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A Randomized Trial of a Representational Intervention for Cancer Pain: Does Targeting the Dyad Make a Difference?

Sandra E. Ward, Ronald C. Serlin, Heidi S. Donovan, Suzanne W. Ameringer, Susan Hughes, Klaren Pe-Romashko, and Ko-Kung Wang

University of Wisconsin-Madison

Abstract

Objective—To determine the efficacy in overcoming attitudinal barriers to reporting cancer pain and using analgesics of an educational intervention presented to patients accompanied by a significant other (SO) compared to patients alone.

Design—Patient-SO pairs (N=161) were randomized to the Dyad condition (patient and SO received the intervention), Solo condition (patient received the intervention), or care-as-usual. Dyad and Solo conditions received the intervention at baseline, and two- and four-weeks later.

Main Outcome Measures—Patients and SOs attitudes about analgesic use and patients' pain outcomes (pain severity, pain relief, interference with life, negative mood, and global quality of life [QOL]) at baseline (T1), five weeks later (T2), and nine weeks later (T3).

Results—Completers' analyses revealed no significant differences between groups at T2. At T3, patients in the Dyad and the Solo groups showed greater decreases in attitudinal barriers compared to controls. T1-T3 changes in patients' barriers mediated between the Dyad and Solo interventions and pain severity, pain relief, pain interference, negative mood, and global QOL.

Conclusion—The intervention was no more efficacious when it was presented to dyads than to patients alone. Conditions under which to include SOs in interventions need to be determined.

Keywords

cancer pain; representational intervention; patient education; dyads

Many persons with cancer are reticent to report pain and to use potent analgesics to control their pain because of their attitudinal barriers, including excessive fear of addiction and fatalism about achieving pain control (Thomason, McCune, Bernard, Winer, Tremont, & Lindley, 1998; Ward, Goldberg, Miller-McCauley, Mueller, Nolan, Pawlik-Plank, et al., 1993). Attempts to overcome these attitudinal barriers have yielded mixed results, with patient education interventions found to be effective for some but not all outcomes such as pain severity and quality of life (de Wit, van Dam, Zandbelt, van Buuren, van der Heijden, et al., 1997; Kim, Dodd, West, Paul, Facione, Schumacher et al., 2004; Oliver, Kravitz, Kaplan, & Meyers,

Correspondence to: Sandra Ward, PhD, RN, FAAN, Helen Denne Schulte Professor, University of Wisconsin-Madison, School of Nursing, K6/348, Madison, WI 53792.

Current affiliations for those no longer at the University of Wisconsin-Madison: Heidi S. Donovan, University of Pittsburgh, Suzanne W. Ameringer, Virginia Commonwealth University, Susan Hughes, Madison, WI, Ko-Kung Wang, New York, NY

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2001; Ward, Donovan, Gunnarsdottir, Serlin, Shapiro, & Hughes, 2008). Many of these interventions have lacked strong guidance from theory and it is therefore challenging to determine precisely why effects are inconsistent. The purpose of the present study was to test the efficacy of an intervention that has evolved from a theoretical perspective on patient education termed the Representational Approach to patient education (Donovan & Ward, 2001; Donovan, Ward, Song, Heidrich, Gunnarsdottir, & Phillips, 2007).

The Representational Approach is based on two complementary theories, one that addresses the structure of knowledge and another that addresses the processes through which knowledge changes. Leventhal's Common Sense Model (Leventhal, & Diefenbach, 1991) focuses on the structure of health-related knowledge, i.e., on person's cognitive representations of health problems and the influence of those representations on coping and outcomes. An illness representation is comprised of information, attitudes, and beliefs that an individual has about a health problem. Studies of illness representations have revealed that they typically include ideas about the identity, cause, timeline, consequences, and cure/controllability of an illness (Lau, Bernard, & Hartman, 1989).

The other theory underpinning the Representational Approach is Hewson's Model of Conceptual Change (Hewson, 1993). According to Hewson, conceptual change involves purposeful effort to restructure existing representations that serve as a basis for understanding the new information. He notes that most representations lack depth and breadth and include *gaps* (missing information), *errors* (misconceptions), and *confusions* that can be the target of patient education efforts (Hewson & Hewson, 1984). If patients become aware that their representations are incomplete, unclear, or erroneous, they may become dissatisfied with their existing knowledge and thereby open to conceptual change. If new information is presented which is intelligible (makes sense), plausible (believable), and fruitful (of clear benefit), it is likely to result in conceptual or representational change.

Given these theoretical underpinnings, interventions based on the Representational Approach to patient education involve eliciting and seeking to understand patients' representations of an illness (or a symptom) before providing new information. Through this process the clinician and patient have the opportunity to recognize gaps, confusions, and misconceptions in the patient's representation. By understanding the individual's representations of the health problem, the clinician can provide new information in an individualized manner that is more likely to be accepted by the patient.

