

Improving Outcomes for Older Adults with Musculoskeletal Pain and Depression: MOTIVATE and Next Steps

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Disclosures



- I have no commercial financial relationships
- Funding that supports my research:
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- Views expressed in this presentation do not reflect the position or policy of the US government



Overview

- Epidemiology of musculoskeletal pain in older adults
- Rationale for biopsychosocial approach
- Behavioral interventions
 - Motivational interviewing
- Development of novel behavioral intervention for comorbid back pain and depressive symptoms in older adults
- Preliminary Data and Next Steps

Overarching Career Goal

- Clinical investigator focused on improving outcomes that matter most for older adults with chronic musculoskeletal pain

Why Aging Population Matters

- NIA: “very large increase in disability caused by increases in age-related” disease (**arthritis and back pain)
 - Implications for social support systems, resources, economy

<http://www.nia.nih.gov/NR/rdonlyres/9E91407E-CFE8-4903-9875-D5AA75BD1D50/0/WPAM.pdf>

Chronic Pain Prevalence Estimates

- In individuals ages 65 and older:¹⁻³
 - Primary care: 20-50%
 - Assisted living: 40-60%
 - Nursing home: 50-80%
- Aging is a risk factor for chronic MSK pain

¹<http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>. ² Helme & Gibson. Clin Geriatr Med 2001; ³Savvas & Gibson Clin Geriatr Med 2016.

Pain in Later Life Increases Risk For

- Falls/Fractures^{1,2}
- Depression/Anxiety³
- Suicidality/Completed suicide⁴
- Social isolation^{5,6}
- Appetite impairment⁷
- Sleep disturbance⁵
- Mobility problems^{8,9}
- ADL onset¹⁰
- Decreased physical functioning¹¹
- Cognitive deficits¹²
- Frailty^{13,14}
- Spousal distress¹⁵

¹Leveille et al. JAMA 2009; ²Arden et al. Arth Car Res 2006; ³Kroenke et al. Gen Hosp Psych 2013; ⁴Racine M. Prog Neuropsychopharm Biol Psych 2017; ⁵Reid et al. *BMJ* 2015; ⁶Makris et al. Pain Medicine 2016; ⁷Bosley et al. J Am Geriatr Soc 2004:247-51; ⁸Patel et al. Pain 2013; ⁹Makris et al. JAGS 2014 ¹⁰Landi et al. J Pain Symptom Manage 2009; ¹¹Reid et al. J Gerontol Med Sci 2005; ¹²Whitlock et al. JAMA Intern Med 2017; ¹³Blyth et al. Pain 2008; ¹⁴Wade et al. J Gerontol 2017; ¹⁵Monin et al. J Gerontol Soc Sci 2017.

Why Back Pain Is Important

- Most common chronic pain condition
- 2nd most common reason for office visit
- Lifetime prevalence up to 84%
- Considerable morbidity
- Costly > \$100 billion/year
- Diagnostic and therapeutic procedures for back pain ↑, yet, patient outcomes have *not* improved

Chronic Low Back Pain Is Multifactorial

- Degenerative disease of lumbar spine ubiquitous → imaging does not correlate with symptoms or disability
- Biopsychosocial factors influence course and outcomes
- Series on Deconstructing Chronic Low Back Pain in Older Adults, Pain Medicine

(Weiner et al, Pain Medicine 2016)

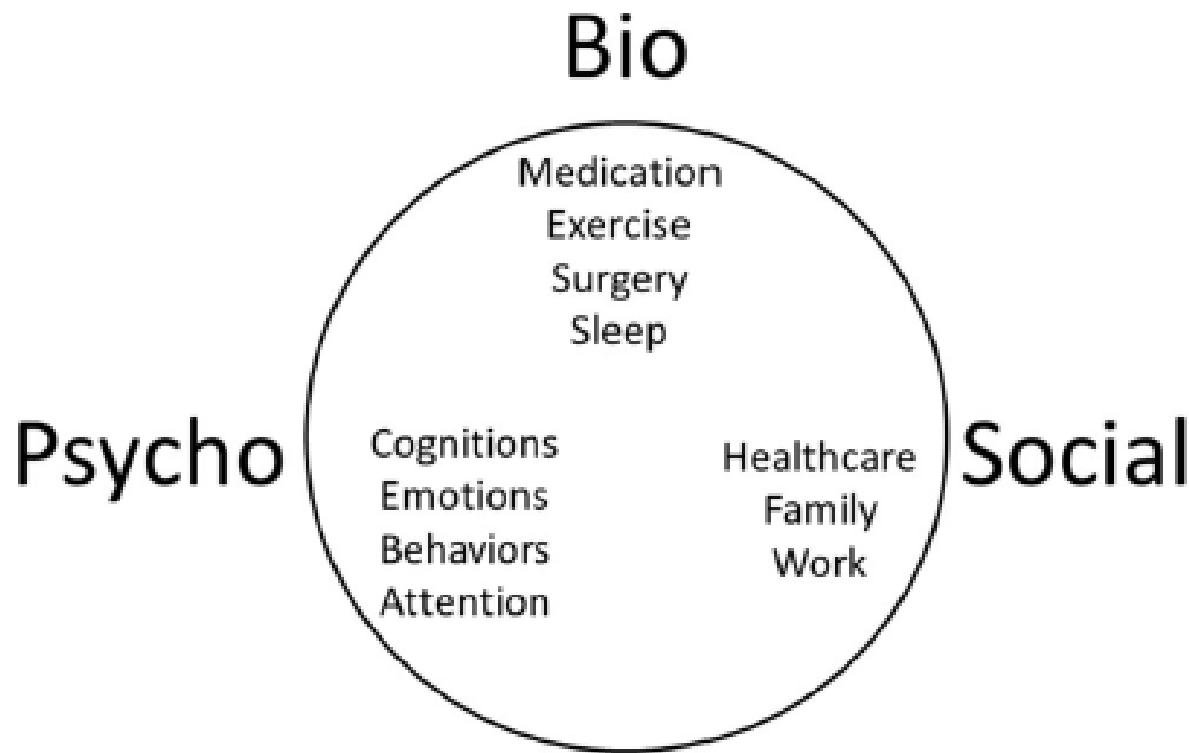
Simultaneous Targeting Low Back Pain and Depression

- 20-50% with comorbid mental health diagnoses
- Risk factors for onset, resistance to treatment, higher recurrence and severity if either untreated
- This overlap population is most time- and resource- consuming
- Often refractory/ most challenging

Interventions Must be Informed By Biopsychosocial Model

Figure 1

The Biopsychosocial Model of Pain Emphasizes the Dynamic Interaction Among Physiological, Psychological, and Social Factors



(Gatchel, 2014;
Deyo, 2014)

Urgent Need for Effective Therapy

- Medications alone and surgery less appealing
 - Multimorbidity, polypharmacy, frailty, fragmented social support systems
 - Long-term NSAIDs often contraindicated in older adults
- Opioids are commonly prescribed
 - Adverse events include: fatal and non-fatal overdose, ED and hospital admissions, altered mental status, falls
 - Evidence that opioids are not more effective than NSAIDs for MSK pain (including spine)

(Krebs et al. JAMA 2018)

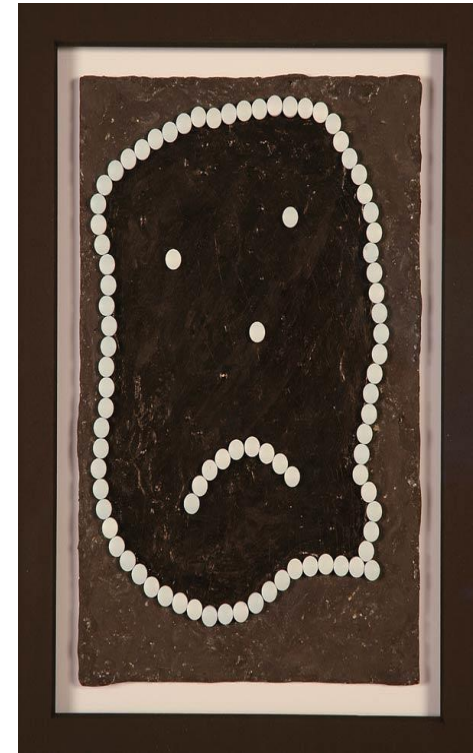
Recent Guidelines

- CDC guidelines for management chronic pain
 - Avoid opioids for chronic pain
- ACP guidelines published in Annals IM, 2017
 - First line: non-pharmacological behavioral



Barriers

- Current pain mindset
 - Quick fix
 - Passive strategies
 - Pain relief over function
- Behavioral treatment often viewed as:
 - An afterthought
 - Less effective
 - Last resort
 - Stigmatized



Happy Pills Ain't So Happy
Mark Collen
Crushed & whole Wellbutrin,
acrylic media, & charcoal.
Pain Exhibit © 2018.

