

2013

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This article was originally published as:

Watts, K. J., Meiser, B., Wakefield, C. E., Barratt, A., Howard, K., Cheah, B. C., Mann, G. J., Lobb, E., Gaff, C., & Patel, M. I. (2013). Online prostate cancer screening decision aid for at-risk men: A randomized trial. *Health Psychology, Advanced Online*, 1-13.
<http://doi.org/10.1037/a0034405>

This article is posted on ResearchOnline@ND at
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Health Psychology

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Online First Publication, November 25, 2013. doi: 10.1037/a0034405

CITATION

Watts, K. J., Meiser, B., Wakefield, C. E., Barratt, A. L., Howard, K., Cheah, B. C., Mann, G. J., Lobb, E. A., Gaff, C. L., & Patel, M. I. (2013, November 25). Online Prostate Cancer Screening Decision Aid for At-Risk Men: A Randomized Trial. *Health Psychology*. Advance online publication. doi: 10.1037/a0034405

Online Prostate Cancer Screening Decision Aid for At-Risk Men: A Randomized Trial

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Objective: This study examines the efficacy of an online screening decision aid (DA) for men with a family history of prostate cancer. **Methods:** Unaffected Australian men (40–79 years) with at least one affected relative completed the first online questionnaire, were randomized to read either the tailored DA (intervention) or nontailored information about prostate cancer screening (control), then completed a questionnaire postreading and 12 months later. The primary outcome was decisional conflict regarding prostate specific antigen (PSA) testing. The impact of the DA on longitudinal outcomes was analyzed by using random intercept mixed effects models. Logistic and linear regressions were used to analyze the impact of the DA on screening behavior and decision regret. Stage of decision-making was tested as a moderator for decisional conflict and decision regret. The frequency of online material access was recorded. **Results:** The DA had no effect on decisional conflict, knowledge, inclination toward PSA testing, accuracy of perceived risk, or screening behavior. However, among men considering PSA testing, those who read the DA had lower decision regret compared with men who read the control materials, $\beta = 0.34$, $p < .001$, 95% confidence interval (CI) = [.22, .53]. **Conclusions:** This is the first study to our knowledge to evaluate the uptake and efficacy of an online screening DA among men with a family history of prostate cancer. Men who were undecided about screening at baseline benefitted from the DA, experiencing less regret 12 months later. In relation to decisional conflict, the control materials may have operated as a less complex and equally informative DA.

Keywords: prostate cancer, prostate cancer screening, family history, decision aid, risk, online

Supplemental materials: <http://dx.doi.org/10.1037/a0034405.supp>

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Registered Trial: Australian and New Zealand Clinical Trials Registry (ACTRN12611000850976).

We thank the men who generously participated in this study. Thank you to our web designer, James McRobert, who constructed the study website and the online questionnaires. We gratefully acknowledge Ursula Sansom-Daly for her contribution to the development of the educational materials. This research was supported by a Cancer Council NSW Strategic Research Partnership (STREP) grant. Bettina Meiser is supported by a Career Development Fellowship Award from the National Health and Medical Research Council Australia and a Cancer Institute New South Wales Career Development Fellowship. Claire Wakefield is supported by an Early Career Development Award from Cancer Institute of NSW.

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Compared with receiving treatment at the time of clinical diagnosis, the balance of evidence suggests that screening for early detection and treatment of some occult cancers (e.g., cervical and colorectal cancers) improves patient prognosis (Andrae et al., 2012; Towler et al., 1998). This is not the case for prostate cancer, where there are uncertain benefits and harms of screening with prostate specific antigen (PSA) testing and/or digital rectal examination (DRE). The differing findings of two large randomized controlled trials examining the potential benefits of screening may have fuelled, rather than resolved, the debate (Barratt & Stockler, 2009). The U.S. Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial randomized over 76,000 men to receive either annual screening (PSA testing and DRE) or usual care. After 7 years of follow-up, the rate of death from prostate cancer did not differ significantly between the two study groups (Andriole et al., 2009). The trial, however, likely underestimated the effects of screening because of substantial contamination by off-study screening in the control arm (Barratt & Stockler, 2009). The European Randomized Study of Screening for Prostate Cancer (ERSPC) trial randomly allocated over 160,000 men to 4-yearly screening with PSA testing or usual care, with follow-up from 3–15 years. While a small survival benefit was associated with annual PSA testing, screening also resulted in more frequent diagnoses and patients with indolent cancer receiving potentially unnecessary treatment (Barratt & Stockler, 2009; Schröder et al., 2009).

In view of this uncertainty, professional organizations encourage clinicians to engage patients in either informed or shared decision-making about prostate cancer screening (Woolf & Krist, 2009). The American Cancer Society (Wolf et al., 2010) recommends the use of patient decision aids (DAs) to present balanced evidence-based information regarding prostate cancer screening to facilitate informed decision-making. A DA contains information about treatment options and the relevant outcomes and assists patients with making informed choices that are consistent with their personal values (Barratt, Trevena, Davey, & McCaffery, 2004; Elwyn et al., 2006). A systematic review of prostate cancer screening DAs found that they improved patient knowledge of screening, led patients to feel more informed about making a decision, and decreased their intention to be screened and their participation in screening (Volk et al., 2007).