The Representational Approach has been used to develop specific interventions for several different types of patient education situations (Song, Kirchhoff, Douglas, Ward, & Hammes, 2005; Ward et al., 2008). In the arena of cancer pain management, the Representational Approach was the basis for *RIDcancerPain*: a Representational Intervention to Decrease Cancer Pain (Ward et al., 2008). The goal of *RIDcancerPain* was to overcome attitudinal barriers to reporting pain and using analgesics and thereby decrease pain severity and improve quality of life. In a randomized trial of adults with metastatic cancer pain, *RIDcancerPain* was compared to standard information (control). Results revealed that compared to control subjects, subjects in *RIDcancerPain* showed greater decreases in attitudinal barriers from baseline to 1 and 2 months later, and greater decreases in pain severity from baseline to 2 months later. Furthermore, changes in attitudinal barriers mediated the effect of *RIDcancerPain* on pain severity. On the other hand, the intervention had no effect on changes in pain severity from baseline to 1 month later, nor did it have an effect on quality of life at either 1 or 2 months. These findings led to considerations for altering the Representational Approach in general and for enhancing the effectiveness of the *RIDcancerPain* intervention in particular.

First, based on literature regarding the importance of significant others in pain management, we speculated that the effectiveness the RIDcancerPain intervention could be enhanced by the inclusion of a significant other. Significant others are friends or family members identified by patients as having important involvement in dealing with the illness the patient is facing. Investigators have shown the importance of significant other involvement in non-cancer pain management (e.g., Keefe, Caldwell, Baucom, Salley, Robinson, Timmons, et al., 1996) and in chronic illness management (Martire, Lustig, Schulz, Miller, & Helgeson, 2004). In a randomized trial of partner involvement in the setting of cancer pain, Keefe and colleagues (Keefe, Ahles, Sutton, Dalton, Baucom, Pope, et al., 2005) demonstrated the benefits of a partner-guided pain management protocol at the end of life. Given these indications of the importance of significant others in pain management, and given that these significant others are likely to have misconceptions (such as exaggerated fear of addiction to medication and fatalism about the possibility of achieving pain relief) in their own representations of cancer pain (Berry & Ward, 1995), it is critical to test whether a representational intervention for cancer pain is more efficacious when presented to patient-significant other dyads compared to patients alone.

The second way that the intervention's effectiveness could be enhanced would be to add elements that provide more support for the process of conceptual change, with an emphasis on translating new information into concrete strategies for behavior change. As a consequence, two key elements were added to the Representational Approach: Goal Setting and Planning, and Follow-up Reinforcement. Goal setting has been shown to be an important component of other psychoeducational interventions as has follow-up reinforcement (Deci & Ryan, 2000; Williams, Minicucci, Kouides, Levesque, Chirkov, Ryan, et al., 2002). These modifications resulted in an updating of the Representational Approach (Donovan et al., 2007) and the RIDcancerPain intervention (now RIDcancerPAIN+).

Our objective was to test the efficacy of RIDcancerPAIN+. We hypothesized that RIDcancerPAIN+ presented to dyads would be superior to RIDcancerPAIN+ presented to patients alone, which would be superior to care-as-usual in decreasing attitudinal barriers, and improving pain severity, pain interference with life, global quality of life, mood and pain relief. We proposed that this effect would be seen from baseline to 5 weeks later and from baseline to 9 weeks later. We predicted that the effect of the intervention on pain outcomes would be mediated by changes in patients' and significant others' attitudinal barriers.

Methods

Design

This was a controlled trial in which subject pairs were blocked by setting (Teaching vs. Non-teaching Facility) to control for possible differences in quality of care and then randomized to one of three study conditions: The "Dyad" condition wherein both patients and their significant others (SOs) received the educational intervention; the "Solo" condition wherein only the patient received the intervention; care-as-usual Control. Measures were taken at baseline (T1) and then 5 weeks later (T2) and 9 weeks later (T3). Randomization was conducted using Excel's RAND Function in repeating blocks of 30. Group assignments were placed in study ID-labeled envelopes, sealed, and remained unopened until after baseline measures had been completed.

Participants

Subjects were pairs of a patient and an SO. The inclusion criteria for patients were: age 18 or older, diagnosed with cancer, responded "yes" when asked if they had had moderate to severe pain in the past two weeks, Eastern Cooperative Oncology Group performance status of 0–2 (out of bed for more than 50% of waking hours), and had an SO who could participate in the

study. Persons who could not read and write in English were excluded. The inclusion criteria for SOs were being age 18 or older and being identified by the patient as the person (friend, spouse, or other family member) who has the most influence in the patient's illness and treatment.

Power analysis determined that three samples of 45 would yield .80 power to detect an effect size of 0.5 standard deviations. As explained in the results section, power of 0.8 is obtained using an analysis of covariance model in which three covariates account for 30% of the variability and for which directional contrasts are assigned a Type I error rate that takes into account two times of testing and three group comparisons. A sample size of 175 was planned to accommodate an attrition rate of up to 30%. Of 543 persons screened, 210 were not eligible (93 had not had moderate to severe pain in the past two weeks, 40 did not have an SO, 69 had too poor performance status, and 6 could not participate in English). Of the 333 who were eligible, 161 (48%) agreed to participate and completed baseline measures (See Figure 1). Of these, 155 (92%) received the allocated intervention, 124 (73%) completed T2 measures and 109 (64%) completed T3 measures. With these sample sizes, power was at least .77 at Time 2 and .70 at Time 3.