Patients Are Asking For Something Else

- “I don’t want another pill. If I go to my doctor they will give me more medication or send me for surgery. That’s a gamble!”



(Makris et al, BMC Geriatrics 2015)

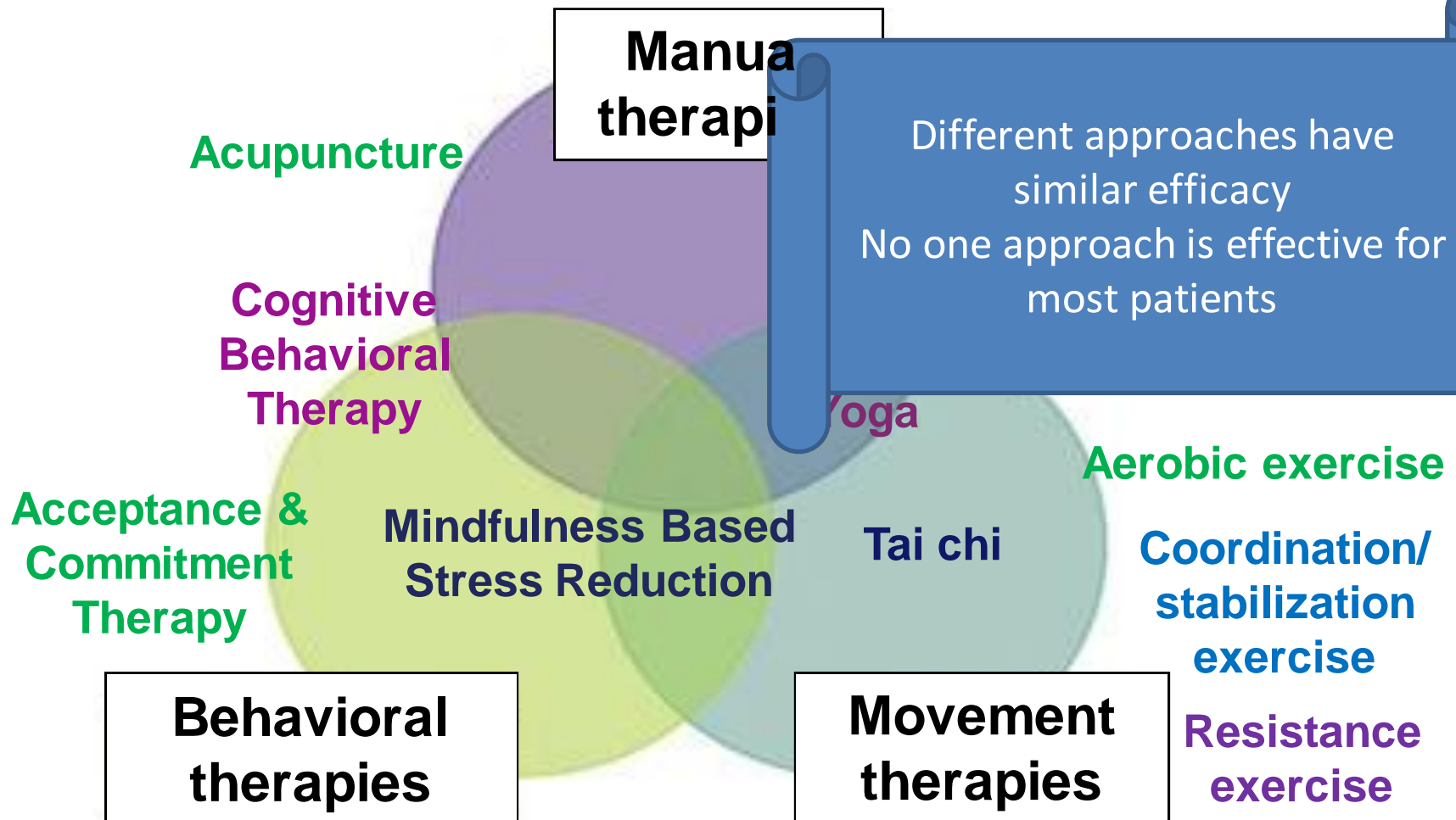
Implementation-ready (sufficient evidence)



STATE OF THE ART CONFERENCE

Non-pharmacological Approaches
to Chronic Musculoskeletal
Pain Management

VA HSR&D



Existing Behavioral Interventions

- Cognitive Behavioral Therapy-chronic pain
 - Cognitive restructuring challenging in older adults
- Mindfulness meditation, tai chi, yoga
- Physical activity
 - Robust literature
- Very few interventions focus exclusively on older adults, or those with comorbid physical and mental health conditions

Mr. L

- 78 yo man with 20+ years episodic LBP, no radicular sx. Bending, lifting exacerbate pain. Rates pain 7/10, unable to garden all afternoon as he used to, avoids church (worried about spasm), declines offers to see friends, poor concentration. Feels hopeless at times and lonely. Grandkids rarely visit.
- He has tried PT, chiropractor, acetaminophen, NSAIDs, Tramadol, opioids, epidural steroid injections.
- Exam is unremarkable aside from thin gentleman using a cane, + paraspinal muscle spasm R>L. Bony hypertrophy of knees, DIP/PIP c/w OA.
- Further assessment indicates PHQ-9 of 14- moderate depressive symptoms.

Novel Intervention Builds on Prior Work

MOTIVATE: Moving to Improve cLBP and Depression in Older Adults

- Develop/adapt/evaluate a telephone delivered behavioral intervention for older adults with comorbid chronic back pain and depression
- Building on Healthy Outcomes Through Patient Empowerment (HOPE)
 - Telehealth study of collaborative goal-setting focused on physical (diabetes) and mental (depression) health
- Our focus is on chronic back pain and depression

Core Components

- Behavioral activation using principles of motivational interviewing
- Goals that are consistent with values will cross cut both physical and psychological diagnoses
- Focus on how older adults are uniquely motivated to make and sustain behavioral change
- 5M's: Matters Most (Values), Mobility, Mind, Multimorbidity, measuring Medications

The 5M's of Aging

| Multicomplexity | Geriatrics healthcare professionals¹ focus on these 4Ms... | When caring for older adults, all health professionals should consider... |
|---|--|--|
| <p>Multicomplexity describes the whole person, typically an older adult, living with multiple chronic conditions, advanced illness, and/or with complicated biopsychosocial needs.</p> | <p>Mind</p> | <ul style="list-style-type: none"> ■ Mentation ■ Dementia ■ Delirium ■ Depression |
| | <p>Mobility</p> | <ul style="list-style-type: none"> ■ Amount of mobility; function ■ Impaired gait and balance ■ Fall injury prevention |
| | <p>Medications</p> | <ul style="list-style-type: none"> ■ Polypharmacy; deprescribing ■ Optimal prescribing ■ Adverse medication effects and medication burden |
| | <p>What Matters Most</p> | <ul style="list-style-type: none"> ■ Each individual's own meaningful health outcome goals and care preferences |

*Adapted by the American Geriatrics Society (AGS) with permission from "The public launch of the Geriatric 5Ms" [on-line] by F. Molnar and available from the Canadian Geriatrics Society (CGS) at <http://canadiangeriatrics.ca/2017/04/update-the-public-launch-of-the-geriatric-5ms/> Accessed July 14, 2020.

Motivation and Physical Activity

- Driving forces responsible for initiation, persistence, direction, and vigor of goal-directed behavior (Oxford Dictionary of Psychology, 2014)
- 89 studies (n = 19,212) assessed changes in motivational constructs for physical activity: intention, stages of change and autonomous motivation
- Behavior change techniques that were beneficial:
 - Behavioral goal setting
 - Self-monitoring (behavior)
 - Behavioral practice/rehearsal
- Increases in intention and stage of change were significantly related to increase in physical activity

(Knittle et al. Health Psychology Review 2018)

Motivational Interviewing (MI)

What is MI

- A collaborative, person centered form of guiding to elicit and strengthen motivation to change
- A method that is used for a particular purpose: to help people resolve ambivalence and move towards change
- It originated with substance use disorders treatment
- It has been used in over 200 randomized clinical trials
- Trials encompass a wide variety of target behaviors
- It is considered an Evidenced Based Treatment
- It is not recommended as a manualized treatment

(Slides courtesy of Dr. Saxon, Introduction to MI)

Spirit of MI

- Partnership: The patient knows his/her world better than we ever will. In MI we honor the patient's expertise. Your purpose as the "helper" is to understand the person with whom you are working and see the world through his/her eyes rather than imposing your own values, desires, and/or goals on the person.
- Acceptance: Acceptance is not the same as approval; it is accepting what you hear without passing judgment (good or bad).
- Compassion: This is not a feeling of sympathy or pity. It is the promoting the welfare of the other and prioritization the other's needs.
- Evocation: A person's own arguments for change are more persuasive than those of the helper. Our job is to draw forth and strengthen motivation based on the patient's goals and values.

