



## Celebrating Nursing Science: The Research-Practice Link

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## CSI = Crime Scene Investigation




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## Evidence!



**1** DNA is made up of four bases, Adenine, Thymine, Cytosine and Guanine, which are linked together in a strand.

**2** Two complementary strands then join together according to basic pairing rules: the A's of one strand pair with the T's of another strand, and the C's pair with the G's.

**3** The result is a double stranded DNA molecule.

**FORENSICS: The DNA Detectives**

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# CSI

- C = Clinical
- S = Science
- I = Investigation -

The Evaluation and Use of Evidence to Improve Patient Care

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## CSI - Similarities

<ul style="list-style-type: none"> <li>• Specific <b>type of crime</b></li> <li>• Gather the evidence</li> <li>• Evaluate the evidence</li> <li>• Draw conclusions from the evidence</li> <li>• Make a decision using the evidence for an <b>individual case</b></li> </ul>	<ul style="list-style-type: none"> <li>• Specific <b>clinical problem/question</b></li> <li>• Gather the evidence</li> <li>• Evaluate the evidence</li> <li>• Draw conclusions from the evidence</li> <li>• Make a decision using the evidence for a <b>group of patients</b></li> <li>• Make a decision using the evidence for an <b>individual patient</b></li> </ul>
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## Objectives

- Describe the process to use to ask an important clinical question
- List the principles to use to evaluate clinical evidence
- Use pain management research as an exemplar of a clinical science investigation
- Discuss strategies for how to use new evidence to improve patient care

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## Choice of a Problem/ Clinical Question

- Important clinical problem/question
  - High volume, risk, and/or cost
- Need to ask a searchable and answerable question
  - The “right” question
  - The Haystack phenomenon = too much information is available
- Use the PICO format to pose the clinical question (Melnyk & Fineout-Overholt, Evidence-Based Practice in Nursing and Health Care, 2005)
  - Helps to find the right evidence

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## PICO Format

- P = Patient population of interest
- I = Intervention of interest
- C = Comparison of interest
- O = Outcome of interest

(Melnyk & Fineout-Overholt, 2005)

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## Patient Population of Interest

- May seem easy to identify
- Without an explicit description, the clinician will have difficulty doing a focused search for the evidence
- Some additional considerations: age, gender, diagnosis, setting of care
  - May help to refine the search parameters
- **Example – Patients with unrelieved cancer pain**
  - ? Inpatient vs. outpatient setting
  - ? Specific type of cancer pain
  - ? Particular age group (elderly)

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## Intervention of Interest

- The more specific the intervention of interest – the more focused the search will be
- **Example – Effect of psychoeducational interventions**
  - Cancer pain management interventions
  - Opioids for cancer pain
  - Nonpharmacologic interventions for cancer pain

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## Comparison Intervention

- Can be a true comparison
  - Placebo
- Can be another treatment or standard care
- **Example – Psychoeducational interventions compared to standard care**

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## Outcome(s) of Interest

- May be more than one outcome of interest
- Identification of the outcome enables the searcher to find evidence that examined the same outcome variable
- **Example – Effect of psychoeducational interventions compared to standard care to improve cancer pain management**
  - Knowledge and attitudes
  - Pain intensity scores
  - Medication intake

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## PICO Format

- P = Patient population of interest
- I = Intervention of interest
- C = Comparison of interest
- O = Outcome of interest
- Asking the right question is the critical step in the process
  - Take your time to refine the clinical question
- Consult with colleagues to refine the question

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## CSI - Similarities

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## Finding the "Right" Evidence

- Get help from a reference librarian
- Choose the right database
  - Cochrane database of systematic reviews
  - National Guidelines Clearinghouse
  - MEDLINE
  - CINAHL – nursing and allied health
  - PsycINFO – behavioral sciences
  - EMBASE – European biomedical

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## How to Judge an Individual Study?

- Validity
  - Were the results of the study obtained via sound scientific methods?
  - Was the study compromised by bias and/or confounding variables?
- Reliability
  - Can the results of this study make a difference when applied in clinical practice?
    - Clinically as well as statistically significant results
- Applicability
  - Can the results be applied in my setting?

