


An Educational Program to Help Patients Manage Androgen Deprivation Therapy Side Effects: Feasibility, Acceptability, and Preliminary Outcomes

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Abstract

Androgen deprivation therapy (ADT), a common treatment for prostate cancer, is associated with physical, psychological, and sexual side effects that reduce patients' quality of life. The authors designed an educational program to prepare patients for managing these side effects. This paper describes an implementation model for national dissemination of the program, testing its feasibility and acceptability at the institutional and patient level. Postprogram changes in patients' self-efficacy to manage side effects and side effect bother are also explored. Patients on or anticipating ADT enrolled in the educational program. Pre and post intervention questionnaires measured patient satisfaction with the program, side effect bother, and self-efficacy to manage ADT side effects. The ADT Educational Program was deemed feasible and acceptable. Five of six targeted sites successfully launched the program with sufficient patient enrolment. Patient attendees were highly satisfied. Self-efficacy, bother, and use of management strategies were interrelated. Lower bother was associated with increased self-efficacy and more use of management strategies, and increased bother was associated with lower self-efficacy and less use of management strategies. Based on pre–post scores, improvements in patients' self-efficacy to manage ADT side effects were also observed. Results demonstrate that this brief educational program is feasible and acceptable to patients and cancer care institutions. The program appears to promote self-efficacy and the uptake of ADT management strategies for ADT side effects. The results of this study support the program implementation and suggest that improvements in self-efficacy after program participation may help patients adapt to ADT side effects.

Keywords

androgen deprivation therapy, prostate cancer, patient education, side effects management, self-efficacy, side effect bother

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Prostate cancer (PCa) is one of the most common cancers diagnosed in men worldwide. Incidence rates are 174,650 new cases per year in the United States and 21,300 in Canada (Canadian Cancer Society's Advisory Committee on Cancer Statistics, 2017; Siegel et al., 2019). Approximately 40% of American prostate cancer patients will be treated with androgen deprivation therapy (ADT) at some point in their disease trajectory (Cooperberg, Grossfeld, et al., 2003; Liede et al., 2016; Meng et al., 2002). ADT is used to reduce testosterone to castrate levels in order to effectively manage prostate cancer growth

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when the disease is locally advanced or metastatic. ADT is also commonly used as an adjuvant treatment to radiotherapy for localized prostate cancer in order to improve the efficacy of radiotherapy. ADT is most commonly administered in the form of a luteinizing hormone releasing hormone agonist or antagonists (delivered via depot injection). These drugs have similar side effects profiles.

ADT has numerous adverse effects that lower patients' quality of life (QOL; Casey et al., 2012; Downing et al., 2019; Skolarus et al., 2014; Tzortzis et al., 2017; Walker & Robinson, 2011). Common side effects include fatigue, hot flashes, and increased risk of metabolic syndrome sarcopenic obesity and osteoporosis (Downing et al., 2019; Elliott et al., 2010). Psychologically, ADT has been associated with increased depression, emotional lability, and cognitive decline (Dinh et al., 2016; Treanor et al., 2017). Erectile dysfunction (ED) and loss of sexual desire are also common and affect both patients and their partners (Casey et al., 2012; Walker & Robinson, 2011; Wibowo et al., 2019).

High levels of symptom bother are associated with ADT side effects; however side effect intensity and bother may be independent of each other. For example, some men may experience ED but are not bothered by it (Benedict et al., 2014; Cooperberg, Koppie, et al., 2003; Kimura et al., 2013; Reeve et al., 2006). Conversely, men with only mild symptoms might be highly bothered by them. The independence of bother and side effect occurrence is likely true for other ADT side effects (e.g., hot flashes, fatigue). Helping patients cope with side effect bother may be as important as reducing the side effects themselves for improving patient QOL.

Despite the negative impact on patient QOL, there have been few programs in North America aimed at preparing patients for ADT. Patients may be warned by their prescribing physician of the most frequent ADT side effects, but information on how to manage those side effects is often lacking. The authors' research has demonstrated that patients (and partners) have poor understanding of the breadth of ADT side effects (Walker et al., 2013) and thus they are limited in their ability to take timely and appropriate action to reduce the adverse impact. Furthermore, providing information alone is often not enough to promote effective behavior change (Kelly & Barker, 2016). Behavioral change is influenced by a myriad of factors, such as motivation, skill, perceived ability, social influence, and behavioral regulation (Michie et al., 2005). These factors need to be considered when designing an intervention to help ADT patients make the behavioral changes required to reduce their side effect burden.

Closely related to having the perceived skill and ability to successfully make behavior changes is the concept of self-efficacy. Research demonstrates that a higher sense of self-efficacy to control symptoms is directly

related to greater QOL (Campbell et al., 2004; Eton et al., 2001; Kershaw et al., 2008). Self-efficacy refers to people's belief that they can "successfully execute the behaviors required to produce outcomes" (Bandura, 1986, p. 193). Psychoeducational interventions in oncology (Lev, 1997), and more specifically within PCa, have been demonstrated to be effective in increasing self-efficacy for both patients' and partners' perceived ability to manage side effects (Weber et al., 2004, 2007). Patients who report higher self-efficacy to cope with cancer and its treatment show better adjustment and QOL than patients with lower self-efficacy (Merluzzi et al., 2018). Interventions that enhance self-efficacy may reduce side effect bother for patients when side effects are otherwise unavoidable.

To the authors' knowledge, their research team is the first in the United States and Canada to design an educational intervention specifically designed to help patients manage ADT side effects. Moving beyond just providing information, this program introduces evidence-based behavior change tools, and aims to improve patients' self-efficacy to implement various strategies to manage the side effects of ADT. The program involves a 1.5 h class and reading the book: "Androgen Deprivation Therapy: An Essential Guide for Men with Prostate Cancer and their Loved Ones" (herein called the "ADT Book") (Wassersug et al., 2014). Originally, published in 2014, the first edition is also available in French (Wassersug, Walker, et al., 2017). A second edition of the English version was published in 2018 (Wassersug et al., 2018). The book presents all known side effects of ADT along with evidence-based management strategies to address those effects (Wibowo et al., 2019), and methods to promote successful uptake of those strategies. With careful consideration of the aforementioned behavioral change influences (Michie et al., 2005), the following are directly addressed in this program: (a) motivation (e.g. through the use of motivational interviewing and values clarification activities), (b) skill and perceived ability (e.g. by teaching specific management strategies and addressing barriers to access them), (c) behavior regulation (e.g. introducing strategies for stress and mood management), and (d) social influence (via the group setting and encouraging partner/loved one participation).