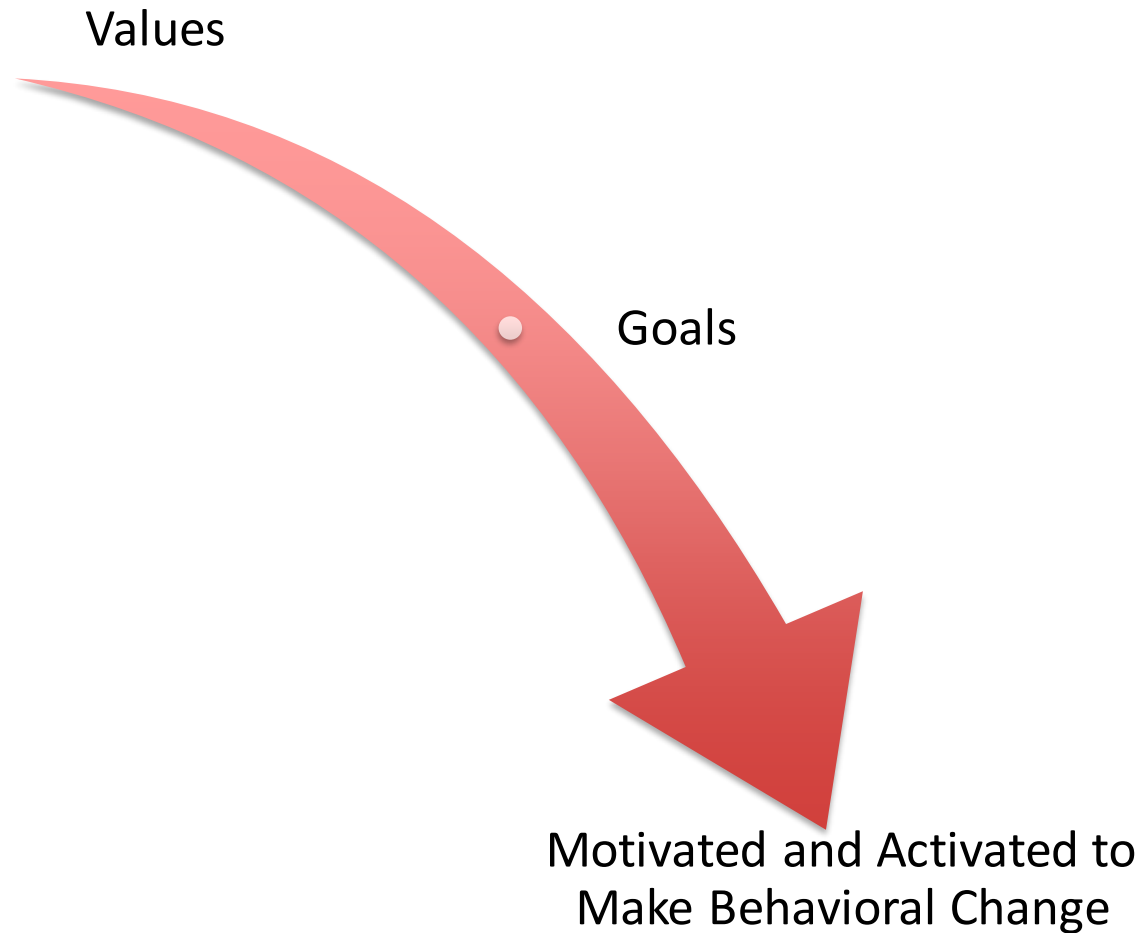
(Slides courtesy of Dr. Saxon, Introduction to MI)

Processes of MI

- Engaging – building the relationship
- Focusing- collaboratively target behavior for change based on the patient's goals and values
- Evoking- evoking change talk about the patient's desired changed and softening sustain talk (talk about maintaining the status quo)
- Planning- setting a change plan collaboratively with the patient, based on patient's goals, values, and resources

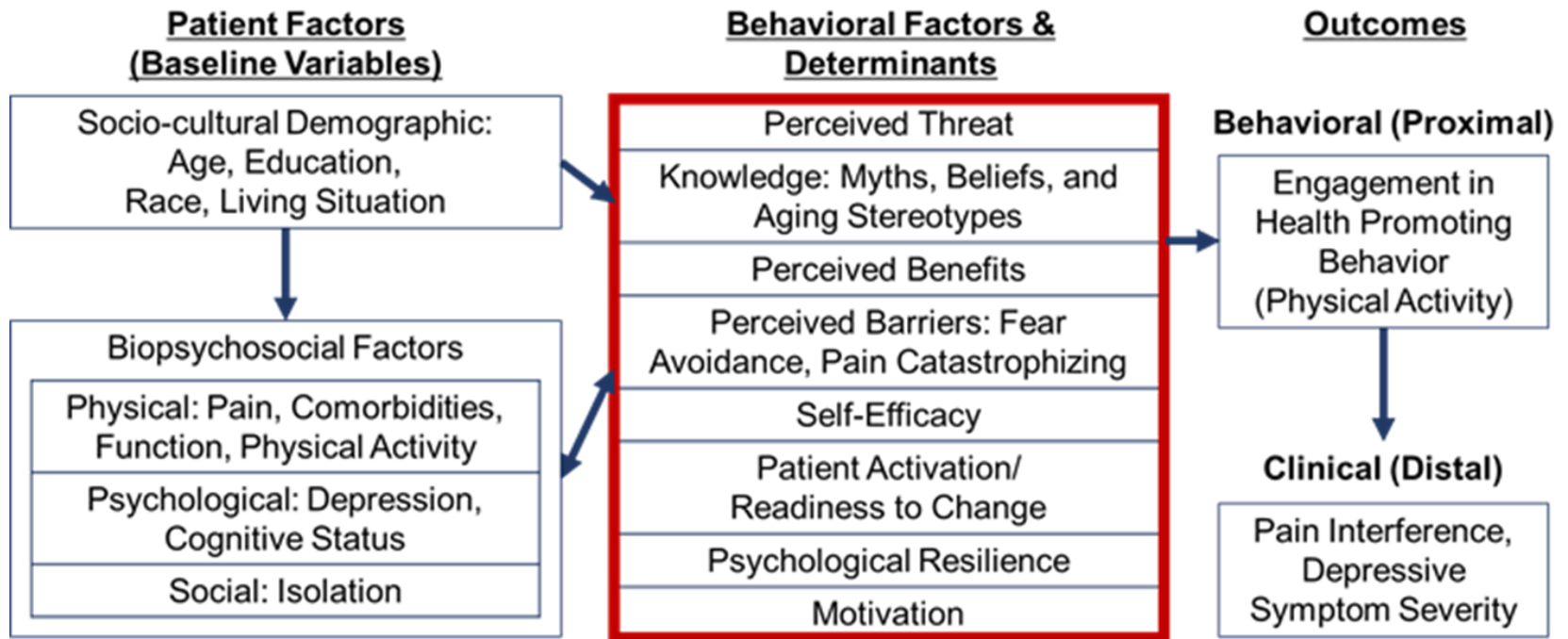
(Slides courtesy of Dr. Saxon, Introduction to MI)

Values-Goals-Behavioral Activation



Conceptual Model

Figure 1: Conceptual Model for MOTIVATE



Phase 1

- **Develop a telephone-delivered behavioral intervention that targets older Veterans (≥ 65 years) with cLBP and comorbid depressive symptoms**
 - Delivered via telephone by a health coach
 - Behavioral activation, goal setting, action planning, motivational interviewing
 - Focus on how older Veterans are uniquely motivated to make/sustain behavioral change

Telephone Health Coaching

- 8 sessions over 10-12 weeks
- Telephone-based delivery is appealing
 - Access for those who are mobility limited
- Types of client-selected goals most often met with telephone health coaching:
 - Physical activity, emotional health, and pain management

