Published in final edited form as:
J Cancer Educ. 2020 August ; 35(4): 808–818. doi:10.1007/s13187-019-01534-1.

Involving patients in the development and evaluation of an educational, training, and experiential intervention (ETEI) to improve muscle invasive bladder cancer treatment decision making and post-operative self-care: A mixed methods approach

Nihal Mohamed[1], **Tung Ming Leung**[1], **Qainat N. Shah**[2], **Sailaja Pisipati**[3], **Donna L Berry**[4], **Emma K. T. Benn**[1], **Cheryl T. Lee**[5], **Simon Hall**[6], **Reza Mehrazin**[1], **John Sfakianos**[1]

[1]Department of Urology and Oncological Sciences, Icahn School of Medicine at Mount Sinai

[2]Albany Medical College

[3]University of Nevada Reno School of Medicine

[4]Dana-Farber Cancer Institute, Harvard Cancer Center

[5]Ohio State University, Department of Urology

[6]Bladder Cancer Advocacy Network

Abstract

Objective: This study aims to describe the acceptability and feasibility of an educational and training experiential intervention (ETEI) we developed to enhance muscle invasive bladder cancer (MIBC) patients with treatment decision making and post-operative self-care.

Material and Methods: 25 patients were randomized to a control group (N=8) or ETEI group (N=17). ETEI group participated in a nurse-led session on MIBC education. The control group received diet and nutrition education. Study questionnaires were completed at baseline and at one-month post intervention.

Results: Our results showed acceptable recruitment (58%) and retention rates (68%). The ETEI group reported increased knowledge (82% vs. 50%), improved decisional support (64% vs. 50%), improved communication (73% vs. 50%), and increased confidence in treatment decisions (73% vs. 50%) compared to the control group. Patients in the control group reported improved diet (50% v. 27%) as well as maintaining a healthy lifestyle (67% vs. 45%) compared to the ETEI group. Patients in the ETEI group reported a significant decrease in cancer worries and increases in self-efficacy beliefs over time compared to the control group.

Corresponding author: Nihal Mohamed, PhD, 1425 Madison Avenue, New York, New York, 10028, nihal.mohamed@mountsinai.org.

[7] Conflict of Interest
There is no conflict of interest to report.

Conclusions: The ETEI was feasible, acceptable and showed a potential for inducing desired changes in cancer worries, and efficacy beliefs.

Keywords

Muscle invasive bladder cancer; treatment decision making; health related quality of life; urinary diversion; educational intervention

1. Introduction

Bladder cancer (BC) is the fifth most common cancer and the fifth leading cause of cancer deaths in the United States (US). According to the Surveillance, Epidemiology, and End Results (SEER) database, it is estimated that 81,190 new cases of BC will be diagnosed in 2018 and 17,240 patients will die of this disease [1]. There has been a decreasing trend in BC mortality rates in the US and Europe [2,3], possibly reflecting reduced occupational exposure to carcinogens, reduced incidence of smoking and increased standard of care [4, 5].

About 25% of newly diagnosed BC cases are muscle invasive, requiring aggressive radical surgery or radiotherapy with or without chemotherapy [6]. The outcomes, however, remain poor despite aggressive systemic treatments [7, 8]. Muscle invasive bladder cancer (MIBC) is a potentially lethal malignancy and continues to pose an enormous challenge, particularly in older patients. The current standard of care for non-metastatic MIBC is radical cystectomy (RC) with lymphadenectomy, followed by urinary diversion (UD) to either a cutaneous stoma or the existing urethra, thus providing excellent local control [9-13]. Neoadjuvant chemotherapy has been proven to enhance survival outcomes in MIBC by eliminating residual disease, although it is not exempt from side-effects [14]. RC and UD are associated with high surgical morbidity and mortality [15, 16].

The three methods of UD currently used are incontinent diversion with a stoma (e.g., ileal conduit, IC), orthotopic continent UD (e.g., neobladder), and continent cutaneous diversion (CCD, e.g., Indiana pouch) [17]. Each of these procedures is associated with a distinct set of post-operative complications and changes in health-related quality of life (HRQOL) [9-13]. Stoma complications are common and have been reported in up to 31% of ileal conduit patients (e.g., hernia and stenosis). [18] Complication rates for both neobladders and continent reservoirs range from 3% to 30%. [19] These complications include pouch leakage and rupture (1.5% to 4.3%) and urinary incontinence (3.2% to 7.4%) [19, 20].

Although all patients' HRQOL declines significantly following cystectomy, this decline is largely associated with the type of urinary diversion and its psychosocial impact [4-12, 21, 22]. Ileal conduit patients report bother with impaired body image and social roles, and sexual barriers due to altered body image, urinary leakage, odor, and frequent stoma care [7-9,11-13]. In continent cutaneous reservoir patients, failure to catheterize as frequently as needed (4-5 times per day) can cause urinary leakage and serious urinary retention conditions. [11,12] Night-time catheterization in these patients may also result in a reduced amount and quality of sleep [23]. For patients with a neobladder, night-time continence is less likely to be achieved [18,24]. Study findings have demonstrated significant associations among urinary incontinence, social isolation, increased psychological distress, and poor

HRQOL in other populations [25,26]. Patients' adaptation to self-care demands introduced by urinary diversions may be further exacerbated by comorbid disease and age-related decline in physical and cognitive functioning (e.g., forgetfulness, manual dexterity affected by arthritis) [12,13, 27,28]. The types of bowel utilized for certain diversions may also result in varied metabolic disorders owing to the different absorptive characteristics of the section of bowel selected for reconstruction, [29] which may further reduce patients' HRQOL and psychosocial adaptation. Thus, treatment decision making is difficult and could be influenced by a variety of factors such as the patient's values, age, manual dexterity, kidney function, preferences for decisional control, expectations about urine control, and concerns about self-catheterization. There is no consensus on the best diversion for patients, as each option has clear advantages and disadvantages and patients' have to live with the consequences of the chosen diversion. [12, 13]. Unfortunately, decisional tools to help these patients with making treatment decisions are lacking.