Experimental Protocols

Solo RIDcancerPAIN+—The intervention was based on the Representational Approach to patient education (Donovan et al., 2007). In the Solo condition, the SOs were asked to step out of the room but no instructions were given about talking (or not talking) to each other about the intervention content. The intervention has seven key elements. For the first element, patients were asked to describe their beliefs about their cancer pain in terms of cause, timeline, consequences, cure, and control. The intervener listened carefully for mention of barriers to pain management such as fear of addiction or concerns about side effects. In the second element, gaps, confusions and misconceptions about reporting pain and using analgesics were identified and discussed. For the third element (creating conditions for conceptual change), patients discussed the limitations or losses that result from these misconceptions. In the fourth element the intervener provided information to fill gaps and replace confusions that had been identified. An educational message had been prepared for each of the common attitudinal barriers (fatalism about cancer pain management, exaggerated fear of addiction, worry about developing tolerance, concern about side effects, fear of being a complainer, worry about masking changes in disease status, and concern about distracting a physician from focusing on cure). The messages were developed from evidence in published, peer reviewed empirical literature, and have been used in previous studies (Ward et al., 2008). These messages were the basis for providing corrective information, but were framed in the context of the individual's specific situation as revealed during elements one to three. The fifth element was a summary and discussion of the benefits of adopting this new information. For the sixth element the patient created a plan for making change to the way he/she manages pain. These six elements were covered in a single session that lasted from 20 to 80 minutes, depending on the number of misconceptions that were elicited in the assessment interview. The seventh element (evaluation and revision of coping plans) took place during follow-up telephone appointments that occurred 2 and 4 weeks after the first session. During these sessions, the intervener reviewed the plan with the patient to discern progress toward goals, to determine which coping strategies had been most useful, and to revise the plan. These follow-up calls lasted approximately 5 to 10 minutes.

Dyad RIDcancerPAIN+—Patients and SOs in the Dyad RIDcancerPAIN+ condition received the above-described RIDcancerPAIN+ intervention together. For example, the patient and the SO were each asked to respond to questions regarding representations of cancer pain so that any misconception that either person had could be addressed. As in the Dyad condition,

the first session (addressing intervention elements 1 to 6) lasted between 20 and 80 minutes, and the follow-up telephone calls lasted approximately 5 to 10 minutes. Before being used in this study, RIDcancerPAIN+ had been pilot tested for feasibility and acceptability with 20 dyads who reported it to be useful and meaningful.

Interventionist training and fidelity—Seven masters-prepared nurses (5) or psychologists (2) served as interventionists. All 7 conducted both Dyad and Solo interventions. Training for this study included a 3-day pain management program provided by University Hospital and Clinics, a two-day workshop with the PI focusing on the theoretical underpinnings of the study, listening to tapes of completed intervention sessions, and practice (role playing) using the intervention manual. Fidelity of the intervention was assured by interventionists checking off steps on an interview guide that listed each of the intervention steps described above.

Care-as-usual—Subject pairs in this condition did not receive any intervention from project staff. At baseline, they brought their completed measures to a meeting with project staff, and were told about the the timing and procedures for remaining data collection. Project staff answered any questions they had about the project.

Instruments

Because patients could be quite ill, we were attentive to minimizing response burden while at the same time retaining sensitive, valid, and reliable measures.

Attitudes about analgesic use—The Barriers Questionnaire II (BQ-II; Gunnarsdottir, Donovan, Serlin, Voge, & Ward, 2002) is a 27-item self-report instrument that measures negative attitudes about reporting pain and using analgesics. Response options range from 0 (*do not agree at all*) to 5 (*agree very much*). The BQ-II has been developed and tested extensively in persons with cancer (Ward et al., 1993; Gunnarsdottir et al, 2002). The content validity of the BQ-II was determined by an expert panel, and construct validity was shown by finding expected relationships between BQ-II scores and other variables, such as patients' reports of the amount of time they spent in moderate to severe pain (Gunnarsdottir et al., 2002) and it has been shown to be responsive to changes in attitudes in tests of patient education interventions (Ward et al., 2007). The internal consistency was excellent in the present study for both the patient and SO ($\alpha = .86$). The three items in the immune subscale were dropped because of high levels of missing data. A mean of the remaining 24 items was used in analyses. Higher scores indicate more negative attitudes.