Mr. L: why telephone coaching is ideal

- Mr. L lives near the border with Oklahoma and drives 3+ hours to see his doctors
- In rural areas there are rarely bio-behavioral services that Mr. L can access
- We will work with Mr. L in his own home
 - Moving towards video-home technology

Session Content

| Session | Title | Brief Content |
|---------|---|---|
| 1 | Introduction: What is This Program About and How Will it Help Me? | Rapport and expectations; assess baseline activities |
| 2 | What is Most Important to You? | Values clarification; health coach links to physical activity practice; tracking steps with pedometer |
| 3 | Setting and Planning Goal #1 | Introduce meaningful/SMART goals; identify physical activity- based goal |
| 4 | Challenging Thoughts and Beliefs | Recognize and redirect; coping statements and gratitude |
| 5 | Setting and Planning Goal #2 | Identify caregiver, spouse, social circle to motivate/ sustain behavior |
| 6 | Setting and Planning Goal #3 | Emphasize sustainability |
| 7 | Learning How to Continue This Program; Preventing Flares, Anticipating Challenges | Highlight skills that have worked; celebrate success |
| 8 | Booster | Talking through barriers |

Stakeholders Inform Intervention Content and Delivery

| Categories | Participants | Number |
|--------------------|---|--------|
| Experts | Physicians (pain experts and geriatricians), chronic disease nurse practitioners, psychologists, behavioral change experts, Lifespan developmental psychology | 10 |
| Patients | Older Veterans with cLBP and depression | 5 |
| Other Stakeholders | Health coach, clinic directors and staff, clinical psychologists, physician assistants, physiatrists, physical therapists, social workers and primary care providers (within/interacting with PACT) | 5 |

Methods

- Semi-structured interviews focused on PARiHS implementation framework to inform topics
 - Experts: conceptual model, session order, outcome assessments and timing
 - Veterans: messaging; wording of session content
 - Other stakeholders: how can intervention be integrated into current practice; how best to communicate results to PACT team; develop intervention with ‘eye for implementation/ dissemination’

Phase 2

- **Pre-test the intervention in older Veterans (n=10) with cLBP and depression and refine its content and delivery, in an iterative process, based on stakeholder feedback**
 - Trained health coach delivers telephone-based intervention

Inclusion Criteria

- Men and women Veterans aged 65+
- Low back pain (+/-radiation) on most days for the past 3 months, that interferes with daily activities
- Depressive symptoms, PHQ-9 \geq 10
- Capable of participating in a home-based physical activity program, without current concerns about active chest pain, shortness of breath, balance issues, or falls

Exclusion Criteria

- No telephone
- Uncorrected hearing or visual disturbance
- Moderate to severe cognitive impairment
- Dependence on wheelchair, bed-bound, or severe balance impairment
- Acute illness requiring hospitalization within the last 4 weeks or acute pain (ex. traumatic fracture)
- Suicidal intent, prior psychotic episodes requiring hospitalization (within last year)

Outcomes for Phase 2

- Feasibility
 - Recruitment rates, fidelity, # sessions/subject, average time/session, and potential harms/risks
 - Use of pedometer
 - Capture of steps/week and impact on cLBP and depression (tracker)

Primary Outcomes

- *Pain interference*
 - PEG-3
- *Physical function/ self-reported disability*
 - Roland Morris Disability Questionnaire
- *Depressive symptoms*
 - PHQ-9

Secondary Outcomes

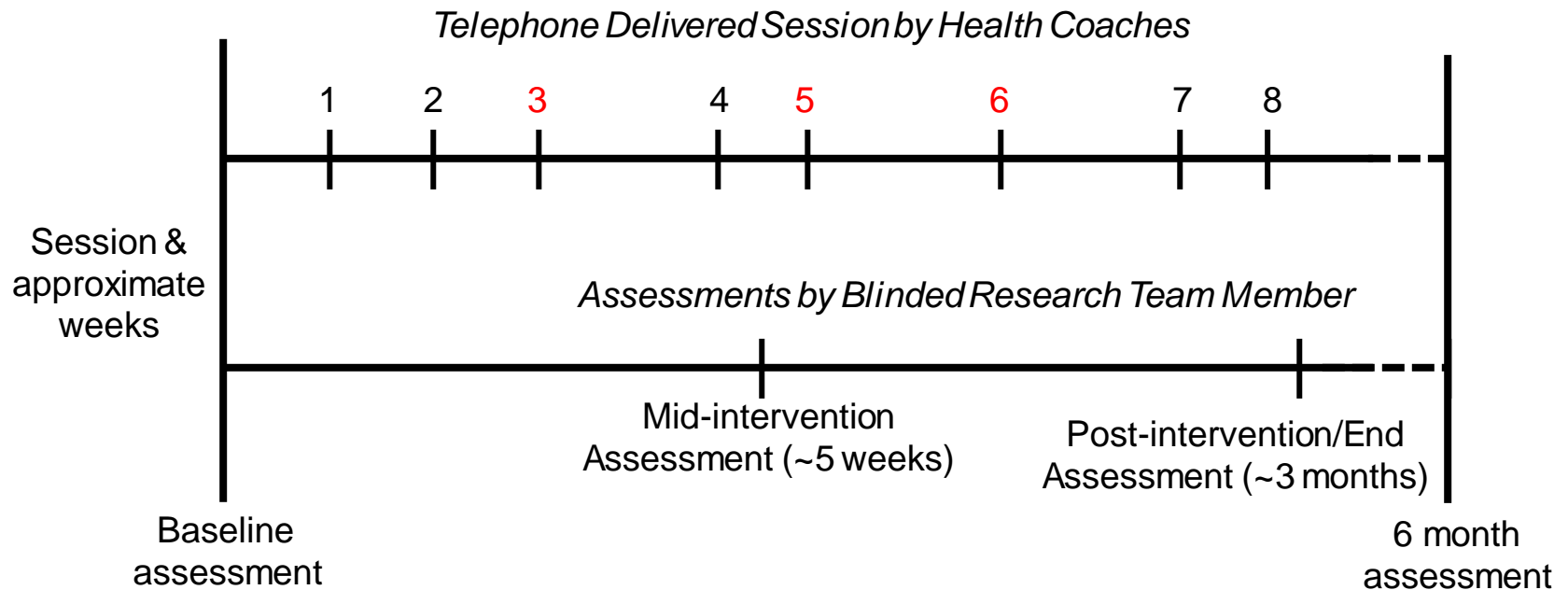
Assessments by blinded research assistant via telephone → Redcap

- Pain interference and pain behavior
 - NIH Patient Reported Outcomes Measurement Information System (PROMIS) instruments (informed by VA NIP and Cornell TRIPLL pilot)
 - Pain Catastrophizing and Fear Avoidance
- Quality of life (PROMIS Global Health) and PROMIS Sleep
- Social functioning including social isolation (PROMIS social isolation, functioning)
- Self-Efficacy (arthritis scale)
- Expectations of Intervention
- Global Impression of Change
- Therapeutic Alliance
- Future Time Perspective (time horizons)
- Contemplation ladder (stages of change) for physical activity
- Resilience (CD-RISC)

Via CPRS, confirmed with Veteran

- Medications: regularly scheduled + as-needed taken in the past 2 weeks
- Appointments (scheduled and urgent) ~ health care utilization
- Distance from VA (assess rural, and importance of telephone based intervention)

