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

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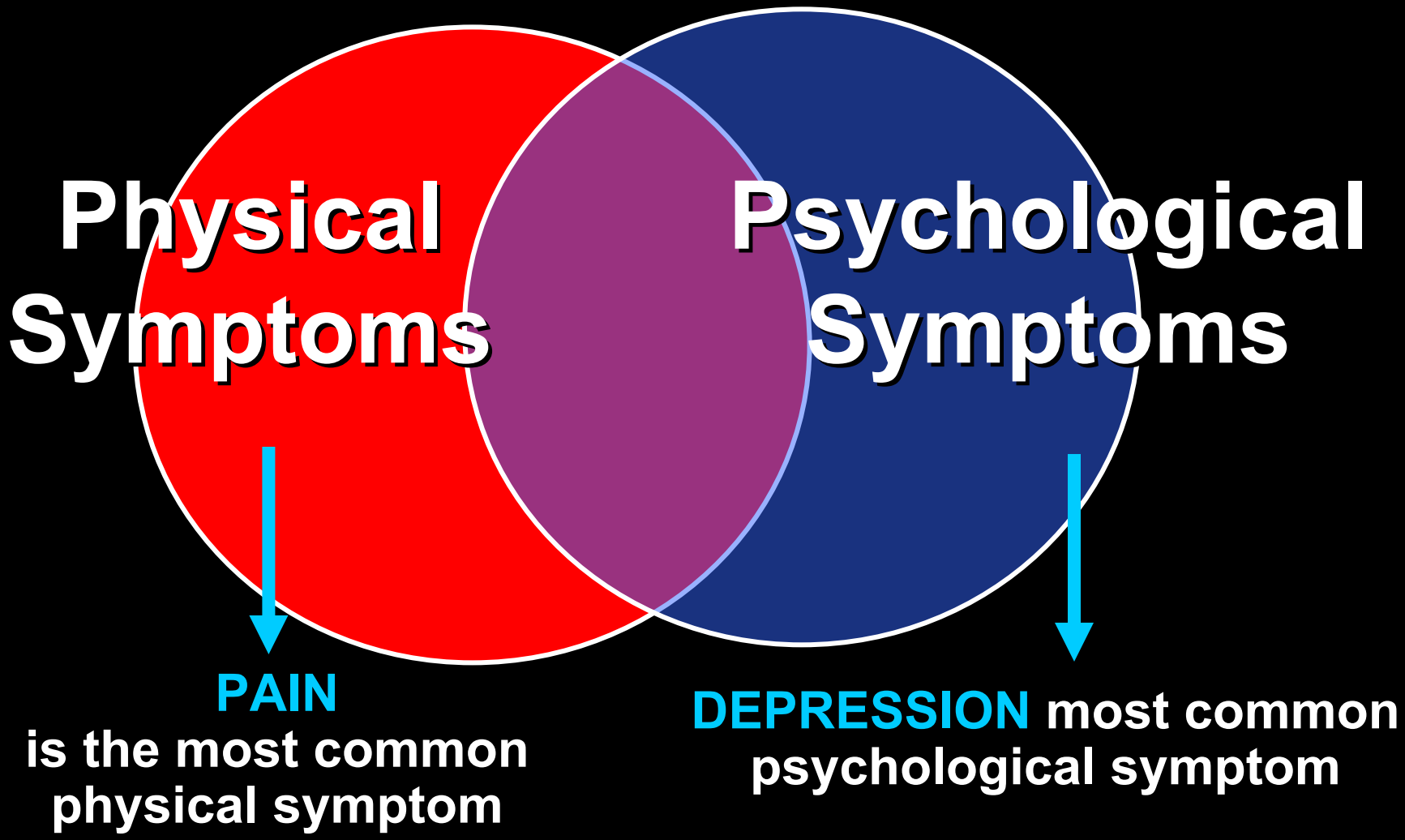
Pain and Depression Dyad



2 Primary Care Pain Trials
SCAMP and ESCAPE

Stepped Care for Affective disorders and Musculokeletal Pain study

Evaluation of Stepped CAre for Chronic Pain: Effectiveness in Iraq/Afghanistan Veterans trial

