mens Health*, 9(2), 163–172.
- Piercy, K. L., Troiano, R. P., Ballard, R. M., Carlson, S. A., Fulton, J. E., Galuska, D. A., ... Olson, R. D. (2018) The physical activity guidelines for Americans. *Journal of American Medical Association*, 320(19), 2020–2028.
- Pitman, A., Sahil, S., Hyde, N., & Hodgkiss, A. (2018). Depression and anxiety in patients with cancer. *The British Medical Journal*, 361, k1415.
- Pushparajah, D. S. (2018). Making patient engagement a reality. *The Patient – Patient Centered Outcomes Research*, 11(1), 1–8.
- Ravi, P., Karakiewicz, P. I., Roghmann, F., Gandaglia, G., Choueiri, T. K., Menon, M., ... Trinh, Q. D. (2014) Mental health outcomes in elderly men with prostate cancer. *Urologic Oncology*, 32(8):1333–40. doi: <https://doi.org/10.1016/j.urolonc.2014.05.005>.
- Sacristán, J. A., Aguarón, A., Avendaño-Solá, C., Garrido, P., Gutiérrez, A., Kroes, R., & Flores, A. (2016). Patient involvement in clinical research: why, when, and how. *Patient Preference and Adherence*, 10, 631–640.
- Sampasa-Kanyinga, H., Zamorski, M. A., & Colman, I. (2018). The psychometric properties of the 10-item Kessler Psychological Distress Scale (K10) in Canadian military personnel. *PLoS One*, 13(4), e0196562.
- Santa Mina, D., Matthew, A. G., Hilton, W. J., Au, D., Awasthi, R., Alibhai, S. M., ... Carlum F. (2014) Prehabilitation for men undergoing radical prostatectomy: a multi-centre, pilot randomized controlled trial. *BMC Surgery*, 14, 89.
- Schulz, P. J. & Nakamoto, K. (2011). “Bad” literacy, the Internet, and the Limits of Patient Empowerment. AAAI Spring Symposium: AI and Health Communication.
- Sharpley, C. F., Bitsika, V., & Christie, D. H. (2008). Psychological distress among prostate cancer patients: fact or fiction? *Clinical Medical Oncology*, 2, 563–752.
- Sharpley, C. F., Bitsika, V., & Christie, D. R. (2010). Incidence and nature of anxiety-depression comorbidity in prostate cancer patients. *Journal of Men's Health*, 7(2), 125–134.

- Singh, F., Newton, R. U., Baker, M. K., Spry, N. A., Taaffe, D. R., Thavaseelan, J., & Galvao, D. A. (2017). Feasibility of presurgical exercise in men with prostate cancer undergoing prostatectomy. *Integrative Cancer Therapy*, *16*(3), 290–299.
- Statistics Canada (2010). *Population projections for Canada. Provinces and Territories 2000–2036*. Statistics Canada catalogue no. 91–520-X, p. 16.
- Watts, S., Leydon, G., Birch, B., Prescott, P., Lai, L., Eardley, S., & Lewith, G. (2014). Depression and anxiety in prostate cancer: a systematic review and meta-analysis of prevalence rates. *The British Medical Journal Open*, *13*(4), e003901.
- Whittemore, A. S., Kolonel, L. N., Wu, A. H., John, E. M., Gallagher, R. P., Howe, G. R., ... Paffenbarger, R. S. Jr. (1995). Prostate Cancer in relation to diet, physical activity, and body size in blacks, whites, and Asians in the United States and Canada. *Journal of National Cancer Institute*, *87*, 652–661.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Affiliations

Gabriela Ilie^{1,2,3,4} · Ross Mason² · David Bell² · Greg Bailly² · Ricardo A. Rendon² · Robert Mann^{5,6} · Joseph G. Lawen² · David Bowes⁴ · Derek Wilke⁴ · Nikhilesh Patil⁴ · Robert D. H. Rutledge⁴

¹ Department of Community Health and Epidemiology, Faculty of Medicine, Dalhousie University, Halifax, Canada

² Department of Urology, Faculty of Medicine, Dalhousie University, Halifax, Canada

³ Department of Psychology and Neuroscience, Dalhousie University, Halifax, Canada

⁴ Department of Radiation Oncology, Faculty of Medicine, Dalhousie University, Halifax, Canada

⁵ Institute for Mental Health Policy Research, Centre for Addiction and Mental Health, Toronto, Canada

⁶ Dalla Lana School of Public Health, University of Toronto, Toronto, Canada