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TITLE: Facilitating Treatment Decision Making, Adjustment, and Coping in Men Newly Diagnosed with Prostate Cancer

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<b>14. ABSTRACT</b>  This study evaluated the efficacy of a patient-spouse centered cognitive-affective counseling session (CARE: cognitive-affective reactions and expectations), to facilitate treatment decision-making for localized prostate cancer (PrCa). Methods: CARE identified treatment-related values and goals and focused on improving knowledge about treatment options. A time and attention matched General Health Information (GHI) session provided nutrition information. Couples (N=300) were enrolled after diagnosis with PrCa, but before a definite treatment decision was made. Data were assessed separately for patients and spouses at baseline, at 6-months, and at 12 months post intervention. Results: Both sessions were well accepted among participants. The goal of CARE to facilitate treatment decision making was best achieved for spouses and among those patient/partners who chose a non-invasive treatment option. Partners were more distressed about the treatment decision compared to patients, especially in the CARE condition and when considering invasive procedures. We interpret this result as an indication that participants in CARE processed the relevant information and that momentarily higher levels of distress were the "cost" of such processing. At 6-mo this effect disappears, underscoring its temporal nature. Conclusions: The results demonstrate the usefulness of integrating a brief counseling session into the decision-making process, and that increases in perceived difficulty of decision-making are short-term.						
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## **Facilitating Decision Making, Adjustment, and Coping in Men Newly Diagnosed with Prostate Cancer**

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### **INTRODUCTION:**

The study evaluated an intervention designed to facilitate treatment decision making, adjustment, and coping among early-stage prostate cancer patients and their spouses/partners, in a randomized controlled trial. The intervention is based on the Cognitive-Social Health Information Processing (C-SHIP) framework that postulates that decision making is determined by cognitive factors (i.e., perceptions about vulnerability; expectancies and beliefs; values and goals), affective factors (i.e., concerns and worry about the disease and its treatment), as well as self-regulatory skills (i.e., the ability to manage distress and effectively execute recommended behaviors). The goal of the Cognitive and Affective Reactions and Expectations (CARE) Intervention is to facilitate treatment decision making by improving understanding of disease and treatment related facts, as well as by preparing the patient and his spouse/partner to anticipate the medical and psychological consequences of the disease and its treatment. This has been achieved in the context of a structured counseling session (approximate duration 45 min). Specifically, the patient's and spouse/partner's cognitive and emotional reactions to the following areas were explored: the treatment itself; potential side effects; long-term treatment success; relationship with others; and stress-management strategies. The efficacy of the intervention was evaluated systematically with a General Health Intervention (GHI) session serving as a comparison condition, controlling for time and attention. In the GHI condition, patients (and their spouses/partners) received and discussed current recommendations for general health (i.e., nutrition and stress management) and explored their own attitudes, beliefs, and feelings on these topics with a health educator. Assessments were obtained at baseline, and 6 weeks later, to assess treatment decisions, and at 6 months and 12 months post baseline to assess long-term adjustment and coping.

### **BODY/RESEARCH ACCOMPLISHMENTS :**

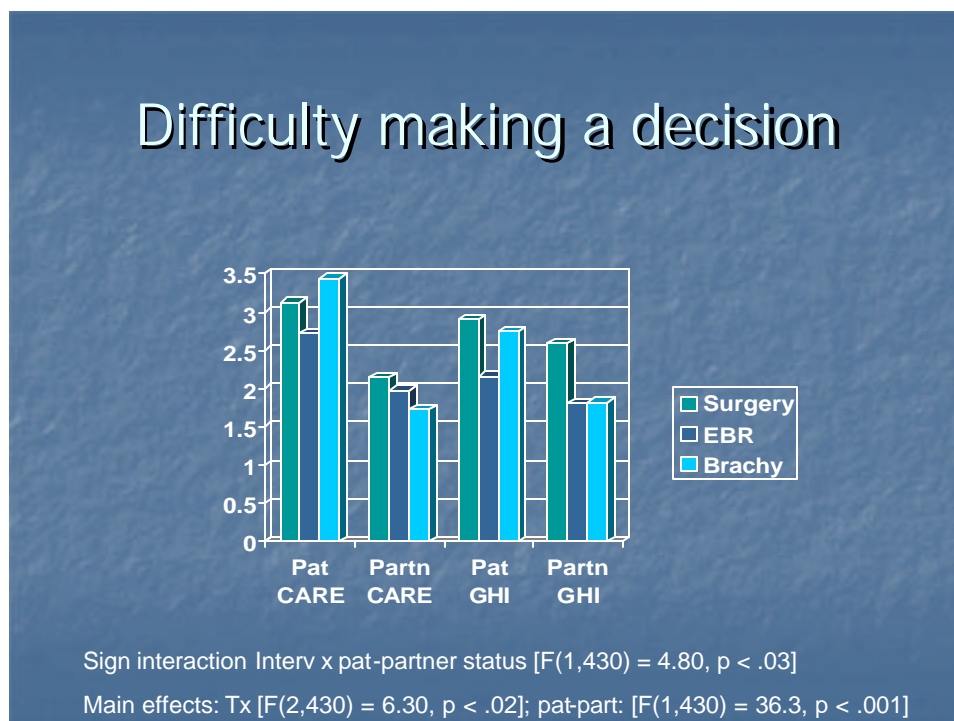
We have used the past year, budgeted as a no-cost extension, to continue data analysis and to write up the results for publication. A copy of the paper submitted to the *Annals of Behavioral Medicine* is attached in Appendix A.