Timing of Assessments and Intervention Sessions



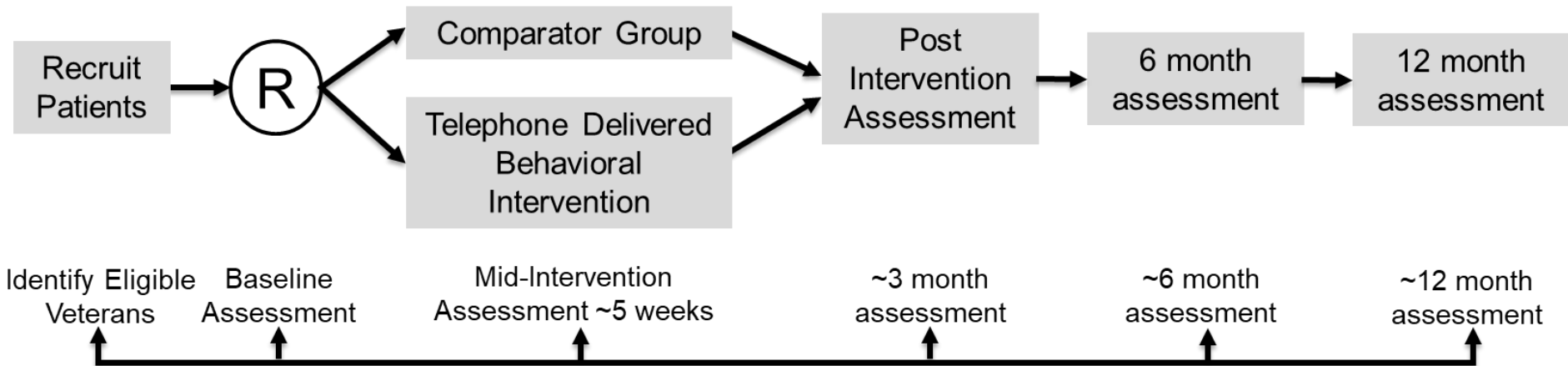
Mr. L: Progress To Date

- Mr. L identified the following values:
 - Being a good grandfather; physically present
 - Linked goals of taking grandson to soccer twice/ week; inviting him to his home on Sundays to walk and watch him practice soccer. Steps increased from ~700/d to 3000/d
 - Cultivating friendships
 - Connection with nature-gardening
 - Linked goals of planting and caring for garden; with friend from church
 - Spirituality/ Religion
 - Linked goals of attending church every Sunday, parking in far end of lot; steps increased, less socially isolated, fewer depressive symptoms
 - Connected with church friends.
- Outcomes we anticipate will improve: step counts, readiness to change, depression PHQ9 scores, self- efficacy, RMDQ- disability, social isolation.
- Strong working alliance with health coach.
- Will he sustain these behaviors? Health coach encouraging engaging his social circle (grandsons and church friends).

Phase 3

- Conduct a pilot RCT to assess feasibility for older Veterans with cLBP and depressive symptoms assigned to receive the MOTIVATE behavioral intervention (n=25) versus waitlist control (n=25)
 - Stratified randomization: age, pain score
 - Outcomes: feasibility and trends in outcomes

Overview of Pilot RCT

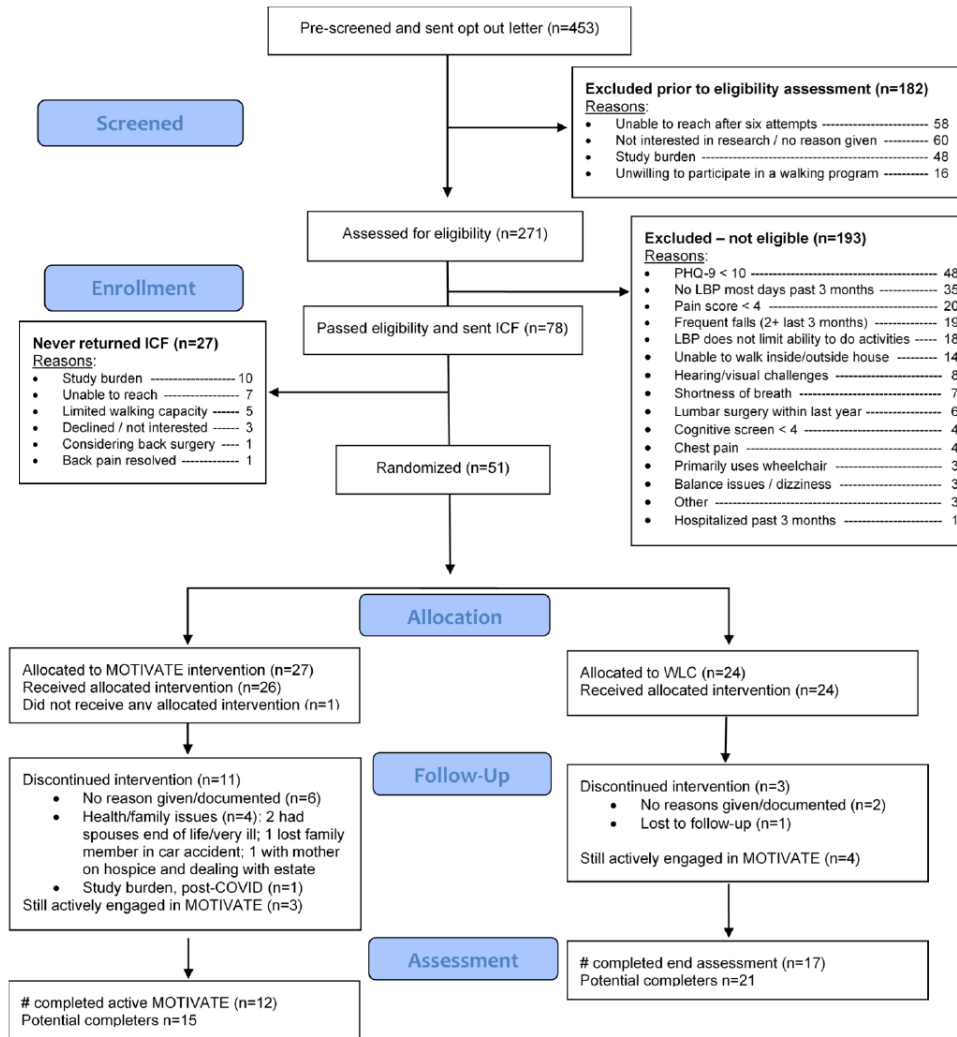


®: Randomized to either comparator group or intervention

Results

- 51 subjects enrolled
- Recruitment rate ~ 11%
- Advanced to recruitment strategy #2: opt out/opt in letter (greatly expanded pool)
- Reasons for screening out
 - Not depressed enough
 - Too active (a good thing, but...): >20% screened out → modified protocol
 - Not interested/ not enough time

Appendix 3: CONSORT of MOTIVATE CDA-2 Pilot RCT



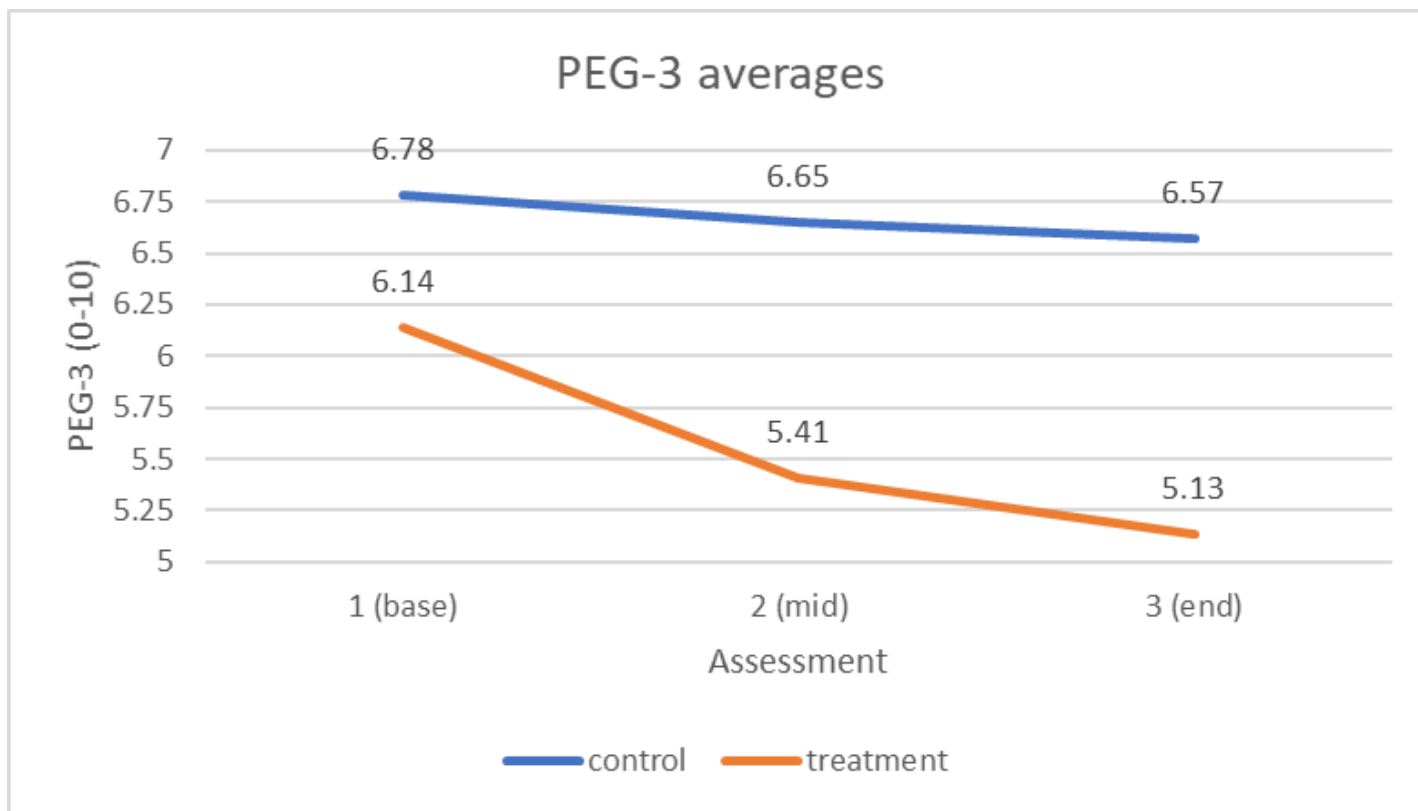
Participant Characteristics (n=51)