The authors tested an earlier version of this book combined with a one-on-one educational session with patients (and partners) in two Canadian cities (Walker et al., 2013). That study established that the program was effective in helping couples maintain sexual intimacy, which was the primary focus of that study. The current study assessed a group-based version of the program and tested a national implementation model examining feasibility and acceptability. Rather than focusing on sexual outcomes as the earlier version did, this study examined outcomes related to broader range of treatment side effects.

This study presents the results of the implementation of the ADT Educational Program on a national level. More specifically, the study examines the feasibility and acceptability of the ADT Educational Program and also changes in patients' self-efficacy to manage side effects and side effect bother after participation in the program. The objectives were to:

1. Examine the feasibility of implementing the ADT Educational Program at the institutional level. This goal included identifying sites willing to implement the program, training program Facilitators within sites, and establishing adequate enrollment of patients into the program. Part of the goal was to determine the characteristics of patients who enrolled in the program, with an aim of getting patients to enroll as close to when they started ADT as possible. Success in implementing the program was also assessed, to gain insights about sustaining the program after the project funding ended.
2. Examine the acceptability of the ADT Educational Program by assessing patient satisfaction. Patient satisfaction outcomes are the following: overall satisfaction with the program, whether patients found any element of the program distressing, whether they would recommend the program to other patients, and whether they found the duration and timing of the program adequate.
3. Explore changes in self-efficacy to manage ADT side effects and side effect bother, after participation in the ADT Educational Program using pre-post questionnaires.
4. Examine predictors of self-efficacy to manage side effects and side effect bother.

Consistent with Objectives 1 and 2, the goal was to engage six target sites in six Canadian cities, and to find and train at least one program facilitator at each site. If/when this was achieved, the authors sought to establish referral pathways effective at enrolling a sufficient number of participants (i.e., five–eight patients plus their partners) to warrant at least monthly or bimonthly classes. The research team further hoped to determine the demographic characteristics of patients who enrolled in the program (e.g., age, duration of ADT at the time of enrollment). It was anticipated that patients would: (a) be satisfied with the program; (b) not report being distressed by participating in the program; (c) recommend the program to others; and (d) find the duration and timing of the program to be appropriate.

Consistent with Objectives 3 and 4, the authors predicted that self-efficacy would increase after participation in the ADT Educational Program. Also, side effect bother

was anticipated to increase between baseline and follow-up given that the majority of patients were expected to have recently initiated ADT. The authors further predicted that higher self-efficacy and greater use of management strategies would be associated with lower side effect bother. Other predictors of ADT side effect bother and self-efficacy were assessed, including side effect occurrence and the influence of patient age.

Method

Participants

Site Participants. Six sites were invited to participate in the study. From west to east, these included the Island Prostate Centre (Victoria), the Vancouver Prostate Centre (Vancouver), the Prostate Cancer Centre (Calgary), Princess Margaret Cancer Centre (Toronto), PROCURE (a Montreal based prostate cancer organization), and the Queen Elizabeth II Health Sciences Centre (Halifax).

Patient Participants. Patients who attended the ADT Educational Program between 2014 and 2017 in four Canadian cities (i.e. Vancouver, Calgary, Toronto, and Halifax) were invited to complete questionnaires before and after attending. Eligibility criteria included English fluency and a plan to be on ADT for at least 6 months. Patients could be on short-term ADT (neoadjuvant or adjuvant to radiotherapy) or on long-term ADT to manage systemic disease. Exclusion criteria included symptomatic metastatic disease (as determined by a skeletal-related event) and an expected ADT duration of <6 months.

Given that the main goal of this study was to examine changes in self-efficacy between baseline and follow-up, a power analysis for a multivariate analysis of variance (MANOVA) with one group and two measurements (baseline and follow-up), with a moderate effect size ($f = .20$), a correlation among measures of .50, power = .80, and $\alpha = .05$ gave an estimated total sample size of 52 participants (Faul et al., 2007).

A total of 120 participants enrolled in the study. From these, five statistical outliers were eliminated: two were on ADT for >2 years, one returned his follow-up questionnaire too late, one was excluded due to advanced age (89 years), and one had significant health comorbidities. Among the 115 participants, 21 did not complete follow up. Participants who did complete follow-up ($n = 94$) and those who did not ($n = 21$) were compared on age, time on ADT at baseline, number of previous cancer treatments, number of comorbidities, number of management strategies used, self-efficacy, and bother scores using non-parametric (Mann–Whitney U) tests with a Bonferroni correction ($\alpha = .003$) to protect against inflated Type I error. Results showed no significant differences between

completers and noncompleters on any of the variables tested at baseline. Participants who did not complete follow-up were excluded from further analyses.

The final sample consisted of 94 men, who completed the survey at baseline (Pre) and follow-up (Post) with an average time gap of 81.5 days ($SD = 22.57$, range = 52–158). At baseline, the men had been on ADT for an average of 89 days ($SD = 138$, range = 0–730). The majority were Caucasian ($n = 79$, 84.9%), partnered ($n = 77$, 81.9%), and retired ($n = 65$, 69.1%). Average age was 68 years (range = 48–85, $SD = 7.7$).

Materials and Measures

ADT Educational Program Description. The ADT Educational Program is designed to support patients who are on, or are starting on ADT. Participation involves reading the ADT Book and attending a 1.5 hr class run by a trained facilitator. The class introduces how ADT works and why it is used to treat PCa. The program reviews the various side effects of ADT as well as strategies to manage those side effects, and is designed to serve not only patients but also their partners.

The program focuses on evidence-based management strategies for ADT side effects as well as improving patients' success in implementing those strategies. A few examples include: vitamin D and calcium for preserving bone health, weight bearing exercise for limiting lean muscle loss and osteoporotic risk, dietary changes for controlling weight gain, and erectile aids for managing erectile difficulties. A full description of the information that is presented on treatment side effects and management strategies for those side effects can be found in Wibowo et al. (2019). A didactic presentation on this content is delivered and opportunities are provided for patients to ask questions as well as discuss how this material may be personally relevant to them. The program is built on the theory of motivation interviewing (MI) and thus incorporates specific methods from that literature (Miller & Rollnick, 2013). Originally used to facilitate behavioral change to overcome addictions, MI has been increasingly applied to other health challenges. The content presented in the class and book are aimed to improve patient's self-efficacy by teaching knowledge, building skill, increasing accessibility and empowering patients through MI. Consistent with MI, patients generate an "Action Plan," based on the SMART goals format (Bovend'Eerd et al., 2009), and identify concrete steps for implementing side effect management strategies determined to be important to them (Wassersug et al., 2018). (Additional information about the program can be found at www.LIFEonADT.com.)