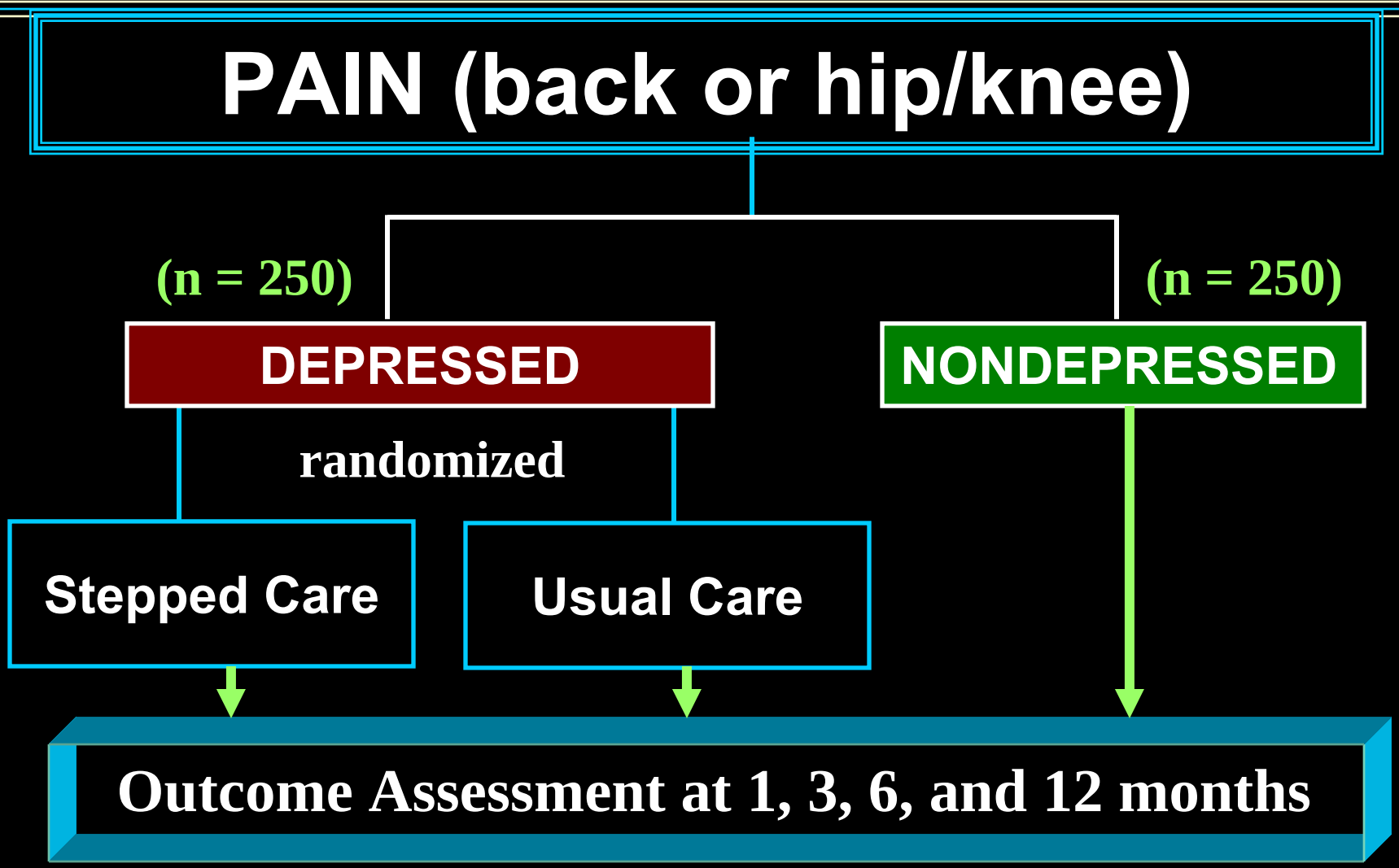
What is a Stepped-Care Intervention?

- 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



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 ≤ 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

WHEN	WHERE	WHAT (Treatment Action)
Baseline	Clinic	Antidepressant started
1 wk	Phone	Check adherence & side effects
3 wk	Phone	Adjust dose if needed
6 wk	Clinic	Change antidepressant if needed
9 wk	Phone	Adjust dose if needed
12 wk	Clinic	Decide if step 2 is warranted

Antidepressant Selection

- Venlafaxine
- Fluoxetine
- Sertraline
- Citalopram
- Buproprion
- Mirtazepine
- Nortriptyline