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## CSI - Similarities

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## Evaluation of the Clinical Evidence

- Need to rate the “strength” of the evidence
  - Based on multiple studies
- Take into account the validity and stability of the evidence when clinical recommendations are made
- Taxonomies are available to rate the strength of the evidence
  - Quality
  - Quantity
  - Consistency

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## Rating the Strength of the Clinical Evidence

- Quality
  - Study design, conduct, analysis
    - Minimize selection bias
- Quantity
  - Number of studies
  - Overall sample size
  - Magnitude of the treatment effect
- Consistency
  - Similar results across studies

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## Rating System for the Hierarchy of Evidence

- Level I: Evidence from a systematic review or meta-analysis of all relevant RCTs or evidenced-based clinical practice guidelines based on systematic reviews of RCTs
- Level II: Evidence from at least one well-designed RCT
- Level III: Evidence obtained from well-designed controlled trials without randomization
- Level IV: Evidence from well-designed case-control and cohort studies
- Level V: Evidence from systematic reviews of descriptive and qualitative studies
- Level VI: Evidence from a single descriptive or qualitative study
- Level VII: Evidence from the opinion of authorities and/or reports of expert committees

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**NINR 20TH ANNIVERSARY**

## Clinical Question in Cancer Pain Management



What is the effectiveness of psychoeducational interventions (I), compared to standard care (C) to improve cancer pain management (O) in oncology outpatients (P)?

What type of cancer pain management education program should I institute in my outpatient setting?

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**NINR 20TH ANNIVERSARY**

## Significance of the Clinical Question

- 50% of oncology outpatients experience moderate to severe pain
- 80% to 90% of oncology patients in the terminal phases of their illness experience moderate to severe pain
- Percentages have not changed in 30 years
- Negative consequences of unrelieved pain

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**NINR 20TH ANNIVERSARY**

## Literature Review

**"Gather the Evidence"**

- CINAHL
- Pub Med
- Cochrane Database of Systematic Reviews
- Review of reference lists




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### Studies of Psychoeducational Interventions to Improve Cancer Pain Management

**"Evaluate the Evidence – Part 1"**

- Majority of the studies focused on changing clinicians' knowledge and attitudes – **NOT ON PATIENTS**
- Only **16** studies in the past 18 years have focused on changing patients' or family caregivers' knowledge, attitudes, and behaviors
  - Five were focused on knowledge and attitudes
  - Eleven were focused on knowledge, attitudes, and behaviors
- Used standard +/- or tailored interventions

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### "Standard" versus "Tailored" Interventions

- **Standard intervention** is one in which all of the participants in the intervention group received the identical intervention.
- **Tailored intervention** is one in which the participants in the intervention group received an intervention that was customized to meet their specific learning needs.

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### Intervention Studies to Change Knowledge of Cancer Pain Management

**"Evaluate the Evidence – Part 1"**

- Four studies focused on patients (*Clottfelter, 1999; Glajchen & Moul, 1996; Lai, 2004; Walker, 1992*)
- One study focused on family caregivers (*Ferrell et al. 1995*)
- All five of these studies used a standard intervention
  - Knowledge scores improved following the intervention
  - Magnitude of the increase in knowledge was not reported

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### Intervention Studies to Change Knowledge and Behaviors Regarding Cancer Pain Management

**"Evaluate the Evidence – Part 1"**

- Eleven studies focused on patients  
*(Anderson et al., 2004; Dalton, 1987; deWit et al., 1997; Ferrell et al., 1994; Keefe et al., 2005; Miaskowski et al., 2004; Oliver et al., 2001; Rimer et al., 1987; Ward et al., 2000; Wells et al., 2003; Yates et al., 2004)*
- All of the studies, except one, were RCTs
- Six of the studies used standard + tailored interventions *(deWit et al., 1997; Miaskowski et al., 2004; Oliver et al., 2001; Rimer et al., 1987; Wells et al., 2003; Yates et al., 2004)*

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### Evaluation of the Evidence on Psychoeducational Interventions for Cancer Pain Management

- Part I = "Gestalt" of the evidence
  - Number of studies
  - Types of studies
  - Do I need to refine my search of the evidence?
- Part II – "Drill down" into the study findings
  - Need some type of framework to organize the evidence
    - Study characteristics
    - Specific characteristics of the various interventions
    - Did the intervention work to improve cancer pain management?

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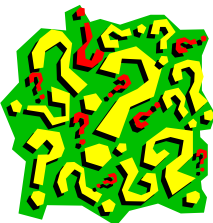
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### Evaluation of the Clinical Evidence

What type of cancer pain education program should I implement in my outpatient clinic to improve patient's knowledge, decrease pain intensity scores, and improve medication intake?