- Age: average 71
- Sex: 80% men
- Race/Ethnicity: 51% White, 41% Black, 8% Hispanic
- Pain intensity (NRS): 6.5/10
- PHQ-9: 12.5/27 (moderate depressive sx)
- Roland Morris Disability: 17.8/24
- Baseline average step counts (session 2): 2,455

Feasibility

- Omron pedometer: easy to use
- Steps: 2,455 at Session 2 (when they begin using the pedometer) → 4,393 at Session 5
- Veterans completed tracker and reviewed with health coach (cumbersome)
- Engagement with health coaches
- Fidelity:
 - Coaches using MI skills of cultivating change talk, softening sustain talk, partnership, empathy
 - Feedback to coaches to prevent drift

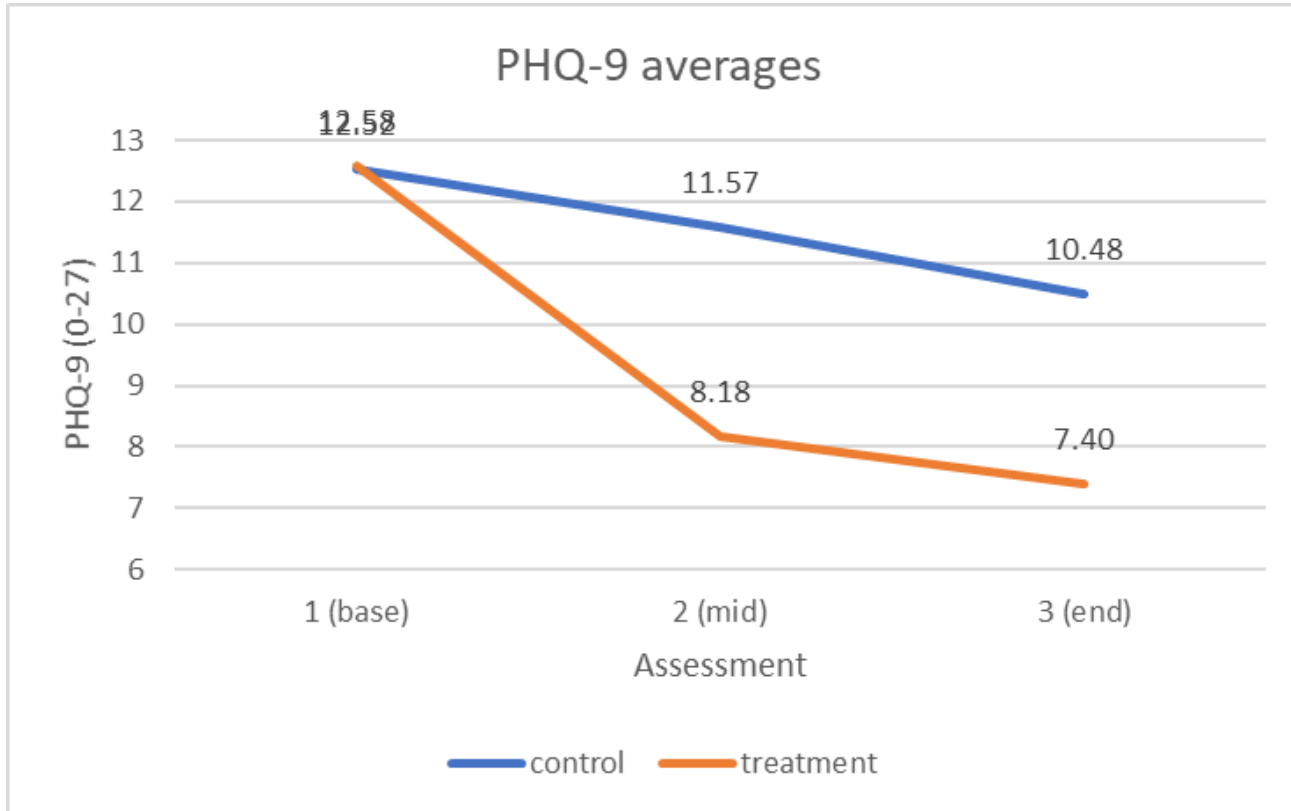
Preliminary Results: PEG-3



PEG-3 Averages with 95% Confidence Intervals (CI)

| | Baseline | Mid (~5 wks) | End (~12 wks) |
|--------------------------------|-----------------------|----------------|----------------|
| Waitlist Control (n=23) | 6.78 (95% CI 6.0-7.6) | 6.65 (5.8-7.6) | 6.57 (5.7-7.5) |
| MOTIVATE (n=17) | 6.14 (5.3-6.9) | 5.41 (4.4-6.4) | 5.13 (4.1-6.1) |

Preliminary Results: PHQ-9



PHQ-9 Averages with 95% Confidence Intervals (CI)

| | Baseline | Mid (~5 wks) | End (~12 wks) |
|--------------------------------|--------------------------|------------------|------------------|
| Waitlist Control (n=23) | 12.52 (95% CI 10.4-14.6) | 11.57 (9.3-13.9) | 10.48 (7.9-13.1) |
| MOTIVATE (n=17) | 12.58 (9.9-15.3) | 8.18 (5.8-10.6) | 7.40 (4.7-10.1) |

Next Steps- HSR&D IIR



Next Steps- HSR&D IIR

Hybrid Type 1 effectiveness/implementation RCT

- Aim 1: Effectiveness RCT of MOTIVATE vs waitlist control
 - n=264 (sites: Dallas and Houston VA + CBOCs)
 - Dropped age eligibility to 60+
 - Expanded to MSK pain + depressive symptoms
 - Can we capture steps, pain, mood using technology?
- Aim 2: Implementation processes (i-PARIHS)
- Aim 3: Intervention delivery costs and budget impact analysis

Outcome Measures, Data Sources, Timing: Informed by CDA-2

| Table 4: Outcome Measures, Source and Timing of Assessment | | | | | | | | | | | |
|--|-----------------|----------|---------------|----------|-----|--|--------|----------|---------------|----------|-----|
| Domain Measured | Source | Baseline | Mid (5 weeks) | End (3M) | 6 M | Domain Measured | Source | Baseline | Mid (5 weeks) | End (3M) | 6 M |
| Socio-demographics | EHR* | X | | | | Primary Outcome | | | | | |
| Substance Use | Survey | X | | | | Pain Interference | Survey | X | X | X | X |
| Comorbidities | EHR | X | | | | Secondary Outcomes | | | | | |
| Body Mass Index | EHR | X | | | | Depressive Symptoms, C-SSRS | Survey | X | X | X | X |
| Mild Cognitive Impairment | Survey | X | | | | Physical Activity (separate from pedometer step counts) | Survey | X | X | X | X |
| Frailty | Survey | X | X | X | X | Self-Efficacy | Survey | X | X | X | X |
| Time Horizons | Survey | X | | | | Pain Catastrophizing | Survey | X | X | X | X |
| Health Care Utilization and Cost (Aims 1-3) | | | | | | Psychological Resilience | Survey | X | X | X | X |
| Medications (see categories in text) | EHR* | X | X | X | X | Pain behavior, sleep, anxiety, quality of life, social function- (PROMIS); Insomnia Severity | Survey | X | X | X | X |
| Emergency Department and Urgent Care visits | EHR* | X | X | X | X | Pain intensity, PEG-3 Widespread Pain Inventory | Survey | X | X | X | X |
| Hospitalizations | EHR* | X | X | X | X | Global Impression of Change | Survey | X | X | X | X |
| Mental Health visits | EHR* | X | X | X | X | Study Related (measured in MOTIVATE) | | | | | |
| Pain related visits: PT, injections, acupuncture | EHR* | X | X | X | X | Treatment Expectancy | Survey | X | | | |
| Cost of intervention delivery (for Aim 3) | Survey, Tracker | X | X | X | X | Therapeutic Alliance | Survey | | X | X | |
| *Data from EHR, confirmed with participant over the telephone | | | | | | Satisfaction with treatment | Survey | | | X | X |

Emphasis on Social Support(s) and Sustainability

Now that you have some strategies to set goals, work on action plans, and get around obstacles, has your confidence level increased?