Measures

Sociodemographic Information. Patients completed a demographic questionnaire at baseline capturing age,

ethnicity, relationship status, education, employment, socioeconomic status, health comorbidities, and previous cancer treatments.

Self-Efficacy and Bother. Patients completed an ADT Management Strategies Inventory (MSI) created by the authors, which includes questions on 17 ADT side effects (Wibowo et al., 2019). These side effects were categorized (see Table 2) based on the results of a confirmatory factor analysis (discussed in the Results). The MSI queried four areas: (a) the occurrence and frequency of side effects, (b) the management strategies for addressing ADT side effects, (c) the degree of bother experienced from each side effect, and (d) the patients' self-efficacy. Side effect bother and self-efficacy are the focus of this paper.

For side effect bother, patients were provided the list of side effects and asked: "How big a problem during the past month, if any, has each of the following been for you?" Response categories include: "no problem," "very small problem," "small problem," "moderate problem," and "big problem." This wording matches that of the Expanded Prostate Cancer Index Composite (EPIC; Wei et al., 2000), a standard questionnaire for outcome assessment in PCa patients. However, the list of side effects surveyed were extended from those in the EPIC.

For side effect self-efficacy, patients were asked to respond to the following question: "I am confident that I have ways to manage. . . ." for each side effect. Responses were ratings on a 10-point Likert scale (0: not confident at all; 10: very confident).

Program Acceptance and Feasibility. Program feasibility was assessed by examining the proportion of sites that were willing to implement the ADT Educational Program, successfully identifying and training one program Facilitator at each site, and sufficient patient enrollment in the program (three–eight patients plus additional partners, per class). Optimal size for similar groups is 7–10 participants (The American Group Psychotherapy Association, 2007).

Program acceptability was assessed by:

- 1) measuring patient satisfaction (participants were asked how satisfied they were with the ADT Educational program; 0: Not at all satisfied, to 4: Very satisfied),
- 2) whether patients found any of the aspects of the class distressing (Yes/No),
- 3) whether they would recommend the class to others (Yes/No),
- 4) if they found the duration and timing of the class appropriate (Yes/No).

Procedures

Implementing the ADT Educational Program. Identification of program sites and training of Facilitators (Objective 1): Target organizations were approached about their interest in offering the ADT Educational Program. Sites invited to participate in a sequential manner, beginning with Calgary, and Vancouver, followed by Victoria, Toronto, Halifax, and Montreal. After a representative from each institution displayed interest in the program, the researchers worked with them to either identify potential Facilitators at each site, or if they wished to be the Facilitator, to obtain administrative support for doing so. Sites were not offered incentives to participate but were offered facilitator training and access to program resources free of charge (e.g., ongoing access to the program website, materials, and the leadership team for questions and support). Costs covered by a grant held by the principal investigators included travel for training, and a year's supply of ADT books.

Participating sites were expected to provide release time and cover the salary of the trained site Facilitators for the time needed to offer the program on a monthly basis. A letter of support from the institution's administrators was requested to ensure that trained sites would follow through with offering the ADT Educational Program on a long-term basis. Sites were approached directly through potentially identified site facilitators, several of whom were affiliated with the study grant.

Facilitators were trained in a single-day session that included a background on the development of the ADT Education Program including research support, instruction in motivational interviewing, review of the ADT Educational Program training manual, and observation of a live ADT class with patient attendees. After class observation, a debriefing session was conducted with the Facilitators. This session included coaching regarding strategies for developing successful referral pathways within their organizations to ensure sufficient patient enrolment in the program, and consideration of factors unique to the individual sites that may have affected program implementation (e.g., differences in setting, providers, access to administrative support for program registration, centralized vs. community pharmacy distribution of ADT drugs, etc.).

Patient enrolment (Objective 1): Initial referral strategies included distribution of post-card-sized advertisements to patients through a variety of methods: new patient orientation packages, attached to ADT prescriptions/medications, and direct from provider to patient in consultations. In the first year of implementation, referrals to the program were slow at all sites until clinical staff "buy-in" was established. It was found that the single best approach to getting that buy-in was to offer in-service style presentations. These presentations were offered to members of the genitourinary team including

physicians and nurses in urology, medical oncology, and radiation oncology, and the pharmacists dispensing the ADT agents. Patient support groups in each city were also informed of the program. Presentation content summarized the research evidence documenting reduced QOL for patients on ADT, as well as an overview of the ADT Program. Presentation content was provided to the Facilitators by the ADT Team. The in-services served to be essential as the research team learned that unless the medical team appreciated the challenges faced by ADT patients, they did not see the need for the ADT Educational Program and therefore did not refer patients.

Program evaluation (Objectives 2, 3, and 4): The evaluation component (i.e., participant questionnaire completion) was not launched until referral pathways to the program were established to ensure sufficient patient enrollment. Therefore, procedures for objectives 2, 3, and 4 were only conducted at sites where objective 1 was met.

Data Collection. Ethics approval was obtained at each site [Vancouver + Victoria (UBC): H14-01463, Calgary (Health Research Ethics Board of Alberta – Cancer Committee): HREBA14-1566, Halifax (Nova Scotia Health Authority): NSHA-RS/2015-286, Toronto (University Health Network): 15-8941-CE. Baseline questionnaires were administered to patients and partners immediately before class attendance, and approximately 3 months later. Written informed consent was obtained from all study participants. Questionnaires were either completed in hardcopy or online (via REDCap; Research Electronic Data Capture survey software). Participants either had their parking covered or received a \$20 gift card.