This paper describes the development and pilot testing of the acceptability and feasibility of an educational and training experiential intervention (ETEI) we designed to assist patients with MIBC treatment decision making and preparation for self-care after RC and UD. Literature reviews in other cancer populations have shown that the utility of such interventions produced higher knowledge, more active participation in decision making and lower levels of decisional conflict [30]. This suggests that a similar intervention for MIBC patients is likely to increase knowledge about RC and UD, reduce decisional conflict and worries about RC and UD, and increase active participation in patient-provider communication about treatment options and outcomes. Our aims were to: (1) develop an intervention to assist MIBC patients with both treatment decision making and preparation for self-care after RC and UD; and (2) evaluate the preliminary evidence for the feasibility (i.e., proof of principle including our ability to recruit patients, conduct the intervention, and evaluate the targeted outcomes), acceptability (i.e., high rating of positive evaluation of the intervention), and effectiveness of the intervention (i.e., preliminary evidence of intervention efficacy).

2. Study Methods

This study was designed as a mixed-methods pilot study using convenience sampling and was approved by the Mount Sinai Health System (MSHS) Research Ethics Service [20]. The first part of the study qualitatively examined unmet informational needs in patients with MIBC at time of diagnosis and after treatment [25]. Results of the qualitative assessment guided the development of the educational and training experiential intervention (ETEI). In the second part of this study, we conducted a feasibility trial to evaluate ETEI. Here, we briefly describe the content of the ETEI, the method of the feasibility study we conducted, and preliminary evidence of the feasibility and acceptability of the ETEI. We evaluated the feasibility of the ETEI based on the proportion of eligible patients, patients who participated in the intervention and control sessions, follow-up retention rates, and duration and completion rate of study assessments [31]. Additionally, we evaluated the acceptance of the ETEI and elicitation of participants' opinions about helpfulness aspects of the study using closed-ended ratings, self-recorded time spent on study educational materials collected though study questionnaires, and satisfaction with the ETEI. The median and interquartile range (IQR) and mean and standard deviation were calculated for continuous variables and frequencies with proportions for categorical variables. Differences between the intervention and control groups in study outcomes were tested using $\chi 2$ and Fisher's Exact Tests, or t-tests and non-parametric tests (e.g., Wilcoxon Rank Sum Test). Statistical analyses were conducted using SAS v 9.4 (Cary, NC).

2.1 The Design of the Intervention

2.1.1 Theoretical perspectives of the intervention—The ETEI was developed based on the Self-Regulation Theory (SRT) [32] and the Ottawa Decision Support Framework (ODSF) [33], drawing on results of our qualitative assessment of MIBC patients' unmet needs and a comprehensive review of patient-centered reported outcomes following MIBC [18]. The core premise of the SRT is that health behaviors are influenced as much by patients' beliefs about the disease and treatment outcomes (e.g., beliefs about cancer control) as by emotional reactions to the health threat (e.g., worries about cancer progression and recurrence) [32]. The ODSF proposes that patients' treatment decisions could be influenced by many factors including physician's treatment recommendation, and personal and external resources (e.g., skills in decision-making, or a level of desired decisional control and its alignment with actual control) [33]. Based on the SRT, we provided information about RC and UD to address patients' misconceptions about and emotional reactions to UD options and self-care requirements (e.g., discouraging avoidant coping and encouraging problem solving coping). Based on the ODSF, we provided information to help with treatment decision making (i.e., risks and benefit of each UD option) to enhance patients' decisions and communication with their physicians.

3. Study Results

3.1. Patients information needs and evaluation of the planned content of the intervention

Our prior publications provide more details about the method, analyses, and results of this developmental phase (18,20,34). Briefly, qualitative interviewing and content analysis of structured interviews of 30 MIBC patients recruited from MSHS showed that 86% searched the Internet for additional information about MIBC and treatment options [18, 34]. None of these patients knew what to expect after cystectomy and a sizable proportion (62.5%) followed their physicians' treatment recommendation. A majority (80%) wished they had more treatment and side-effect information, which they thought would have benefitted their decision making and self-care. Younger patients (< 60 years) were less satisfied with the lack of discussions about potential change in sexual function than older patients (≥ 60 years). More women than men experienced difficulties with self-care (e.g., self-catheterizing and utility of stoma appliances. When asked about the need for an educational intervention and the proposed content of the educational and training content of the ETEI, a majority (90%-85%) of patients reported satisfaction with the proposed educational and training components and 95% recommended the ETEI for their informal caregivers [20]. Draft materials for the ETEI were developed by the research team and reviewed for appropriateness, readability, literacy level, and comprehension by the research group, study consultants, and the survivorship group of the Bladder Cancer Advocacy Network (BCAN) [34]. The intervention materials were revised in keeping with participants' feedback to arrive at the final intervention materials that were evaluated in the feasibility trial. A time and attention control condition (i.e., a booklet on diet and nutrition after RC and UD and a food diary) was designed by the research team guided by The National Cancer Institute (NCI), the American Cancer Society (ACS) and the United Ostomy Association of America (UOAA) recommendations on healthy eating after cancer. Three research team members (a clinician, a nutritionist, and a behavioral therapist) refined and finalized the content and literacy level of the modified diet and nutrition materials for patients undergoing UD (e.g., portion sizes with food models after UD, dietary goals and approaches including weight loss vs. a regular balanced diet, recommendations to improve diet and nutrient and fluid intake, and common food substitutions) before the feasibility trial.[35,36]