The Internet provides an easy, automated, anonymous, and cost-effective means of delivering evidence-based health information (Krist, Woolf, Johnson, & Kerns, 2007; Ziebland et al., 2004). Health information can be readily customized on the Internet by using either *targeted approaches* (focus on groups) or *tailored approaches* (individual). Tailoring is the process of providing individualized messages. Tailored health information requires an assessment in which data from a specific individual and related to a given health outcome are used to determine the most appropriate messages to meet that person's needs (Rimer & Kreuter, 2006). Six previous studies have evaluated the efficacy of Web-based DAs among men (Allen et al., 2010; Ellison et al., 2008; Evans et al., 2010; Frosch, Kaplan, & Felitti, 2003; Ilic, Egberts, McKenzie, Risbridger, & Green, 2008; Krist et al., 2007), but only two of these contained content group tailored to a man's family history of prostate cancer (Ellison et al., 2008) and individually tailored according to personal risk factors (Allen et al., 2010). Both DAs signifi-

cantly enhanced knowledge scores among men allocated to the intervention compared with controls in both studies.

To date, however, no studies have evaluated an online DA with risk information individually tailored to the risk status of unaffected men with a family history of prostate cancer. Tailored risk information is important given that men with a relevant family history overestimate their cancer risk (Miller et al., 2001), and they report unmet information needs (Wakefield et al., 2008a). Such men are also more likely to undergo PSA testing (McDowell, Occhipinti, Gardiner, Baade, & Steginga, 2009). Reviews of primary and secondary prevention programs have found that tailored information is more likely to be read and recalled, and has a greater impact on people's intentions and behavior, than generic information (Kroeze, Werkman, & Brug, 2006; Skinner et al., 2002; Walters, Wright, & Shegog, 2006). Tailoring is also likely to increase perceived interest in the messages being conveyed (Skinner et al., 2002; Walters et al., 2006).

The potential moderating influence of a man's stage of decision-making (SDM) about prostate cancer screening has not been examined in previous DA trials. SDM refers to an individual's readiness to engage in decision-making, progress in making a choice, and willingness to (re)consider options (O'Connor, 2000). In a study conducted among 214 female breast cancer patients who were carriers of a *BRCA1* or *BRCA2* mutation, baseline decision status moderated the impact of a tailored interactive DA designed to assist with risk management options (Schwartz et al., 2009). After disclosure of genetic test results, women were randomized to receive the tailored DA (CD-ROM format) plus usual care, or usual care only. Among women who at baseline had not yet made a final decision about how to manage their breast cancer risk, use of the DA resulted in a significant reduction in decisional conflict, an increase in decision satisfaction, and an increase in the likelihood of reaching a final risk management decision (Schwartz et al., 2009). These effects were not evident for participants who had already made a decision at baseline. Therefore, SDM about PSA testing may influence whether a DA will be of benefit to at-risk men in relation to decisional uncertainty and subsequent decision regret regarding screening choice.

The objective of this randomized controlled trial was to evaluate the efficacy of an online individually tailored prostate cancer screening DA (intervention) compared with online nontailored educational materials about prostate cancer screening (control) on decision-related outcomes and screening behavior among unaffected men with a family history of prostate cancer.

It was hypothesized that participants allocated to the DA, compared with participants in the control group, would across time (baseline to 12 months): (a) show a larger reduction in decisional conflict and a greater increase in knowledge about prostate cancer screening; (b) be more accurate about their perceived risk of developing prostate cancer; and (c) be more confident about their propensity toward or against screening; It was further hypothesized that 12 months after the intervention when men have had time to make a decision and to reflect upon their screening choice, participants in the DA group would: (d) be less likely to have had a PSA test; and (e) show greater change in decisional conflict and lower decision regret, with this effect moderated by stage of decision making about PSA testing.

Method

The Ottawa Decision Support Framework (O'Connor et al., 1998) provided the framework for the development of the DA. The framework identifies several determinants of health care decisions that may be problematic and modifiable by DAs, including poor knowledge, unrealistic expectations, high uncertainty, and unclear values (O'Connor et al., 1999). In the current study, we developed a DA that specifically targeted several potential barriers to at-risk men's decision about prostate cancer screening, including insufficient knowledge about the risks and benefits of screening, decisional uncertainty, unclear values, and a tendency to overestimate one's risk of developing prostate cancer (Miller et al., 2001; Wakefield et al., 2008a). Full details of the development and pilot-testing of the DA are available elsewhere (Wakefield et al., 2011).

Materials

Tailored decision aid (intervention). The online DA comprised 25 screens including the home page, five "requested reading" screens, and six "optional reading" screens; the remaining screens were related to the study. The requested reading screens included an interactive personal worksheet and a values clarification exercise (VCE; 4 additional screens). Participants were also presented with individually tailored statistics about their chances of being diagnosed with, and dying from, prostate cancer, with and without screening based upon a combination of their age and the number of their first-degree relatives (FDR) and/or second-degree relatives (SDR) previously diagnosed with prostate cancer (Howard, Barratt, Mann, & Patel, 2009).

Nontailored materials (control). It has been argued that a psychosocial intervention should be compared with a comparison condition that closely resembles the intervention but without the elements thought to be actively therapeutic (Shapiro & Shapiro, 1997); such a condition is also referred to as an attention control. Hence, the information in the control materials (18 screens) was identical to that contained in the DA, with the following exceptions: (a) the personal worksheet, (b) the two example worksheets, (c) a screen entitled "is it common to inherit an increased chance of developing prostate cancer?" and (d) the tailored risk statistics. There were three "requested reading" screens and five "optional reading" screens.

The online materials also included an in-text glossary of terms and navigation instructions for both groups. Supplementary Figure 1 shows the content of the DA and the control materials.