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**Evaluation of Specific Study Characteristics**

Studies were evaluated for similarities and differences in seven specific characteristics:

- Participant characteristics
- Type of intervention
- Length of time for the intervention
- Sustainability of the intervention
- Outcome measures evaluated
- Clinically significant changes




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**Participant Characteristics**

- Only 1561 patients
- Mean age = 53 to 67.7 years
- Sex distribution equal
  - Issue of stratification
- Diagnoses – breast, prostate, or lung cancer
- Multiple pain etiologies




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**Types of Interventions**

- Studies that combined structured and tailored components as part of an intervention appear to be the most effective in increasing knowledge and teaching behaviors to improve outcomes.
- Six RCTs of psychoeducational interventions for cancer pain management used both components




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## Length of Time for the Intervention



- Issue of "dose"
- **Individual** interventions lasted from 15 to 90 minutes
  - In 6 studies, the intervention was administered as a single session
- **Total time** for the intervention ranged from 15 to 420 minutes
- **Lack of consistency in the studies done to date makes it impossible to determine the optimal length of time for a psychoeducational intervention for cancer pain management**

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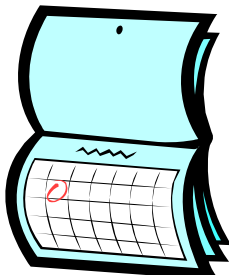
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## Sustainability of the Intervention



- Only two studies evaluated the sustainability of the intervention (de Witt et al., 1997; Wells et al., 2003)
- Effects were not sustainable

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## Outcome Measures

- Most common outcome measure was knowledge regarding cancer pain management
- Other outcome measures in some studies:
  - Changes in pain intensity
  - Medication use or adherence with the regimen
  - Changes in the severity of side effects
  - Changes in pain's level of interference with function
  - Changes in mood and QOL
- Only Miaskowski et al. (2004) included all of these outcome measures

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## Clinically versus Statistically Significant Differences

- Extremely important issue
- In pain management – a change of greater than or equal to one-half of the standard deviation is considered clinically significant (~30% decrease in pain, Farrar, 2000)
- The majority of the studies did not provide sufficient data to evaluate for clinically significant differences
- Only Miaskowski et al. study (2004) produced statistically and clinically significant changes in several outcome measures

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## Effectiveness of the PRO-SELF® Program

- Randomized clinical trial of a psychoeducational intervention compared to standard care
- Oncology outpatients with pain from bone metastasis (homogeneous sample)
- Primary outcomes
  - Changes in pain intensity scores over time (average and worst pain)
  - Changes in opioid analgesic prescriptions and intake (total opioid dose and ATC opioid dose)

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## Research Team

- Christine Miaskowski, RN, PhD
- Marilyn Dodd, RN, PhD
- Claudia West, RN, MS
- Steven Paul, PhD
- Debu Tripathy, MD
- Peter Koo, PharmD
- Karen Schumacher, RN, PhD

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## Research Funding

- Grant (CA 64734) from the National Cancer Institute
- Unrestricted grants from:
  - Janssen Pharmaceutica
  - Purdue Pharma LP

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## Standard Care Group Procedures

- Patient version of AHCPR Cancer Pain Guideline
- Home visits – weeks 1, 3, & 6
- Taught to complete the pain management diary on a daily basis
- Telephone interviews – weeks 2, 4, & 5

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**PRO-SELF® Group Study Procedures**

- “Academic detailing” session during week 1 visit
  - Test of knowledge and attitudes using the Pain Experience Scale (PES)
  - Used responses on the PES as the basis for the education
- PRO-SELF® Pain Control Booklet
- Use of a pillbox
- Pain management diary
- Script to speak with MD/nurse

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**PRO-SELF® Group Study Procedures**

- Home visits – weeks 1, 3, and 6
- Telephone coaching sessions – weeks 2, 4, and 5
- *Publication with the details of the intervention – West et al. Oncology Nursing Forum 30(1): 65-73, 2003.*
- <http://nurseweb.ucsf.edu/conf/cancerpain>