3.2. Designing intervention materials and delivery method

The ETEI is designed to: 1) provide accurate information about MIBC treatment and diversion options, 2) create realistic expectations, 3) identify and explore values and goals to provide a context for making "preference sensitive" decisions and choices, 4) validate feelings and concerns and provide emotional support, and 5) provide information and tangible support to enhance skills needed for stoma and pouch care following treatment. Four booklets and a question list were provided to the patients during a 1-hour consultation with the nurse research coordinator (i.e., intervention group) to discuss the booklets, answer questions, and clarify misconceptions about RC and UD. The booklets and question list were written at a sixth to ninth grade reading level. The first booklet, "*What You Need to Know about Cystectomy and Urinary Diversion*" was 19 pages and included information about MIBC, cystectomy, benefits and risks of each UD, and information about support resources available for patients and their families. The second booklet, "*How To Care For Yourself After Surgery: Caring For An Ileal Conduit*", was 25 pages and included information about ileal conduit procedure, the importance of stoma location selection, stoma care, emptying, changing, and cleaning stoma appliances, challenges patients may encounter with this procedure (e.g., changes in sexual function, traveling, going back to work), and red-flag symptoms. The third booklet, "*How To Care For Yourself After Surgery: Caring For A Continent Cutaneous Reservoir (Indiana Pouch)*", was 23 pages long and included information about this procedure, what to expect after surgery, how to empty and irrigate Foley catheters, how to empty an Indiana pouch, challenges patients may encounter with this procedure, and red-flag symptoms. The fourth booklet, was 25 pages long and included information about orthotopic neobladder procedure, what to expect after surgery, how to empty and irrigate Foley catheters, how to self-catheterize to empty or irrigate a neobladder, challenges patients may encounter with this procedure, and red-flag symptoms. The question list included questions about issues deemed important during the time of diagnosis, following surgery, and during survivorship (e.g., follow-up care plans and surveillance, changes in sexual function after UD, and access to stoma care units in the community). The training component of the ETEI involves trying out a stoma bag filled with saline solution for 24 h - 48 h to get a sense of how it feels to have an ileal conduit and related self-care. Patients in the intervention group received a stoma pouch at the end of the 1-hour consultation with the nurse and were encouraged to use the stomal appliances at home before making a final decision about MIBC treatment.

3.3. The pilot feasibility study

In the feasibility trial, new eligible patients were recruited from MSHS were randomized to either a intervention or time-and-attention control arm ($1_{control}$:$2_{intrvention}$) to allow for potential exploration of intervention mechanisms in the ETEI group. Our inclusion criteria were limited to participants between 18-85 years, with a recent diagnosis of MIBC, who had not undergone cystectomy yet, and were English speaking. The method and delivery of and materials used in the time-and-attention control session mirrored those used in the intervention group. A trained research coordinator conducted the 1-hour session with patients allocated to the control group to discuss diet and nutrition using ACS guidelines of healthy diet for patients with cancer [37] and provided a food diary to keep records of food intake for 24-48 hours before surgery. Patients were identified by their treating physicians and invited to participate in the study. Those who agreed to participate, after consultation with the physician, met with the research coordinator for consent procedures and completing a baseline questionnaire. An 1-hour meeting with the nurse research coordinator (ETEI group) or the research assistant (control group) was scheduled based on the patient's study allocation and time preferences before their follow-up clinical consultation with the physicians to discuss MIBC treatment options. [23]. A second questionnaire was mailed to study participants 1 month after baseline and included all study measures in addition to a section evaluating the intervention or the diet and nutrition sessions and materials, depending on the patient's study allocation. Participants were compensated for time and effort in the feasibility trial ($20 per completion of study assessment). All study protocols (i.e., both qualitative and quantitative study methods) were reviewed and approved by the Institutional Review Board at the Icahn School of Medicine at Mount Sinai.

3.4. Usability and perceived utility information:

To evaluate the use and the perceived utility of both the ETEI and the diet and nutrition control materials, we created 12–items assessing their impact on different aspects related to treatment decisions and patient-centered reported outcomes. These items included: perceived knowledge about MIBC, UD options and their side effects, enhanced treatment decision making, improved ability to talk with the physician about treatment options and their outcomes, reduced anxiety and worries, increased self-confidence about disease self-management, value clarification (i.e., sorting out what is important to the patient in treatment decision making), improved diet and nutrition, reduced weight, improved lifestyle (i.e., having a healthier lifestyle because of the received diet and nutrition education), and preparation for changes in sexual function after treatment. The instructions ask patients to indicate whether the ETEI or the diet and nutrition information received as applicable supported the required positive changes described above. Response categories range from 1 (strongly disagree) to 5 (strongly agree). Items were dichotomized to 1 (agree) and 2 (disagree/neutral) to allow for better presentation of participants input and group comparison by means of Fishers Exact test. Participants in each group also reported estimated time spent reading study materials in minutes.

Decisional Conflict Scale (DCS): This scale consists of 16 items and measures 4 aspects of modifiable factors contributing to uncertainty regarding treatment decision making (3 items), the individual's ability to make an informed decision (3 items); value clarity (3 items), and receipt of support with decision making (4 items). Response categories range from range from 1 (strongly disagree) to 5 (strongly agree) [33, 38]. The internal consistency, validity, and reliability of the DCS have been well-documented in prior research [38] (Cronbach Alpha for the total scale = .78). Both the total scale and the 4 subscales are used to examine differences between the two study groups in decisional conflict.

Cancer-related Worries: We used 3 items modified from The Cancer Worries Inventory [25] to assess cancer related worries including worries about cancer recurrence, cancer progression, and cancer metastasis. Items response categories range from range from 1 (not at all) to 5 (extremely). Factor analyses of the 3 items indicated a unified component and the reliability of this scale was high (Cronbach Alpha = .96). A mean score of the 3 items was used to construct a cancer-related health worries score for descriptive and comparative analyses. We have also used 1 item from the Functional Assessment of Cancer Therapy – Bladder Cancer scale (FACT-BL) (e.g., “I feel nervous”) [39].

Self-efficacy Beliefs—We used 2 separate items from the General Self-Efficacy (GSE) Scale [40] to examine different aspects of self-efficacy and control beliefs: 1) goal achievement, 2) and problem-solving skills. Items response categories range from 1 (not at all) to 5 (extremely).

Diet and nutrition—We have used 1 item selected from the Center for Epidemiologic Studies Depression Scale (CES-D) to assess the potential impact of the diet and nutrition education materials on the patient’s eating behavior after surgery (e.g., ”I did not feel like eating; my appetite was poor”) [41]. Items response categories range from range from 1 (not at all) to 5 (extremely).

3.5. Study sample

Patients (N = 43) presenting at MSHS, Department of Urology at the Icahn School of Medicine for a first or second consultation regarding MIBC treatment were invited to participate in the study. Twenty-five (58.1%) agreed to participate in the study. Of these, 17 were randomized to the intervention group and 8 to the control group. Of the 17 patients in the intervention group, 11 completed the 1-month assessment (attrition rate, 35%). Six of the 8 patients from the control group completed the 1-month assessment (attrition rate, 25%). We did not observe statistically significant differences in demographic or clinical characteristics between participants who completed the study and those who dropped out ($p > .05$; data not shown). Reasons cited by participants who declined or discontinued the study included lack of interest, limited time, and poor health condition after surgery.