Pain severity—Pain severity was a composite score composed of five items. One item addressed the amount of time the patient had spent in moderate to severe pain during the past week, with response options from 1 to 5 (*never, sometimes, often, almost always, and always*). This item has been used in a number of studies addressing adequacy of pain management (Einhorn, 1994) and reliability and validity has been supported by its moderate positive correlation with other pain severity scales (Gordon, Pellino, Adams-McNeil, Miaskowski, Donovan, & Ward, 2002). Another item addressed the intensity of usual pain during the past week, with response options from 0 to 3 (*none, mild, moderate, and severe*). An advantage of this item is that it is simple and allows participants to make overall evaluations of their pain. This item has shown significant moderate positive correlations with other pain severity items (Ward et al., 2008). The other three items in the composite were intensity items (worst pain, least pain, and pain now) from the Brief Pain Inventory Short Form (BPI; Daut, Cleeland, & Flanery, 1983), with response options from 0 (*no pain*) to 10 (*pain as bad as I can imagine*). These items have been widely used in cancer research and have demonstrated reliability, validity, and sensitivity to change (Serlin, Mendoza, Nakamura, Edwards, & Cleeland, 1995). The composite pain severity score was created by computing Z scores for

each item, summing them, and then computing a T-score with a range from 0 to 100 with higher scores indicating greater pain severity. Internal consistency was $\alpha = 0.79$.

Interference with activities—Pain interference was assessed with the BPI Short Form (Daut & Cleeland, 1983). Patients rated on a 0 (*does not interfere*) to 10 (*completely interferes*) scale the extent to which, in the past week, pain had interfered with: general activity, mood, walking ability, normal work (including housework), relations with other people, sleep and enjoyment of life. This scale has been used widely in the cancer pain literature and has been shown to be a valid, reliable, and sensitive measure (Serlin et al., 1995). A mean of the items was used in analysis. Internal consistency was $\alpha = .89$.

Global Quality of Life (G-QOL)—In light of comments about the burden of QOL measures from subjects in a pilot study, we were very selective about this matter. G-QOL was assessed with four items from two established QOL measures, the FACT-G (Cella, Tulsky, Gray, Sarafian, Linn, Bononi, et al., 1993) and the QLQ-C30 (Aaronson, Ahmedzai, Bergman, Bullinger, Cull, Duer, et al., 1993). The two QOL items from the FACT-G were: “I am enjoying the things I usually do.” And “I am content with the quality of my life right now.” The two items from the QLQ-C30 were: How would you rate your overall physical condition during the past week?” and “how would you rate your overall quality of life during the past week?” A composite G-QOL score was used in the analyses; Z scores for the four QOL items were summed and then T-scores were created with a range of 0 to 100. Higher scores indicate better quality of life; reliability was $\alpha = 0.86$.

Negative Mood—Negative mood was assessed with a subscale of the Quality of Life Questionnaire QLQ – C30 (Aaronson et al, 1993). The 6 items (e.g., tenseness, worry, depression, trouble concentrating) have response choices of 0 (*not at all*) to 4 (*very much*). There is evidence for the reliability and validity of the QLQ-C30 and its subscales (Aaronson et al., 1993; King, Winstanley, Kenny, Viney, Zapart & Boyer, 2007). A mean of the items was used; higher scores indicate more negative mood. Alpha was 0.85.

Pain relief—On a single item, participants rated the relief they obtained from pain management activities in the past week (McQuay & Moore, 1999). Response options are from 0 to 4 with verbal descriptors of *no relief*, *slight relief*, *moderate relief*, *a lot of relief*, *complete relief*. Positive correlations with other numerical and analog pain relief scales have been demonstrated the validity of this item (McQuay & Moore, 1999) and it is sensitive to pain interventions (Farrar, Berlin, & Strom, 2003).

Study Participation Evaluation Form—After completing the other T3 measures, patients responded to seven questions about how being in the study influenced their thinking and behavior related to pain management (e.g. “confident talking to a physician about pain”). Response choices ranged from 0 to 4, *strongly disagree* to *strongly agree*. An additional item asked patients if they talked to the SO more about their pain management since joining the study, with responses of *a lot more* (4) to *a lot less* (0). SOs responded to three questions about whether study participation changed their thinking about cancer pain, pain medicine, and whether they talked more with the patient about pain management, with response options of 0 to 4.

Procedure

This study was conducted in six outpatient oncology clinics and one inpatient oncology unit in the Midwest. IRB approval was obtained at all sites Potentially eligible patient were identified by clinic staff and then screened for eligibility by research staff. After eligibility was determined, a member of the research staff contacted the subject pair and scheduled a baseline

appointment at a convenient time and location (usually the patient's home). One or two days prior to this appointment, the pair was contacted again to be reminded of the need for each of them to complete their baseline questionnaire and bring it to the appointment. On the day of the appointment, randomization envelopes were opened. Those randomized to the Solo and Dyad conditions received the intervention. Measures were mailed to both patient and SO subjects at T2, 5 weeks after baseline, and T3, 9 weeks after baseline. Individually addressed stamped return envelopes were enclosed for each of them. After the three sets of measures were completed, each of the subjects in the pair was reimbursed with \$30 for their time and effort. Following T3, patients and SOs were asked to complete the study evaluation form.

