CARE MANAGEMENT FOR EFFECTIVE USE OF OPIOIDS (CAMEO)

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Study Team

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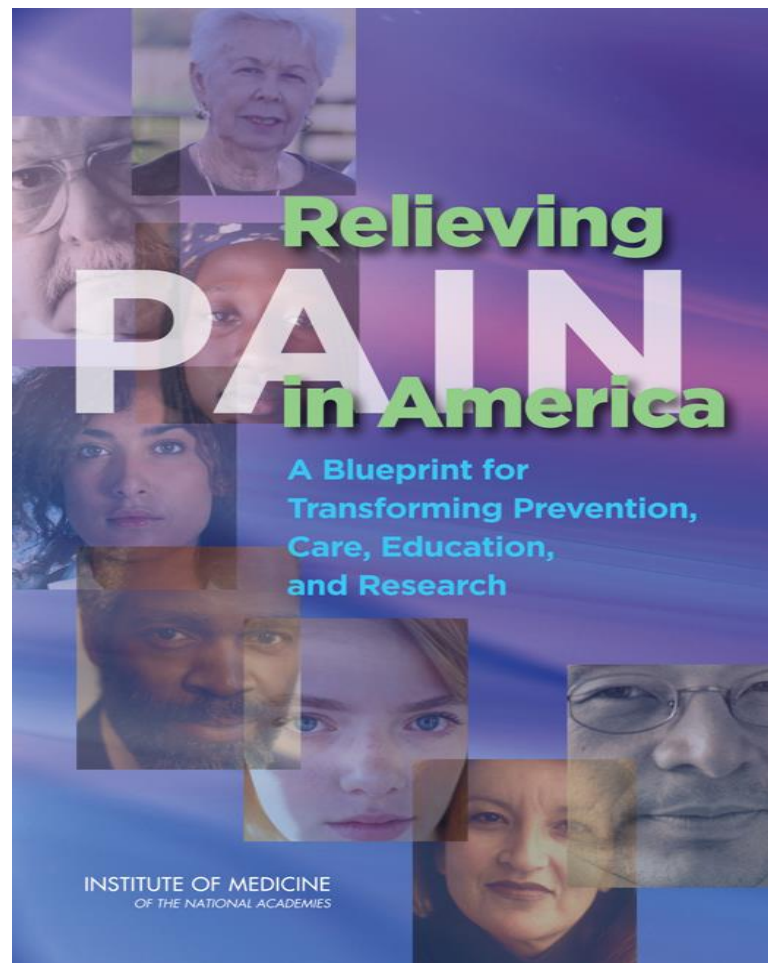- **Win Turner, RPH**
- **Alan Zillich, PharmD**

