The Personal Patient Profile-Prostate, Decision Support for Men With Localized Prostate Cancer: A Multi-center Randomized Trial

Donna L Berry, PhD, RN, FAAN[1], **Barbara Halpenny, MA**[1], **Fangxin Hong, PhD**[1,2], **Seth Wolpin, MPH, PhD, RN**[3], **William B Lober, MD**[4], **Kenneth J Russell, MD**[5], **William J Ellis, MD**[6], **Usha Govindarajulu, PhD**[7], **Jaclyn Bosco, PhD**[1], **B Joyce Davison, PhD, RN**[8], **Gerald Bennett, PhD, APRN, FAAN**[9], **Martha K Terris, MD**[10], **Andrea Barsevick, PhD, RN, FAAN**[11], **Daniel W Lin, MD**[6,12], **Claire C Yang, MD**[6,12], and **Greg Swanson, MD**[13]

[1]Dana-Farber Cancer Institute, Phyllis F. Cantor Center, Boston, MA

[2]Dana-Farber Cancer Institute, Department of Biostatistics and Computational Biology, Boston, MA

[3]University of Washington (UW) Biobehavioral Nursing & Health Systems, Seattle, WA

[4]UW, Biobehavioral Nursing & Health Systems, Medical Education & Biomedical Informatics, Seattle, WA

[5]UW, Department of Radiation Oncology, Seattle, WA

[6]UW, Department of Urology, Seattle, WA

[7]Brigham and Women's Hospital, Department of Medicine, Boston, MA

[8]University of Saskatchewan, Saskatoon, Canada

[9]Georgia Health Sciences University, College of Nursing, Augusta, GA, United States; Charlie Norwood VA Medical Center, Research and Development Service Line, Augusta, GA

[10]Charlie Norwood VA Medical Center, Division of Surgery, Urology Section, Augusta, GA, United States; Georgia Health Sciences University, Department of Surgery, Section of Urology, Augusta, GA

[11]Fox Chase Cancer Center, Philadelphia, PA

[12]VA Puget Sound Healthcare System, Seattle, WA, United States; UW, Department of Urology, Seattle, WA

[13]South Texas Veterans Health Care System, San Antonio, TX; University of Texas Health Science Center at San Antonio, Department of Radiation Oncology, TX

Abstract

Corresponding author: Donna L Berry, Dana-Farber Cancer Institute, 450 Brookline Ave, LW-518, Boston, MA 02115, 617.632.1909 (tel); 617.582.8550 (fax), donna_berry@dfci.harvard.edu.

OBJECTIVE—The purpose of this trial was to compare usual patient education plus the Internet-based, Personal Patient Profile-Prostate, versus usual education alone, on conflict associated with decision making, plus explore time-to-treatment and treatment choice.

METHODS—A randomized, multi-center clinical trial was conducted with measures at baseline, one and six months. Men with newly diagnosed localized prostate cancer who sought consultation at urology, radiation oncology or multi-disciplinary clinics in four geographically-distinct American cities were recruited. Intervention group participants used the Personal Patient Profile-Prostate, a decision support system comprised of customized text and video coaching regarding potential outcomes, influential factors, and communication with care providers. The primary outcome, patient-reported decisional conflict, was evaluated over time using Generalized Estimating Equations to fit generalized linear models. Additional outcomes, time-to-treatment, treatment choice and program acceptability/usefulness, were explored.

RESULTS—A total of 494 eligible men were randomized (266 intervention; 228 control). The intervention reduced adjusted decisional conflict over time as compared with the control group, for the *uncertainty* score (estimate −3.61; (confidence interval, −7.01,−0.22) and *values clarity* (estimate −3.57; confidence interval (−5.85,−1.30) Borderline effect was seen for the *total* decisional conflict score (estimate −1.75; confidence interval (−3.61,0.11). Time-to-treatment was comparable between groups, while undecided men in the intervention group chose brachytherapy more often than in the control group. Acceptability and usefulness were highly rated.

CONCLUSION—The Personal Patient Profile-Prostate is the first intervention to significantly reduce decisional conflict in a multi-center trial of American men with newly diagnosed localized prostate cancer. Our findings support efficacy of P3P for addressing decision uncertainty and facilitating patient selection of a prostate cancer treatment that is consistent with the patient values and preferences.

Keywords

prostate cancer; randomized trial; Internet; decision making; decisional conflict

Introduction

Approximately 217,730 American men were diagnosed with prostate cancer in 2010, while about 32,050 died from prostate cancer in the same year.[1] To date, no North American randomized trial clearly demonstrates that aggressive therapy for localized prostate cancer (LPC) results in a survival advantage, except for men with highest risk disease.[2] In 2010, the National Comprehensive Cancer Network published guidelines[3] recommending active surveillance for men with low-risk LPC and a life expectancy <10 years and those with very low-risk LPC and life expectancy <20 years. For men seeking intervention, there are a myriad of options: prostatectomy of various approaches, cryosurgery, external beam radiotherapy, brachytherapy and hormonal therapy. Choosing a course of action is difficult for most men and both decisional conflict (DC) and uncertainty experienced by men with LPC have been documented in qualitative[4–6] and quantitative studies. [7,8] There is a growing body of evidence that men with a recent diagnosis of LPC make their treatment decision by strongly considering their personal characteristics and factors, such as, the relative importance of maintaining sexual function or friends' experiences with prostate cancer. [5,8–13]

The Ottawa Decision Support Framework (ODSF)[14,15] identified decisions that are informed, values-based (decision quality) and implemented without undue delay (action) as the goal in health care. In the framework, decisional conflict (DC) is a factor amenable to

interventions that enhance decision making by addressing patients' decisional needs and result in a quality decision.