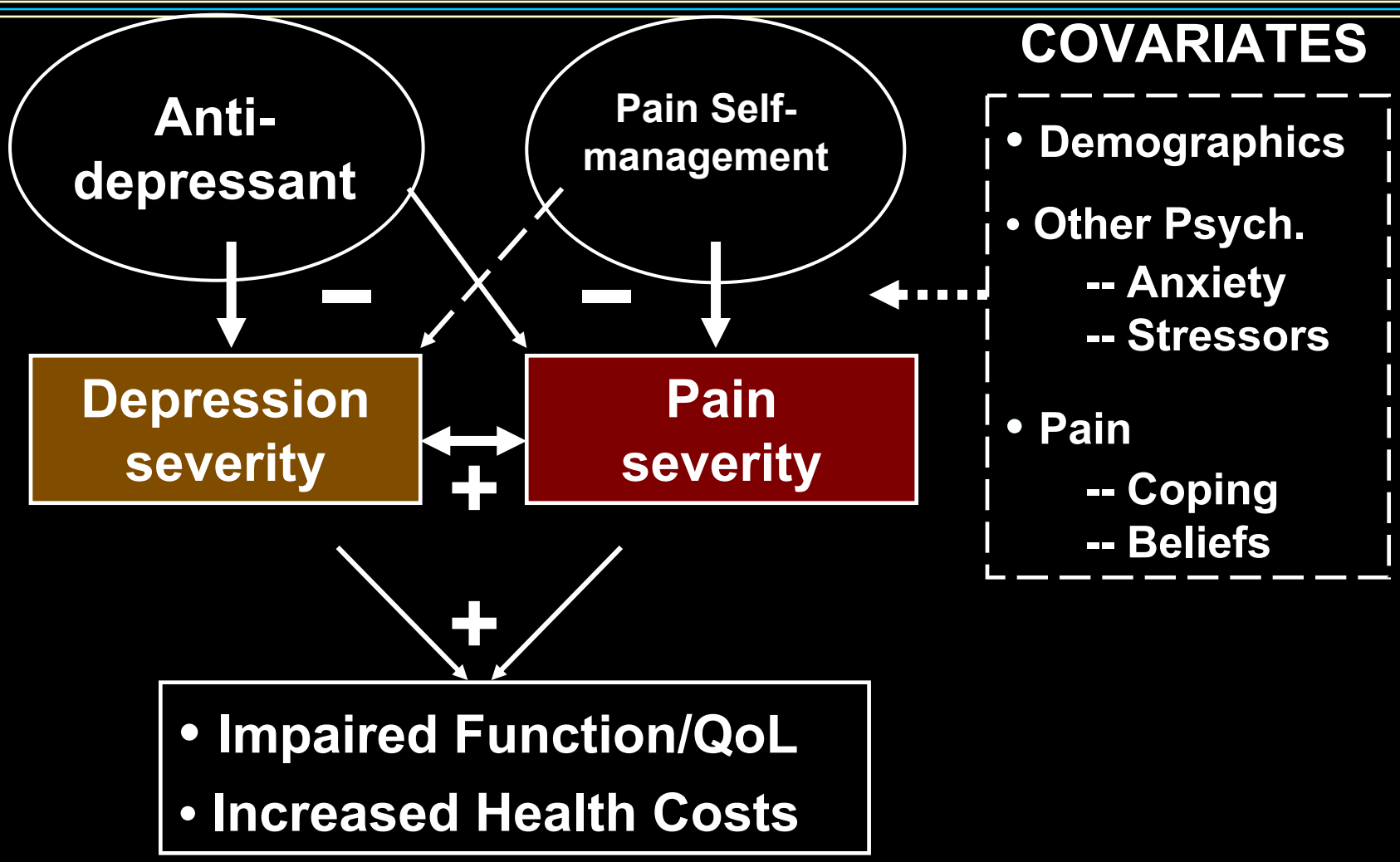
Step 2 – Pain Self-Management

WHEN	WHERE	WHAT (Treatment Action)
12 wk	Clinic	PSMP – Session 1
14 wk	Phone	PSMP – Session 2
16 wk	Clinic	PSMP – Session 3
18 wk	Phone	PSMP – Session 4
20 wk	Clinic	PSMP – Session 5
22 wk	Phone	PSMP – Session 6
24 wk	Clinic	Close Phase 2. Phone q 3 mo.