Participants

Eligible participants were recruited from May 2010 to September 2011. Men who (a) had not been diagnosed with prostate cancer, (b) were aged 40–79 years, (c) had at least one FDR or SDR with a previous diagnosis of prostate cancer, (d) were proficient in English, and (e) were able to give informed consent were eligible to participate. The study was approved by the appropriate institutional review board. In view of the low participation rate in the pilot phase of the DA (Wakefield et al., 2011), multiple recruitment strategies were employed. As an incentive to participate, AUD20 was donated to the Cancer Council NSW for prostate cancer research for every man who enrolled in the trial. Unaffected

Australian males in the community were invited to participate in advertisements placed in the weekend edition of three Australian newspapers and in a radio broadcast. A link to the study website (www.prostatescreening.org.au) was placed on the Cancer Council NSW website; and in the electronic newsletters of Rotary Australia, and the University of New South Wales, Sydney. A targeted mail-out of a study package was also sent to patients diagnosed with prostate cancer since 2008 who had attended a private urology clinic, located in Sydney NSW, to give to their male relatives.

Procedure

Contingent upon a participant's responses to three initial eligibility questions (age and personal and family history of prostate cancer), participants in the intervention group were automatically directed to 1 of 8 versions of the DA containing risk statistics regarding the chance of being diagnosed with, or dying from, prostate cancer with or without annual screening over the next 10 years, tailored to their age group (40–49 years, 50–59 years, 60–69 years, or 70–79 years) and risk status (moderate or high risk). Risk status was determined using published estimates of the numeric increase in risk for differing types and numbers of affected relatives (Howard et al., 2009). Participants were classified as moderate risk if they had: either one FDR or one SDR previously diagnosed with prostate cancer, or two SDRs previously diagnosed with prostate cancer, or one FDR and one SDR affected with prostate cancer. Participants were classified as high risk if they had two affected FDRs or three or more FDRs or SDRs affected (Wakefield et al., 2011). Supplementary Figure 2 illustrates risk classification. Participants were not provided with feedback about their risk status.

Computerized blocked randomized assignment was used to allocate participants individually, with each block of six participants randomized to 1 of 2 parallel groups—the intervention or control group. For allocation of the participants, a computer-generated list of random numbers was used, except when the number of participants in one condition exceeded the other condition by more than three; whenever this occurred, the next allocation was to the under-represented group, with random allocation recommencing after that. This method was employed to achieve balanced randomization (1:1). Allocation concealment was achieved through the automated randomization process such that at the time of allocation, neither participants nor the study coordinator knew which treatment arm participants were allocated to. It was not possible to blind participants or the data analyst to treatment arm allocation.

Men registered to participate by entering an e-mail address and a password at the study website, and then provided informed consent. After account activation, men were asked to answer the eligibility questions. Ineligible men were unable to proceed and were directed to general information about prostate cancer screening (Cancer Council NSW, 2009). Eligible men were instructed to complete the first questionnaire (Time 1), read the "requested reading" sections, and then immediately afterward complete the second questionnaire (Time 2). Participants allocated to the DA were also asked to complete the personal worksheet. At 12 months an automated e-mail prompted men to complete the third questionnaire (Time 3). A further two reminder e-mails were sent by the study coordinator 2 and 4 weeks after the automated e-mail.

Outcomes

Primary outcome. Decisional conflict (DC) regarding PSA testing was assessed at all time points using the validated low literacy version of the Decisional Conflict Scale (DCS; O'Connor, 1993 [updated 2010]; O'Connor, 1995). We elected to use the low literacy version of the DCS because it had fewer items and was more suited to an online format, minimizing participant burden. Ten items assessed participants' uncertainty regarding current intention about having a PSA test in the next year with response options of 0 = "Yes", 2 = "Unsure," and 4 = "No." Scores were converted to a 0–100 scale and ranged from 0 (*no DC*) to 100 (*extremely high DC*). Cronbach's alpha in the present study was .91 at baseline.

Secondary outcomes. Knowledge of prostate cancer screening, perceived risk of developing prostate cancer, and inclination toward having a PSA test were assessed at all time points. Screening behavior was assessed at Times 1 and 3. Decision regret regarding PSA testing was assessed at Time 3.

Measures

Demographic data collected included employment status, occupation, marital status, language spoken at home, and highest level of education completed.

Knowledge. Ten items were developed for this study based upon expert input from the researchers and a review of the literature. The items included: six concept items - two of these items were drawn from Radosevich et al. (2004), and four numeric items were adapted from Mathieu et al. (2007). The items were designed to assess understanding of the (a) pros and cons of PSA testing (items 1–3), (b) inheritance and relevance of a family history of prostate cancer (items 4–6), and (c) the chances of being diagnosed with or dying from prostate cancer with or without screening (items 7–10). Details of the items and the response options are in Supplementary Table 1. A score of one was given for a correct answer and a score of zero for an incorrect or "don't know" response. Total knowledge score was calculated by summing the correct responses (range = 0–10). Cronbach's alpha in the present study was .61 at baseline.

Perceived risk. A single item was adapted from (Kasparian, Meiser, Butow, Simpson, & Mann, 2009). Participants were asked to rate their chance of developing prostate cancer on an 11-point visual analogue scale where 0 = "no chance," and 100 = "100% chance, meaning you will definitely get it."

Inclination regarding PSA testing. Using a single item adapted from O'Connor (1996a [modified 2003]), participants were asked "At this point in time, are you leaning toward wanting to have a PSA test, or not?" (response options 1 = "I am leaning toward having a PSA test"; 2 = "I am not sure yet"; 3 = "I am leaning toward NOT having a PSA test").

Stage of decision making. A single item assessed men's SDM (O'Connor, 2000 [modified 2003]). Participants were asked "At the moment, how far along are you with your decision regarding PSA testing?" Response options 1–4 included: "I have not yet thought about the options"; "I am considering the options"; "I am close to choosing an option"; and "I have already made a choice."