To address decisional needs, investigators have developed patient education programs, [16–19] nurse coaching telephone interventions[20] or websites[21] to inform men about medical options and facilitate a decision. However, only a few have been evaluated in randomized trials[16,17,20] and none have comprehensively addressed the personal preferences which men bring to the decision. Furthermore, components of DC have either not been measured, were compared to historical controls only, [19] or, as in Davison's work, were not found to be significantly different between trial arms,[17] despite being cited by Cochrane reviewers[22] as key attributes with which to evaluate the impact of health treatment decisions for LPC. Thus, the evidence for any decision support system tested in the LPC setting is quite limited with regard to reducing DC. Experts continue to call for validated and tested decision support programs as integral components of treatment consultation.[23]

The Personal Patient Profile – Prostate (P3P) is a tailored, Internet technology that has been developed and evaluated for feasibility and acceptability.[24] We report now on an efficacy trial that focused on facilitating LPC treatment decision making by addressing both medical and personal factors relevant to each participant's decision. The purpose of the study was to compare DC over time at one and six months after enrollment in men receiving usual patient education strategies plus the P3P, versus usual patient education strategies alone, as preparation for consultation with a cancer specialist, in a diverse, multi-center sample of men with LPC. We hypothesized lower levels of DC in the intervention group and report those findings in this paper. In addition, we explored the effect of the P3P on time-to-treatment and treatment choice.

Methods

This prospective, randomized clinical trial was conducted at six institutions in four cities: Seattle, San Antonio, Philadelphia and Augusta, Georgia, between March 2007 and November 2009. Overseen by the Fred Hutchinson Cancer Research Center/University of Washington Cancer Consortium Review Board, all study centers had active approval for the duration of the trial and analyses. Eligible participants had T1 or T2, histologically-proven LPC, were consulting with specialists who perceived that each participant was a candidate for at least two treatment options, and had not begun therapy. Risk level was not calculated. Men with advanced disease or those who had received prior treatment were excluded. All men were able to read English or Spanish at 6th grade level, estimated by the research assistant during the written consent process. The sample was intended to include a diverse group of men for whom a choice between two or more care options was available.

Consenting patients were invited to complete validated questionnaires comprising (1) the P3P query component (Table 1); and (2) research measures, on touch-screen computers in clinic waiting rooms prior to the consult visit with a cancer specialist. Men who had home broadband Internet access could complete the P3P in advance; they were emailed a secure link, username, and password, and access was authenticated using Lightweight Directory Access Protocol (LDAP). Home users viewed consent elements before using the program, and all participants provided written consent in clinic. Participants were randomized automatically by the P3P application to study groups (1:1 using a simple randomization scheme with no blocking); assignment was not blinded to participants, who knew whether or not they received the intervention, but blinded to study staff unless participants serendipitously revealed use of the intervention. The 1-month and 6-month follow-up measures were obtained online or by mail questionnaire.

Intervention and Measures

The P3P intervention was designed to provide basic education about LPC management and also deliver education customized to the specific preferences and concerns of each user and then coach the user on how to share these issues with the physician consultant. The development and pilot testing of the program demonstrated a practical, highly acceptable intervention and have been reported previously.[24] The following categories of participant responses in the query section of P3P formed the foundation of the coaching and educational intervention: age, race and ethnicity, influential personal factors[8] (e.g., erectile function concerns), information priorities,[10] decisional control preferences[10] and current symptoms.[25] Table 1 illustrates the method in which the text and video intervention was tailored to the participants' personal factors and delivered in five distinct sections corresponding to the categories above for the intervention group participants.

Our interface[24] applied expert recommendations for graphic display of communicating risk for health outcomes[27,28] and closely adhered to the National Cancer Institute's recommendations[29] for appropriate user-interface design. After completing the P3P query component, both groups were offered links to reputable websites [30] for prostate cancer education.[31–34] Men in both groups also received the usual patient education resources for each clinic, typically books or pamphlets.

To obtain our primary outcome of self-reported decisional conflict, home users were prompted to enter the study website and clinic users received mailed questionnaires with postage-paid return envelopes at one and six month(s) after completing the baseline query. The Decisional Conflict Scale (DCS) [35] addresses 5 key aspects of conflict inherent in patient decision making (Table 2). O'Connor's research team developed the questionnaire as a diagnostic tool for uncertainty about a course of action relevant to health. Such uncertainty and conflict has been documented in high-stake health decision scenarios in which outcomes are uncertain and evidence for the best medical approach is either mixed or lacking.[22] The questionnaire has been utilized in thousands of subjects in over 30 trials. Cronbach's alpha coefficients for the DCS in this trial ranged across three time-points: subscales of *uncertainty (.83–.90), informed (.86–.90), values clarity (.87–.89), support (.59–.81), effective decision (.88–.89)*, and *total score* (.93–.94).

Sociodemographic and clinical characteristics were self-reported at baseline. Baseline anxiety was measured by the Spielberger State-Trait Anxiety Inventory.[36] Cronbach's alpha coeeficients were .96 (state) and .94 (trait) in this sample. Time-to-treatment start was collected via self-report and confirmed through medical record review when available. P3P program user acceptance was measured in the intervention arm after initial P3P use with the Acceptability E-scale.[37] Cronbach's alpha for the six-item Acceptability E-scale was .79. Additional items were added to rate *value of the information* and *usefulness* of specific components.

Analyses

With the target sample size of 498 (214/arm, estimating a 14% attrition rate), the study was designed to have 90% power at .05 significance level to detect an effect size of .32 in DCS scores. Baseline characteristics and scores were summarized by group with descriptive statistics and compared using the Wilcoxon rank sum test for continuous variables and Fisher's exact test/Chi-square test for categorical variables.

The DCS data were collected at baseline, 1-month and 6-month. For each subscale and the total score, item scores were: a) averaged; b) multiplied by 25; resulting scores ranged from 0 (low conflict) to 100 (high conflict). [38] Data were classified as missing for a given subscale if one-third of items were missing or for the total score if any subscale score was

missing. Many men had not made a baseline treatment decision (48%) and could not report on the effectiveness of decision making; this "missing" percentage decreased at one and six months to 22% and 19%, respectively. The analysis of DC includes all participants for the first four subscales, *uncertainty*, *informed, values clarity and support*, and only participants who had made a decision by six months for the fifth subscale, *effective decision* and the *total score*.