BACKGROUND

Chronic pain in the US

100 MILLION ADULTS

1 in 3
AMERICANS
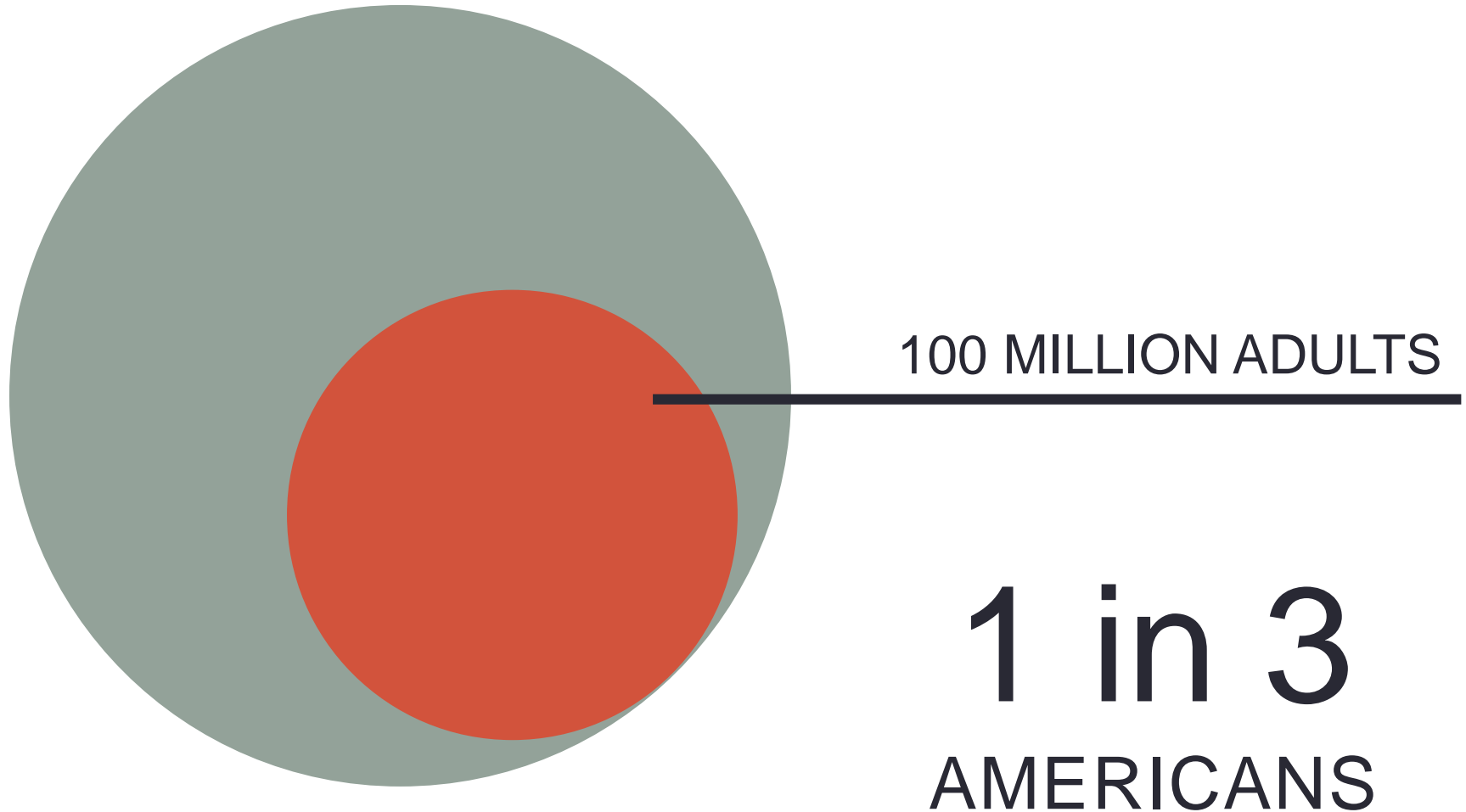
High costs of chronic pain

Costs $560–$635 billion/ yr

Chronic Pain

- **As population ages, number with pain conditions expected to rise**

  - **back pain and osteoarthritis**

Pain: A major problem among military veterans

- **50% of Veterans in primary care report chronic pain** (Kerns et al., 2003; Clark, 2002)

- **Prevalence as high as 75% in women Veterans** (Haskell et al., 2006)

Importance

- **Low back pain is common**

- **Enormous burden in patient suffering**

- **Detriments to quality of life**

- **Most common cause of disability**

- **Exorbitant health care costs**

Optimal Approach for Treating Chronic Low Back Pain

- **??**

- **Options – Many!**
  - **- Medications**
  - **-   Psychological**
  - **- Injections**
  - **- Surgery**
  - **- Physical**
  - **- Complementary**

- **Evidence for individual approaches**

  - **Limited time frames (few months, few estimates of durability)**

  - **"Efficacy" rather than "Effectiveness" or "Comparative Effectiveness"**

Treating Chronic Low Back Pain

- **Evidence supported analgesic treatment and cognitive behavioral therapy for CLBP**
  - **Had not been compared head to head**