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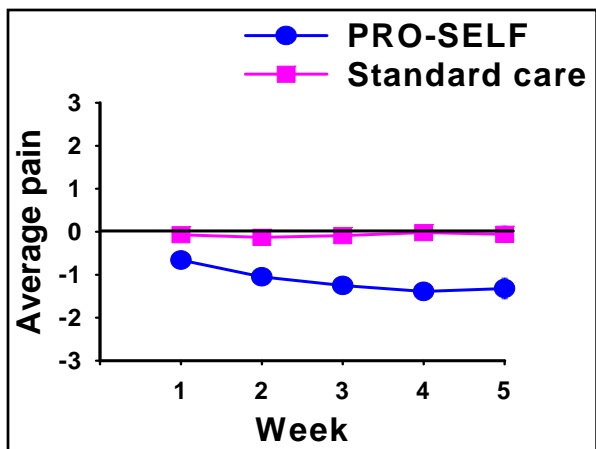
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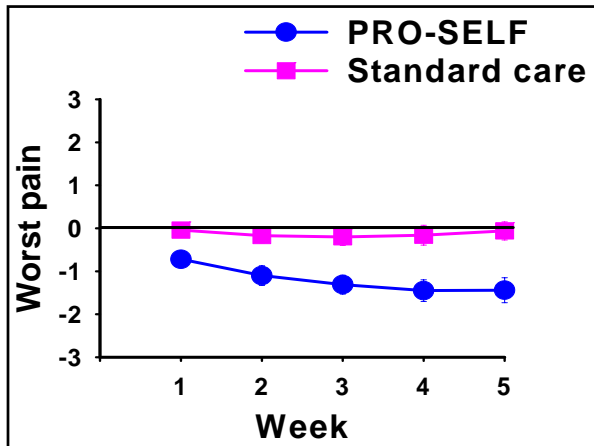
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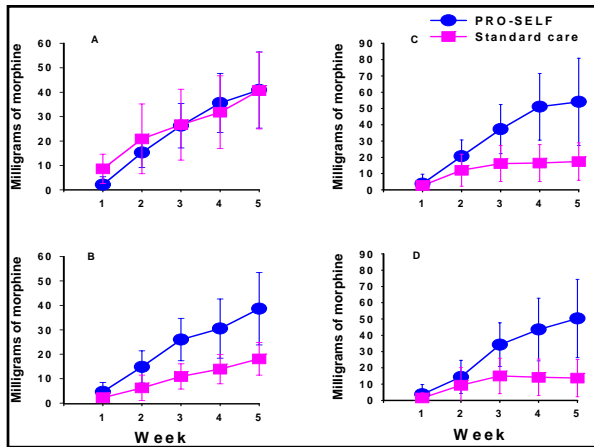
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## Conclusions

- Statistically and clinically significant reductions in pain intensity
  - Average pain = 28.4%
  - Worst pain = 27.0%
- Total opioid consumption in the PRO-SELF® group increased by 39 mg/day ( $\pm$  131.7 or 28.6% increase) compared to 18mg/day ( $\pm$  56.2 or 21.9% increase) in the standard care group
- ATC opioid consumption in the PRO-SELF® group increased by 50 mg/day ( $\pm$  164.2 or 24.8% increase) compared to 14 mg/day ( $\pm$  65.6 or 9% increase) in the standard care group

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## Critique of the PRO-SELF Intervention

- Based on the review of the evidence – the PRO-SELF intervention is the only psychoeducational intervention that produced statistically and clinically significant improvements in knowledge scores and decreases in pain intensity scores
- Can it be used in oncology clinical practice?
  - Only patients with pain from bone metastasis
  - Well educated patients (14 years)
  - Primarily Caucasian patients

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## Elements of the PRO-SELF Intervention

- Structured and **tailored** components
  - Knowledge test + **tailored education**
  - Educational booklet
  - Pain management diary
  - Pillbox
  - Script to use with MD/nurse
  - **Coaching and skills training**
- Total time for the intervention was 4.5 hours
  - Home visits – 3 at about 90 minutes
  - Phone calls – 3 at about 20 minutes
- Duration of the intervention = 6 weeks

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## CSI - Similarities

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## Critical Question

- Does "one size fit all"?
- Use of clinical judgment
  - Evidenced-based practice is not cookbook care!
- Importance of ongoing assessments
  - Is the intervention working?
  - How does the intervention need to be changed for a particular patient?
- New concept in evaluating the effectiveness of interventions in RCTs

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## Responder Analysis and Secondary Patient Outcomes