We conducted an intent-to-treat analysis using Generalized Estimating Equations (GEE) to fit a generalized linear model of the DC outcomes, accounting for correlation among outcomes at 1- and 6- months within each individual. We fit a separate model for each subscale and the total score. Attrition was assumed missing-at-random and validated by checking baseline characteristics with the participants with complete data, no imputation was performed.[39] In addition to randomized group effects, we considered a list of preselected covariates previously identified to influence decision making outcomes[8] which included individual baseline measures of anxiety, DC subscale scores and demographic/clinical factors. The associations between the intervention and the DC outcomes were adjusted for the covariates. Factors that were significantly (p 0.05) associated with at least one subscale or total score in multivariable analysis formed an inclusive list of covariates for estimating group effects. A type III p-value was used to assess overall significance. All statistical tests were two-sided at a significance level of 0.05.

We conducted exploratory analyses to further understand the effect of the intervention on DC. Time-to-treatment start was defined as the time between study entry and treatment start (or watchful waiting), was censored at the last follow-up date for participants who remained undecided, and was compared between groups using a log-rank test. Treatment choices made at one and six months by men without baseline treatment preferences were described and compared by group. User acceptance and satisfaction with the intervention were examined using descriptive statistics.

Results

Sample

A total 494 eligible participants were enrolled (Figure 1) over 27 months and allocated to the control (n=228) or intervention groups (n=266) using simple randomization.[40] Because the initial study design included six sites with at least 72 participants planned per site, we chose to employ simple randomization to allocate participants to study groups. This strategy may generate imbalance between groups, but according to Elliot,[40] produces samples that are at least 95% as efficient as those derived from more complex randomization strategies. Our actual sample of 228 control and 266 intervention group participants falls within the expected limits of simple randomization, as we confirmed through repeated simulation of 500-person samples. Although recruitment problems at two sites resulted in enrollment of 25 or fewer participants, there was no significant difference in group allocation by site (p=.70).

Table 3 describes sociodemographic, clinical characteristics and baseline measures of the randomized participants. There were no significant differences between groups for any baseline measure. Study centers with Hispanic/Latino populations were Veterans Administration facilities; all spoke and read English and no participant chose to use the P3P Spanish version. The 1-month follow-up questionnaire was completed by 89% of all participants, and 88% completed at 6-months. The P3P initially was accessed from a home computer by 339 (69%) participants; 254 (58%) at one month and 227 (52%) at six months answered online versus by mail.

Primary outcomes

A total of 467 participants completing the 1-month, 6-month, or both DC questionnaires were included in the analysis. The following variables were considered, but not retained in the covariate list included baseline state anxiety, decision preference stated at baseline and whether the P3P was accessed in clinic or at home. We observed significant correlations among the covariates retained in the model. The estimated effects and 95% confidence intervals (CI) from the GEE analyses are listed in Table 4. The P3P intervention, compared with the control group, significantly reduced DC over time for the two subscales of *uncertainty,* −3.61 units (95% CI, −7.01 to −.22) (p= 0.04) and *values clarity*, −3.57 units (95% CI, −5.85 to −1.30) (p= 0.002). This change corresponds to 13.3% and 17.2% of the baseline variability (as seen in Table 3) for the uncertainty and values clarity subscales, respectively. We observed a borderline effect for the total DC score with −1.75 units reduction (95% CI, − 3.60 to −.011) (p= 0.07), but the reduction was not statistically significant in the informed, support and effective decision subscales.

Decisional conflict resulting from inadequate information with which to make a decision (*informed* subscale) was significantly associated with clinical site, being older, non-white, having less income, more trait anxiety, plus baseline measures of inadequate information and support. The DC relevant to lack of *values clari*ty was associated with clinical site, less income, minimal pre-enrollment use of the Internet and baseline lack of *values clarity and* inadequate *support.* Conflict related to perceived *support* significantly decreased as men were further from biopsy by number of weeks, with the largest decrease between one and two weeks, plus associations with clinical site, non-white race and baseline *support* scores. Being an *effective decision* maker was associated only with baseline *support* scores. Finally, the *total* DC score was associated with clinical site, time since enrollment and baseline *uncertainty* and lack of *support.*

Exploratory outcomes

While the difference was not statistically significant, men without a baseline treatment preference in the intervention group started treatment (including a watchful waiting decision) sooner than those in the control group. There was no significant difference in the median time to treatment in the intervention (1.8 months) and the control (1.9 months) group (p = .15). Among the 235 undecided men, we observed 2.5 months for control and 2.0 months for intervention participants (p = .35).

The majority of undecided men at baseline ultimately made a choice within 6 months of enrollment (Table 5). There were no significant differences between groups among men who selected a watchful waiting approach, prostatectomy or external beam radiotherapy. While only 23 men chose brachytherapy by 6-months overall, we observed a significantly higher proportion in the intervention group.

P3P program acceptability and usefulness were highly rated. Scores for the Acceptability Escale[37] averaged 25.1 (SD=3.8), meeting our previously-established criteria for good acceptability. The new *value of information* item mean score was 3.8 (SD=1.0). Of the intervention components, *links to external websites* and teaching on *statistics* were rated most highly; all five components were rated with a usefulness mean of >3.7.