Data Analysis

Categorization of Side Effects. In order to reduce the large number of side effects to a more manageable set for analysis, a two-step data reduction procedure was conducted. First, possible categories for the side effects were proposed based on the team's clinical and research experience with men on ADT and the guidelines proposed by the ADT Working Group (Elliott et al., 2010). Five categories of side effects were proposed: (a) body feminization, (b) physical changes, (c) psychological changes, (d) sexual changes, and (e) medical risks (see Table 2). Two side effects were not included in the categorization because they were qualitatively different from the rest—body hair loss (queried only for occurrence) and relationship strain (considered an indirect effect of other side effects, and not a direct effect of ADT). Furthermore, while patients were surveyed about the fifth proposed category, medical risks, this category is not a focus of the current paper. Medical risks were considered different than the other categories as patients were asked if they have learned that they are at risk for these changes, and not if they are experiencing them.

The second step involved testing whether the categories proposed were empirically valid. Confirmatory factor analysis was used to examine whether the list of side effects actually fit the proposed categories. Because there were four different side effect-related outcomes (i.e., side effect occurrence, use of management strategies for each side effect, degree of side effect bother, and degree of side effect self-efficacy), one confirmatory factor analysis was conducted on each of the four outcomes. Comparative fit index (CFI) and Tucker–Lewis Index (TLI) $\geq .90$, and root mean square error of approximation (RMSEA) $\leq .08$ were indicators of good fit (Browne & Cudeck, 1993; Hu & Bentler, 1999; Marsh et al., 2004).

Differences Over Time and Between Side Effect Categories. Two 2 (Pre–post comparison) \times 4 (Categories) repeated-measures MANOVAs were conducted in order to examine changes between baseline (pre) and follow-up (post) and differences among the four side effect categories (i.e., body feminization, physical, psychological, and sexual side effects) for both outcomes of bother and self-efficacy.

Predictors of Primary Outcomes. Predictors of bother and self-efficacy were tested using hierarchical linear models with R package *nlme* (Pinheiro et al., 2018). To examine predictors of bother and self-efficacy, a number of sequential nested models were tested (Hox, 2010). Model 1 examined the intercept-model only. Model 2 introduced all level 1 predictors (i.e., intervention, occurrence of side effects, bother, and self-efficacy) as fixed effects. In Model 3, all level 2 predictors—i.e., age, and for sexual the difference in age between partners, plus changes in the strategies used to manage sexual changes—were added in as fixed effects. Model 4 included the random effects of all level 1 predictors. To avoid convergence problems, the random effects of each level 1 variable at a time (Hox, 2010) were examined and only those that were statistically significant were retained. Finally, in Model 5, interactions between the intervention effect and all significant level 1 and level 2 predictors were examined. Each nested model was compared with the previous one. Models were only retained when new significant effects were found and the overall fit improved significantly. For simplicity, only the final significant models are presented here.

Results

Feasibility of the ADT Educational Program (Objectives 1 and 2)

Of the six sites that were initially contacted (Calgary, AB; Vancouver, BC; Victoria, BC; Toronto, ON; Quebec, QC; and Halifax, NS), all showed interest and were willing to implement the program. The program was not implemented

in Quebec, despite interest, as a potential Facilitator at that site could not be identified. Thus, the program was implemented (i.e., Facilitators identified, trained, and program launched) in five of the six approached sites. The program was ultimately sustained (i.e., offered with sufficient patient enrolment) in four of those five sites.

Regarding patient enrolment, the minimum class size was three patients (plus additional partners/support persons) but the ideal class attendance was determined to be six–eight patients. While initially classes were attended by only one or two patients (plus support), as the program became more established at each site, attendance increased and classes were capped at 10 patients (plus support). Increased enrollment indicated that the program had great acceptance among patients and referring health-care providers. Most sites had sufficient attendees (six–eight per class) in order to offer classes monthly. However, Halifax offered classes on a bimonthly basis, and Victoria implemented the program as one-on-one sessions due to insufficient volume to warrant regular group offerings. Sociodemographic characteristics of the patients enrolled are presented in Table 1. Specific to objective 1, participants had been on ADT for an average of 89 days at the time of enrollment, with more than half of the sample on ADT for less than 3 months. Finally, as the program became more successful regarding patient attendance and satisfaction, all of the four implementing sites (Vancouver, Calgary, Toronto, and Halifax) moved the program to become a permanently operationally funded program, thus meeting the important feasibility criteria for sustainability.

Regarding patient satisfaction, 84 participants who completed both assessments, and 20 who completed only the baseline assessment, returned the feedback form (immediately following class attendance). No significant differences between completers and noncompleters were found on overall satisfaction with the program (Mann–Whitney $U = 693.50$, $p = .41$), whether they found any element of the program distressing (Cramer's $V = 0.04$, $p = .69$), would recommend the program, or about the duration and timing of the class (Cramer's $V = 0.06$, $p = .58$).

Participants were overall satisfied with the program ($M = 3.66$, $SD = .54$). The majority of them were highly satisfied with the program (providing a rating of 3 or 4 on the response scale, $n = 97$, 97%), whereas no patients reported low satisfaction (0 and 1 on the response scale) and only three (3%) were somewhat satisfied (3 on the response scale). The majority 85.2% ($n = 75$) did not find any element of the class distressing, 100% ($n = 92$) would recommend the class to others, and 87.2% ($n = 82$) found the duration and timing appropriate. Of those who did not rate the class duration and/or timing as satisfactory ($n = 12$, 12.8%), six participants found it too short, three too long, and three reported the specific time slot for the class as problematic.

Table 1. Sociodemographic Characteristics of Participants in the ADT Educational Program Evaluation.

Variables	N	%	M	SD	Range
Days pre- and post-survey			81.5	22.6	52–158
Days on ADT			89.0	138.7	0–730
ADT duration at baseline					
Less than 3 months	45	58.4			
More than 3 months	32	41.6			
Age			68.4	7.7	48–85
City					
Calgary	22	23.4			
Halifax	8	8.5			
Toronto	18	19.1			
Vancouver	46	48.9			
Ethnicity					
White/Caucasian	79	84.9			
Black/African-Canadian	4	4.3			
Middle eastern/Arab/Indian	2	2.2			
Asian/Oriental/Pacific islander	7	7.5			
Other	1	1.1			
Relationship	77	81.9			
Relationship status					
Living with partner/spouse	70	90.9			
Not living together	7	9.1			
Relationship duration (years)			34.0	16.9	0.5–62
Partner's age			64.8	8.7	42–84
Partner's gender					
Female	75	97.4			
Male	2	2.6			
Marital status					
Never married	6	6.4			
Married/civil union	62	66			
Common law separated	7	7.4			
Separated/divorced	13	13.8			
Widowed	5	5.3			
Employed					
Full time	20	21.3			
Part time	6	6.4			
Not employed, but looking	3	3.2			
Retired	65	69.1			
Education					
Grade school or less	1	1.1			
Some high school or technical	3	3.2			
High school or technical	19	20.2			
Some college	14	14.9			
College/graduate/professional degree	57	60.6			
Income					
\$10,000–\$30,000 CAD	11	12.6			
\$30,001–\$100,000 CAD	48	55.2			
More than \$100,000 CAD	28	32.2			

CAD = Canadian dollars.