- Interesting paper by Dionne et al. on responder analysis
  - *Trends in Pharmacologic Sciences* 26(3): 125-130, 2005
- Categorized patients in the **PRO-SELF©** group based on change in mean of average and worst pain intensity scores
  - Responders =  $\geq 30\%$  decrease in pain
  - Partial responders = 1% to 29% decrease in pain
  - Non-responders = 0% or increase in pain
- Evaluated for differences in POMS, SF-36, and pain interference scores, among the three responder groups, using analysis of covariance

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**NINR 20TH**

### Results of Responder Analysis

- Results of responder analysis
  - 49.4% (n=44) – complete responders
  - 24.7% (n=22) – partial responders
  - 25.8% (n=23) – non-responders
- No significant differences were found among the three responder groups in:
  - Demographic characteristics
  - Disease characteristics
  - Treatment characteristics
  - Baseline pain scores

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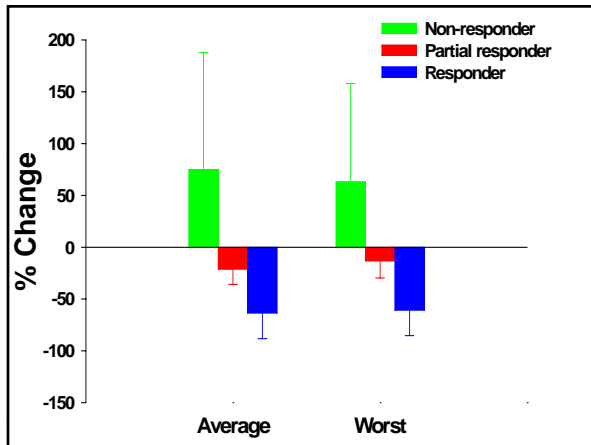
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**NINR 20TH**

### Responder Analysis for POMS Scores

- No differences among the three responder groups in:
  - Tension
  - Anger
  - Vigor
  - Fatigue
  - Confusion
  - TMD score

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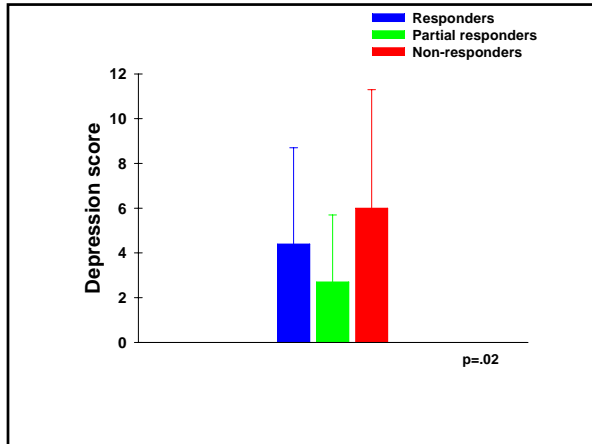
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### Responder Analysis for SF-36 Scores

- No differences among the three responder groups in:
  - General health
  - Physical functioning
  - Role limitations – physical
  - Role limitations - emotional