Discussion

The P3P is the first intervention to significantly reduce *uncertainty* and decisional conflict associated with *values clarity* in a multi-center, American sample of men with newly diagnosed localized prostate cancer. Significantly lower conflict scores were estimated for *decision uncertainty and values clarity* when adjusted for confounding or influential

variables. The content of both of these subscales centers on the challenge of making a decision that is best suited to the individual respondent. The P3P was developed to address men's personal factors that influence a treatment decision, bringing those factors to the forefront along with medical factors and prepare a man to engage in shared decision making along with his clinician.[24] Notably, the qualitative work[5] on which P3P was founded revealed a basic process of "making the best choice for me" (p. 97). Contemporary researchers and clinicians have continued the call for effective interventions that support men and consulting providers engaged in treatment decision making for LPC. [41–43] The low-risk patient today will hear a menu of treatment approaches including active surveillance and various modalities. Our study builds on results of previous work (ours and others) which described the clinical dilemma and pilot-tested various interventions. In a single-institution pilot trial, Davison and colleagues[17] found no difference in DC between an informational video compared to individualized information topics, but observed higher patient satisfaction with the individualized information. Mishel and colleagues[20] reported a non-tailored booklet and DVD intervention, supplemented (or not) by four nurse phone calls to reinforce the materials between diagnosis of LPC and the treatment options review visit. In this racially diverse sample, the intervention groups (men alone or with partners) reported higher prostate cancer knowledge, problem solving skills and patient-provider communication at four weeks compared to men who received a handout on staying healthy. While these results demonstrate the ability of a nurse-enhanced educational intervention to educate men who reported better problem solving skills and communication with physicians, the labor intensity of such an intervention may preclude widespread use in many settings.

Our findings are consistent with studies in other health decision settings, including the contexts of prostate cancer screening,[44–47] colorectal cancer screening[48,49] genetic testing,[50,51] breast cancer surgery[52,53] and ovarian cancer risk management. [54] Randomized trials have shown the impact of decision support interventions on reduced DC, most often measured by the total score of the DCS. Despite the wide use of DC as an outcome in such trials, few studies have conducted analyses adjusting for baseline measures and demographics. Thus, we cannot place the statistically significant reduction in DC subscales of *uncertainty* and *values clarity* DC in the context of previous trials results. We do know among cancer screening studies that analyzed all subscales of the DCS, the *informed* and *values clarity* subscales were most often impacted by decision support interventions in the short term (e.g., two weeks).[45,48,49] We believe the lack of an intervention effect on the *informed* subscale in our trial may be related to the number of men who had stated a treatment preference before using the intervention and the estimated influence of income which could be a surrogate for a high level of resourcefulness in gathering information prior to study enrollment. Alternatively, since we analyzed our outcomes over six months and not immediately after using the intervention, any short term increase in knowledge may have equilibrated between groups. The finding that men who were farther out from biopsy at study enrollment eventually reported more decision *support* also suggests the preparation already engaged in by nearly half the sample was key. This pre-enrollment preparation time also may explain why decisional conflict related to lack of information and inadequate support was not significantly impacted by the P3P intervention.

Men who were younger, of white race, and reported higher incomes also reported lower conflict relevant to being *informed*. Non-white men perceived less decision *support*. These findings are consistent with studies of health disparities[55,56] and suggest the need to further customize the P3P information and coaching to minority race and ethnic populations, those who are most likely to benefit from decision support.

A relationship between use of the Internet prior to study enrollment and reduced DC in only the *values clarity* subscale is interesting and a new finding in the LPC setting. Perhaps the

Internet use did not simply add to being informed, but was most influential by helping men rule out treatment options that did not match their own values and preferences. The significant association of *uncertainty* scores with baseline trait anxiety is consistent with our prior descriptive work[8] and the clinical observation that men with anxious personalities are more challenged by the complexities of the LPC treatment decision.

Despite controlling for the clinical and sociodemographic variables and baseline DC and anxiety measures, the study center at which the patient received consultation was a significant predictor of our DC outcomes. Perhaps some unmeasured component of clinical procedures (e.g., disclosure methods of new cancer diagnosis, treatment option presentation style, time between consultation and decision) may have influenced the experience of DC. Future analysis and research on such variables will be necessary to address these differences.

Our results indicated that the P3P intervention did not significantly reduce the time to treatment start, but that for men who were undecided before using the intervention, time to treatment was shorter. Many unmeasured, confounding variables are likely to impact time to treatment and the intervention was not designed to speed a decision. Participants may have been searching for decision assistance for weeks to months. Given that half of our sample was at least 4 weeks past the biopsy and reported knowing a treatment preference at enrollment, the P3P intervention may not have had the same impact as if the sample had been enrolled earlier in the decision making process. Additional research is warranted to examine such an outcome. Reduced delay to treatment has been theorized as an indication of decision quality in the ODSF.[15] We explored treatment decisions among men without a baseline treatment preference by group. Our results are similar to recent findings of the national Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) registry in that about half of our sample chose a form of invasive therapy (prostatectomy or brachytherapy). Cooperberg and colleagues[57] reported about half of 11,892 men seen in 36 urology practices chose prostatectomy and 12% chose external beam radiotherapy. Contrary to CaPSURE, a lower proportion of men chose prostatectomy and a higher proportion chose external beam radiotherapy in our study, a finding likely due to the fact that we recruited men from radiation oncology practices as well as urology. Also, more men in our P3P intervention group chose brachytherapy than the control group, suggesting the intervention prompted men to discuss their personal concerns with consulting physicians and may have subsequently heard more about the options that best matched their concerns.

This trial is limited primarily by the apparent influence of unknown or unmeasured variables that may have affected the outcomes. No stratification factors were employed. It is possible that the intervention integrity, in time allotted in the clinic for users without home access, was not balanced between groups. Our results are limited to North American English speakers.

Further development and testing of the P3P is indicated to enhance the impact of the intervention on other aspects of DC, notably providing enhanced information specific to race, and delivering the intervention at a time when decision support need is the greatest, resulting in more effective decision making. The most straightforward test of efficacy next will be exclusively in the urological setting soon after biopsy results are known and before the first options consult.

Our findings have implications for clinical practice. Addressing men's personal factors such as concerns about potential adverse outcomes and impact on quality of life, the influence of significant members of a man's social network, misunderstandings about the various care and treatment options appears to have empiric benefit to the man with LPC. The P3P

facilitates and customizes this approach to preparing for the treatment decision. Not all practices have access to the P3P at this time, however we plan to deploy the program on the Internet in the near future. In the meantime, clinicians are encouraged to include the personal factors during the options consult.