Results

Descriptive information for baseline variables

The mean (SD) age of the 161 patients who completed baseline measures was 58.54 (11.77), with a range of 20 to 88. The mean (SD) age of the SOs was 55.58 (14.13), with a range of 18 to 85. See tables 1 and 2 for other demographic information. Baseline variables for the patient sample are presented in Table 3. Dyads who stayed on study (subjects who completed at least T2 measures) were compared to dyads who dropped out. The only significant difference between these groups was that patients who dropped had significantly higher pain relief scores at baseline than those who stayed on study. For SOs who dropped versus those who remained in the study, there were no differences in demographic, general health or baseline measures. There were no significant differences in the proportion of dyads who dropped from the Control ($n = 16$, 28%) Solo ($n = 11$, 21%) and Dyad ($n = 10$, 20%) conditions.

Hypothesis testing

Completers analyses were used for hypothesis testing. Separate analyses of covariance were conducted to examine the effects of the intervention at T2 and T3. The dependent variables used in these analyses included patient and SO attitudes (barriers), pain severity, pain interference, global QOL, negative mood, and pain relief. Change scores for T1-T2 and T1-T3 were computed for each dependent variable by subtracting the later score (T2 or T3) from the earlier score (T1) (see Tables 4 and 5). A positive change score for attitudes, pain severity, pain interference and negative mood is a desired outcome, while a positive change score for pain relief and global quality of life is an undesired outcome. Each ANCOVA used a 3 Group (Dyad vs. Solo vs. Control) $\times$ 2 Gender (male vs. female) $\times$ 2 Site of care (Teaching vs. Non-teaching Facility) design with three covariates – age, baseline (T1) score of the dependent variable being tested, and patients' years of education. Baseline scores were used as a covariate because the ANCOVA of change scores with baseline (T1) scores as a covariate yields covariate adjusted means that are corrected for regression to the mean (Laird, 1983).

In order to control Type I error rate across tests conducted for both the T1 to T2 and the T1 to T3 changes, the Holm (1979) sequentially rejective multiple test procedure was used. According to this method, for each of the dependent measures, the more significant of the two ANCOVA F statistics, one examining T1 to T2 change, the other T1 to T3 change, was tested for significance using an assigned Type I error rate of .025. If this result was not significant, then that effect was reported as non-significant at either time. If the result was significant, the remaining omnibus ANCOVA test statistic was examined for significance using an assigned Type I error rate of .05. Whenever an ANCOVA was found to be statistically significant according to the Holm method, the three treatment effect pairwise comparisons were tested as directional contrasts using Shaffer's (1986) improved sequentially rejective multiple test procedure, which takes into account the nature of prior statistically significant results in assigning Type I error rates to the contrasts.

Main effects of the interventions—With respect to attitudinal barriers, at T2 there were no significant differences between intervention groups. At T3 patients in both the Dyad group ($t(90) = -3.293$, $p = .001$, $d = 1.423$) and the Solo group ($t(90) = -2.119$, $p = .018$, $d = .872$) showed significantly greater decreases in barriers scores compared to those in care-as-usual Control. There were no intervention effects on SOs' barriers scores. With respect to hypotheses regarding pain outcomes, the T1-T2 change in pain relief was significantly higher in the Dyad condition than in the Solo condition ($t(97) = 2.436$, $p = .008$, $d = .850$), but neither group differed from Control. Neither the ANCOVA for T1 to T2 change nor the T1 to T3 change in pain severity, pain interference, global QOL or negative mood revealed any overall intervention effects.

Test of mediation—The tests of mediation were conducted according to the method of joint significance (Serlin, Jacobs, & Franke, 1995). In this method, a variable is declared to be a mediator if the two indirect paths, one from the independent variable to the mediator and the other from the mediator to the dependent variable, are found to be statistically significant when each path is tested at the nominal Type I error rate. The overall Type I error rate was split according to the Holm (1979) procedure among the four possible mediating scenarios: 1) Change in patient's or 2) SO's barriers scores from T1 to T2 would serve as a mediator between intervention and changes in outcomes from T1 to T2, or 3) change in patient's or 4) SO's barriers scores from T1 to T3 would serve as a mediator between intervention and changes in outcomes from T1 to T3. Each of the indirect paths was tested on a directional basis.

Of these four scenarios, the only significant intervention-mediator path was from the intervention to a change in patients' barriers scores from T1 to T3, as previously reported. As a result this was the only mediation relationship that was tested. The path from T1 – T3 change in patients' barriers scores to each of the outcomes was tested using an ANCOVA model. The analysis was a 3 Group (Dyad vs. Solo vs. Control) $\times$ 2 Gender (male vs. female) $\times$ 2 Site of Care (Teaching facility vs. Non-teaching Facility) ANCOVA with four covariates [age, baseline (T1) score of the dependent variable being tested, years of education, and change in barriers scores]. A significant relationship between T1-T3 barriers change scores and outcome measure change scores would establish the mediator-outcome variable path. At T3, patients' barriers change scores mediated the effects of the Dyad and Solo interventions on pain severity [$F(1,105) = 10.08$, $p = .001$, $\eta^2 = .103$], pain relief [$F(1,103) = 3.88$, $p = .026$, $\eta^2 = .043$], pain interference [$F(1,104) = 8.28$, $p = .003$, $\eta^2 = .087$], negative mood [$F(1,104) = 3.47$, $p = .033$, $\eta^2 = .038$], and global quality of life [$F(1,99) = 4.95$, $p = .015$, $\eta^2 = .057$].