Table 2. Categorization of Side Effects.

Body feminization	Physical	Sexual	Psychological	Medical risks	Other*
hot flashes, breast tenderness, breast enlargement	hair loss, genital shrinkage, fatigue, weight gain, muscle loss	erectile dysfunction, loss of sexual desire	memory problems, depression, emotional changes	osteoporosis, type II diabetes, cardiovascular disease	body hair loss, relationship strain

Note. *"Other" side effects were not included in the proposed five-factor model but are included here for completeness sake so that the full list of 17 surveyed side effects are presented.

Table 3. Model Fit of the Four Confirmatory Factor Analyses.

Outcome	χ^2	df	CFI	TLI	RMSEA	90% RMSEA
Occurrence	125.90***	81	.906	.878	.054	.035 - 0.72
Strategies	113.89**	78	.960	.946	.049	.029 - .068
Bother	114.73**	79	.950	.934	.049	.030 - .066
Self-Efficacy	175.21***	79	.928	.904	.080	.067 - .094

Note. * $p < .05$. ** $p < .01$. *** $p < .001$.

df = χ^2 degrees of freedom; CFI = comparative fit index; TLI = Tucker–Lewis index; RMSEA = root mean square error of approximation; 90% RMSEA: 90% confidence interval around the RMSEA value. CFI and TLI values $\geq .90$, and RMSEA values $\leq .08$ were indicators of good fit (Browne & Cudeck, 1993; Hu & Bentler, 1999; Marsh et al., 2004).

Confirmatory Factor Analysis

Confirmatory factor analyses were used to cluster the number of individual side effects into the side effect categories for each outcome (i.e., side effect occurrence, use of management strategies, side effect bother, and side effect self-efficacy). The five proposed categories of side effects (see Table 2) were confirmed to be a good fit for each outcome (see Table 3; Browne & Cudeck, 1993; Hu & Bentler, 1999; Marsh et al., 2004). All factor loadings were greater than .424 for side effect occurrence, and greater than .402, .487, .641 for use of management strategies, side effect bother, and side effect self-efficacy, respectively, indicating a strong association between the individual side effects and their corresponding category. These results confirm that side effects were all successfully grouped according to the proposed categories (see Table 3) thus reducing 17 side effects to five categories: (a) body feminization, (b) physical side effects, (c) psychological side effects, (d) sexual side effects, and (e) medical risks. As previously mentioned, the last category was excluded from further analyses.

Changes in Side Effect Bother and Self-Efficacy (Objective 3)

The results for bother showed a multivariate significant effect for pre–post comparison ($F(1, 93) = 21.80, p < .001, \eta^2_p = .19$), with overall bother from ADT side effects increasing over time. A significant multivariate effect for categories ($F(3, 91) = 36.65, p < .001, \eta^2_p =$

.55), with post hoc comparisons, identified differences among the categories. In order of most to least bothersome, sexual side effects were the highest, followed by physical side effects, then body feminization and psychological side effects. The latter two were not significantly different from each other. No interactions were observed ($F(3, 91) = 1.54, p = .20, \eta^2_p = .05$).

Results for self-efficacy showed a significant multivariate effect for pre–post comparison ($F(1, 93) = 10.69, p < .01, \eta^2_p = .10$) revealing an overall increase in self-efficacy over time. A significant multivariate effect for categories ($F(3, 91) = 15.40, p < .001, \eta^2_p = .34$) was observed, with post hoc comparisons showing greater self-efficacy for managing body feminization, physical and psychological side effects, than for sexual side effects.

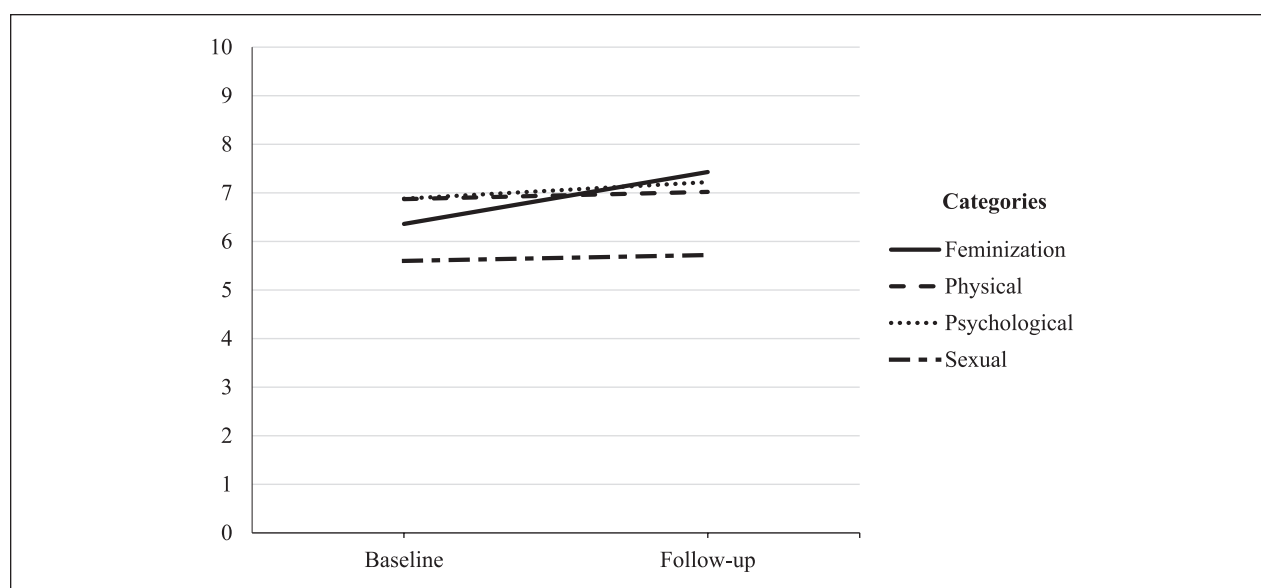
An interaction was found between pre–post comparison and categories ($F(3, 91) = 6.40, p < .01, \eta^2_p = .17$). Whereas self-efficacy for managing physical, psychological, and sexual side effects increased only minimally between baseline and follow-up, self-efficacy for managing body feminization increased to a greater magnitude. As a result, self-efficacy for managing body feminization and sexual side effects differed at follow-up, but not at baseline (see Table 4 and Figure 1).