Conclusion

The P3P is the first customized decision support technology for LPC to be evaluated in a multi-center trial in various regions of the United States. Our findings support efficacy of P3P for addressing decision uncertainty and facilitating patient selection of a prostate cancer treatment that is consistent with the patient values and preferences. The effects were measureable and modest and were observed in the dimensions that were expected to have the greatest impact considering the timing of the intervention in the patients' care. Given that the P3P intervention is a feasible, low-risk, educational intervention and is automated, requiring very little provider time or effort, we are encouraged to proceed with further testing and implementation.

Acknowledgments

References

1. Siegel R, Ward E, Brawley O, Jemal A. Cancer statistics, 2011: The impact of eliminating socioeconomic and racial disparities on premature cancer deaths. CA Cancer J Clin. 2011; 61:212–36. [PubMed: 21685461]

2. Wilt, T. The VA/NCI/AHRQ CSP #407: Prostate cancer intervention versus observation trial (PIVOT): main results from a randomized trial conparing radical prostatectomy to watchful waiting in men with clinically localized prostate cancer. Presented at the American Urological Association Annual Meeting Plenary Session; Washington DC. May 17, 2011;

3. Prostate Cancer Panel. Prostate Cancer, NCCN Clinical Practice Guidelines in Oncology. National Comprensive Cancer Network; 2010.

4. O'Rourke ME, Germino BB. Prostate cancer treatment decisions: a focus group exploration. Oncol Nurs Forum. 1998; 25:97–104. [PubMed: 9460777]

5. Berry DL, Ellis WJ, Schwien CC, Woods NF. Treatment decision making by men with localized prostate cancer: the influence of personal factors. Urologic Oncology. 2003; 21:93–100. [PubMed: 12856636]

6. Bailey DE Jr, Wallace M, Mishel MH. Watching, waiting and uncertainty in prostate cancer. J Clin Nurs. 2007; 16:734–41. [PubMed: 17402955]

7. Steginga SK, Occhipinti S, Gardiner RA, Yaxley J, Heathcote P. Prospective study of men's psychological and decision-related adjustment after treatment for localized prostate cancer. Urology. 2004; 63:751–6. [PubMed: 15072894]

8. Berry DL, Ellis WJ, Blasko JB, et al. Factors That Predict Treatment Choice and Satisfaction with the Decision in Men with Localized Prostate Cancer. Clinical Genitourinary Cancer. 2006; 5:219–226. [PubMed: 17239276]

9. Feldman-Stewart D, Brundage MD, Van Manen L. A decision aid for men with early stage prostate cancer: theoretical basis and a test by surrogate patients. Health Expect. 2001; 4:221–34. [PubMed: 11703496]

10. Davison BJ, Gleave ME, Goldenberg SL, Degner LF, Hoffart D, Berkowitz J. Assessing information and decision preferences of men with prostate cancer and their partners. Cancer Nurs. 2002; 25:42–9. [PubMed: 11838719]

11. Patel HR, Mirsadraee S, Emberton M. The patient's dilemma: Prostate cancer treatment choices. Journal of Urology. 2003; 169:828–833. [PubMed: 12576794]

12. Steginga SKSO, Gardiner RA, Yaxley J, Heathcote P. Making decisions about treatment for localized prostate cancer. BJU Int. 2002; 89:255–260. [PubMed: 11856106]

13. Diefenbach MA, Dorsey J, Uzzo RG, et al. Decision-making strategies for patients with localized prostate cancer. Semin Urol Oncol. 2002; 20:55–62. [PubMed: 11828358]

14. O'Connor, A.; Jacobsen, M. Decisional Conflict: Supporting people experiencing uncertainty about options affecting their health. Ottawa: Ottawa Hospital Research Institute; 2007. at https://decisionaid.ohri.ca/ODST/pdfs/DC_Reading.pdf [Accessed August, 2011]

15. Ottawa Health Research Institute. Ottawa Decision Support Framework: Update, Gaps and Research Priorities. Ottawa: 2010. at http://decisionaid.ohri.ca/odsf.html [accessed 12 May 2011]

16. Auvinen A, Hakama M, Ala-Opas M, et al. A randomized trial of choice of treatment in prostate cancer: the effect of intervention on the treatment chosen. BJU Int. 2004; 93:52–6. discussion 56. [PubMed: 14678367]

17. Davison BJ, Goldenberg SL, Wiens KP, Gleave ME. Comparing a generic and individualized information decision support intervention for men newly diagnosed with localized prostate cancer. Cancer Nurs. 2007; 30:E7–15. [PubMed: 17876177]

18. Holmes-Rovner M, Stableford S, Fagerlin A, et al. Evidence-based patient choice: a prostate cancer decision aid in plain language. BMC Med Inform Decis Mak. 2005; 5:16. [PubMed: 15963238]

19. Steginga SK, Ferguson M, Clutton S, Gardiner RA, Nicol D. Early decision and psychosocial support intervention for men with localised prostate cancer: an integrated approach. Support Care Cancer. 2008; 16:821–9. [PubMed: 17960429]

20. Mishel MH, Germino BB, Lin L, et al. Managing uncertainty about treatment decision making in early stage prostate cancer: a randomized clinical trial. Patient Educ Couns. 2009; 77:349–59. [PubMed: 19819096]

21. Diefenbach MA, Butz BP. A multimedia interactive education system for prostate cancer patients: development and preliminary evaluation. J Med Internet Res. 2004; 6:e3. [PubMed: 15111269]

22. O'Connor AM, Bennett CL, Stacey D, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2009:CD001431. [PubMed: 19588325]

23. Chamie K, Saigal CS, Litwin MS. Patients and solipsism: the psychology of decision making for prostate cancer treatment. Urol Oncol. 2011; 29:233–4. [PubMed: 21714161]

24. Berry DL, Halpenny B, Wolpin S, et al. Development and evaluation of the personal patient profile-prostate (P3P), a Web-based decision support system for men newly diagnosed with localized prostate cancer. J Med Internet Res. 2010; 12:e67. [PubMed: 21169159]

25. Szymanski KM, Wei JT, Dunn RL, Sanda MG. Development and validation of an abbreviated version of the expanded prostate cancer index composite instrument for measuring health-related quality of life among prostate cancer survivors. Urology. 2010; 76:1245–50. [PubMed: 20350762]

26. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. Can J Nurs Res. 1997; 29:21–43. [PubMed: 9505581]

27. Ancker JS, Senathirajah Y, Kukafka R, Starren JB. Design features of graphs in health risk communication: a systematic review. J Am Med Inform Assoc. 2006; 13:608–18. [PubMed: 16929039]

28. Apter AJ, Paasche-Orlow MK, Remillard JT, et al. Numeracy and communication with patients: they are counting on us. J Gen Intern Med. 2008; 23:2117–24. [PubMed: 18830764]

29. Usability.gov. US Department of health and Human Services; 2011. at http://usability.gov/guidelines/index.html [Accessed 14 May 2011]

30. Fagerlin A, Rovner D, Stableford S, Jentoft C, Wei JT, Holmes-Rovner M. Patient education materials about the treatment of early-stage prostate cancer: a critical review. Ann Intern Med. 2004; 140:721–8. [PubMed: 15126256]

31. American Society of Clinical Oncology. Prostate Cancer. Alexandria, VA: ASCO; 2011. at http://www.cancer.net/patient/Cancer+Types/Prostate+Cancer [Accessed 18 May 2011]

32. National Cancer Institute. What you need to know about prostate cancer. Bethseda: 2011. at http://www.cancer.gov/cancertopics/wyntk/prostate [Accessed 18 May 2011]

33. The Prostate Centre. Prostate Cancer. Toronto: Princess Margaret Hospital; 2011. at http://www.cancer.gov/cancertopics/wyntk/prostate [Accessed 18 May 2011]

34. US TOO International. Prostate Cancer Education & Support. Illinois: 2011. at http://www.ustoo.com/Contact_UsTOO.asp [Accessed 18 May 2011]

35. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995; 15:25–30. [PubMed: 7898294]

36. Spielberger, C. State-Trait Anxiety Inventory for Adults (Form Y). Palo Alto, CA: Mind Garden, Inc; 1983.

37. Tariman JD, Berry DL, Halpenny B, Wolpin S, Schepp K. Validation and testing of the Acceptability E-scale for web-based patient-reported outcomes in cancer care. Appl Nurs Res. 2011; 24:53–8. [PubMed: 20974066]

38. O'Connor, AM. User Manual-Decisional Conflict Scale. Ottawa Health Research Institute; Updated 2010at http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf [Accessed at 8 Dec 2010]

39. Twisk J, de Vente W. Attrition in longitudinal studies. How to deal with missing data. J Clin Epidemiol. 2002; 55:329–37. [PubMed: 11927199]

40. Elliott MN, McCaffrey DF, Lockwood JR. How important is exact balance in treatment and control sample sizes to evaluations? J Subst Abuse Treat. 2007; 33:107–10. [PubMed: 17376636]

41. Lin GA, Aaronson DS, Knight SJ, Carroll PR, Dudley RA. Patient decision aids for prostate cancer treatment: a systematic review of the literature. CA Cancer J Clin. 2009; 59:379–90. [PubMed: 19841280]

42. Zeliadt SB, Ramsey SD, Penson DF, et al. Why do men choose one treatment over another?: a review of patient decision making for localized prostate cancer. Cancer. 2006; 106:1865–74. [PubMed: 16568450]

43. Kuban DA. Localized prostate cancer: the battle of treatment options enters the larger arena. Oncology (Williston Park). 2009; 23:867, 873. [PubMed: 19839428]

44. Allen JD, Othus MK, Hart A Jr, et al. A randomized trial of a computer-tailored decision aid to improve prostate cancer screening decisions: results from the take the wheel trial. Cancer Epidemiol Biomarkers Prev. 2010; 19:2172–86. [PubMed: 20716619]

45. Frosch DL, Bhatnagar V, Tally S, Hamori CJ, Kaplan RM. Internet patient decision support: a randomized controlled trial comparing alternative approaches for men considering prostate cancer screening. Arch Intern Med. 2008; 168:363–9. [PubMed: 18299490]

46. Taylor KL, Davis JL 3rd, Turner RO, et al. Educating African American men about the prostate cancer screening dilemma: a randomized intervention. Cancer Epidemiol Biomarkers Prev. 2006; 15:2179–88. [PubMed: 17119044]

47. Volk RJ, Jibaja-Weiss ML, Hawley ST, et al. Entertainment education for prostate cancer screening: a randomized trial among primary care patients with low health literacy. Patient Educ Couns. 2008; 73:482–9. [PubMed: 18760888]

48. Dolan JG, Frisina S. Randomized controlled trial of a patient decision aid for colorectal cancer screening. Med Decis Making. 2002; 22:125–39. [PubMed: 11958495]

49. Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. BMJ. 2010; 341:c5370. [PubMed: 20978060]

50. Hall MJ, Manne SL, Winkel G, Chung DS, Weinberg DS, Meropol NJ. Effects of a Decision Support Intervention on Decisional Conflict Associated with Microsatellite Instability Testing. Cancer Epidemiol Biomarkers Prev. Jan 8.2011 Epub ahead of press. 10.1158/1055-9965.EPI-10-0685

51. Wakefield CE, Meiser B, Homewood J, Ward R, O'Donnell S, Kirk J. Randomized trial of a decision aid for individuals considering genetic testing for hereditary nonpolyposis colorectal cancer risk. Cancer. 2008; 113:956–65. [PubMed: 18618513]

52. Goel V, Sawka CA, Thiel EC, Gort EH, O'Connor AM. Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer. Med Decis Making. 2001; 21:1–6. [PubMed: 11206942]

53. Whelan T, Levine M, Willan A, et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: a randomized trial. JAMA. 2004; 292:435–41. [PubMed: 15280341]

54. Tiller K, Meiser B, Gaff C, et al. A randomized controlled trial of a decision aid for women at increased risk of ovarian cancer. Med Decis Making. 2006; 26:360–72. [PubMed: 16855125]