Study Participation Evaluation

Summaries of responses to the study evaluation are in Table 6. Patients in the Dyad and Solo conditions reported significantly higher scores for every item compared to those in the control group. Effect sizes for the Dyad v. Control comparison ranged from $d = 0.60$ to $d = 1.31$, and for the Solo v. Control comparison from $d = 0.36$ to $d = 1.08$. Dyad and Solo patients did not differ on any evaluation items. SOs in the Dyad group had significantly higher scores on the evaluation items concerning the way they think about cancer pain and how they think about pain management compared to SOs in the Control group. SOs in the Solo group did not differ from those in the Control group.

Discussion

Some, but not all, hypothesized effects were found in this study. With respect to attitudinal barriers, there were no significant differences between the three groups at 5-weeks, but at 9-weeks patients who experienced the Representational Intervention in either the Dyad group or the Solo group showed greater decreases in attitudinal barriers compared to controls. There

were no group differences on baseline to 9-week changes in SO barriers scores. With respect to hypotheses regarding mediation, changes in patients' barriers mediated between the Dyad and Solo interventions and all of the outcomes -- pain severity, pain relief, pain interference, negative mood, and global quality of life.

Several interpretations can be drawn from this pattern of findings, all of which rest on the notion that the model tested (intervention affects attitudes which affect outcomes) is an incomplete depiction of the complexity of the pain management situation. That is, the Representational Approach guides the content and the process of the intervention and demonstrates superiority to care-as-usual with respect to changes in attitudes about pain management, but for this attitude change to translate into improved outcomes several other steps are needed. Some actions that need to occur include the patient contacting a care provider, receiving advice and making use of prescribed medications.

This idea that there may be intervening, unmeasured, variables between the intervention and the outcomes explains why we see a mediational effect for patients' barriers scores without seeing a main effect of the intervention on the outcomes. That is, we have a situation wherein the dependent variables are quite distal from the independent variable, and, as Shrout and Bolger (2002) explain, as outcomes become more distal the more likely it is that there are additional links in a causal chain, or that other competing causes or random factors (e.g. various patterns of patients' declining health) are having an impact on the outcomes. In such circumstances, Shrout and Bolger conclude, one may be able to detect mediation but not the overall effect. This perspective on mediation sets aside the first step of Baron and Kenny's classic (1986) approach. That is to say, Baron and Kenny originally argued that mediation could not be established unless one first demonstrated a main effect of the independent variable on the outcome, but they have rescinded that opinion (Kenny, 2006) and instead now agree with others (e.g., MacKinnon & Luecken, 2008) that such a step is not a requisite condition for establishing mediation. Again, this perspective is particularly apropos in situations, such as seen in the present study, wherein the dependent variables are rather distal to the intervention. The bottom line importance of this perspective in the present study is that the Dyad and Solo interventions changed patients' barriers scores which in turn affected each of the outcome variables that were studied.

The hypothesis that the Dyad condition would be superior to the Solo condition was not supported. Instead both the Dyad and the Solo conditions were superior to control with respect to changes in patients' barriers scores. Perhaps the collection of data on barriers from both patients and significant others in all three groups had an adverse impact on our ability to determine the superiority of the Dyad intervention relative to the Solo intervention. Completion of the questionnaires may have stimulated a level of discussion that was sufficient to result in a decrease in patients' barriers scores regardless of whether the SO received the intervention. But if completing measures and then talking to each other had an effect on patients' attitudes, then why not on SO attitudes? It is critical to determine the conditions under which it is useful to include significant others. Most previous studies of dyadic interventions have used two group designs (dyad intervention versus care-as-usual), and such interventions have proven effective compared to care-as-usual (Keefe et al., 2005; Song et al., 2005); rarely has a three group design been used to determine if such interventions are superior to care-as-usual *and* to solo interventions.

The need to further examine Dyad and Solo interventions is highlighted by a challenging finding. At 5-weeks (but not at 9-weeks) the Dyad and Solo groups differed significantly on pain relief, with those in the dyad condition having improved and those in the Solo condition having gotten worse, but neither of these two groups differed significantly from the control condition whose relief scores had not changed. The fact that relief scores behaved differently

than the other outcomes was not a surprise, based on work demonstrating the distinctness of positive versus negative evaluations of mood and similar constructs (Watson & Tellegen, 1985). We had not included the relief item in the pain composite measure because it calls for a judgment of how good something is, while the severity items call for a judgment of how bad something is. But why did those in the Solo condition get worse and why did this occur at 5-weeks but not at 9-weeks? Resentful demoralization at not having been allocated to the Dyad condition could have occurred, but why in the Solo group and not the control group, and only at 5-weeks but not 9-weeks? Despite our efforts to control error rate, it could be a Type I error.