On a scale of 0-10, how confident are you that you can continue to use your strategies to reach your goals?

0---1---2---3---4---5---6---7---8---9---10

Not confident at all

Extremely confident

AS WE DEVELOP YOUR GOALS, KEEP IN MIND YOU ARE NOT ALONE!

Think about who you can rely on to support you in your efforts to increase activities. These people are your support network and they can offer direct help or emotional support.

Members of your support network and some examples of how they can help you engage in activities

SIGNIFICANT OTHER/SPOUSE

Plan and go out with you around town

FAMILY

Assist with new hobbies and crafts

FRIENDS OR CO-WORKERS

Go to social activities with you

OTHER COMMUNITY SUPPORT (e.g. pastor, friends in senior centers, neighbors, congregation)

Provide practical help, like transportation, as well as emotional support and encouragement

PETS

Encourage activity by needing walks and play

REFLECTING ON YOUR PROGRESS



BE _____
PATIENT
WITH YOURSELF! _____

Remember that confidence takes time to build, and your confidence will naturally increase as you continue to work towards your goals and achieve goal success!

Who can you rely on in your support network?

How can they help you increase your activities?

How will you reach out to them for support?



LET'S TALK ABOUT:

What's been working for you

.....

What you are having difficulty with

.....

Whether you are making the progress you want

.....

Where would you like to go from here

.....

How to help you be successful moving forward

Safety and Suicide Assessment Protocol

MOTIVATE Suicide Assessment Algorithm for Participants

Patient Name _____ Study # _____ Date / /

Location: Dallas/ Houston (circle one)

Assessment of suicidal ideation and intent in MOTIVATE participants will be guided by the following **algorithm**. This assessment will be conducted by study personnel to determine if suicidal ideation is present at outcomes assessment visits (screening, baseline, mid, end phone assessments). If suicidal ideation is present, this assessment will be used to determine risk level and follow-up evaluation needed

Always asked at Screening and End Outcomes Assessment

1st Step: Columbia Suicide Severity Rating Scale (C-SSRS) Screener.

| | Yes | No |
|--|-----|----|
| 1. Over the past month, have you wished you were dead or wished you could go to sleep and not wake up? | | |
| 2. Over the past month, have you actually had any thoughts of killing yourself? | | |
| <i>If response to item 2 is NO, go directly to item 6. If response to item 2 is YES, ask items 3, 4, 5, and 6.</i> | | |
| 3. Over the past month, have you been thinking about how you might do this? | | |
| 4. Over the past month, have you had these thoughts and had some intention of acting on them? | | |
| 5. Over the past month, have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan ? | | |
| 6. In your lifetime, have you ever done anything, started to do anything, or prepared to do anything to end your life (for example, collected pills, obtained a gun, gave away valuables, went to the roof but didn't jump)? | | |
| <i>If item 6 is YES, ask item 7.</i> | | |
| 7. Was this within the past 3 months? | | |

ACTIONS Based on Secondary Screen (C-SSRS Screen)

| | Procedure* |
|--|---|
| No Yellow Responses for Items 1 and 2 | Veteran is considered <u>low risk</u> . Veteran will be assessed at next study visit. |
| Only Yellow Responses | Veteran is considered <u>low risk</u> . Veteran will be assessed at next study visit. |

| | Procedure* |
|---|--|
| Any Orange Responses with no Red Responses | Veteran is considered <u>moderate risk</u> . Site PI (Dr. Makris or Dr. Hundt) will determine possible next steps (see 2nd step below). ** |
| Any Red Responses | Veteran is considered <u>high risk</u> . Initiate warm transfer to VA National Veterans Crisis Line- Call: 1-800-273-8255 then Press 1. Site PI will determine if additional steps (see 2nd step below) need to be taken. ** |

* For each screen result a research note is entered into CPRS.

** For each screen result, Site PI will be informed and will determine additional steps.

2nd Step: Comprehensive Suicide Risk Evaluation

The 2nd step is initiated if the participant has a positive screen (**C-SSRS**) that is deemed moderate to high risk. A Licensed Independent Practitioner will conduct these steps. At Dallas, this will be PI, Dr. Makris. At Houston, this will be site-PI, Dr. Hundt. For any Veteran already enrolled in a Mental Health clinic, we will notify the appropriate MH coordinator for further assessment. If needed, we can also refer to PC-MHI for further evaluation with a Licensed Independent Practitioner. We will ensure that this warm hand-off will occur the same day, per National protocols. The 2nd step is guided by the VA's Directive on the Assessment of Suicide and local study site policies and practices, and may include:

- Contact the local suicide prevention coordinator and inform them of the screen results to determine a plan of care
- If Veteran is already engaged in mental health care, contact the participant's mental health provider and inform them of the screen results to determine a plan of care
- If Veteran is not already engaged in mental health care, initiate a warm-hand off to a mental health provider in primary care or mental health clinic for a comprehensive evaluation and plan of care
- Study staff will also provide the participant with the VA National Veteran Crisis Line (1-800-273-8255) and/or offer to call the VA Warm Transfer with the participant present (in accordance with the VA Warm Transfer Protocol)

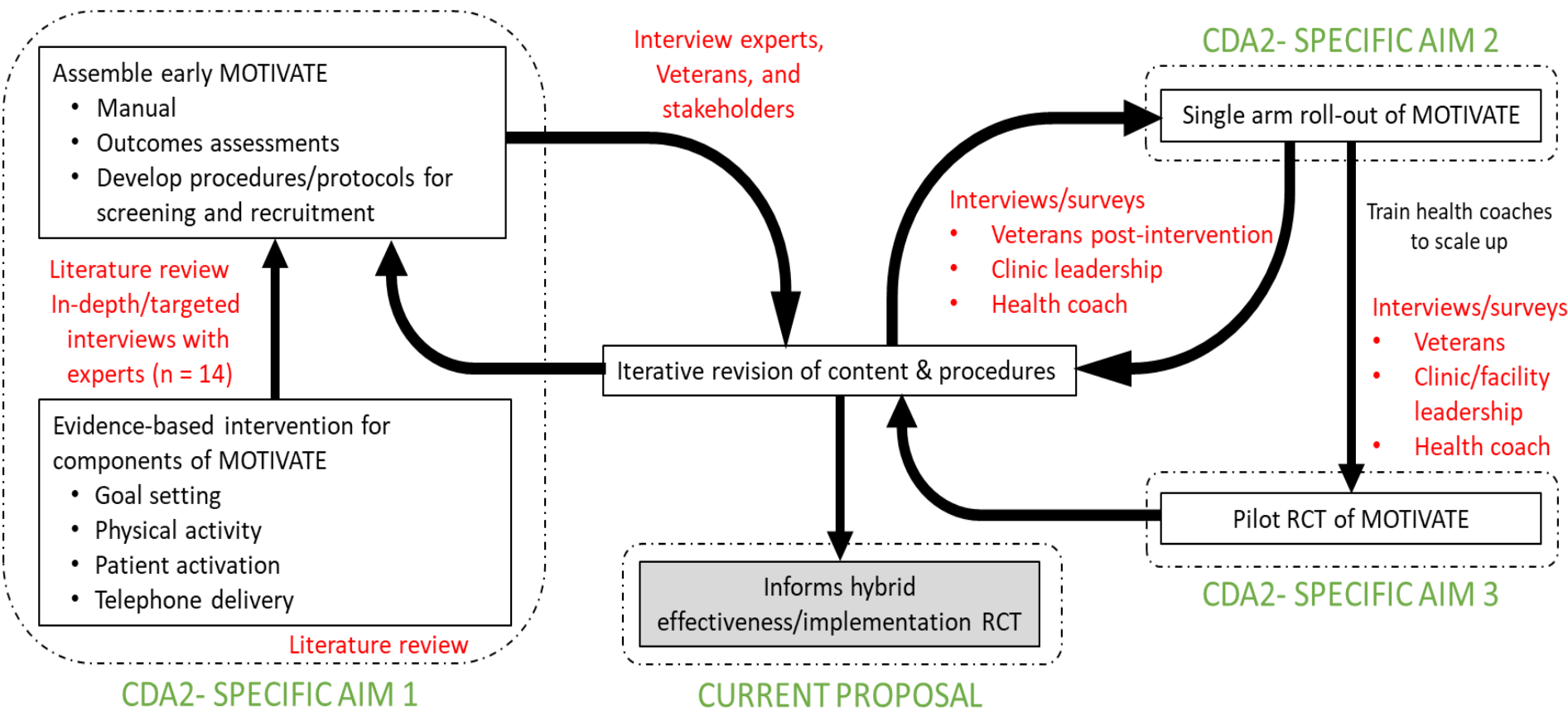
Always asked at Baseline and Mid Intervention Outcomes Assessment

Suicide Algorithm initiated due to positive screen

A "positive" suicide screen is based on a PHQ-9, item 9, response of 1 ("several days"), 2 ("more than half the days"), or 3 ("nearly every day"). The Research Staff will inform site study staff of screening results immediately after the interview.