55. Drake BF, Keane TE, Mosley CM, et al. Prostate cancer disparities in South Carolina: early detection, special programs, and descriptive epidemiology. J S C Med Assoc. 2006; 102:241–9. [PubMed: 17319238]

56. Polacek GN, Ramos MC, Ferrer RL. Breast cancer disparities and decision-making among U.S. women. Patient Educ Couns. 2007; 65:158–65. [PubMed: 16870385]

57. Cooperberg MR, Broering JM, Carroll PR. Time trends and local variation in primary treatment of localized prostate cancer. J Clin Oncol. 2010; 28:1117–23. [PubMed: 20124165]
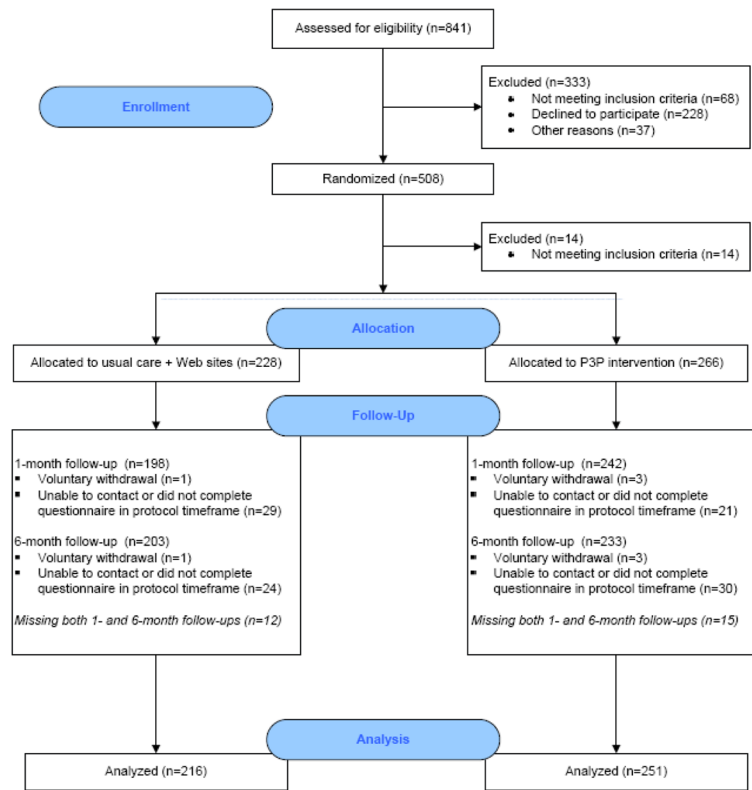
Figure 1.

Table 1

P3P intervention customization based on the patient's Personal Profile[24]

Patient Query Section	Intervention Delivered to Patient
Demographics: • English or Spanish-speaking • Date of birth • Self-reported ethnicity • Self-reported race	• All videos featured a patient actor close in age and matched for ethnicity/race and language • Clinician actors were matched to race.
Prostate Cancer Information Priorities: • Stage of Disease • Prognosis • Treatment Options • Side Effects • Home Self Care • Impact on Family • Sexuality • Social Activities • Family Risk	• Priority topics plus those chosen by patient are briefly summarized on-screen • At the end of the intervention, the patient received printed teaching sheets on each topic
Preferred Role in the Treatment Decision (Control Preferences Scale)[26]	• Text and video coaching customized to patient's ethnicity/race and age • In the video (on-line supplement), doctor acknowledged patient's preference • Patient was offered opportunity to view text and video for other control preferences
Influential People: • Co-workers • Friends Outside Work • Spouse/Partner • Other Family Members	• Text and video coaching was offered for the patient to express who are influential people in his decision process • Doctor in the video acknowledged their importance and helped the patient compare his own views and situation to those of influential people • Patient printed the teaching information with "fill in the blank" text he could use to prepare for the exam visit
Influential Outcomes: • Survival • Bladder Function • Bowel Function • Sexual Function	• Text and a graphic illustration taught numeracy skills for understanding statistics about possible outcomes • Text and video coaching customized to age and ethnicity/race offered for the patient to express the influential factors in his decision process • Doctor in the video acknowledged importance and suggested a relative likelihood of each treatment option's impact on these factors
Current symptoms: (EPIC-26 questionnaire)[25] • Urinary • Bowel • Sexual	• Text and video coaching customized to age and ethnicity/race was offered on each symptom experienced as a problem. • In the video, the patient reported his symptom and the doctor offered how various treatments may impact symptoms differently.

Table 2

Decisional Conflict Scale,[38] all items within five subscales[+]

Uncertainty Higher score = greater uncertainty	1. I am clear about the best choice for me.
	2. I feel sure about what to choose.
	3. This decision is easy for me to make.
Informed Higher score = less informed	4. I know which options are available to me.
	5. I know the benefits of each option.
	6. I know the risks and side effects of each option.
Values Clarity Higher score = lack of clarity about personal values	7. I am clear about which benefits matter most to me.
	8. I am clear about which risks and side effects matter most.
	9. I am clear about which is more important to me (the benefits or the risks and side effects).
Support Higher score = lack of support	10. I have enough support from others to make a choice.
	11. I am choosing without pressure from others.
	12. I have enough advice to make a choice.
Effective Decision Higher score = ineffective decision	13. I feel I have made an informed choice.
	14. My decision shows what is important to me.
	15. I expect to stick with my decision.
	16. I am satisfied with my decision.