Study limitations include that measures of variables that could explain the causal chain from intervention to outcome were not used. For example, we did not track whether patients received changed analgesic prescriptions from their clinicians. Also, it is unknown if individual clinicians reinforced or dismissed the intervention messages. Given that many of the clinical sites involved in the study have been involved in pain quality improvement efforts for some time, it is unlikely that clinicians would have been dismissive of patients raising concerns about pain control (Gordon, Pellino, Adams-McNeil, Miaskowski, Donovan & Ward, 2002). In fact, it may be that the sites on study could be providing better than average pain management, a situation that would raise the bar for detecting intervention effects over and above the care-as-usual condition.

The present study provides some support for interventions based on the Representational Approach to patient education. The findings are consistent with those seen in a previous study of pain management in persons with cancer (Ward et al., 2008) and in end-of-life decision making (Song et al., 2005). Future researchers should consider ways to optimize the strength of the intervention, such as by combining this patient education approach with feedback to providers about patients' symptoms (Haywood, Marshall, & Fitzpatrick, 2006). Future work could include more measures of intervening variables, should strive to determine the conditions under which such interventions are helpful, and assess their cost effectiveness.

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Figure 1.
Enrollment and retention.

Table 1

Patient Demographic and Health-Related Variables at Baseline by Treatment Group (N = 161)

Variables	Dyad (n = 51)		Solo (n = 53)		Control (n = 57)	
	N	%	N	%	N	%
Teaching (v. not-teaching) site	31	60.8	31	58.5	33	57.9
Male (v. female) gender	24	47.1	22	41.5	19	33.3
Married (v. not)	42	82.4	35	66.1	36	63.1
Race						
African American	3	5.9	4	7.5	6	10.5
American Indian	0	0.0	1	1.9	0	0.0
Caucasian	46	90.1	47	88.7	50	87.7
More than one race	1	2.0	0	0.0	1	1.8
Other	1	2.0	1	1.9	0	0.0
Income						
Below \$20,000	11	21.6	20	37.8	14	24.6
\$20,000–49,999	17	33.3	14	26.4	22	38.5
\$50,000–99,999	15	29.4	13	24.5	7	12.3
Over 100,000	1	2.0	5	9.4	7	12.3
No response	7	13.7	1	1.9	7	12.3
Cancer Diagnosis						
Lung	13	25.5	9	17.0	4	7.0
Breast	12	23.5	11	20.8	8	14.0
Gastrointestinal	8	7.8	11	20.8	19	33.3
Genitourinary	4	7.8	5	9.4	4	7.0
Gynecologic	7	13.7	8	15.1	10	17.5
Hematology	1	2.0	2	3.8	5	8.8
Other	3	5.9	5	9.4	3	5.3
Multiple	7	13.7	0	0.0	2	3.5
Missing	0	0.0	2	3.8	2	3.5
Other health problems present	28	54.9	27	50.9	24	42.1
Currently on chemotherapy	15	29.4	20	37.7	21	36.8
Relationship: SO is						

Variables	Dyad (n = 51)		Solo (n = 53)		Control (n = 57)	
	N	%	N	%	N	%
Spouse	40	78.5	32	60.4	36	63.1
Parent	2	3.9	5	9.4	3	5.3
Child	4	7.8	6	11.3	9	15.7
Sibling	2	3.9	2	3.8	3	5.3
Grandchild	0	0.0	1	1.9	1	1.8
Niece/nephew	0	0.0	1	1.9	0	0.0
Friend/Other	3	5.9	6	11.2	5	8.8

Note. GI = gastrointestinal; GU = genitourinary; GYN = Gynecological; SO = significant other.

Table 2

Significant Other Demographic and Health-Related Variables at Baseline by Treatment Group (N = 161)

Variables	<u>Dyad (n = 51)</u>		<u>Solo (n = 53)</u>		<u>Control (n = 57)</u>	
	N	%	N	%	N	%
Male (v. female) gender	20	39.2	22	41.5	22	38.6
Married (v. Not)	44	86.3	36	67.9	45	78.9
Race						
African American	4	7.8	4	7.5	6	10.5
Caucasian	47	92.2	48	90.6	50	87.7
Missing	2	3.9	2	3.8	2	3.6
Income						
Below \$20,000	11	21.6	14	26.4	12	21.1
\$20,000–49,999	17	33.3	18	34.0	19	33.3
\$50,000–99,999	17	33.3	10	18.9	12	21.1
Over 100,000	1	2.0	4	7.5	7	12.3
Health problems						
Arthritis	10	20.4	6	11.8	7	12.5
Cardiac	15	30.6	9	17.6	9	16.1
Cancer	0	0	2	3.9	4	7.1

Table 3

Mean (SD) of Baseline Variables by Completion Status (N = 161)

Variable (possible range)	Completed Baseline Only (n = 37)		Completed Baseline & T2 (n = 124)			
	M	SD	M	SD	t	p
Patient Data						
Age	57.76	12.46	58.88	12.41	-0.48	0.63
Education (years)	14.11	2.72	13.56	2.69	1.08	0.28
Barriers (0-5)	1.86	0.91	1.63	0.74	1.36	0.44
Pain Severity (0-100)	51.15	10.20	49.67	9.96	0.78	0.44
Pain Relief (0-4)	2.63	0.78	2.30	0.69	2.43	0.02
QOL-Pain Interference with Life (0-10)	5.32	2.68	5.55	2.16	-0.55	0.58
G-QOL (0-100)	50.77	9.63	49.77	10.14	0.53	0.59
QOL-Negative Mood (1-4)	2.44	0.74	2.31	0.73	0.94	0.35
Significant Other Data						
Age	54.03	13.59	56.05	14.30	-0.76	0.45
Education (years)	14.22	2.90	13.65	2.67	1.12	0.27
Barriers (0-5)	1.92	0.68	1.92	0.75	-0.00	0.99

Note. G-QOL = global quality of life; SO = significant other.

