Stepped-Care as an Approach to Manage Chronic Pain and its Comorbidities

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Pain and Depression Dyad

Physical Symptoms

PAIN is the most common physical symptom

Psychological Symptoms

DEPRESSION is the most common psychological symptom
2 Primary Care Pain Trials

SCAMP and ESCAPE

Stepped Care for Affective disorders and Musculooskeletal Pain study

Evaluation of Stepped CARE for Chronic Pain: Effectiveness in Iraq/Afghanistan Veterans trial
What is a Stepped-Care Intervention?

- Starting with lower intensity, less costly treatments (Step 1)
- “Stepping up” to more intensive, costly, or complex treatments
  - In patients that are “poor responders”
- Low Back Pain (Von Korff), PGW Syndrome (Engel)
SCAMP

Funded by National Institute of Mental Health - RO1 MH071268-01 (Kroenke, PI)
SCAMP DESIGN

PAIN (back or hip/knee)

(randomized) (n = 250) (n = 250)

DEPRESSED

NONDEPRESSED

Outcome Assessment at 1, 3, 6, and 12 months

Stepped Care

Usual Care
Clinical Trial Inclusion

- Pain located in low back, hip or knee
- Persistent pain for > 3 months
- Brief Pain Inventory score of ≥ 5 (moderate pain severity)
- Moderate depression (PHQ-9 ≥ 10)
Exclusion Criteria

- Non-English speaking
- Moderately severe cognitive impairment
- Bipolar disorder or schizophrenia
- Current disability claim being adjudicated for pain
- Tried to cut down on drugs or alcohol in the past year
- Currently pregnant or planning to become pregnant
- Anticipated life expectancy $\leq 12$ months
STUDY SITES

- Roudebush VAMC
- Primary Care Center at Wishard
  - Other IUMG primary care clinics
HYPOTHESES

Depression/pain care management will, compared to usual care:

**Primary Hypothesis**
- Reduce pain and/or depression severity

**Secondary Hypotheses**
- Improve health-related quality of life (HRQL), including work and social functioning
- Improve pain beliefs/behaviors
- Be cost-effective in terms of QALYs
# Step 1 – Pharmacotherapy

<table>
<thead>
<tr>
<th>WHEN</th>
<th>WHERE</th>
<th>WHAT (Treatment Action)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Clinic</td>
<td>Antidepressant started</td>
</tr>
<tr>
<td>1 wk</td>
<td>Phone</td>
<td>Check adherence &amp; side effects</td>
</tr>
<tr>
<td>3 wk</td>
<td>Phone</td>
<td>Adjust dose if needed</td>
</tr>
<tr>
<td>6 wk</td>
<td>Clinic</td>
<td>Change antidepressant if needed</td>
</tr>
<tr>
<td>9 wk</td>
<td>Phone</td>
<td>Adjust dose if needed</td>
</tr>
<tr>
<td>12 wk</td>
<td>Clinic</td>
<td>Decide if step 2 is warranted</td>
</tr>
</tbody>
</table>
Antidepressant Selection

- Venlafaxine
- Fluoxetine
- Sertraline
- Citalopram
- Bupropion
- Mirtazepine
- Nortriptyline
## Step 2 – Pain Self-Management

<table>
<thead>
<tr>
<th>WHEN</th>
<th>WHERE</th>
<th>WHAT (Treatment Action)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 wk</td>
<td>Clinic</td>
<td>PSMP – Session 1</td>
</tr>
<tr>
<td>14 wk</td>
<td>Phone</td>
<td>PSMP – Session 2</td>
</tr>
<tr>
<td>16 wk</td>
<td>Clinic</td>
<td>PSMP – Session 3</td>
</tr>
<tr>
<td>18 wk</td>
<td>Phone</td>
<td>PSMP – Session 4</td>
</tr>
<tr>
<td>20 wk</td>
<td>Clinic</td>
<td>PSMP – Session 5</td>
</tr>
<tr>
<td>22 wk</td>
<td>Phone</td>
<td>PSMP – Session 6</td>
</tr>
<tr>
<td>24 wk</td>
<td>Clinic</td>
<td>Close Phase 2.  Phone q 3 mo.</td>
</tr>
</tbody>
</table>
Pain Self-Management Program
*(example components)*

- Education – pain; vocabulary; red flags;
- Identifying /modifying fears and beliefs
- Goal-setting and problem-solving
- Exercise – strengthening; aerobic; etc.
- Relaxation; deep-breathing;
- Handling pain flare-ups
- Working with clinicians and employers
SCAMP CONCEPTUAL MODEL