**Evaluation of Intervention sessions.** Upon agreeing to participate in the study, couples were randomized into the CARE or the GHI condition. Preliminary analyses of data assessing the acceptability and usefulness of these sessions suggest that both of the sessions are well accepted. For the CARE intervention, 62% of patients indicated that the session was quite a bit or very useful in understanding potential side-effects of prostate cancer treatment; 74% indicated that there was enough information to make a treatment decision; 76.5% thought the information about side-effects was above average, good, or excellent; 74% indicated that the discussion about treatment consequences was above average, good, or excellent; and 64% thought it provided a good or excellent forum to hear the partner's treatment opinions. Most importantly, 71% of patients indicated that the information provided was useful for treatment decision making, that the information was very understandable (95%), and that the focus on patients' values and goals during

the session was very important (74%). Overall, 44% rated the sessions as excellent, 35% as good; 6% as above average (the remaining 15% rated the sessions as average or poor (1.6%)).

The GHI session that focused on nutritional needs during prostate cancer treatment was equally well accepted. Patients indicated that the session was quite a bit or very helpful in understanding the potential link between nutrition and prostate cancer (52%), and that it addressed concerns about nutrition quite a bit or very much (76%). Patients rated the nutritional information we provided with respect to specific treatment options very highly: for surgery (45% good to excellent); external beam radiation (52% good to excellent). Overall, 26% rated the sessions as excellent, 31% as good; 16% as above average (the remaining 27% rated the sessions as average or poor (9.1%)).

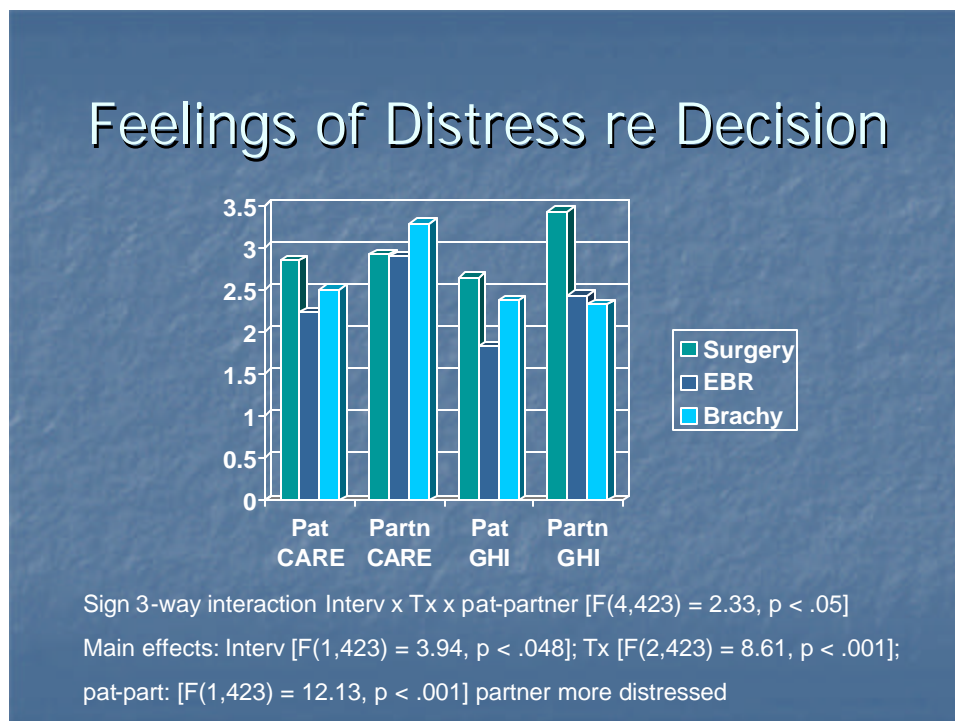
**e) Efficacy of intervention.** Based on analyses of the baseline data there were no differences by study group with regard to worry and distress about, and satisfaction with one's treatment decision. A three-factor analysis of variance (Intervention vs control; treatment (surgery, external beam radiation, brachytherapy; and patient/partner status) with treatment difficulty as the outcome variable, revealed that the CARE intervention worked best for spouses/partners to reduce perceived difficulty of decision making ( $F(1,430) = 4.80, p < .03$ ; see figure 1).