- **"Opioid conundrum"**
  - **Prescriptions had increased**
  - **Concerning trends in opioid overdose and admissions for OUD treatment**
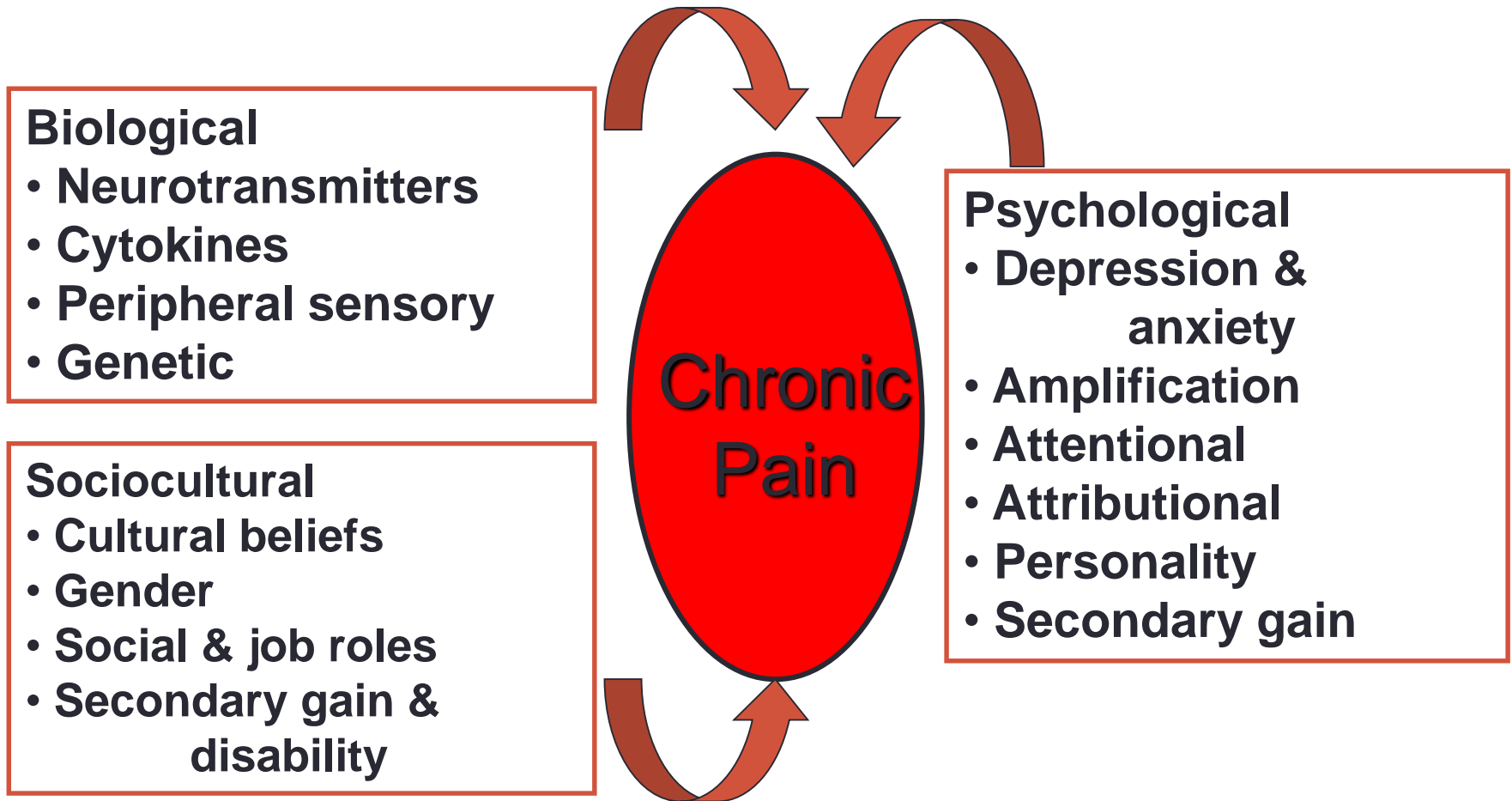
STUDY OBJECTIVE AND AIMS