Table 4

Mean and Standard Deviation of T1-T2 Change Scores by Group (N = 124)

T1 - T2 Change Score	Dyad (n = 41)			Solo (n = 42)			Control (n = 41)		
	n	M	SD	n	M	SD	n	M	SD
Pain Severity	40	1.18	13.33	42	-3.54	10.99	41	1.44	11.24
QOL - Pain Interference	40	1.02	2.02	41	0.08	2.60	41	0.88	2.43
G-QOL ^I	39	-2.89	9.21	40	2.28	8.86	41	-0.32	8.63
QOL - Negative Mood	37	0.14	0.57	40	-0.20	0.68	41	0.07	0.56
Pain Relief [*]	37	-0.22 ^a	0.94	38	0.24 ^a	0.84	37	-0.05	0.90
Patient Barriers	38	0.57	0.77	42	0.36	0.73	40	0.10	0.59
Significant Other - Barriers	40	0.57	0.77	42	0.36	0.73	36	0.10	0.59

Note. Mean scores are covariate adjusted for age, education and baseline value. Means that have the same superscript differ significantly:

^a $t(97) = 2.436, p = 0.008, d = .85$.

^I G-QOL = global quality of life.

^{*} Negative change score indicates improvement.

Table 5

Mean and Standard Deviation of T1-T3 Change Scores by Group (N = 109)

T1 - T3 Change Score	Dyad (n = 35)				Solo (n = 36)				Control (n = 38)			
	n	M	SD	n	n	M	SD	n	n	M	SD	n
Pain Severity	34	0.02	13.21	36	-1.47	11.44	38	1.69	9.83			
QOL - Pain Interference	33	0.94	2.53	35	0.24	2.47	37	0.97	2.41			
G-QOL ^I	34	-1.84	9.81	35	0.88	8.78	38	-0.47	8.27			
QOL - Negative Mood	34	0.16	0.67	35	-0.35	1.35	38	0.03	0.56			
Pain Relief *	30	-0.19	0.54	36	0.23	0.84	36	-0.14	1.02			
Patient - Total BQ	32	0.72 ^a	0.88	36	0.43 ^b	0.64	37	0.08 ^{a,b}	0.75			
Sig. Other - Total BQ	34	0.65	0.71	36	0.28	0.74	36	0.24	0.57			

Note. Mean scores are covariate adjusted for age, education and baseline values. Means that have the same superscript differ significantly.

^at (90) = -3.293, p = 0.001, d = 1.423;

^bt (90) = -2.119, p = 0.018, d = 0.872.

^IG-QOL = global quality of life.

* Negative change score indicates improvement.

Table 6

Mean (SD) Study Participation Evaluation by Patients and SOs by Group (N = 105)

Item	Dyad		Solo		Control		F	Effect Sizes			
	M	SD	M	SD	M	SD	df	C. v. S.	d	C. v. D.	S. v. D.
<u>Patient</u>											
How think about cancer pain	2.97	0.76	2.82	0.83	1.97	0.96	2,102	14.19*	0.99*	1.17*	0.18
How think about pain medicine	3.09	0.71	2.79	1.01	2.03	0.96	2,102	13.16*	0.84*	1.17*	0.33
How manage pain	2.88	0.73	2.38	1.10	1.68	1.03	2,102	13.96*	0.72*	1.24*	0.52
Confident talking with physician	3.03	0.68	3.00	0.56	2.41	1.14	2,100	6.14*	0.70*	0.73*	0.04
Confident using pain medicine	3.21	0.48	3.03	0.76	2.16	1.04	2,102	17.43*	1.08*	1.31*	0.22
Manage medicine side effects	2.71	0.58	2.91	0.83	2.08	1.04	2,102	9.43*	0.98*	0.75*	0.24
Pain better managed	2.94	0.69	2.79	0.77	2.08	1.14	2,102	9.43*	0.79*	0.96*	0.17
<u>SO</u>											
How think about cancer pain	2.73	1.10	2.17	0.99	2.05	1.20	2,102	3.65*	0.11	0.62*	0.51
How think about pain medicine	2.70	1.08	2.31	0.99	2.03	1.1	2,102	3.30*	0.26	0.61*	0.36
Talk to patient	3.91	0.95	3.65	0.73	3.56	0.77	2,100	1.70	0.11	0.43	0.32

Note. C = control; S = solo; D = Dyad.

* p<.05., Tukey HSD.