Predictors of Side-Effect Bother (Objective 4)

For body feminization, the final model for bother showed that, in general, patients reported low levels of bother (intercept = 1.67, range: 1–5), and that their level of bother increased over time ($B = 0.39, p < .001$). Results

Table 4. Mean, Standard Deviations, and Comparisons for Bother and Self-Efficacy.

	Range	Baseline			Follow-up		
		Observed range	M	SD	Observed range	M	SD
Bother							
Body feminization	1–5	1–4.33	1.67	0.84	1–4.5	2.00	0.80
Physical	1–5	1–4.75	1.90	0.92	1–4.75	2.33	0.91
Psychological	1–5	1–4.33	1.64	0.83	1–4.67	1.89	0.94
Sexual	1–5	1–5	3.12	1.50	1–5	3.29	1.58
Self-efficacy							
Body feminization	0–10	0–10	6.32	2.36	0–10	7.38	2.04
Physical	0–10	1.50–10	6.94	1.82	0.5–10	7.09	1.77
Psychological	0–10	2–10	6.86	1.91	0–10	7.18	1.97
Sexual	0–10	0–10	5.54	2.63	0–10	5.79	3.01

**Figure 1.** Interaction between the pre–post comparison and side effect categories, effect on self-efficacy.

also showed that using more strategies to manage body feminization was associated with less bother ($B = -0.08$, $p < .001$). A significant interaction between self-efficacy and the pre–post comparison ($B = -0.12$, $p < .001$) indicated that body feminization bother increased more between baseline and follow-up for men with low levels of self-efficacy than for men with high levels of self-efficacy (see Table 5 and Figure 2).

Participants reported low levels of bother related to physical side effects (intercept = 1.88), and bother increased between baseline and follow-up ($B = 0.45$, $p < .001$). A significant negative effect of self-efficacy indicated that patients who reported higher levels of self-efficacy, also reported lower levels of bother about their physical side effects ($B = -0.19$, $p < .001$; Table 5).

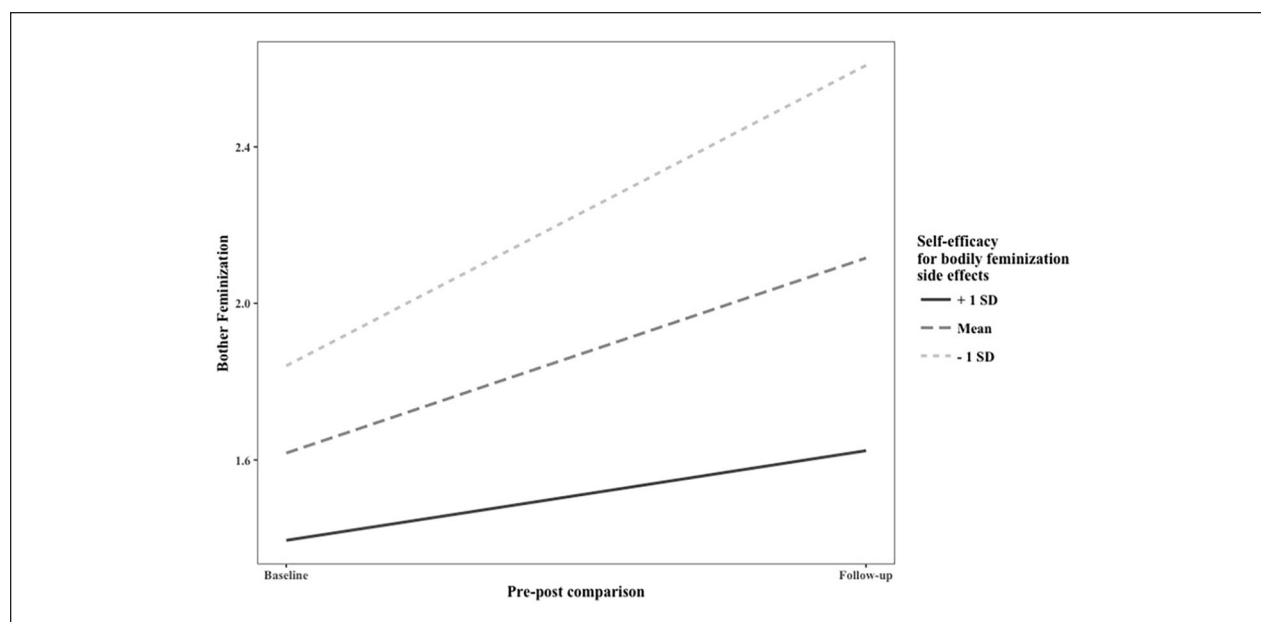
For psychological side effects, patients also reported low levels of bother from the psychological changes they experienced (intercept = 1.62) and bother also increased over time ($B = 0.27$, $p < .01$). Older patients ($B = -0.03$, $p < .001$), those who used more strategies to manage their side effects ($B = -0.13$, $p < .001$), and those who reported greater self-efficacy ($B = -0.08$, $p < .001$), reported less bother (see Table 5).

Patients reported high levels of bother related to their sexual side effects (intercept = 3.20). In contrast to the other categories, bother about sexual side effects did not change over time. Patients, who used more strategies ($B = 0.07$, $p < .001$) and those who reported less self-efficacy to manage sexual side effects ($B = -0.23$, $p < .001$) reported greater bother (see Table 5).

Table 5. Final Models for Bother About Bodily Feminization, Physical, Psychological, and Sexual Side Effects.

	Body feminization	Physical	Psychological	Sexual
Level 1				
Intercept	1.67***	1.88***	1.62***	3.20***
Pre-post comparison	0.39***	0.45***	0.27**	
Strategies	-0.08***		-0.13***	0.07**
Self-efficacy		-0.19***	-0.08***	-0.23***
Level 2				
Age			-0.03***	
Age difference				
Change sexual strategies				
Interactions				
Pre-post comparison* Self-efficacy	-0.12***			
Pre-post comparison*Strategies				
Pre-post comparison*Age				
Random effects				
Intercept	0.54***	0.62***	0.46**	0.94*
Residual	0.46***	0.53***	0.53**	0.95*

Note. * $p < .05$. ** $p < .01$. *** $p < .001$.