[+]Responses for each item range from 0) strongly agree to 4) strongly disagree

Table 3

Baseline Sociodemographic and clinical characteristics, and decision conflict scores by intervention and control group of men with localized prostate cancer (N=494)

	Control (N=228)		Intervention (N=266)	
	n	**%**	**n**	**%**
Baseline demographics				
Age (Median and range)	62	(40–84)	63	(45–86)
College degree or higher	129	56.6	151	56.8
Married/Partnered	173	75.9	205	77.1
Annual Income 35,000 or less	55	24.2	55	20.7
Race: minority or multiple race	38	15.7	37	13.9
Ethnicity: Spanish/Hispanic/Latino	9	3.9	6	2.3
Clinical characteristics				
Treatment preference at baseline[+]	114	50	137	51.5
4 weeks since biopsy	152	66.6	177	66.6
	Mean	**SD**	**Mean**	**SD**
State-Trait Anxiety Inventory				
State	39.6	13.7	40.1	12.8
Trait	33.1	10.1	33.7	10.3
Decisional conflict scale				
Uncertainty	52.4	27.2	52.3	26.7
Informed	37.3	22.9	38.9	24.6
Values Clarity	33.9	20.8	35.8	21.5
Support	30.2	16.1	29.4	16.7
Effective decision	26.5	16.3	28.2	16.2
Total score	29.4	15.7	30.8	15.6

[+]Participant reported a treatment approach preference prior to consultation

SD= standard deviation

Table 4

Estimation of study group effect on subscales and total decisional conflict scores using generalized estimating equations adjusted for pre-specified baseline co-variates (N=467)

	Uncertainty		(Un) Informed		(Lack of) Values Clarity		(Lack of) Support		(In) Effective Decision		Total DC score	
	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value
Study Group Intervention	−3.61 (−7.01,−0.22)	0.04	−1.84 (−4.01,0.33)	0.1	−3.57 (−5.85,−1.30)	0.002	−1.06 (−3.19,1.07)	0.3	−1.66 (−3.66,0.34)	0.1	−1.75 (−3.61,0.11)	0.07
Age	0.10 (−0.17,0.37)	0.5	0.21 (0.04,0.38)	0.02	0.08 (−0.12,0.27)	0.4	−0.01 (−0.2,0.17)	0.9	0.08 (−0.08,0.23)	0.3	0.05 (−0.1,0.21)	0.5
Race White	0.002 (−5.68,5.69)	1.0	−6.18 (−9.91,−2.45)	0.001	−3.61 (−7.90,0.67)	0.1	−4.06 (−7.62,−0.50)	0.03	0.60 (−3.06,4.26)	0.7	−2.21 (−5.58,1.17)	0.2
Annual income ^^		0.8		0.001		0.03		0.2		0.1		0.07
Baseline Internet as information source	1.50 (−2.51,5.50)	0.5	−1.25 (−3.87,1.37)	0.3	−3.14 (−5.94,−0.34)	0.03	0.51 (−2.17,3.19)	0.7	−1.90 (−4.64,0.84)	0.2	−2.03 (−4.43,0.38)	0.1
Weeks since biopsy ^++		0.3		0.1		0.1		0.02		0.7		0.2
Baseline trait anxiety	0.21 (0.02,0.40)	0.03	0.12 (0.02,0.23)	0.03	0.08 (−0.04,0.20)	0.2	0.09 (−0.03,0.22)	0.1	0.05 (−0.08,0.17)	0.5	0.08 (−0.02,0.18)	0.1
Baseline uncertainty subscale	0.40 (0.31,0.48)	<.0001	0.0005 (−0.05,0.05)	1.0	0.04 (−0.01,0.10)	0.1	0.05 (−0.002,0.1)	0.06	0.03 (−0.01,0.08)	0.2	0.1 (0.05,0.14)	<.0001
Baseline informed subscale	−0.11 (−0.24,0.01)	0.08	0.08 (0.001,0.17)	0.05	−0.04 (−0.11,0.04)	0.3	−0.01 (−0.08,0.06)	0.8	−0.007 (−0.07,0.06)	0.8	−0.04 (−0.10,0.03)	0.3
Baseline values clarity subscale	0.01 (−0.12,0.15)	0.9	0.04 (−0.04,0.12)	0.3	0.12 (0.03,0.20)	0.007	−0.02 (−0.10,0.06)	0.6	0.033 (−0.03,0.10)	0.3	0.05 (−0.01,0.12)	0.1
Baseline support subscale	0.12 (−0.02,0.26)	0.1	0.19 (0.11,0.28)	<.0001	0.16 (0.06,0.25)	0.001	0.36 (0.26,0.47)	<.0001	0.21 (0.12,0.29)	<.0001	0.20 (0.12,0.28)	<.0001
Time 6 vs. 1 mo	−7.11 (−9.37,−4.86)	<.0001	−0.12 (−1.71,1.47)	0.9	−0.68 (−2.35,1.00)	0.4	−1.60 (−3.23,0.03)	0.06	−0.95 (−2.49,0.59)	0.2	−1.40 (−2.76,−0.05)	0.04
Study Site ^		0.01		0.01		0.05		0.02		0.02		0.01

Negative coefficients indicate lower conflict than the reference group.

^^
  $18,000, $18,001–35,000, $35,001–55,000, $55,001–85,000, >$85,000

++ 1 or fewer, 2, 3, 4 or more;

^
  6 study sites

DC=decisional conflict; CI=confidence interval

Table 5

Treatment decision outcomes by intervention or control group at 1-month and 6-months for 227 men[1] who declared no treatment preference at study enrollment

Treatment decision	Intervention Group N=120		Control Group N=107		p^2	p^3
	1 month	6 months	1 month	6 months		
Undecided	15 (13)	14 (12)	16 (15)	12 (11)	0.14	0.92
WW	9 (7.5)	4 (3.3)	5 (4.7)	5 (4.7)		0.74
EBRT	24 (20)	23 (19)	19 (18)	22 (21)		0.79
Brachytherapy	20 (17)	18 (15)	7 (6.5)	5 (4.7)		0.01
Prostatectomy	37 (31)	42 (35)	42 (39)	49 (46)		0.10
Missing	15 (13)	19 (16)	18 (17)	14 (13)		0.56

[1] Excludes men who reported the least common treatment choices: cryosurgery (n=1), high intensity focused ultrasound (n=2), or other (n=5)

[2] Overall p-value for the difference between the intervention group and control group, regardless of treatment choice at 6-months

[3] Treatment-specific p-values for the difference between the intervention group and control group for each treatment choice at 6-months

WW = Watchful waiting; EBRT = external beam radiation therapy