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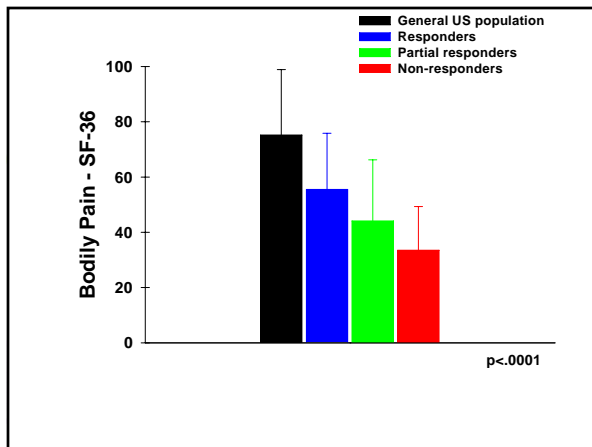
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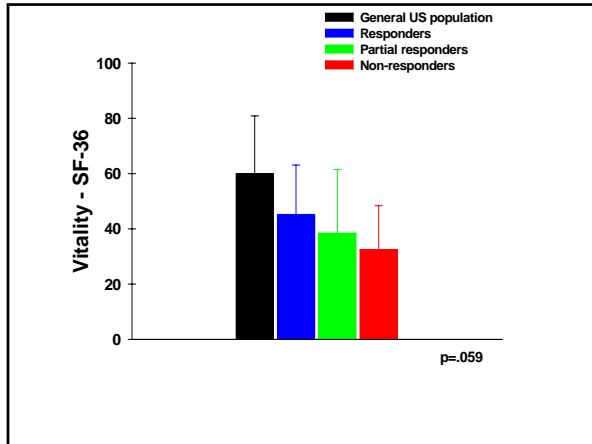
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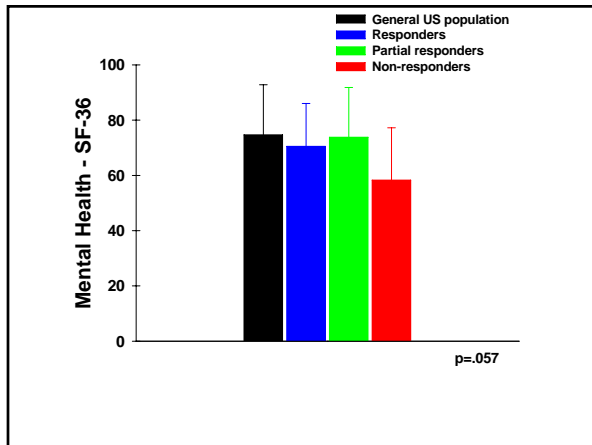
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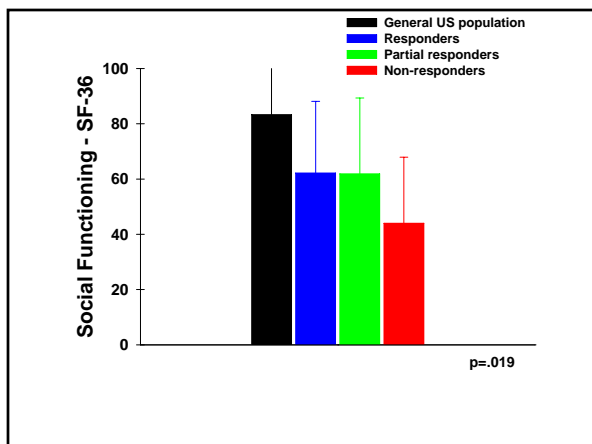
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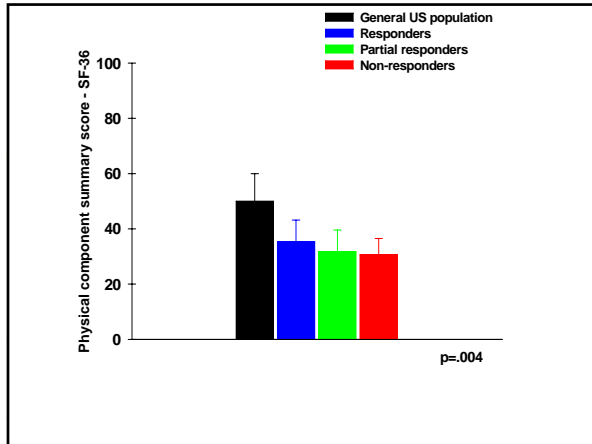
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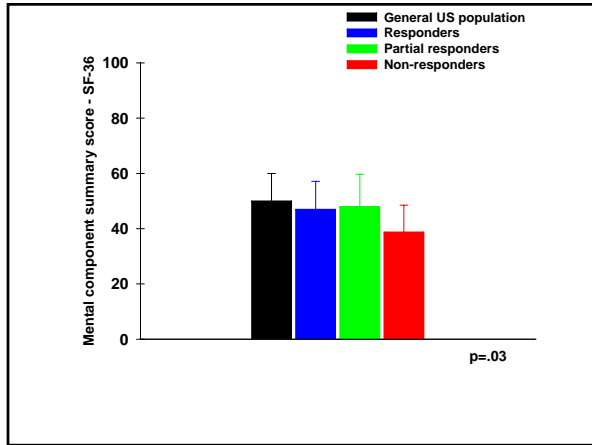
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### Responder Analysis for Interference Scores on BPI

- No differences among the three responder groups in:
  - Sexual activity (p=.072)