Screening behavior. A single item was administered at baseline. A similar item has been used in other studies to assess prostate cancer screening behavior (Glenn et al., 2012): "Have you ever had a PSA test to screen for prostate cancer?" (Response options 1–4

included: "No"; "Yes, I had a PSA test more than 12 months ago"; "Yes, I have had one PSA test in the last 12 months"; and "Yes, I have had more than one PSA test in the last 12 months." At 12 months, participants were asked whether they had had a PSA test since reading the online materials and if so, whether they had had one or more PSA tests in that period (response options 1–3: "No"; "Yes, I have had one PSA test in the last 12 months"; "Yes, I have had more than one PSA test in the last 12 months").

Decision regret. Distress or remorse following a decision about PSA testing was assessed at 12 months using the validated Decision Regret Scale (Brehaut et al., 2003; 5 items, response options: 1 = "strongly agree" through 5 = "strongly disagree"). Scores were converted to a 0–100 scale, and each item was summed and averaged to obtain a final score: 0 (*no regret*) to 100 (*high regret*; O'Connor, 1996b [updated 2003]). Cronbach's alpha in the present study was .89.

A target sample size of 64 participants in each group provided sufficient power (80%) to detect a 0.5 effect size difference between groups (i.e., a medium effect size; Cohen, 1988) in the primary outcome variable (decisional conflict). A medium effect size was elected because this has been considered clinically important in a range of cancer-related scenarios (Norman, Sloan, & Wyrwich, 2003).

Data Analyses

An intention-to-treat analysis was undertaken of all eligible participants who were randomized and who completed Questionnaire 1 irrespective of whether they read the online materials. To assess the impact of the DA on accuracy of perceived risk, participants were classified as either "accurate", or "inaccurate" (an underestimator or an overestimator; Meiser et al., 2001). Accuracy of perceived risk was determined by comparing each participant's actual (objective) risk of prostate cancer with his perceived risk. Actual risk (RR) of prostate cancer, based on his self-reported family history (i.e., RR of 2.0 or 5.0) by 0.11 (the average lifetime risk of prostate cancer of 1 in 9; Australian Institute of Health and Welfare, 2007). Participants whose perceived risk fell either one response option below or above their objective risk were categorized as accurate (Meiser et al., 2001). For example, a man at moderate risk (with an actual risk of 0.22 [RR 2.0 \times 0.11]) was categorized as accurate if he rated his perceived risk anywhere between 10% and 30%. Participants whose perceived risk fell more than one response option below or above their objective risk were categorized as inaccurate ($n = 6$ underestimators, $n = 45$ overestimators). Because of the small number of "underestimators," all inaccurate responses were combined for the data analyses.

Random intercept linear mixed effects models were used to analyze longitudinal continuous outcomes—DC and knowledge about prostate cancer screening. Linear regression with adjustment for baseline DC was used to analyze decision regret (measured at 12 months), while logistic regression was used to evaluate the effect of the DA on screening behavior. Decisional conflict, decision regret, and knowledge scores were log-transformed to reduce data skewness and to improve model fitting. Before log-transformation of DC and decision regret scores, a value of 5 was added to the original scores, because the minimum was zero. This

did not change interpretation, because their original scales were arbitrary. Population-averaged logistic generalized linear mixed effects models were used to analyze longitudinal binary outcomes, inclination, and accuracy of perceived risk.

Unadjusted analyses and then adjusted analyses were performed to investigate the effects of additional covariates that may have predicted the outcome. To account for curvilinear changes in the outcome measures over time, quadratic time terms were included in the models where necessary. To investigate the effect of the DA, time by treatment group interaction terms were also included in the statistical models. Tests were two-sided, and p values $< .05$ were considered significant.

Results

One hundred thirty-eight eligible men were randomized ($n = 69$ Intervention and $n = 69$ Control) and completed the baseline questionnaire (Time 1); 102 participants completed the second questionnaire (Time 2), and 90 completed the third questionnaire (Time 3). Figure 1 summarizes the flow of recruitment.

Sample Characteristics

The baseline sample characteristics are presented in Table 1. A direct logistic regression was performed to assess whether a number of factors predicted attrition. Participant attrition over the study did not differ significantly as a function of age (less than 60 years, 60 years or over), $B = .04$, odds ratio [OR] = 1.04, $p = .07$ (95% CI = 0.99–1.08); level of education (nonuniversity qualified, university qualified), $B = -.44$, OR = .64, $p = .26$ (95% CI = .29–1.39); or risk group (moderate risk, high risk), $B = -.56$, OR = .58, $p = .28$ (95% CI = .21–1.56). Proportion of total screens accessed and group allocation did predict attrition. Respondents in the DA group were less likely to complete all questionnaires, $B = -.96$, OR = .38, $p < .05$ (95% CI = .17–.85), and respondents who accessed a larger proportion of total screens were more likely to complete the study, $B = .04$, OR = 1.04, $p < .001$ (95% CI = 1.02–1.06).

Use of the Website and Reading of the Materials

The mean number of requested reading screens accessed was 6.43 of 9 screens by men in the intervention group ($SD = 3.24$); and 2.64 of 3 screens by controls ($SD = 0.87$). The proportion of men who accessed each of the requested reading screens and optional reading screens on the website is presented in Table 2. Of the men who completed the second questionnaire, the majority reported having read the information materials “from the first page to the last page” or “quite thoroughly” (74%). Of the men allocated to read the DA, 51% completed the VCE.

Means for continuous variables and proportions for dichotomous variables are presented in Table 3.

Primary Outcome: Decisional Conflict

Using a linear mixed effects model with random baseline measurements, the effect of the intervention on DC was not statistically significant after adjusting for age and SDM ($\beta = 0.97$, $p = .47$), 95% CI = [.90, 1.05]. SDM did not moderate the effect of the intervention on DC ($\beta = 1.04$, $p = .33$), 95% CI = [.96, 1.13]. In

the interests of parsimony, SDM was, therefore, removed from the model, and the model adjusting for age only is reported hereafter. The quadratic effect of time was significant ($\beta = 1.07$, $p < .001$), 95% CI = [1.05, 1.09], indicating that changes in decisional conflict scores were curvilinear over time for both groups. Specifically, DC decreased substantially immediately after reading the education materials and this effect was sustained at 12 months.