Table 1 shows the baseline characteristics of our study sample. Participants were mainly non-Hispanic White (88%), above 65 years of age (64%), male (60%), had some college or higher education (68%), and not employed at the time of assessment (72%). There were no significant differences in baseline demographic characteristics between the control and intervention group. However, significantly more participants in the control group were current smokers than the intervention group ($p = 0.032$).

3.6. Treatment decision making

The majority of patients (95.6%) made a treatment decision at 1-month post-baseline. 15 (68%) opted for ileal conduit, 1 (4.5%) opted for Indiana pouch, and 6 (27.3%) for neobladder. 14 (70%) reported that ileal conduit was recommended by their physicians, 1 (5%) reported that Indiana pouch was recommended by their physicians, and 5 (25%) reported that neobladder was recommended by their physicians. 14 (58.3%) participants reported having received a strong recommendation of UD from their physician. 9 (37.5%) indicated that the physician's recommendation was moderately strong whereas only 1 (4%) reported that the physician's recommendation was not very strong (Table 2).

3.7. Intervention and time-and-attention evaluation:

Table 3 shows responses on educational material in the control and intervention group. At 1 month, more participants in the intervention group reported increased knowledge about bladder cancer and its treatment (82% vs. 50% than the control group), support with decision making (64% vs. 50%), improved patient-physician communication (73% vs. 50%), increased confidence (73% vs.50%), improved value clarification (64% vs. 50%), better preparation for changes in sexual function (55% vs. 17%) and reduced anxiety (73% vs. 33%). A larger proportion of participants in the control group reported that the diet and nutrition session and materials helped with weight reduction (50% vs. 18%), improved their diet (50% vs. 27%), as well as maintained a healthy lifestyle (67% vs. 45%). Average time spent on reading the printed materials was 70 minutes (SD= 9.27) for the intervention group and 43 minutes (SD= 17.80) for the control group. While these differences between the groups were identified, none were found to be significant.

3.8. Cancer Worries:

Participants reported elevated levels of cancer worries at both baseline and 1 month thereafter. However, participants in the ETEI group reported a significant decrease in cancer worries over time (baseline: 9 (6, 12) to 1 month: 4 (3, 6); $P < .05$) compared to the control group (baseline (5, 11) to 1 month: 5 (3,13); $P > .05$). Medians and interquartile ranges are depicted in Table 4.

3.9. Decisional Conflict:

Examining decisional conflict at baseline showed moderate levels that did not change significantly from baseline to 1 month thereafter in the total score as well as the in each of the 5 measured subscales, including uncertainty, informed decision, value clarification, decision support, and effective decision (see Table 4).

3.10. Self-Efficacy Beliefs:

Examining differences between the 2 study groups with regard to self-efficacy at 1 month showed similar values of the medians and interquartile ranges; however, the p value of the non-parametric test we used was significant, suggesting that the intervention was beneficial in improving self-efficacy beliefs. Further exploration of the mean values and standard deviation in both groups showed higher values in the intervention group (results not shown here) compared to the intervention group (see Table 4).

3.11. Diet and Nutrition:

We did not observe statistically significant differences between the two study groups with respect to diet and nutrition at baseline or the 1-month assessments.

4. Discussion

With an increased emphasis on engaging patients as partners in their care, effective ways to involve patients in the healthcare decision-making process must be found and applied in patients' care [30-32]. This is particularly relevant to MIBC patients given the necessity of weighing the benefits and risks of treatment options and their deferential impact on patients' HRQOL and disease self-management strategies. Here, we described the development and preliminary evaluation of an educational and training experiential intervention (ETEI) for patients making decision about MIBC treatment. Although the findings included in this paper are based on a small pilot feasibility study, results can be inferred as initial indicators of the feasibility, usability, and efficacy of the ETEI intervention.

Regarding the feasibility of the study, our recruitment rate was 58% and drop-out rate over the period between the study two assessments was about one-third of the study sample (32%). These rates are acceptable and within the ranges reported in prior studies in BC and other newly diagnosed patients undergoing invasive cancer surgeries [42-43]. We have also successfully completed both the intervention and the diet and nutrition (control) sessions as planned and all patients reported reading study educational materials, with 70 minutes and 43 minutes average time spent on study materials by the intervention group and the control group, respectively.

Our prior evaluation of the proposed content of the intervention showed a high rate of acceptability of the ETEI proposed content (90.5%) [20]. Our current results confirmed patients' acceptability and indicated high rates of helpfulness of both the intervention session and materials as depicted by patients' responses to the study closed-ended ratings, and self-recording and usage collected though study questionnaires.

Our prior qualitative assessment of patients' unmet informational needs showed that key factors that contribute to MIBC patients' difficulty in making an informed decision about MIBC include not only a lack of thorough information about RC and UD options and decisional tools to assist patients and their family caregivers with treatment decisions, but also limited resources in clinical settings available to assist patients with information [18, 34]. For newly diagnosed MIBC patients, decisional and self-care supportive care primarily consist of brief pre-operative consultations with the physician and ostomy nurses to discuss surgery, treatment options, and self-care preparations and stoma site selection [20]. Self-care skills education is introduced to the patient during hospital stay at times when patients' learning skills and cognitive function could be negatively influenced by pain, fatigue, or depression [18], A pre-surgical, comprehensive education and availability of decisional tools are likely to improve both treatment decision making and preparation for disease self-management after MIBC treatment.

According to the US Preventive Services Task Force, a comprehensive decisional tool should: a) provide adequate information about the risks, benefits, and limitations of the procedure; b) enhance the patient's ability to participate in decision-making with care providers at a personally desired level; and c) help the patient make a decision that is consistent with his/her personal preferences and values [44]. In line with the US Preventive Services Task Force guidelines, our study results showed that more patients in the intervention groups reported increased knowledge about bladder cancer and UD options, support with the decision, improved value clarification, increased confidence, and improved patient-physician communication compared to patients in the control group.