Study Objective

- **To compare the effectiveness of pharmacological treatment and optimization vs. cognitive behavioral therapy for Veterans with chronic lower back pain on chronic opioid therapy**
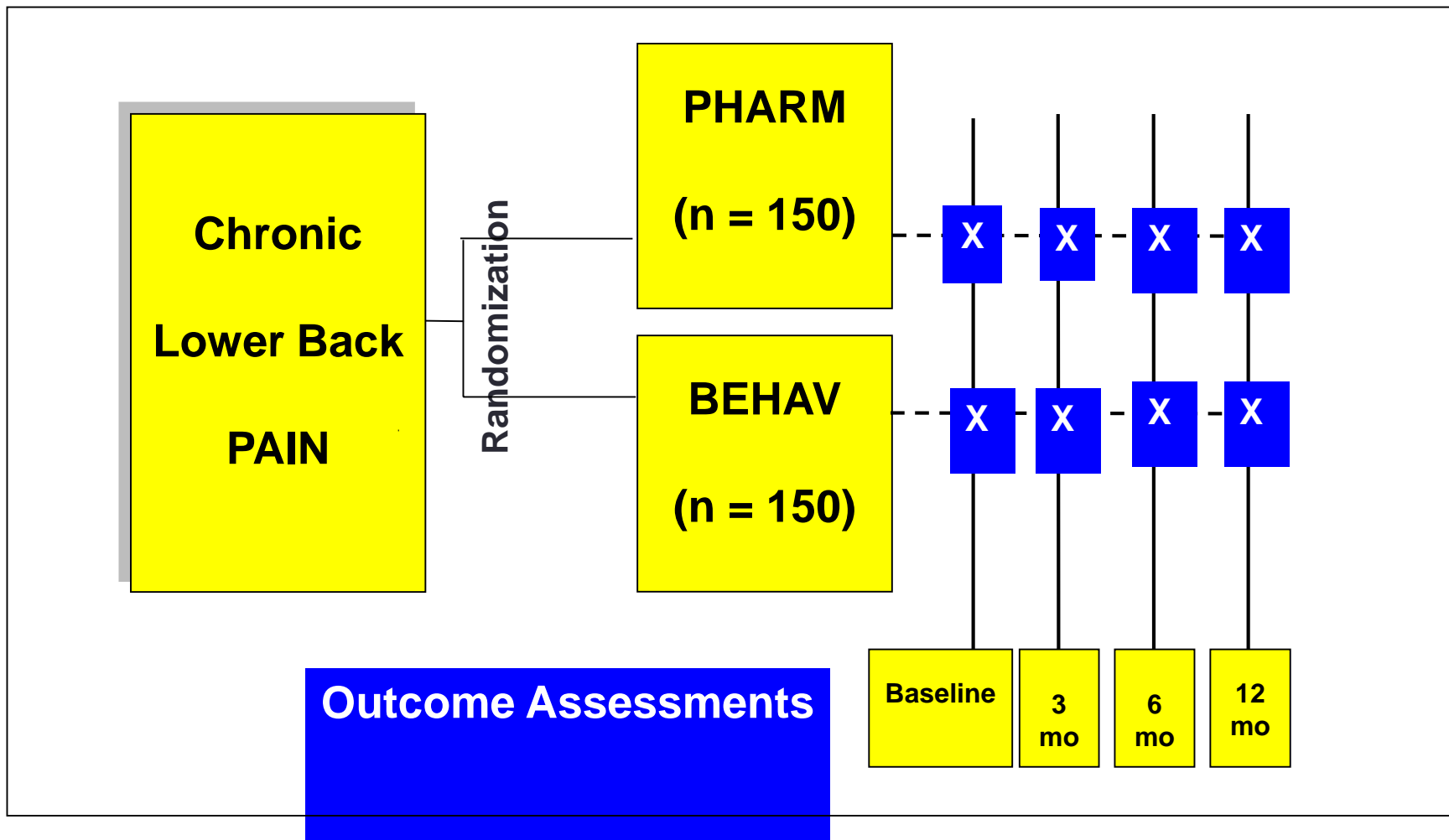
Specific Aims

- **Compare PHARM vs. BEHAV on pain impact, intensity, and interference at 6 and 12 months**

- **Compare intervention effects on other outcomes**
  - **Patient global impression of change**
  - **Health-related quality of life**
  - **Pain beliefs**
  - **Opioid dose**

- **Compare cost-effectiveness of interventions**

Biopsychosocial Model

Biological
- **Neurotransmitters**
- **Cytokines**
- **Peripheral sensory**
- **Genetic**

Sociocultural
- **Cultural beliefs**
- **Gender**
- **Social & job roles**
- **Secondary gain & disability**

Chronic Pain

Psychological
- **Depression & anxiety**
- **Amplification**
- **Attentional**
- **Attributional**
- **Personality**
- **Secondary gain**

CAMEO Trial Design

Setting

- 5 primary care clinics at Roudebush (Indianapolis) VA Medical Center

- 2 Community-based outpatient clinics
  - Bloomington
  - Terre Haute

Participants

- **N = 261 Veterans**

- **Moderate to severe chronic low back pain**
  - **Brief Pain Inventory 5 or greater**
  - **> 6 months**

- **On long-term opioid therapy > 3 months**

Exclusion Criteria

- **Severe medical conditions**

- **Active psychosis**

- **Schizophrenia**

- **Active Suicide ideation**

- **Pending back surgery**

- **Moderately severe cognitive impairment**

- **Active substance use disorder**

- **Pregnant or planning to become pregnant**

- **Involved in ongoing pain trial**

INTERVENTIONS

Interventions

- Pharmacological (PHARM) arm
  - Nurse care management
  - Focused on analgesic treatment and optimization according to algorithm

- Behavioral (BEHAV) arm
  - Cognitive behavioral therapy delivered by clinical psychologists