Secondary Outcomes

Knowledge of prostate cancer screening. The DA had no significant effect on knowledge after adjusting for language spoken at home ($\beta = 1.0$, $p = .88$), 95% CI = [.99, 1.01]. The quadratic effect of time was significant ($\beta = 0.98$, $p < .001$), 95% CI = [.98, .99] for both groups taken together, suggesting that the longitudinal change in knowledge was curvilinear (i.e., knowledge increased immediately after reading the materials and this effect was sustained at 12 months).

Accuracy of perceived risk. There was no effect of the DA on change in accuracy of perceived risk after adjusting for education, $B = 0.02$, $p = .62$, OR = 1.02, 95% CI = [.95, 1.09]. A logistic mixed effects model showed a significant quadratic effect of time for both groups collectively, indicating curvilinear change over time in accuracy, $B = -0.05$, $p < .05$, OR = 0.96, 95% CI = [.92, .99]. In the intervention group, the pattern of data suggest that the proportion of men who were accurate about their perceived risk increased immediately after reading the information materials (from 40% to 68%), but the proportion then decreased toward baseline levels (48%) at 12 months.

Inclination regarding PSA testing. There was no effect of the DA on inclination after adjusting for education, $B = -0.02$, $p = .85$, OR = 0.98, 95% CI = [.84, 1.15], and for both groups together, participants' inclination regarding PSA testing did not change over time, $B = 0.10$, $p = .47$, OR = 1.10, 95% CI = [.85, 1.42].

Screening behavior. At baseline, 62% of controls and 56% of men in the intervention group had had at least one PSA test in the previous 12 months. At Time 3, the proportions for each group were 75% and 69%, respectively. After adjusting for baseline DC and age, the DA had no effect on screening behavior at 12 months, $B = -0.17$, $p = .57$, OR = 0.85, 95% CI = [.48, 1.51].

Decision regret. Compared with the control materials, the DA resulted in lower decision regret at 12 months' follow-up after adjusting for baseline DC and education ($\beta = 0.34$, $p < .001$), 95% CI = [.22, .53]. The intervention effect was modified by SDM ($\beta = 3.28$, $p < .001$), with a significant effect among men who were undecided about PSA testing at baseline ($\beta = 0.34$, $p < .001$). Among men who had not yet made a choice about PSA testing, decision regret was 63% lower at follow-up for those who read the DA ($M = 11.7$, $SD = 11.7$) compared with men who read the control materials ($M = 31.4$, $SD = 7.5$).

A summary of the results of the data analyses are provided in Table 4.

Discussion

At-risk men face a complex, value-laden decision about prostate cancer screening because there is no clear evidence that the benefits of screening outweigh the harms. Guided by the Ottawa