Our results also showed that patients in the intervention group reported significantly fewer cancer-related worries over time compared to the control group. Similar results were reported in prior studies that applied psychosocial interventions to improve patients' adjustment to treatment outcomes [43-44]. Although we did not apply any psychosocial component to specifically reduce cancer worries or anxiety, our intervention was designed to provide accurate information about RC and UD options, validate patients' concerns, and correct wrong information and unrealistic expectations. It is likely that these aspects of the ETEI were influential in reducing worries and concerns over time.

Comparative analyses showed that participants in the intervention group reported significant increases in efficacy beliefs, measured as abilities to achieve and accomplish goals, as well as improved problem-solving abilities. Because of the significant physical (e.g., urinary function, self-care needs) and psychosocial changes (e.g., altered body image) associated with RC, patients need to learn how to prioritize their goals and learn new skills to adjust to life after their procedure. Provision of information about potential treatment outcomes before surgery and preparing patients for what lies ahead is likely to increase their control beliefs and abilities to learn and apply new coping strategies to reduce stress and deal with future challenges. Our intervention materials included recommendations from patients we interviewed regarding how to deal with challenges (e.g., traveling, going back to work). It is likely that these components, in addition to improved knowledge about treatment outcomes, contributed to increased efficacy beliefs in the intervention group.

Despite assessing the impact of the intervention on reducing patient decisional conflict using standardized measures, our results revealed no significant differences between the intervention and the control groups or within the intervention group overtime. Although the content of the ETEI utilized in this study was comprehensive, additional specific decisional aid content areas were not included. The intervention utilized in this study did not include any exercise to help patients prioritize their preferences and values nor was the ETEI information tailored to any age or gender. This may be an area of concern due to the high value-based characteristics of the decision about UD, multiple options, and the different requirements for self-care (e.g., utility of stomal appliances vs. self-catheterization).Values clarification is a process by which patients can form and communicate the desirability and preferences of each treatment option [40]. Values clarification exercise may include ranking and rating different features of UD options to facilitate treatment decision making (i.e., ranking and rating of risks and benefits of each UD option based on preferences), viewing other patients engaged in decision making, and identifying one's own similarity (e.g., based on age, gender, race) to the values and preferences of patients making similar choices. Research in prostate cancer patients has shown that including a value clarification exercise can improve decision making and reduce decisional regret in newly diagnosed cancer patients [45], Finally, although we used a 6th and 9th grade reading levels in all intervention materials, but we believe that lowering these reading levels further is likely to maximize benefits gained in vulnerable patients (e.g., low literacy patients).

The study results regarding the control group’s evaluation of the diet and nutrition session and materials stand in contrast to those reported by the intervention group. More patients in the control group reported that the diet and nutrition session and materials helped reduce their weight, improved their diet; and helped maintain a healthy lifestyle. Additionally, the control group reported significant decreases in poor appetite over the assessment points compared to the intervention group. Although we pointed out that this study did not attempt to estimate potential benefits of a diet and nutrition education on patient outcomes, these results suggest that the educational materials and the session that patients in the control group addressed health-related needs and improved patient outcomes in relevant areas. Recent qualitative assessments of bladder cancer patients needs have showed preferences for more information about changes in diet and bowel function after surgery, [46-47] which makes the diet and nutrition information ideal for an intervention targeting these issues per se.

5. Study limitations

This study had several limitations. Our study is designed and conducted as a pilot study to explore acceptability, usability, and preliminary efficacy of the intervention we developed. Although the limited size of the study sample allows for confirming acceptability and feasibility study, the results concerning the efficacy of the intervention (i.e., reduced worries and increased self-efficacy beliefs) and the control materials (i.e., reduced appetite loss) should be considered with caution due to the small group sizes. A larger randomized study will be able to test the efficacy of the intervention on study outcomes controlling for potential covariates (e.g., age, gender, treatment type). Additionally, we limited the study to 1-month after baseline. Since many patients will not be able to apply the knowledge gained from the intervention material to use catheters and apply learned skills to empty internal pouches, we expect that extended follow-up assessments will reveal stronger effects of the intervention on study outcomes. Another area of limitation is not including the primary family caregiver in this study. From study participants’ anecdotal report, it became clear to us that the majority of patients involved their family caregivers in the decision making as well as disease in self-management and post-operative care (e.g., utility of stomal appliances and catheters). Thus, including family caregivers will be necessary to evaluate the full impact of the intervention on patients and caregivers and explore the added value of support provided by caregivers on patients’ outcomes. Finally, sick and frail patients were more likely to drop out of the study. This is a potential bias since the most vulnerable patients who are likely to benefit from the intervention were less likely to participate. Our future studies will explore other mechanism for intervention delivery to sustain vulnerable patients’ participations and benefits.

6. Conclusions

In patients with MIBC making decisions about UD options, our intervention was feasible, acceptable and showed a potential for inducing desired changes in cancer worries, and efficacy beliefs. These data support the future implementation of ETEI in clinical trials to further explore and confirm its efficacy in a larger, diverse sample of patients with MIBC.

Acknowledgements

This study is supported by mentored research scholar grants from the American Cancer Society (121193-MRSG-11-103-01-CPPB), and the National Cancer Institute (1R03CA165768-01A1).

We would like to thank Mr. Holden Kata for his help in the editing of this manuscript. We would also like to show our gratitude to the participants in this study and the BCAN Survivorship Working Group in providing input on the original version of the intervention materials.