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



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

Baseline Characteristic	Stepped Care (N=123)	Usual Care (N=127)	Non depressed (N=250)
Mean (SD) age, yr	55.2 (12.6)	55.8 (11.0)	62.5 (14.1)
Women, n (%)	69 (56.1%)	63 (49.6%)	127 (50.8%)
Race, n (%)			
White	75 (61.0%)	76 (59.8%)	140 (56.0%)
Black	42 (34.1%)	49 (38.6.7%)	100 (40.2%)
Married, n (%)	48 (39.0%)	44 (34.7%)	97 (38.8%)
Mean (SD) no. of medical diseases	2.7 (1.6)	2.6 (1.4)	2.6 (1.4)
Clinical site, n (%)			
University clinics	73 (59.3%)	75 (59.1%)	152 (60.8%)
Veteran administration (VA)	50 (40.7%)	52 (40.9%)	99 (39.2%)

Baseline Characteristics SCAMP Participants

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

SCAMP 3-Month Outcome: Depression

Clinical Outcome	Intervention (105)	Usual Care (106	Between group diff erence (95% CI)	t	P value
SCL-20 Depression					
Baseline	1.8 (0.7)	1.9 (0.6)	-0.1		
3-month	1.02 (0.62)	1.73 (0.7)	-0.71 (-0.89 to -0.54)	-7.71	< .0001
Major Depression diagnosis					
3-month	42 (40%)	80 (75.5%)			< .0001