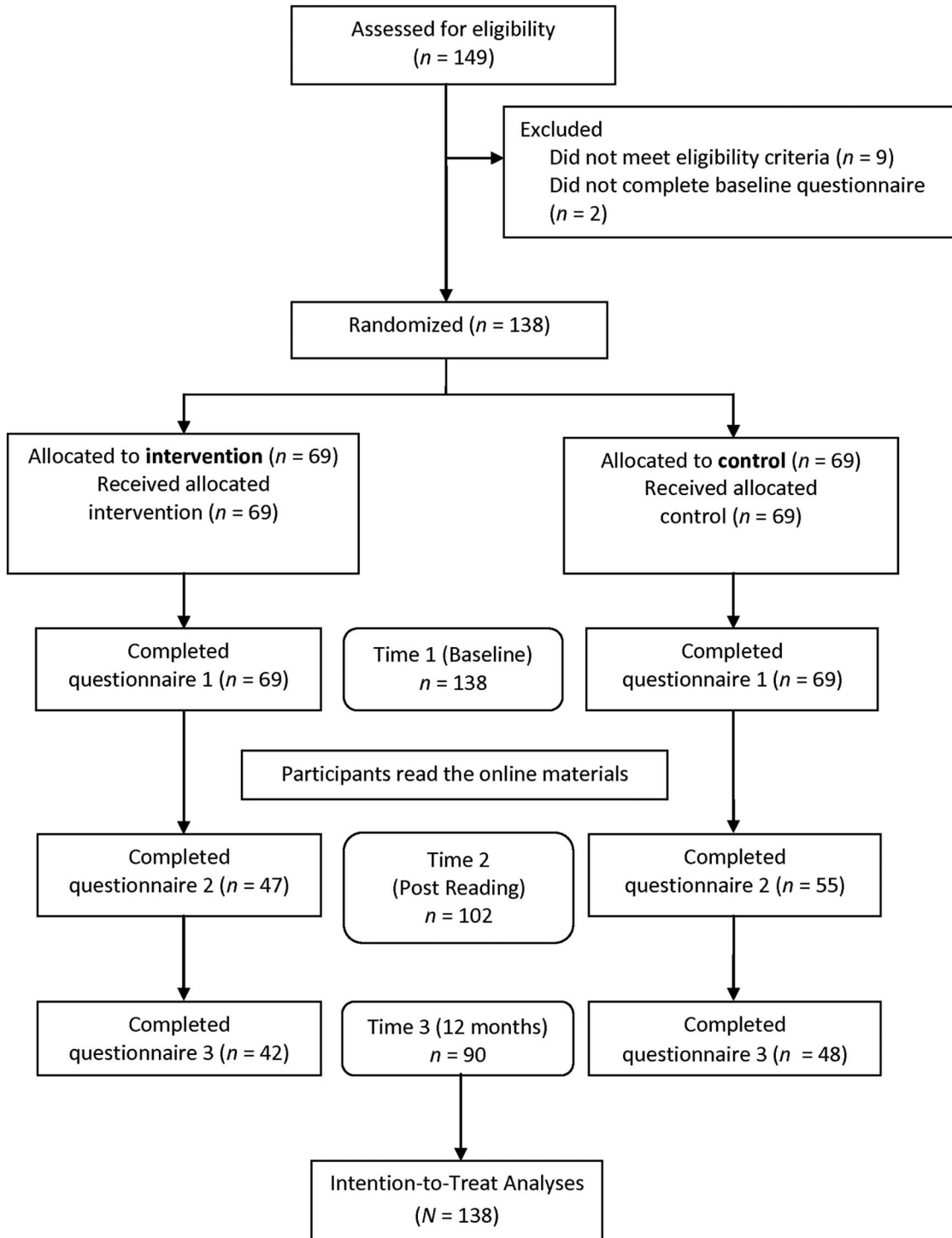


Figure 1. Recruitment flow for the randomized trial comparing an online tailored prostate cancer screening decision aid with online nontailored control materials.

Decision Support Framework, we tested the impact of an individually tailored online decision aid designed to address several potential barriers to informed decision making among at-risk men.

Contrary to expectation, there was no significant impact of the DA on decisional conflict, knowledge, or accuracy of perceived

risk. Decisional conflict scores decreased and knowledge scores increased across time for both groups. There was a trend for the proportion of men who were accurate about their perceived risk of developing prostate cancer to increase immediately after the intervention, but this benefit was not maintained at 12 months. The

Table 1
Demographic Characteristics of Participants at Baseline (N = 138)

Description	Control (N = 69)	Intervention (N = 69)	Total (N = 138)
Age in years, M (SD)	56.5 (9.9)	55.4 (9.0)	55.9 (9.4)
Relationship status, n (%)			
Never married	3 (4.3)	1 (1.4)	4 (2.9)
Widowed/separated or divorced	8 (11.6)	10 (14.5)	18 (13.0)
Married/cohabiting	58 (84.1)	58 (84.1)	116 (84.1)
Language spoken at home, n (%)			
English	64 (92.8)	63 (91.3)	127 (92.0)
Language other than English	5 (7.2)	6 (8.7)	11 (8.0)
Family history of prostate cancer, n (%)			
One first- or second-degree relative	50 (72.5)	47 (68.1)	97 (70.3)
Two or more first- or second-degree relatives	19 (27.5)	22 (31.9)	41 (29.7)
Highest level of education, n (%)			
High school only	12 (17.4)	8 (11.6)	20 (14.5)
Certificate/diploma	20 (29.0)	21 (30.4)	41 (29.7)
Undergraduate degree	25 (36.2)	17 (24.6)	42 (30.4)
Postgraduate degree	12 (17.4)	23 (33.3)	35 (25.4)
Employment status, n (%)			
Employed (full-time or part-time)	49 (71.0)	51 (73.9)	100 (72.5)
Retired	20 (29.0)	16 (23.2)	36 (26.1)
Unemployed	0 (0)	2 (2.9)	2 (1.4)

direction of decisional conflict and knowledge scores accords with earlier studies in which patient education materials about prostate cancer screening in a variety of formats reduced uncertainty and improved knowledge among unaffected men (Davison, Kirk, Degner, & Hassard, 1999; Krist et al., 2007; Taylor et al., 2006). The absence of an intervention effect on decisional conflict, knowledge, and accuracy may have occurred because the control materials had similar content to the DA, with the exception of the interactive personal worksheets, the tailored risk information, and the example worksheets. It appears that the tailored components unique to the DA did not contribute to change over and above the educational components of the materials. The control materials, therefore, may have functioned as a less detailed DA by providing men with non tailored information about the benefits and harms of screening, thus impacting

positively, and to a similar degree as the more complex DA, upon men's decisional uncertainty and knowledge.

The absence of an intervention effect for accuracy was unexpected given that exposure to a DA containing expressed probabilities about the chances of a particular health outcome has previously resulted in a higher proportion of people with accurate risk perceptions (Stacey et al., 2011). Of note is that men allocated to the control group showed a trend for lower accuracy over time, suggesting that information about prostate cancer screening may not be enough to influence unrealistic expectations about risk. Given the pattern over time for accuracy in the intervention group, the individually tailored risk statistics may be more effective in the short- to medium- term (Kroeze et al., 2006; Skinner et al., 2002) when at-risk men are actively considering PSA testing, such as

Table 2
Proportion of Men Who Accessed Specific Pages of the Online Educational Materials

Type	Description of web page	Control, n (%)	Intervention, n (%)	Total sample, N (%)
Available to all participants				
R	Prostate cancer including description and prevalence	63 (91.3)	59 (85.5)	123 (89.1)
R	Family history of prostate cancer	61 (88.4)	57 (82.6)	118 (85.5)
R	Prostate cancer screening	58 (84.1)	58 (84.1)	117 (85.0)
O	Prevention of prostate cancer	34 (49.3)	25 (36.2)	58 (42.0)
O	Possible outcomes of a PSA test	14 (20.3)	11 (15.9)	25 (18.1)
O	Side effects of treatment	11 (15.9)	10 (14.5)	21 (15.2)
O	Science studies	4 (5.8)	3 (4.3)	7 (5.1)
O	Further information	14 (20.3)	5 (7.2)	19 (13.8)
Specific to Intervention				
R	Tailored risk statistics	—	54 (78.2)	—
R	My worksheet (home page)	—	45 (65.2)	—
R	What is the decision I face?	—	44 (63.8)	—
R	Weigh the options (VCE)	—	35 (51.0)	—
R	How sure I feel	—	40 (58.0)	—
R	What are the next steps?	—	40 (58.0)	—
O	Example worksheets	—	22 (31.9)	—

Note. N = 138 (n = 69 Control, n = 69 Intervention). R = requested reading; O = optional reading; VCE = values clarification exercise.