**SCAMP CONCEPTUAL MODEL**

**COVARIATES**
- Demographics
- Other Psych.
  -- Anxiety
  -- Stressors
- Pain
  -- Coping
  -- Beliefs

**Depression severity**

**Pain severity**

- Impaired Function/QoL
- Increased Health Costs

**Anti-depressant**

**Pain Self-management**

**Impaired Function/QoL**

**Increased Health Costs**

**Demographics**

**Other Psych.**

**Pain**

**Coping**

**Beliefs**
MEASURES

► Brief Pain Inventory
► SCL-20 depression scale
► HRQoL: -- generic (SF-36)
     -- pain-specific (Roland)
► Other pain (coping, beliefs, self-mgmt)
► Other psych (anxiety, somatization)
► Treatment satisfaction
Baseline and 3-Month Data
## Baseline Characteristics SCAMP Participants

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Stepped Care (N=123)</th>
<th>Usual Care (N=127)</th>
<th>Non depressed (N=250)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age, yr</td>
<td>55.2 (12.6)</td>
<td>55.8 (11.0)</td>
<td>62.5 (14.1)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>69 (56.1%)</td>
<td>63 (49.6%)</td>
<td>127 (50.8%)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>75 (61.0%)</td>
<td>76 (59.8%)</td>
<td>140 (56.0%)</td>
</tr>
<tr>
<td>Black</td>
<td>42 (34.1%)</td>
<td>49 (38.6%)</td>
<td>100 (40.2%)</td>
</tr>
<tr>
<td>Married, n (%)</td>
<td>48 (39.0%)</td>
<td>44 (34.7%)</td>
<td>97 (38.8%)</td>
</tr>
<tr>
<td>Mean (SD) no. of medical diseases</td>
<td>2.7 (1.6)</td>
<td>2.6 (1.4)</td>
<td>2.6 (1.4)</td>
</tr>
<tr>
<td>Clinical site, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University clinics</td>
<td>73 (59.3%)</td>
<td>75 (59.1%)</td>
<td>152 (60.8%)</td>
</tr>
<tr>
<td>Veteran administration (VA)</td>
<td>50 (40.7%)</td>
<td>52 (40.9%)</td>
<td>99 (39.2%)</td>
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</tbody>
</table>
### Baseline Characteristics SCAMP Participants

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Stepped Care (N=123)</th>
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<th>Non depressed (N=250)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment status n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>36 (29.3%)</td>
<td>28 (22.1%)</td>
<td>53 (21.2%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>59 (31.7%)</td>
<td>40 (31.5%)</td>
<td>127 (50.8%)</td>
</tr>
<tr>
<td>Retired</td>
<td>48 (39.0%)</td>
<td>59 (46.5%)</td>
<td>70 (28.0%)</td>
</tr>
<tr>
<td>BPI pain severity</td>
<td>6.2 (1.8)</td>
<td>6.1 (1.8)</td>
<td>5.4 (1.8)</td>
</tr>
<tr>
<td>BPI Interference</td>
<td>6.8 (2.2)</td>
<td>7.1 (2.0)</td>
<td>4.8 (2.2)</td>
</tr>
<tr>
<td>SCL-20 Depression</td>
<td>1.8 (0.7)</td>
<td>1.9 (0.6)</td>
<td>0.7 (0.5)</td>
</tr>
<tr>
<td>Roland disability</td>
<td>17.3 (4.5)</td>
<td>17.6 (4.1)</td>
<td>12.6 (5.5)</td>
</tr>
<tr>
<td>Back Pain</td>
<td>76 (61.8%)</td>
<td>75 (59.1%)</td>
<td>126 (50.8%)</td>
</tr>
<tr>
<td>Hip or knee pain</td>
<td>47 (38.2%)</td>
<td>52 (40.9%)</td>
<td>122 (49.2%)</td>
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</table>
## SCAMP 3-Month Outcome: Depression

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Intervention (105)</th>
<th>Usual Care (106)</th>
<th>Between group difference (95% CI)</th>
<th>t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCL-20 Depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.8 (0.7)</td>
<td>1.9 (0.6)</td>
<td>-0.1</td>
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<tr>
<td>3-month</td>
<td>1.02 (0.62)</td>
<td>1.73 (0.7)</td>
<td>-0.71 (-0.89 to -0.54)</td>
<td>-7.71</td>
<td>&lt; .0001</td>
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<tr>
<td><strong>Major Depression diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3-month</td>
<td>42 (40%)</td>
<td>80 (75.5%)</td>
<td></td>
<td></td>
<td>&lt; .0001</td>
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</table>
## SCAMP 3-Month Outcome: Pain

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Intervention (105)</th>
<th>Usual Care (106)</th>
<th>Between group difference (95% CI)</th>
<th>t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BPI Pain Severity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6.2 (1.8)</td>
<td>6.1 (1.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-month</td>
<td>5.1 (2.5)</td>
<td>5.8 (2.15)</td>
<td>-0.67 (-1.26 to -0.08)</td>
<td>-2.24</td>
<td>&lt; .026</td>
</tr>
<tr>
<td><strong>BPI Interference</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Baseline</td>
<td>6.8 (2.2)</td>
<td>7.1 (2.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-month</td>
<td>4.9 (2.7)</td>
<td>6.4 (2.5)</td>
<td>-1.49 (-2.15 to -0.82)</td>
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<td>&lt; .0001</td>
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## SCAMP 3-Month Outcome: Disability