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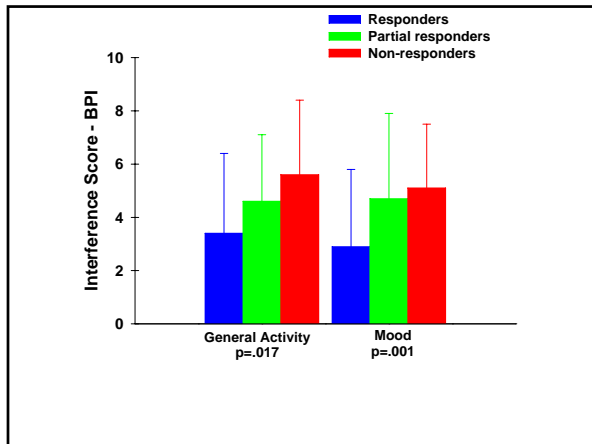
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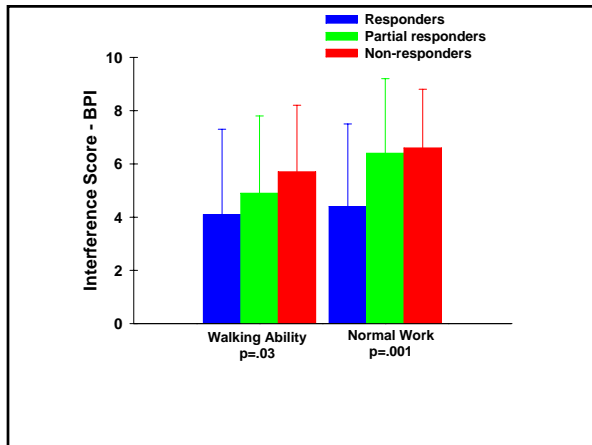
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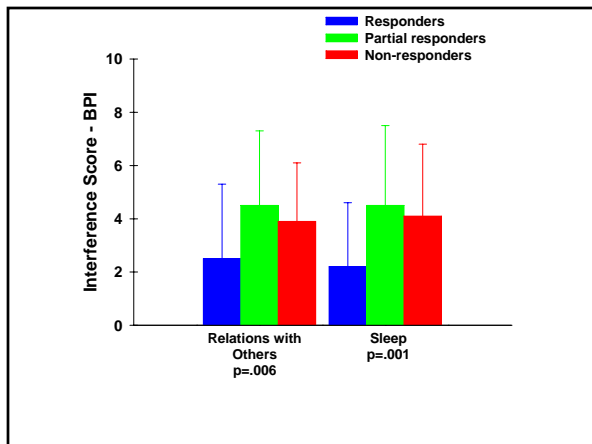
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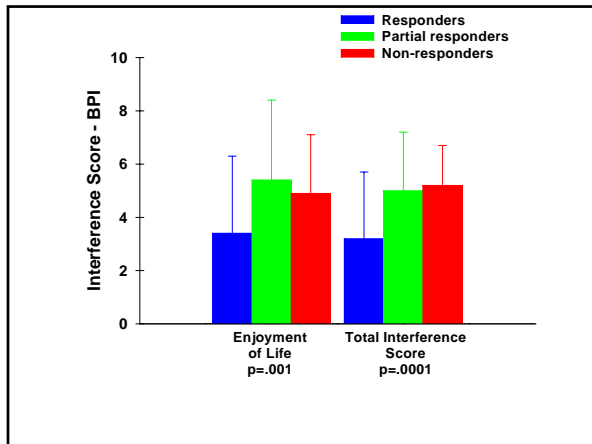
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## Conclusions

- One size psychoeducational intervention does NOT fit all oncology patients
- Even with the relatively small sample sizes, differences in outcomes were found among the three responder groups
- Explanation of the lack of a treatment effect
  - Too low a dose of the intervention
  - Incorrect intervention
- Need to re-assess patients to determine the effectiveness of **any** intervention

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## Creation of a Vision for Change

- Need “out-of-the-box” thinking
- Need to instill the notion of “best practice” in all of the nursing staff
  - It would be unthinkable not to implement the very best practices for our patients
- Create a climate for change
  - Identify strengths
  - Identify weaknesses
  - Outline opportunities for success
  - Delineate the threats to complete the project and develop strategies to overcome them
- Action, Persistence, and Patience

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 **8 Steps for Successful Change**

1. Increase a sense of urgency
2. Build the guiding team
3. Get the vision right
4. Communicate for "buy-in"
5. Empower action and remove barriers
6. Create short-term wins
7. Don't let up
8. Make the change stick

*(Kotter & Cohen, 2002)*

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**Happy Anniversary to NINR!**



The collage features a blue square with yellow plus signs and the text 'NINR 20th ANNIVERSARY', a photograph of the Golden Gate Bridge, and a photograph of a modern building interior.

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