Table 3
Means and SDs for Continuous Variables and Proportions for Dichotomous Variables for Time 1, Time 2, and Time 3

Description	Control			Intervention		
	<i>n</i>	Time 1	<i>n</i>	Time 2	<i>n</i>	Time 3
Continuous variables, <i>M</i> (<i>SD</i>)						
Decisional conflict	69	36.7 (30.2)	55	14.0 (18.8)	49	15.5 (20.9)
Knowledge	69	6.4 (2.0)	52	7.8 (1.9)	47	8.1 (1.2)
Decision regret		—		—	43	15.1 (16.5)
No. of all screens accessed ^a		—	69	3.7 (1.9)		
No. of requested screens accessed ^b		—	69	2.6 (0.9)		
Dichotomous variables, frequency (%)						
Accuracy of perceived risk of prostate cancer						
Accurate		35 (51.5)		28 (50.9)		19 (39.6)
Inaccurate		33 (48.5)		27 (49.1)		29 (60.4)
Inclination						
Leaning towards/away from PSA testing		60 (88.2)		50 (90.9)		46 (95.8)
Unsure		8 (11.8)		5 (9.1)		2 (4.2)
Screening behavior						
Had a PSA test in last 12 months		43 (62.3)		—		36 (75.0)
Have not had a PSA test in last 12 months		26 (37.7)		—		12 (25.0)
Stage of decision-making						
Still considering options		13 (18.8)		—		—
Have already made a choice		56 (81.2)		—		—

Note. *N* = 138. PSA = prostate specific antigen. For continuous measures, higher scores indicate a higher level of decisional conflict, better knowledge, a higher level of decision regret, and more Web screens accessed.

^a Total number of screens (Control *n* = 18, DA *n* = 25). ^b Total number of requested screens (Control *n* = 3, DA *n* = 9).

Table 4

Summary of Results of Mixed Model, Logistic, and Linear Regressions Examining the Effect of the Intervention on Change in Decisional Conflict, Knowledge, Decision Regret, Accuracy of Perceived Risk, Inclination Regarding Prostate Specific Antigen (PSA) Testing, and Screening Behavior

Outcome	Adjusted analyses: Continuous variables				95% Confidence interval
	Exponentiated estimate (β)	<i>t</i>	<i>p</i>		
Decisional conflict ^a					
Time (linear)	0.42	-8.15	<.001		0.34-0.52
Time (quadratic)	1.07	7.92	<.001		1.05-1.09
Group	1.01	0.09	.93		0.75-1.36
Age (years)	0.96	-4.96	<.001		0.95-0.98
Time \times group	1.00	0.07	.95		0.97-1.04
Knowledge ^a					
Time (linear)	1.29	7.38	<.001		1.20-1.38
Time (quadratic)	0.98	-7.16	<.001		0.98-0.99
Group	1.06	0.96	.34		0.94-1.19
Language spoken at home	1.08	0.74	.46		0.87-1.34
Time \times group	1.00	0.15	.88		0.99-1.01
Decision regret ^a					
Group	0.34	-4.75	<.001		0.22-0.53
Stage	0.45	-3.97	<.001		0.31-0.67
DCS (baseline)	1.30	5.16	<.001		1.18-1.44
Education	1.37	3.01	<.01		1.12-1.69
Group \times stage	3.28	4.65	<.001		1.98-5.43
Adjusted analyses: Binary variables					
Outcome	<i>B</i>	Odds ratio	<i>t</i>	<i>p</i>	95% Confidence interval
Accuracy ^b					
Time (linear)	0.52	1.68	2.21	<.05	1.06-2.66
Time (quadratic)	-0.05	0.96	-2.49	<.05	0.92-0.99
Group	-0.10	0.91	-0.31	.76	0.49-1.67
Education	0.74	2.09	2.52	<.05	1.18-3.71
Time \times group	0.02	1.02	0.50	.62	0.95-1.09
Inclination regarding PSA testing ^c					
Time (linear)	0.10	1.10	0.73	.47	0.85-1.42
Group	-0.03	0.97	-0.06	.95	0.38-2.47
Education	-0.83	0.43	-1.65	.10	0.16-1.17
Time \times group	-0.02	0.98	-0.20	.85	0.84-1.15
Screening behavior ^d					
Group	-0.17	0.85	-0.57	.57	0.48-1.51
DCS (baseline)	-0.36	0.70	-2.30	<.05	0.51-0.94
Age (years)	0.07	1.07	4.03	<.001	1.04-1.11

Note. DCS = Decisional Conflict Scale.

^a Raw scores were log transformed before entering into the analyses. ^b Coded as a dichotomous variable: 0 = *inaccurate*, 1 = *accurate*. ^c Coded as a dichotomous variable: 0 = *unsure*, 1 = *I am leaning towards having a PSA test/I am leaning towards not having a PSA test*. ^d Coded as a dichotomous variable: 0 = *I have not had a PSA test in the last 12 months*, 1 = *I have had a PSA test in the last 12 months*. Coding for Group: 0 = *control* and 1 = *intervention*; coding for Language at Home: 0 = *language other than English*, 1 = *English*; coding for Education (coded as a dichotomous variable): 0 = *nonuniversity qualified*, 1 = *university qualified*; coding for Stage (coded as a dichotomous variable): 0 = *not yet made a choice about PSA testing*, 1 = *I have already made a choice*.

prior to or as an adjunct to a consultation with their health care provider. This claim, however, requires further research where the immediate and long term impact of a tailored DA on at-risk men's determinants of decision making about prostate cancer screening are examined.