References

1. National Cancer Institute. SEER Stat Fact Sheets: Bladder Cancer. http://seer.cancer.gov/statfacts/html/urinb.html. Accessed July 2018.
2. Bosetti C, Bertuccio P, Chatenoud L, Negri E, La Vecchia C, Levi F. Trends in mortality from urologic cancers in Europe, 1970–2008. European urology. 2011;60:1–15. [PubMed: 21497988]
3. Edwards BK, Ward E, Kohler BA, Eheman C, Zauber AG, Anderson RN, et al. Annual report to the nation on the status of cancer, 1975– 2006, featuring colorectal cancer trends and impact of interventions (risk factors, screening, and treatment) to reduce future rates. Cancer. 2010; 116:544–73. [PubMed: 19998273]
4. Ferlay J, Randi G, Bosetti C, Levi F, Negri E, Boyle P, et al. Declining mortality from bladder cancer in Europe. BJU international. 2008;101:11–9.
5. Schottenfeld D, Fraumeni JF Jr. Cancer epidemiology and prevention: Oxford University Press; 2006.
6. Burger M, Catto JW, Dalbagni G, Grossman HB, Herr H, Karakiewicz P, et al. Epidemiology and risk factors of urothelial bladder cancer. European urology. 2013;63:234–41. [PubMed: 22877502]
7. Babjuk M, Oosterlinck W, Sylvester R, Kaasinen E, Böhle A, Palou-Redorta J, et al. EAU guidelines on non–muscle-invasive urothelial carcinoma of the bladder, the 2011 update. European urology. 2011;59:997–1008. [PubMed: 21458150]
8. Stenzl A, Cowan NC, De Santis M, Kuczyk MA, Merseburger AS, Ribal MJ, et al. Treatment of muscle-invasive and metastatic bladder cancer: update of the EAU guidelines. European urology. 2011 ;59:1009–18. [PubMed: 21454009]
9. Clark PE. Urinary diversion after radical cystectomy. Current treatment options in oncology. 2002;3:389–402. [PubMed: 12194804]
10. Hardt J, Filipas D, Hohenfellner R, Egle UT. Quality of life in patients with bladder carcinoma after cystectomy: first results of a prospective study. Quality of Life Research. 2000;9:1–12. [PubMed: 10981202]
11. Krupski T, Theodorescu D. Orthotopic neobladder following cystectomy: indications, management, and outcomes. Journal of Wound Ostomy & Continence Nursing. 2001;28:37–46.
12. Stein JP, Lieskovsky G, Cote R, Groshen S, Feng A-C, Boyd S, et al. Radical cystectomy in the treatment of invasive bladder cancer: long-term results in 1,054 patients. Journal of clinical oncology. 2001;19:666–75. [PubMed: 11157016]
13. Sluder U, Danuser H, Hochreiter W, Springer J, Turner W, Zingg E. Summary of 10 years' experience with an ileal low-pressure bladder substitute combined with an afferent tubular isoperistaltic segment. World Journal of Urology. 1996;14:29–39. [PubMed: 8646238]
14. Grossman HB, Natale RB, Tangen CM, Speights V, Vogelzang NJ, Trump DL, et al. Neoadjuvant chemotherapy plus cystectomy compared with cystectomy alone for locally advanced bladder cancer. New England Journal of Medicine. 2003;349:859–66. [PubMed: 12944571]

15. Konety BR, Allareddy V, Herr H. Complications after radical cystectomy: analysis of population-based data. Urology. 2006;68:58–64. [PubMed: 16806414]
16. Kim SP, Booqian SA, Shah ND, Kames RJ, Weight CJ, Moriarty JP, et al. Contemporary trends of in-hospital complications and mortality for radical cystectomy. BJU international. 2012; 110:1163–8. [PubMed: 22443271]
17. Turner WH, Studer UE. Cystectomy and urinary diversion. Semin Surg Oncol. 1997; 13(5):350–8. [PubMed: 9259091]
18. Mohamed NE, Herrera PC, Hudson S, Revenson TA, Lee CT, Quale DZ, et al. Muscle invasive bladder cancer: examining survivor burden and unmet needs. The Journal of urology. 2014;191:48–53. [PubMed: 23911603]
19. Miller SM, Diefenbach MA. C-SHIP: A cognitive-social health information processing approach to cancer In Krantz D (Ed.), Perspectives in Behavioral Medicine. 1998; 219–244. NJ: Lawrence Erlbaum.
20. Mohamed NE, Pisipati S, Cassara M, Goodman S, Lee CT, Knauer CJ, Mehrazin R, Sfakianos JP, Given B, Quale DZ, Hall S. Patients' Evaluation of an Educational and Training Experiential Intervention (ETEI) to Enhance Treatment Decision and Self-Care Following the Diagnosis of Muscle Invasive Bladder Cancer. JOJ Urology & Nephrology. 11 2017;4(2): 555638
21. Okada Y, Oishi K, Shichiri Y, Kakehi Y, Hamaguchi A, Tomoyoshi T, Yoshida O. Quality of life survey of urinary diversion patients: comparison of continent urinary diversion versus ileal conduit. Int J Urol. 1997;4(1): 26–31. [PubMed: 9179663]
22. Asgari M, Safarinejad M, Shakhssalim N, Soleimani M, Shahabi A, Amini E. Sexual function after non-nerve-sparing radical cystoprostatectomy: a comparison between ileal conduit urinary diversion and orthotopic ileal neobladder substitution. International braz j urol. 2013;39:474–83. [PubMed: 24054377]
23. Mohamed NE, Chaoprang Herrera P, Hall S, Diefenbach MA. An Educational Intervention for Patients with Invasive Bladder Cancer Society of Behavioral Medicine. San Francisco 2013.
24. Rammant E, Bultijnck R, Sundahl N, Ost P, Pauwels NS, Deforche B, Pieters R, Decaestecker K, Fonteyne V. Rehabilitation interventions to improve patient-reported outcomes and physical fitness in survivors of muscle invasive bladder cancer: a systematic review protocol. BMJ Open. 2017;7(5)e016054.
25. D'errico GM, Galassi JP, Schanberg R, Ware WB. Development and Validation of the Cancer Worries Inventory. Journal of Psychosocial Oncology. 2000; 17(3-4): 119–137. DOI: 10.1300/J077v17n03_07
26. Légaré F1, Ratté S, Stacey D, Kryworuchko J, Gravel K, Graham ID, Turcotte S. Interventions for improving the adoption of shared decision making by healthcare professionals. Cochrane Database Syst Rev. 2010; 12(5):CD006732.
27. Shariat SF, Sfakianos JP, Droller MJ, Karakiewicz PI, Meryn S, Bochner BH. The effect of age and gender on bladder cancer: a critical review of the literature. BJU international. 2010;105:300–8. [PubMed: 19912200]
28. Foundation Change. Consumers and Canadian health care trending analysis 2004. The Change Foundation in partnership with IBM Business Consulting 2005:27.
29. Berry DL, Nayak M, Halpenny B, et al. Treatment Decision Making in Patients with Bladder Cancer. Bladder Cancer. 2015; 1(2): 151–158. [PubMed: 27376115]
30. Wright JL, Porter MP. Quality-of-life assessment in patients with bladder cancer. Nat Clin Pract Urol, 2007;4(3): 147–54. [PubMed: 17347659]
31. Leon AC, Davis LL, Kraemer HC. The Role and Interpretation of Pilot Studies in Clinical Research. Journal of psychiatric research. 2011;45(5):626–629. [PubMed: 21035130]
32. Leventhal H, Diefenbach MA, Leventhal EA. Illness cognition: Using common sense to understand treatment adherence and affect cognition interactions. Cognitive Therapy and Research. 1992; 16:143–163.
33. Ottawa Health Research Institute. Ottawa decision support framework: Update, gaps and research priorities. http://decisionaid.ohri.ca/odsf.html. Accessed August 2018.
34. Mohamed NE, Pisipati S, Lee CT, Goltz HH, Latini DM, Gilbert FS, et al. Unmet informational and supportive care needs of patients following cystectomy for bladder cancer based on age, sex,