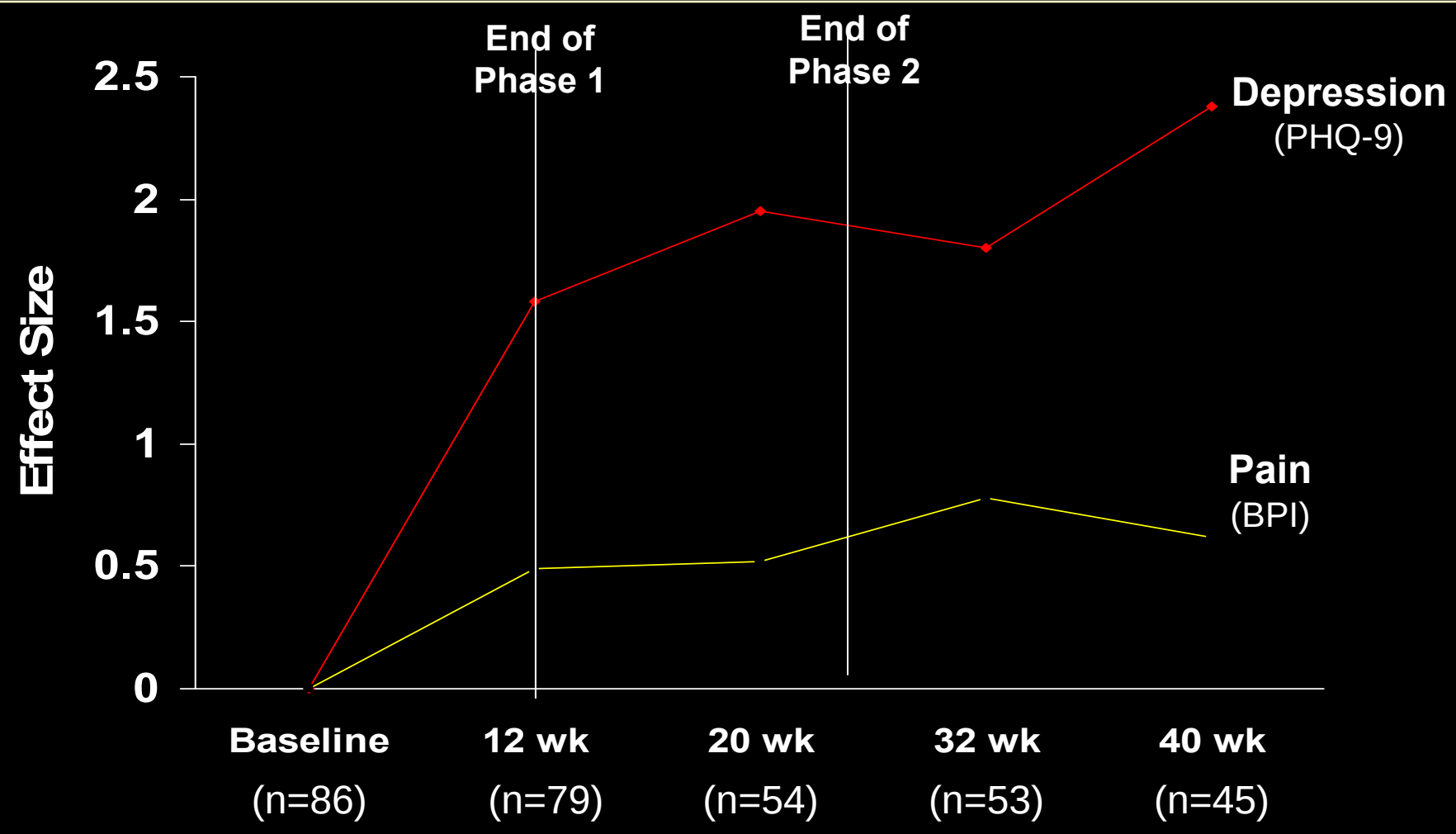
SCAMP 3-Month Outcome: Pain

Clinical Outcome	Intervention (105)	Usual Care (106	Between group diff erence (95% CI)	t	P value
BPI Pain Severity					
Baseline	6.2 (1.8))	6.1 (1.8)			
1-month	5.1 (2.5)	5.8 (2.15)	-0.67 (-1.26 to -0.08)	-2.24	< .026
BPI Interference					
Baseline	6.8 (2.2)	7.1 (2.0)			
1-month	4.9 (2.7)	6.4 (2.5)	-1.49 (-2.15 to -0.82)		< .0001

SCAMP 3-Month Outcome: Disability

Clinical Outcome	Intervention (105)	Usual Care (106	Between group diff erence (95% CI)	t	P value
Roland Disability					
Baseline	17.3 (4.5)	17.6 (4.1)			
3-month	13.8 (6.8)	16.8 (5.7)	-3.01 (-4.71 to -1.32)	-3.5	< .0006
Disability Days					
3-month	31.8 (32.4)	44.5 (33.5)	-12.8 (-21.7 to –3.81)	-2.81	.0054

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

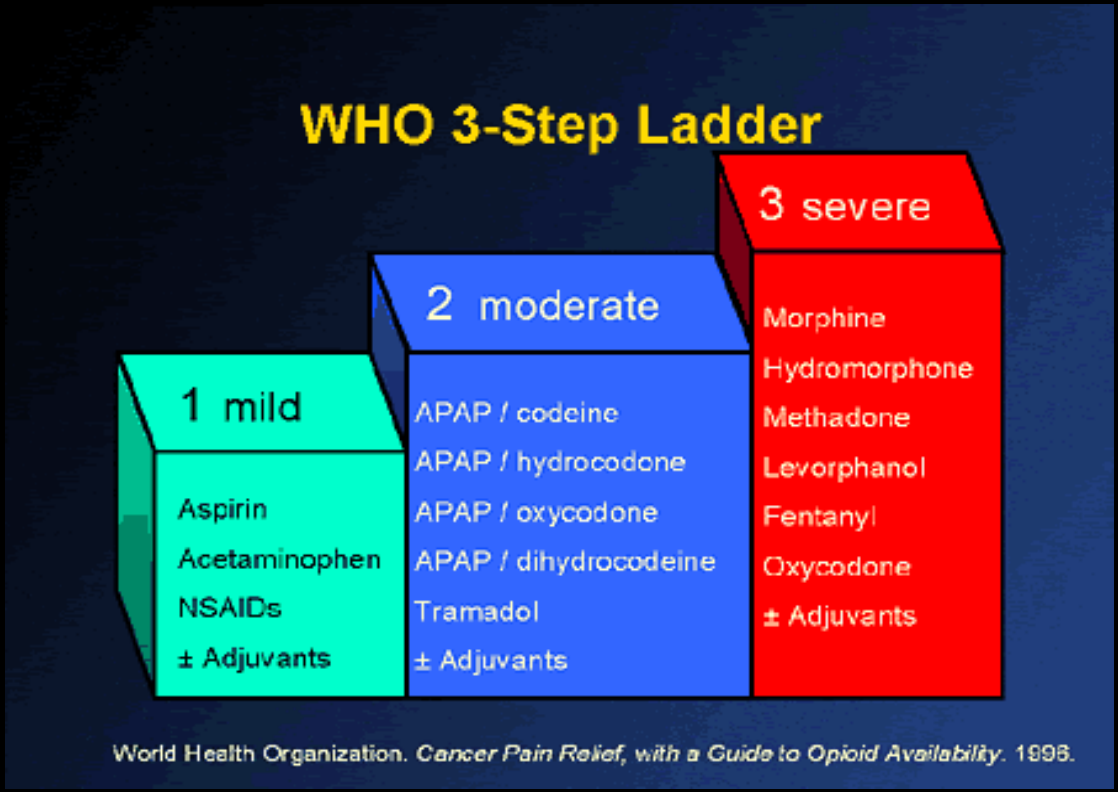
DESIGN: SUMMARY

- 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



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 w/ 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

QUESTIONS/COMMENTS