The VCE is an important component of the DA designed to assist at-risk men to clarify their values regarding the possible outcomes of PSA testing. Of the participants allocated to the DA, only 51% completed the VCE, with a further 13% of men accessing the worksheet but not completing it. Therefore, the potential benefit of this component of the DA may have been

obscured. Completion of VCE in previous DA studies have ranged from 23% among young women diagnosed with breast cancer considering fertility options (Peate et al., 2012) to 74% among women at high risk of breast cancer considering genetic testing (Wakefield et al., 2008b). We did not ask participants their reasons for (non)completion of the VCE. The most common reason for noncompletion reported in previous studies is that a decision had already been made (Peate, Watts, & Wakefield, 2013). At baseline, 59% of our participants reported having had at least one PSA test during the preceding 12 months, and 77.5% reported having already made a choice

about screening; these two factors may have contributed to non completion of the VCE. Given that explicit VCEs improve values-based health choices (Stacey et al., 2011), the preferred format and depth of the VCE should also be further investigated to ensure that it is optimally utilized.

There were no significant effects of the DA on inclination regarding PSA testing or on screening behavior. The proportion of men who were confident about their propensity toward or away from having a PSA test remained high for both groups over the course of the study, and a similar proportion of men allocated to the control materials and the DA reported having had a PSA test after reading the online materials (75% and 69%, respectively). These findings contrast with a recent Cochrane review evaluating the efficacy of DAs for people facing health-related decisions (Stacey et al., 2011). The review found that exposure to DAs compared with usual care was associated with a reduction in the proportion of people who remained undecided post intervention and with fewer men electing to have PSA testing. In the current study, there were only a small proportion of men who reported being unsure about their leaning toward or away from PSA testing (11.8% Control, 8.8% DA), and it may have been difficult to detect an intervention effect given the small cell sizes. In several previous studies, FDRs of affected men were much more likely to report having had a PSA test compared to men in the general population (McDowell, Occhipinti, Gardiner, & Chambers, 2012; Shah, Zhu, Plamer, & Wu, 2007; Spencer et al., 2006). The high screening prevalence among at-risk men may have reduced the potential for the intervention to significantly impact screening behavior.

Stage of decision making did not influence the effect of the DA on decisional conflict. There was, however, an intervention effect on decision regret, which was moderated by SDM. Men who were undecided about PSA testing at baseline who received the DA had significantly lower levels of decision regret about PSA testing at 12 months compared with men who had already made a decision. Decision regret is a highly negative experience, including knowledge that another choice would have resulted in a better outcome. High levels of decision regret are associated with lower satisfaction with the decision made (Brehaut et al., 2003). Undecided men benefitted from the intervention because they had lower levels of regret, which suggests they were comfortable with their choice. Undecided men allocated to the control group had the highest level of regret at 12 months. General information about prostate cancer screening, without personalized risk information, may impact negatively on the quality of the decision process. Participants' satisfaction with their decision about PSA testing was not measured. A future study is required to determine at-risk men's satisfaction with their screening decision immediately after tailored decision support and in the longer term, and to test the association of satisfaction with quality of the decision process.

Several limitations of the study are acknowledged. We used an unvalidated measure of knowledge and the internal reliability of the scale was not optimal. The measure, however, included items assessing knowledge of the benefits and harms of PSA testing, which is a key component of making an informed decision about prostate cancer screening (Wolf et al., 2010). We did not include measures of the other components of informed decision-making, which include consistency of men's screening decision with their values and attitudes (Marteau, Dormandy, & Michie, 2001). We cannot, therefore, infer whether men made an informed and

values-consistent choice about screening after reading the DA. Perceived risk and inclination regarding PSA testing were assessed using single items which may have reduced their reliability and face validity.

The questionnaires involved self-report items. It was beyond the scope of this study to verify men's family history or their screening behaviors with medical records. Australian men, however, are able to provide an accurate family history of prostate cancer (Gaff et al., 2004). The high proportion of men in the current study who reported having had a PSA test previously, at baseline (80%) and at follow up (72%) is comparable to the lifetime prevalence of PSA testing among FDRs of affected Australian men aged 40–65 years (83.6%) (McDowell et al., 2012) and is comparable to the prevalence rates shown for FDRs of affected men in a review of primarily North American studies (44% to 95%; McDowell et al., 2009). The generalizability of the study findings may be limited because the participants were self-selected, predominantly Caucasian, and well educated.

Despite these limitations, this study is one of very few community-based investigations in the field. It is the only randomized controlled trial, to our knowledge, to evaluate an online DA providing individually tailored risk information designed to address the unmet screening information needs of men at risk of developing prostate cancer. It is also the first randomized controlled trial, to our knowledge, to report men's usage of different components of online educational materials about prostate cancer screening.

Conclusions

Unaffected men with a family history of prostate cancer, who were undecided about PSA testing, benefitted most from an online tailored prostate cancer screening DA. These men experienced lower levels of regret following their screening decision. The DA had no impact upon change in potential determinants of decision making about screening, including decisional uncertainty, knowledge, and accuracy of risk perceptions, and it did not influence screening behavior. An online tailored DA may be of optimal benefit to at-risk men who are at the point of making a decision about PSA testing, such as just prior to, or as an adjunct to a consultation with a physician to discuss screening. Future prospective studies are required to explore further the specific components of a DA that promote informed decision making about prostate cancer screening among at-risk men.

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Received October 17, 2012

Revision received April 5, 2013

Accepted June 11, 2013 ■