Action based on PHQ-9 screen: Participants that screen positive on the PHQ-9, item 9 will move to Steps 1 and 2 listed above.

Continuous Veteran and Stakeholder Engagement



Clinical Implications/ Future Directions

- Overarching goal to develop high quality, effective interventions that can be feasibly integrated into care for older adults, *without placing additional burden on healthcare providers*
- Improving *access* to adjunctive behavioral options developed for and with older adults
- Health coaching can *augment* care received in primary, specialty and mental health care
- Incorporate *technology* to capture dynamic variables and assist with sustainability
- How can we use social environment (including caregivers, family, friends) to help sustain behavior

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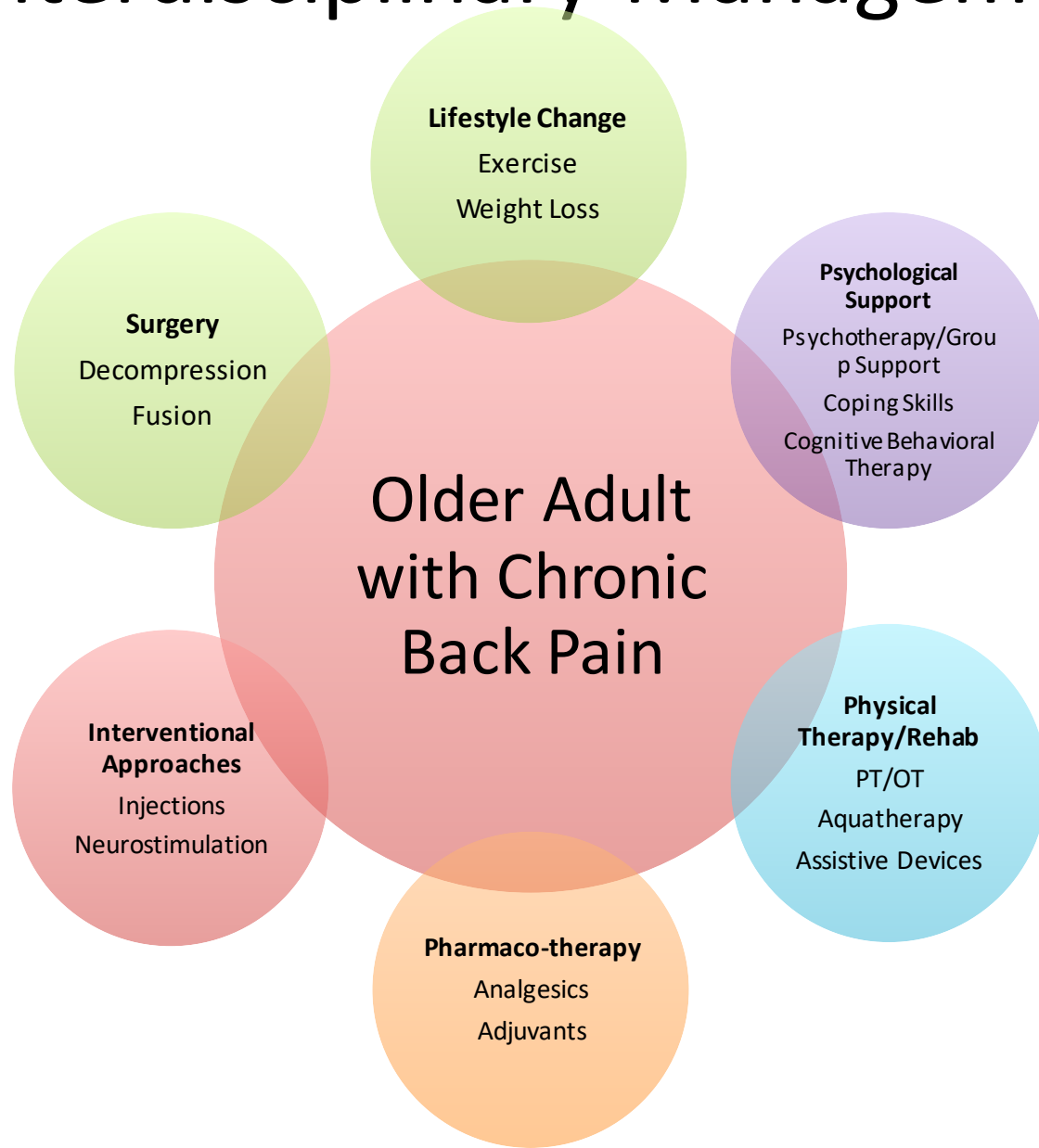
Thank You

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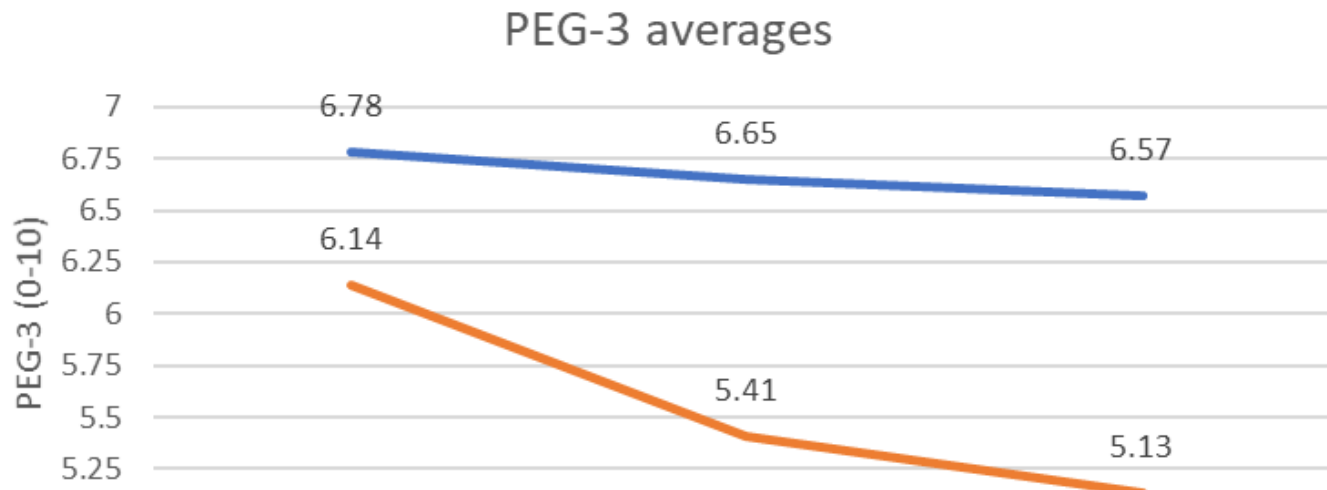
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Components of Multimodal, Interdisciplinary Management



Preliminary Results: PEG-3



PEG-3 Averages with 95% Confidence Intervals (CI)

| | Baseline | Mid (~5 wks) | End (~12 wks) |
|--------------------------------|-----------------------|----------------|----------------|
| Waitlist Control (n=23) | 6.78 (95% CI 6.0-7.6) | 6.65 (5.8-7.6) | 6.57 (5.7-7.5) |
| MOTIVATE (n=17) | 6.14 (5.3-6.9) | 5.41 (4.4-6.4) | 5.13 (4.1-6.1) |

PEG-3 Averages with 95% Confidence Intervals (CI)

| | Waitlist Control (n=23) | MOTIVATE (n=17) |
|-----------------|-------------------------|-----------------|
| Baseline | 6.78 (95% CI 6.0-7.6) | 6.14 (5.3-6.9) |

Preliminary Results: PHQ-9