and treatment choices. Urologic Oncology: Seminars and Original Investigations: Elsevier; 2016 p. 531. e7-.e14.

35. Bloch A, Cassileth BR, Holmes MD, & Thomson CA. Eating Well, Staying Well During and After Cancer. Atlanta, GA: American Cancer Society, 2004.
36. Nutrition in cancer care-Patient Version, https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-pdq. Accessed March 2019.
37. Rock CL, Doyle C, Demark-Wahnefried W, et al. Nutrition and physical activity guidelines for cancer survivors. CA: A Cancer Journal for Clinicians 2012;62(4):242–274.
38. O'Connor AM. Validation of a Decisional Conflict Scale. Medical Decision Making. 1995; 15(1):25–30. [PubMed: 7898294]
39. Cella DF et al. The functional assessment of cancer-therapy scale—development and validation of the general measure. J Clin Oncol. 1993; 11:570–579. [PubMed: 8445433]
40. Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In Weinman J, Wright S, & Johnston M, Measures in health psychology: A user's portfolio. Causal and control beliefs (pp. 35–37).
41. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. Applied Psychological Measurement. 1977; 1(3):385–401.
42. Osborn RL, Demoncada AC, Feuerstein M. Psychosocial interventions for depression, anxiety, and quality of life in cancer survivors: meta-analyses. Int J Psych Med 2006;36:13–34.
43. Hart SL, Hoyt MA, Diefenbach M, Anderson DR, Kilboum KM, Craft LL, Steel JL, Cuijpers P, Mohr DC, Berendsen M, Spring B, Stanton AL. Meta-analysis of efficacy of interventions for elevated depressive symptoms in adults diagnosed with cancer. J Natl Cancer Inst. 2012; 104(13):990–1004. [PubMed: 22767203]
44. US Preventive Services Task Force. Screening for prostate cancer: US preventive services task force recommendation statement. Ann Intern Med. 2008; 149: 185–191 [PubMed: 18678845]
45. Sheridan SL, Griffith JM, Behrend L, Gizlice Z, Jianwen Cai, Pignone MP. Effect of adding a values clarification exercise to a decision aid on heart disease prevention: a randomized trial. Med Decis Making. 2010;30(4):E28–39. doi: 10.1177/0272989X10369008. [PubMed: 20484089]
46. Fitch MI, Miller D, Sharir S, McAndrew A. Radical cystectomy for bladder cancer: A qualitative study of patient experiences and implications for practice. Can Oncol Nurs J. 2010 Fall;20(4): 177–87. [PubMed: 21171541]
47. Perils N, Krahn M, Alibhai S, Finelli A, Ritvo P, Bremner KE, Kulkami G. Conceptualizing global health-related quality of life in bladder cancer. Qual Life Res. 2014 10;23(8)2153–67. [PubMed: 24729055]

Table 1:

Demographic and socioeconomic characteristics of bladder cancer participants at baseline (n=25).

Demographic characteristics	All	Control	Intervention	p-value
Number of participants	n = 25	n = 8	n = 17	
Age				
All	68±7.9 (>65: 64%)	67±9.3 (>65: 50%)	69±7.2 (>65: 71%)	0.711
Male	68±8.4 (>65: 60%)	65±9.3 (>65: 40%)	70±8.0 (>65: 70%)	0.515
Female	69±7.4 (>65: 70%)	69±10.8 (>65: 67%)	69±6.5 (>65: 71%)	0.833
Gender				1
Male	15 (60%)	5 (62%)	10 (59%)	
Female	10 (40%)	3 (38%)	7 (41%)	
Race				0.344
White	19 (76%)	5 (62%)	14 (82%)	
Non-White	6 (24%)	3 (38%)	3 (18%)	
Ethnicity				1
Non-Hispanic	22 (88%)	7 (87%)	15 (88%)	
Hispanic/Latino	3 (12%)	1 (13%)	2 (12%)	
Marital status				0.673
Married	13 (52%)	5 (62%)	8 (47%)	
Not married	12 (48%)	3 (38%)	9 (53%)	
Education				1
Some college or above	17 (68%)	5 (62%)	12 (71%)	
Below college	8 (32%)	3 (38%)	5 (29%)	
Employment				0.156
Employed	7 (28%)	4 (50%)	3 (18%)	
Not employed	18 (72%)	4 (50%)	14 (82%)	
Income (Mean)	55,826±37213.9	82,500±45961.1	42,489±29874.0	0.24
BMI				0.719
Mean±SD	27±3.6	27±3.7	26±3.7	
Range	(17-33)	(21-33)	(17-32)	
Current smoker	3 (16%)	3 (38%)	1 (6%)	**0.032**

[*] Data are summarized as mean ± standard deviation, median (interquartile range), or frequency (%).

[**] Categorical variables compared with fisher’s exact tests; Continuous variables compared with Mann-Whitney U Tests – Mean (Frequency) presented.