**Figure 2.** Interaction between self-efficacy and pre-post comparison.

Predictors of Side-Effect Self-Efficacy

A moderate level of self-efficacy in managing body feminization side effects (intercept = 6.18, range: 0–10) was observed, and self-efficacy increased over time ($B = 1.33$, $p < .001$). Experiencing less bother ($B = -0.82$, $p < .001$) was associated with greater self-efficacy (see Table 6).

Results for physical side effects showed moderate levels of self-efficacy to deal with these side effects (intercept = 6.76) and participants' self-efficacy increased over time ($B = 0.50$, $p < .05$). Experiencing less bother ($B = -0.82$, $p < .001$) for physical side effects was associated with a greater sense of self-efficacy (see Table 6).

Regarding psychological side effects, participants also reported a moderate sense of self-efficacy to manage

Table 6. Final Models for Self-Efficacy About Body Feminization, Physical, Psychological, and Sexual Changes.

	Body feminization	Physical	Psychological	Sexual
Level 1				
Intercept	6.18***	6.76***	6.92***	5.98***
Pre–post comparison Occurrence	1.33***	0.50**	0.44**	
Strategies				0.12**
Bother	–0.82***	–0.82***		–0.81***
Level 2				
Age				
Age difference				
Change sexual strategies				
Random effects				
Intercept	1.99**	1.06**	1.38**	1.47**
Residual	0.83**	1.19**	1.14**	1.30**
Bother				0.97**

Note. ** $p < .01$. *** $p < .001$.

them (intercept = 6.92), which also increased over time ($B = 0.44, p < .01$).

Finally, for sexual changes, patients showed moderate levels of self-efficacy (intercept = 5.98). Self-efficacy did not change between baseline and follow-up, but using more strategies ($B = 0.12, p < .01$) and experiencing less bother ($B = -0.81, p < .001$) were both associated with greater self-efficacy (see Table 5).

Discussion

Feasibility for this dissemination model of a national ADT Educational Program was demonstrated. Feasibility outcomes included adequate site and Facilitator identification, establishment of sufficient referral pathways to ensure patient enrolment, and high patient satisfaction with the program. Furthermore, several institutions sustained the program through internal budgets once the grant funding to develop the program had concluded. This article documents increases in patients' self-efficacy to manage ADT side effects and in side effect bother after participation in the program.

The ADT Educational Program was thus deemed feasible and acceptable. Successful program implementation required identification of interested sites and potential Facilitators. The Facilitator training model worked effectively to equip Facilitators to offer the program at their respective sites. Lessons learned from establishing patient referrals pathways for the program were applied in the sequential addition of each new site, resulting in successful implementation of the program in four major Canadian cities. Patients not only reported high levels of satisfaction with the program, but also said that they would recommend it to other ADT patients. The duration of the

program was assessed as appropriate for a large majority of patients. Of note, attrition in this study was not related to the program itself or any other variables assessed at baseline, which also attests to the quality of the program.

Program implementation largely followed the framework introduced Proctor et al. (2009), which involved several program assessments. Proctor et al. (2009) identified seven implementation outcomes: (a) feasibility, (b) fidelity, (c) penetration, (d) acceptability, (e) sustainability, (f) uptake, and (g) costs. While the primary focus of the current study was on feasibility and acceptability, the remaining five outcomes were also considered in the following ways:

Fidelity adherence was an ongoing task. Efforts were made during Facilitator training to ensure fidelity by using a standardized training manual and standardized program content. Facilitators were also trained in motivational interviewing (MI), and in observing the live ADT class were able to understand how MI influences the style of delivery of the program. Trained Facilitators maintained routine contact (every few months) with the ADT program team in order to ensure ongoing fidelity. All new Facilitators were trained in the same format by the original ADT Team rather than using a “train the trainer” approach in an effort to maintain fidelity.

Penetration was established when successful patient referral pathways at each site were secured. The greatest success was seen at sites in which all new ADT patients were phoned and invited to attend the class by ADT program staff.

Efforts to ensure sustainability also relied heavily on estimation of costs. Program costs were estimated upfront and provided to potentially interested sites. Costs for implementing and sustaining the program included the

ongoing costs of ADT books for class attendees as well as program advertisements, and staff time to facilitate classes and register patients. Obtaining a letter at the outset from site administrators affirming their stated commitment to offer the program on an ongoing basis was a fundamental part of our sustainability plan. Periodic email check-ins with Facilitators (roughly every 6 months) to discuss recruitment strategies also help to sustain patient enrollment.

Uptake was measured by the success with which various cancer centers took up the program and embraced it as a part of standard of care. This was achieved in four of the six target sites. Dissemination of the ADT program to other sites should consider all of the Proctor et al. (2009) implementation outcomes to match or exceed the initial pilot implementation.

The research team hoped that participating in the ADT Educational Program would increase patients' self-efficacy, and at best attenuate side effect bother, when side effects could not be eliminated. As predicted, self-efficacy increased postintervention for all side effect categories and in particular for body feminization. Levels of self-efficacy were moderate for all categories, but were lowest for sexual side effects. Side effect bother also increased postintervention for all categories, as predicted. Patients' bother was generally low for body feminization, physical and psychological side effects, but high for sexual side effects. This finding is consistent with research documenting high and unremitting bother associated with sexual changes provoked by ADT (Wassersug, Westle, et al., 2017). As patients were relatively new to ADT, it was reasonable to presume that the occurrence of ADT side effects would increase between the baseline and follow-up, thereby increasing side effect bother.

The results indicate that there was an inter-relationship between self-efficacy, bother, and use of management strategies. The general trend was that lower bother is associated with increased self-efficacy and use of more management strategies, and higher self-efficacy is associated with lower bother and use of more management strategies.