Pharmacological Arm

- **Algorithm-based co-analgesic treatment**

- **Guideline-concordant opioid management**

- **Delivered by nurse care manager**

- **Supervised by study MD/PharmD**

Pharmacological Arm

- **Algorithm-based co-analgesic treatment**

- **Guideline-concordant opioid "rules"**

- **Telephone-delivered by nurse care manger**

- **Supervised by study MD/PharmD**

Analgesic Algorithm: Non-opioids

Step	Analgesic
Step 1 (Simple analgesics)	• **Acetaminophen** • **Naproxen**
Step 2 (other NSAIDs)	• **Ibuprofen** • **Meloxicam** • **Etodolac** • **Diclofenac** • **Salsalate**
Step 3 (Topicals, gabapentin, muscle relaxants, tramadol)	• **Capsaicin (topical)** • **Gabapentin** • **Cyclobenzaprine** • **Tramadol**
Step 4 (TCAs)	• **Nortriptyline** • **Amitriptyline**

Analgesic Algorithm: Opioids

Step	Analgesic
Step 5 (SA opioids)	• Hydrocodone/acetaminophen • Oxycodone/acetaminophen
Step 6 (LA opioids)	• Morphine SR • Morphine IR • Methadone

Pharmacological Arm

- **Weekly case management meetings**

- **Regular contacts w/ participants to**
  - **Monitor pain/function**

  - **Response to treatment**

  - **Assess for side effects**

Behavioral Arm

- **8 phone or face-to-face contracts in 6 months**

- **Emphasis on:**
  - **Pain coping skills**
  - **Pain self-management**

- **Delivered by clinical psychologist and clinical psychology PhD students**

Behavioral arm

Pain Self-Management/Coping Skills

- **Overview and causes of CLBP**
- **Identifying pain triggers and influences**
- **Handling pain flare-ups**
- **Increasing physical activity**
- **Goal Setting and planning**
- **Problem solving**
- **Overcome fear of movement/re-injury**
- **Positive thinking**
- **Activity-rest cycling**
- **Scheduling pleasant activities**
- **Relaxation and deep breathing**
- **Attention-diversion techniques**
- **Tips for better sleep**
- **Effective communication with providers**
- **Reframing or changing cognitions**

Behavioral Arm

- **Supervised by clinical psychologist**

- **CBT treatment manual**

MEASURES

Primary Outcome

- **Brief Pain Inventory total score ("Pain impact")**

- **Between-group difference of 1-point**
  - **Clinically meaningful difference (0.3 SD effect size)**
  - **Mixed effects models for repeated measures**

Brief Pain Inventory

SEVERITY

Describe your pain (past week)

- At its worst
- At its least
- On average
- Right now

IMPAIRMENT

How has pain interfered with your

- General activity
- Mood
- Walking ability
- Work
- Relationships
- Sleep
- Enjoyment of life

Additional measures

- **Pain severity**
- **Pain disability**
- **Psychological symptoms**
- **Stress**
- **Opioid misuse**
- **Opioid side effects**
- **Health-related quality of life (HRQL)**

- **Pain beliefs and coping**
- **Treatment response**
- **Opioid dose**
- **Back function**
- **Self-management behaviors**
- **PROMIS (sleep, fatigue)**
- **Health care utilization/costs**

RESULTS

Sample characteristics (*n*=261)

- **Mean age: 57.9 (9.5)**

- **Sex: 92.3% men**

- **Married: 53.3%**

- **Race:**
  - **73.2% White**
  - **20.7% Black**

- **Income**
  - **71.9% adequate**

Sample characteristics (*n*=261)

- **Duration of pain = 22 years**

- **Disability compensation = 74%**

- **Comorbidity (0-14) = 3.8**

Pain treatments, n (%)	
Pain clinic	165 (63.2)
Pain school	59 (22.6)
Psychiatrist/psychologist	152 (58.7)
Physical therapy	184 (70.8)
Orthopedist/rheum	156 (59.8)
Surgery for back	73 (28.2)
Chiropractor	122 (46.9)
Acupuncture	33 (12.7)
Massage	56 (21.5)

Baseline Pain Measures

Measure	PHARM Mean (SD)	BEHAV Mean (SD)	P-value
BPI Total (Impact)	6.45 (1.79)	6.49 (1.67)	0.8230
BPI-Pain severity	6.78 (1.65)	6.76 (1.47)	0.9295
BPI-Pain Interference	6.34 (2.07)	6.39 (1.99)	0.8265