[*] P-values in bold indicate statistical significance at the p<0.05 level

Table 2:

Clinical and Treatment Characteristics of Study Participants at Baseline

Treatment characteristics at Baseline	**All (n=25)**	**(n=8)**	**Intervention (n=17)**	**p-value**
Did you make treatment decision				1
Yes	22 (95.6%)	7 (100%)	15 (93.7%)	
No	1 (4.4%)	0 (0%)	1 (6.3%)	
What treatment are you leaning toward?				0.174
Ileal conduit	15 (68.2%)	3 (42.8%)	12 (70.6%)	
Continent reservoir	1 (4.5%)	1 (14.4%)	3 (17.6%)	
Neobladder	6 (27.3%)	3 (42.8%)	2 (11.8%)	
Doctor’s treatment preference				0.325
Ileal conduit	14 (70%)	3 (50%)	11 (68.7%)	
Continent reservoir	1 (5%)	1 (16.7%)	3 (18.7%)	
Neobladder	5 (25%)	2 (33.3%)	1 (6.3%)	
Are you insured?				1
Yes	25 (100%)	25 (100%)	25 (100%)	
No	0 (0%)	0 (0%)	0 (0%)	
How strong was treatment recommendation?				0.7713
Very strong	14 (58.3%)	4 (50%)	10 (62.5%)	
Moderately strong	9 (37.5%)	4 (50%)	5 (31.3%)	
Not very strong	0 (0%)	0 (0%)	0 (0%)	
Not at all strong	1 (4.2%)	0 (0%)	1 (6.2%)	
Number of comorbidities	2±2.2	1±1.7	2±2.5	0.8348

[*] Categorical variables compared with fisher’s exact tests; Continuous variables compared with Mann-Whitney U Tests – Mean (Frequency) presented.

[*] P-values in bold indicate statistical significance at the p<0.05 level

Table 3:

Responses on educational materials from control group and intervention group.

Printed Material at 1 Month	**Control (n=6)**	**Intervention (n=11)**	**p-value**
Increased my knowledge about bladder cancer and its treatment	3 (50%)	9 (82%)	0.3077
Helped (supported) me make treatment decisions	3 (50%)	7 (64%)	1
Helped me talk to my doctors about my bladder cancer	3 (50%)	8 (73%)	1
Made me feel less anxious or upset about my bladder cancer	2 (33%)	8 (73%)	0.2028
Made me feel more confident in how I deal with my bladder cancer	3 (50%)	8 (73%)	1
Sort out what's important to me for choosing a treatment?	3 (50%)	7 (64%)	1
Made me feel less confident in how I deal with my bladder cancer	0 (0%)	0 (0%)	1
Helped me know more about bladder cancer, its treatment, and short and long-term side effects	3 (50%)	9 (82%)	0.3077
Helped me reduce my weight	3 (50%)	2 (18%)	0.2168
Helped me improve my diet	3 (50%)	3 (27%)	0.2657
Helped me maintain a healthy life style	4 (67%)	5 (45%)	0.5804
Helped me prepare for changes in my sexual function after treatment	1 (17%)	6 (55%)	1
Time spent on reading printed materials (min) (Mean±SD)	43±17.80	70±39.27	0.2

[*] Categorical variables compared with fisher’s exact tests; Continuous variables compared with Mann-Whitney U Tests – Mean (Frequency) presented.

[*] P-values in bold indicate statistical significance at the p<0.05 level

Table 4:

Cancer worries and concern in participants with bladder cancer at baseline and 1 month

			Control		Intervention	
	Full Sample at baseline (n=25)	**Full Sample at 1 Month (n=17)**	**Baseline (n =8)**	**1 month (n = 6)**	**Baseline (n = 17)**	**1 month (n = 11)**
Provisional cancer and treatment related worries	8 (5.3, 12)	4.5 (3, 7)	7 (5, 11)	5 (3, 13)	9 (6, 12)	4 (3, 6) *
FACT-BL						
I feel nervous	2 (1, 3)	0 (0, 1)	1.5 (1, 2)	0 (0, 2)	2 (1.75, 3)	0 (0, 1) ***
Center for epidemiologic studies depression scale						
I did not feel like eating; my appetite was poor	1 (0, 1)	0 (0, 0.25)	1 (1, 1)	0 (0, 0) **	0 (0, 1)	0 (0, 1.5)
Self-efficacy belief						
It is easy for me to stick to my aims and accomplish my goals	3 (3, 4)	3 (3, 3.3)	3 (3, 4)	3 (3, 3)	3 (3, 4)	3 (3, 4) †
If I am in trouble, I can usually think of a solution.	3 (3, 4)	3 (3, 3.3)	3 (3, 3.3)	3 (3, 3)	3 (3, 4)	3 (3, 4) †
Decision Score						
Total score	25 (5, 28)	25 (10.5, 25.5)	21 (11, 29)	25 (13, 25)	25 (5, 28)	25 (7.5, 26)
Uncertainty score	25 (17, 33)	25 (17, 33)	25 (23, 33)	25 (25, 33)	25 (17, 50)	25 (8.5, 29)
Informed score	25 (0, 25)	25 (12.7, 25)	21 (6, 25)	25 (17, 25)	25 (0, 25)	25 (12.5, 25)
Values score	25 (0, 25)	25 (6, 25)	25 (12.5, 29)	25 (17, 25)	25 (0, 25)	25 (4, 25)
Support score	12 (0, 25)	25 (9, 25)	18.5 (0, 25)	25 (0, 25)	12 (0, 25)	25 (12, 25)
Effective score	25 (0, 31)	25 (0, 25)	25 (0, 28.25)	25 (0, 25)	25 (0, 31)	25 (3, 25)

*Categorical variables compared with fisher’s exact tests; Continuous variables compared with Mann-Whitney U Tests – Median (IQR) presented.

Compared with baseline:

*p<0.05,

**p<0.01,

***p<0.001

Compared with control group :

†p<0.05,

††p<0.01,

†††p<0.001

Note:

Item groups	**Scale meaning**
Provisional cancer and treatment related worries	Higher score means more worries
FACT-BL	Higher score means more worries
Center for epidemiologic studies depression scale	Higher score means more depressed
Self-efficacy belief	Higher score means doing better

Item groups	**Scale meaning**
Provisional cancer and treatment related worries	Higher score means more worries
FACT-BL	Higher score means more worries
Center for epidemiologic studies depression scale	Higher score means more depressed
Self-efficacy belief	Higher score means doing better