Influence of Self-Efficacy on Bother

Greater self-efficacy predicted lower levels of bother for all side effect categories, which is consistent with past research reporting that higher self-efficacy is associated with better adjustment to cancer and improved QOL (Campbell et al., 2004; Weber et al., 2007). Therefore, self-efficacy appears to have a buffering effect on bother. In fact, for bother associated with body feminization, an interaction was observed between pre-post comparison and levels of self-efficacy. Specifically, the increase in bother over time was greater for patients with lower

levels of self-efficacy, than for patients with higher levels of self-efficacy. Increasing self-efficacy may be just as important as trying to reduce side effect bother by reducing side effect occurrence. Indeed other researchers have reported that interventions that improve self-efficacy are effective at alleviating patient's suffering (Chirico et al., 2017; Haugland et al., 2016; Porter et al., 2008). Interventions for PCa patients based on self-efficacy theory suggest that when men have experiences successfully managing their symptoms, it leads to a sense of mastery that works to improve men's confidence that they will be able to successfully manage future symptoms. This reduces disease burden (Latini et al., 2009; Torbit et al., 2015; Watson et al., 2016).

Influence of Bother on Self-Efficacy

The data reveal that high bother was associated with lower self-efficacy for all categories except for psychological side effects. This is consistent with self-efficacy theory, which states that high stress or bother undermines self-efficacy (Bandura, 1977). This has important clinical implications. In states of high bother or arousal, patients are less likely to expect successful behavioral outcomes (Bandura, 1977). Research with other oncology populations (e.g., bone marrow transplant patients) demonstrates that high distress leads to passive escape-avoidance coping behaviors (e.g., wishing things would get better, hoping a miracle would happen; Mytko et al., 1996), which are known to undermine self-efficacy and further compound distress. In this context, higher self-efficacy could help create a sense of control over the illness experience (Helgeson et al., 2006; Torbit et al., 2015), improving not only the patients' ability to manage side effects but also how they feel about those side effects (i.e., bother).

Influence of Management Strategies on Bother and Self-Efficacy

Use of more management strategies predicted lower bother for body feminization and psychological side effects. For these categories, many options of side effect management were presented. Patients may find that using several strategies together (e.g., using a fan and wearing easily removable layers of clothing to manage hot flashes) helps them cope better with side effects.

Use of management strategies did not predict bother associated with physical side effects. It is possible that the strategies suggested for physical side effects may require more effort and take longer to observe an effect. For example, exercise for weight loss is long-term whereas using a fan for a hot flash is immediate. In contrast, the opposite effect was observed for sexual side effects in that more strategy use was associated with

higher bother. This could be because sexual strategies are more difficult to implement and sustain, or because management strategies were found to be ineffective. For example, past research has demonstrated that many established strategies for recovery of erectile function are less effective when the men are on ADT (Elliott et al., 2010; Traish & Guay, 2006) and even when the strategies are effective, compliance is poor (Matthew et al., 2005). Patients may continue to try new strategies after abandoning old ones. This persistent searching without finding a satisfactory strategy could exacerbate side effect bother.

Use of more management strategies predicted higher self-efficacy for sexual side effects only. A variety of different kinds of sexual strategies were introduced to patients. (Wibowo et al., 2019). Some of these strategies help restore penile erectile (e.g., intracavernosal injection) but also strategies were introduced that could be used when erections could not be recovered (e.g., non-penetrative options). Therefore, even if the patient's first attempted strategy did not work, he had many other strategies to try. Helping patients believe they have ready access to a variety of side effect management strategies may increase self-efficacy, thereby buffering side effect bother.

Finally, different effects were found for the various side effect categories. First, consider the finding that more management strategy use was associated with more bother but also higher self-efficacy for sexual effects—but not for other side effects. Managing sexual side effects may require more support than is provided by a simple educational program, and interventions may need to target side effect categories differently. Second, the finding—that increases in bother related to body feminization were greater for patients with low self-efficacy than for patients with high self-efficacy—suggests that, similar to what Helgeson et al. (2006) reported, patients with different baseline levels of self-efficacy may receive differential benefit from educational programs.

Limitations

Although the results of the ADT Educational Program are promising, there are a number of limitations that affect the conclusions about this study. Mainly, in examining participant outcomes, the lack of a control comparison group makes it impossible to discern if pre–post changes (i.e., improvements in self-efficacy) are specifically due to the program, rather than just passage of time. Similarly, conclusions cannot be drawn about the extent to which improvements in self-efficacy may have attenuated side effect bother, because side effects (and bother) are expected to increase after ADT is implemented. Future research needs to incorporate randomization to a control

comparison group (e.g., treatment as usual or active control alternatives) in order to demonstrate the overall effectiveness of the ADT Educational Program in influencing side effect bother and self-efficacy.

The population sample in this study is homogenous (i.e., largely White, highly educated, high socioeconomic status men, in long-term relationships). As such, it is difficult to generalize these findings to other populations. The vast majority of these patients were using luteinizing hormone-releasing hormone drugs and anti-androgens; therefore, these findings may not be applicable to patients on other androgen-suppressing protocols (e.g., high dose estrogen or orchiectomy).

Patient evaluation of the ADT Educational Program was optional and had a delayed start. Only about 20% of those who took the program participated in the evaluation. Thus, selection bias may have occurred. It could be that only higher educated or higher socioeconomic status patients opt into the program evaluation. Lastly, the sample size is limited in terms of capacity to enter more predictors into the model; therefore, several key predictors were identified based on theory and the clinical experience of the authors.

Conclusions

This study demonstrates that the ADT Educational Program is both feasible and acceptable. It also shows high acceptance of the program on a national level in several key institutions, and also among patient participants. The outcome evaluation shows changes in patient self-efficacy in managing side effects after participation in the program, and suggests that increased self-efficacy may potentially lessen patients' side effect burden. When self-efficacy is high, patients tend to experience less bother from ADT side effects. Furthermore, the use of more management strategies for specific side effects is associated with improved self-efficacy, and generally less bother (except for sexual bother).

This study suggests that high self-efficacy may buffer the impact of high side effect bother. Therefore, in an effort to reduce bother, while it may be ideal to eliminate side effects altogether, it may not be absolutely necessary. In reality, ADT side effects may be reduced, but often are not eliminated. Sometimes interventions to treat side effects may be avoided by patients because they are considered unappealing, invasive, or are associated with other side effects. Interventions to support patients should prioritize enhancing self-efficacy rather than focusing exclusively on side effect reduction. This study demonstrates that a low intensity program (i.e., a book plus a 1.5 h class) that promotes self-efficacy and the uptake of ADT management strategies can help patients cope with side effect bother brought on by ADT.

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Research Involving Human Participants

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committees involved and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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