Disability and psychological

Measure	PHARM Mean (SD)	BEHAV Mean (SD)	P-value
Roland Disability	16.6 (4.7)	16.7 (4.2)	0.8164
PHQ-9 Depression	11.2 (6.4)	11.2 (5.8)	0.9970
Pain catastrophizing	23.9 (12.8)	24.4 (11.3)	0.7407

Results: Pain Impact

BPI total score (pain impact) was decreased 0.64 points ([SD] = 0.22) in the BEHAV group at 12 months

Decreased by 1.14 points (SD = 0.23) in the PHARM group

Between group difference of 0.5 points, p = 0.0423

Results: Pain Intensity

BPI pain intensity decreased by 0.40 points in the BEHAV group (SD = 0.19)

Decreased by 1.02 points (SD = 0.20) in the PHARM group

Between group difference of 0.62, p = 0.0044).

Pain interference

Mean decrease from baseline in the BPI interference score was 0.71 points in the BEHAV group

1.19 points in the PHARM group

Between group difference of 0.48 points; p = 0.0846

Limitations

- **All Veterans; Do results apply to other patients (non-Veterans)?**

- **Conducted at a single medical center**

- **No control group to definitely determine treatment effect relative to usual care**

Conclusion

A nurse care management intervention focused on pharmacological management reduced pain impact and intensity more than a behavioral intervention involving cognitive behavioral therapy.
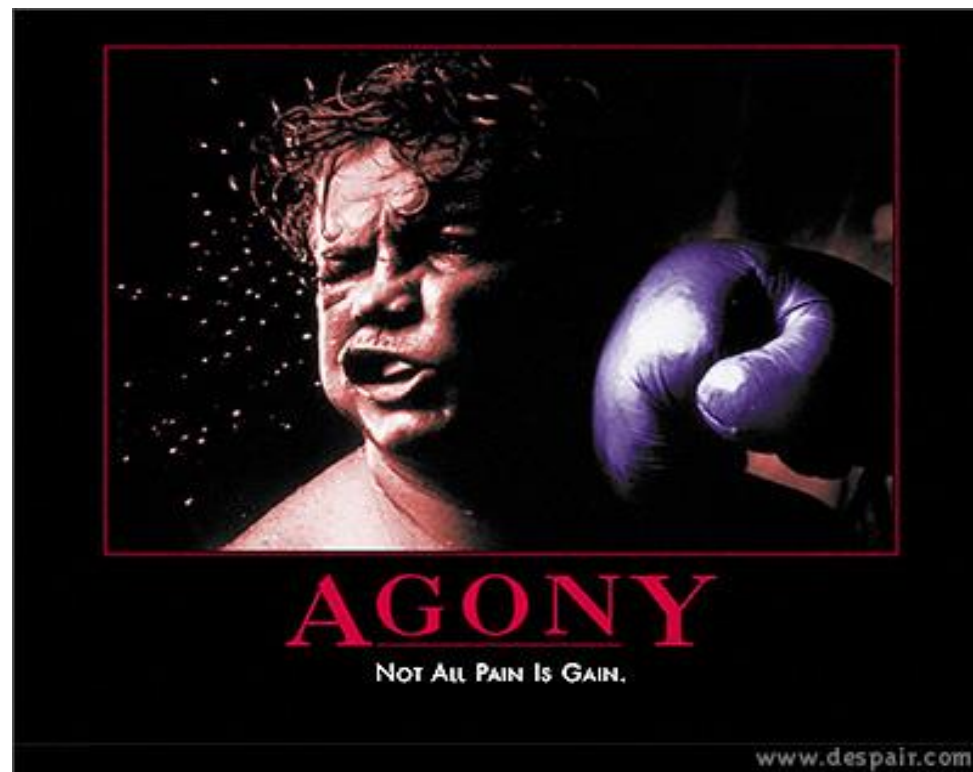
Discussion

- **Both treatment groups improved, but improvement was modest**
  - **PHARM group improvement was statistically significant but between-group difference may not represent clinically significant differences**

- **Future Directions**
  - **Side effects and costs may differ favoring the BEHAV group**
  - **To Improve treatment effects, will need combination therapy especially for patients with "complex" chronic pain**

Pre-emptive responses to potential questions

- **Secondary outcomes**

- **Opioid dose at baseline and follow-up**

- **Fidelity to treatment manual**

- **Adherence to intervention contacts**

- **Economic evaluation**

QUESTIONS?

Thank you for attending