With regard to chosen treatment, patients and spouses both found it more difficult to make a decision if it involved the more invasive surgical procedures (i.e., prostatectomy and brachytherapy;  $F(2,430) = 6.30, p < .02$ ). Overall, however, patients found it more difficult to make a treatment decision compared to spouses ( $F(1,430) = 36.3, p < .001$ ).

With regard to feelings of distress during the decision process, using the same multivariate analysis approach, we obtained a three-way interaction between Intervention type (CARE vs. GHI), treatment, and patient/partner status ( $F(4,423) = 233, p < .05$ ; see figure below). We interpret this interaction as follows, partners felt higher levels of

distress about the treatment decision, especially when they considered an invasive procedure such as surgery or brachytherapy and if they were randomized into the CARE condition.



These results are not entirely surprising, given the nature of the CARE intervention, which by reviewing all treatment related issues and connecting those issues to personal goals and values might have momentarily made the decision somewhat more distressing. We interpret this result as an indication that participants processed the relevant information and that increased perceived difficulty is the “cost” of such processing. When examining this variable at the 6-month assessment point, this difference disappears, further reinforcing that this was a temporary effect.

The emotionally taxing nature of the treatment decision is also reflected in elevated levels of worry about the decision. We found a significant main effect for worry about the decision among patients who chose surgery as a treatment ( $F(2,427) = 3.22, p < .037$ ). Additionally, we found higher levels of worry among patients compared to partners, as expressed by a significant main effect of patient/partner status with regard to worry about treatment decision ( $F(1,427) = 5.40, p < .021$ ).

We next examined the long-term effects of the CARE/GHI sessions on the treatment decision variables using data collected at the 6-mo assessment point. The study group differences for the variable indicating that a decision was difficult disappeared. Thus, the issues that influenced treatment decision did not persist. Still, patients, compared to their partners, perceived the decision as more difficult, six months after diagnosis and independent from study group ( $F(1,400) = 4.02, p < .046$ ). Similarly, the differences in distress by study group that were found at baseline, disappeared. The only difference that persisted were significantly elevated perceived feelings of distress about the treatment

decision among partners compared to patients ( $F(1,404) = 15,83, p < .001$ ). Thus, even six months after diagnosis, patients found the treatment decision more difficult, but their partners showed higher levels of distress about the decision.

At 6-months, patients were significantly more likely to endorse the belief that they would choose their treatment again, compared to their partners ( $F(1,400) = 4,02, p < .46$ ). In contrast, partners indicated that they were significantly more satisfied with the treatment compared to patients ( $F(1,366) = 4,97, p < .026$ ).

### **OTHER ACCOMPLISHMENTS –YEAR 3:**

#### **KEY RESEARCH ACCOMPLISHMENTS:**

- Data analysis
- Presentation of results to two national conferences

### **REPORTABLE OUTCOMES**

Based on our data analyses of the baseline data set we had two accepted presentations at the annual meetings of the American Society of Preventive Oncology (ASPO) and the Society of Behavioral Medicine (SBM) in 2004.

Diefenbach, M.A., Dorsey, J.D., Horwitz, E., Uzzo, R., Greenberg, R., Pollack, A., Raysor, S., Gillespie, D. (2004, March). Treatment decisions among prostate cancer patients and spouses: results from a randomized trial. Presentation at 28th Annual Meeting of the American Society of Preventative Oncology, Bethesda, MD

Diefenbach, M.A., Dorsey, J.D., Horwitz, E., Uzzo, R., Greenberg, R., Pollack, A., Raysor, S., Gillespie, D. (2004, March). A patient-spouse centered intervention to facilitate treatment decision making for localized prostate cancer: results from a randomized trial. Presentation at the 25th Annual Meeting of the Society of Behavioral Medicine, Baltimore, MD

### **CONCLUSIONS**

We have used the past year as a no-cost extension to further explore and analyze the data. We have found promising results that underscore the efficacy of our intervention. These results have been written up in a paper that has been submitted to the Annals of Behavioral Medicine and is under review. Further results were presented at two national conferences.