<table>
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<tr>
<th>Clinical Outcome</th>
<th>Intervention (105)</th>
<th>Usual Care (106)</th>
<th>Between group difference (95% CI)</th>
<th>t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roland Disability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>17.3 (4.5)</td>
<td>17.6 (4.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-month</td>
<td>13.8 (6.8)</td>
<td>16.8 (5.7)</td>
<td>-3.01 (-4.71 to -1.32)</td>
<td>-3.5</td>
<td>&lt; .0006</td>
</tr>
<tr>
<td>Disability Days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-month</td>
<td>31.8 (32.4)</td>
<td>44.5 (33.5)</td>
<td>-12.8 (-21.7 to –3.81)</td>
<td>-2.81</td>
<td>.0054</td>
</tr>
</tbody>
</table>
Response of pain and depression in SCAMP Trial during Phase 1 (optimized antidepressant therapy) and Phase 2 (pain self-management)
ESCAPE

Funded by VA Rehabilitation Research and Development

Merit Review – F44371 (Bair-PI)
STUDY PURPOSE

➢ To conduct a randomized controlled trial to evaluate the effectiveness of a stepped care approach for OEF/OIF vets with disabling spinal or extremity pain
RCT: Stepped care intervention vs. usual care in OEF/OIF Vets with disabling chronic pain

Participant enrolled from 2-sites

Spine (lumbar or cervical) or extremity pain

Outcome assessments: baseline, 1, 3, 6 months

Primary outcomes: pain related disability and pain severity

Secondary outcomes: psychological distress, work functioning, HRQL, negative pain beliefs and coping, self-efficacy, satisfaction
INTERVENTION: **STEP 1**

- Pain Self-Management Program (Damush, Lorig)
  - Analgesic management (WHO Ladder)
  - Education
  - Activity Scheduling (return to normal activities)
  - Monitor depressive, anxiety, PTSD symptoms
  - Encourage discussion with primary care MD/NP
  - Introduce other strategies (e.g. deep breathing)
- Flexible delivery (6 sessions, phone vs. face)
WHO ANALGESIC LADDER

WHO 3-Step Ladder

1 mild
- Aspirin
- Acetaminophen
- NSAIDs
- ± Adjuvants

2 moderate
- APAP / codeine
- APAP / hydrocodone
- APAP / oxycodone
- APAP / dihydrocodeine
- Tramadol
- ± Adjuvants

3 severe
- Morphine
- Hydromorphone
- Methadone
- Levorphanol
- Fentanyl
- Oxycodone
- ± Adjuvants

INTERVENTION: STEP 2

- “Brief” Counseling Therapy →
  - Cognitive behavioral therapy-based
  - 6 sessions delivered via phone

- Delivered if inadequate response to step 1

- Compared to usual care
DETAILS OF TREATMENT

- All aspects of intervention delivered by nurse case manager
- Weekly case management meetings (Bair, Ang, Nurse, Project manager)
- Regular contacts with participants to monitor pain/disability, response to treatment, introduction of self-management strategies
MEASURES

- Demographics
- Roland Disability Scale
- Graded Chronic Pain Scale
- PHQ-9, Anxiety, PTSD
- Pain related fear
- Self-efficacy
- Satisfaction with care
- Stressors
- SF-36
- Work functioning
NEXT STEPS

- IRB approved
- VA R&D approved
- Awaiting Walter Reed IRB
- Planning meetings
- Funding arrived July 1st
- Recruitment to start October 15th
Collaborative Grants

- Disparities in pain management (Burgess-IIR)
- Opioid Variation (Dobscha-IIR)
- Decision support for PTSD & Pain (Trafton- DOD PTSD RFA)
Opportunities to Collaborate

- Secondary papers from SCAMP
- Qualitative data
  - Focus groups, provider interviews
- Multi-site effectiveness study
  - Combine pharmacologic and non-pharmacologic treatment
- Multi-site prospective cohort study to assess incidence of opioid misuse
  - Recycle NIDA grant application
Opportunities to Collaborate

- Long-term opioid trials
- Clinical trial of commonly used tools in pain management
  - Urine drug screens
  - Opioid agreements
- Interpersonal therapy for chronic pain
- “Social work intervention” in patients with chronic pain and “life chaos”
Opportunities to Collaborate

- “Biomarkers” research in patients with pain and depression
- “Imaging” studies of dyad
- Endothelial progenitor cell function in patients with depression/pain
Next Grants

- VA HSR&D CDTA (June 2008)
- VA HSR&D Merit Review (June 2008)
- VA Cooperative Studies Grant
Leading Ideas at this time

- Formative evaluation of ESCAPE
- Cost-effectiveness evaluation of ESCAPE
- Care management intervention
  - Patients with psychosocial stressors or life chaos