

# Scalable Interventions for Veterans with Chronic Pain: Phase 1 of the Learning to Apply Mindfulness to Pain (LAMP) Trial

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# Today's Seminar

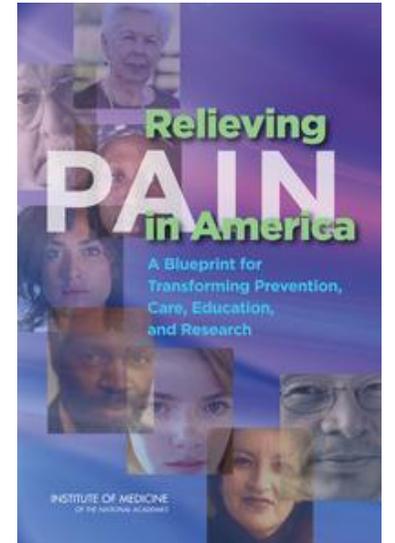
- I. Background: Need for scalable, non-pharmacological interventions for Veterans with chronic pain & Pain Management Collaboratory (PMC)
- II. Overview of LAMP study (Learning to Apply Mindfulness to Pain)
- III. Intervention refinement process
- IV. Questions

# I. Background:

Why we need scalable, non-pharmacological interventions for Veterans with chronic pain

# Dual public health crises: chronic pain & opioids

- > 100 million US adults
- \$635 billion/year in health care and lost productivity (IOM, 2011)
- 47,000 Americans died of opioid overdose in 2017 (CDC, 2018)



# Veterans disproportionately affected by chronic pain & opioids (IOM, 2011)

- Up to 50% of male Veterans & 78% of female Veterans report pain (Haskell, 2006; Kerns; 2003; Nahin, 2017; Girona, 2006)
- Co-exists with mental and physical health conditions that affect Veterans (e.g., PTSD, substance abuse, depression; Stecker, 2010)
- VA patients: almost 2X rate of accidental fatal poisoning; opioid analgesics are drug class most commonly involved (Bohnert, 2011)

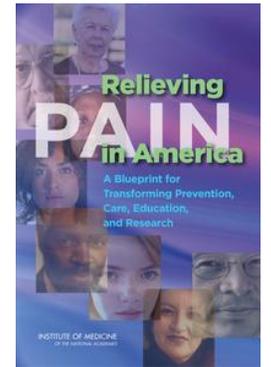
# Consensus: Need to shift from “opioid-centric” pain management to multi-modal models that use evidence-based non-pharmacological treatments (NPTs)



CLINICAL GUIDELINES | 4 APRIL 2017

## Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians FREE

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians \*



## CDC Guideline for Prescribing Opioids for Chronic Pain



## VA/DoD CLINICAL PRACTICE GUIDELINE FOR OPIOID THERAPY FOR CHRONIC PAIN



Critical need to provide effective, non-pharmacological treatment to vast numbers of Veterans with chronic pain & comorbid conditions (Kligler, 2018)



**Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain**

*Benjamin Kligler, MD MPH<sup>1,2</sup>, Matthew J. Bair, MD MS<sup>1,3</sup>, Ranjana Banerjee, MBA PhD<sup>1</sup>, Lynn DeBar, PhD<sup>4,5</sup>, Stephen Ezeji-Okoye, MD<sup>1</sup>, Anthony Liel, DC<sup>1,6</sup>, Jennifer L. Murphy, PhD<sup>1</sup>, Fredhelm Sandbirk, MD<sup>1</sup>, and Daniel C. Chetikh, PhD<sup>7</sup>*

# NIH-DoD-VA Pain Management Collaboratory Funding Initiative

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Goal: Study effectiveness of nondrug approaches to chronic pain management in military and Veteran health care delivery systems

\$81 million in grants over 6 years

Funds Coordinating Center & 11 Pragmatic Clinical Trials Demonstration Projects (UG3/UH3)

## II. Overview of



## Long-term goal

Reduce chronic pain and comorbid conditions among Veterans,

through non-drug, evidence-based approaches (**Mindfulness-Based Interventions**),

that are “Veteran-Centric,” designed to optimize engagement, adherence, and sustainability,

and are deliverable to large numbers of Veterans (“scalable”)

# Mindfulness-Based Interventions (MBIs)

- Mindfulness: “the awareness that arises by paying attention, on purpose, and non-judgmentally, to present moment experience” (Kabat-Zinn 1990)
- MBIs: Mindfulness meditation training & practice → attention regulation, body awareness, emotional regulation, shifts in self-perception
- Mindfulness-based stress reduction (MBSR; Kabat-Zinn): predominant MBI

# Mindfulness-Based Interventions (MBIs): non-drug, evidence-based strategies for chronic pain

- Systematic reviews (Bawa 2015; Chiesa, 2011; Gotnik, 2015; Hilton, 2016; Rosenzweig, 2010) - MBIs improve:
  - pain intensity, pain acceptance, \*physical functioning (\*mixed)
  - comorbidities (e.g., depression, anxiety, sleep difficulties)

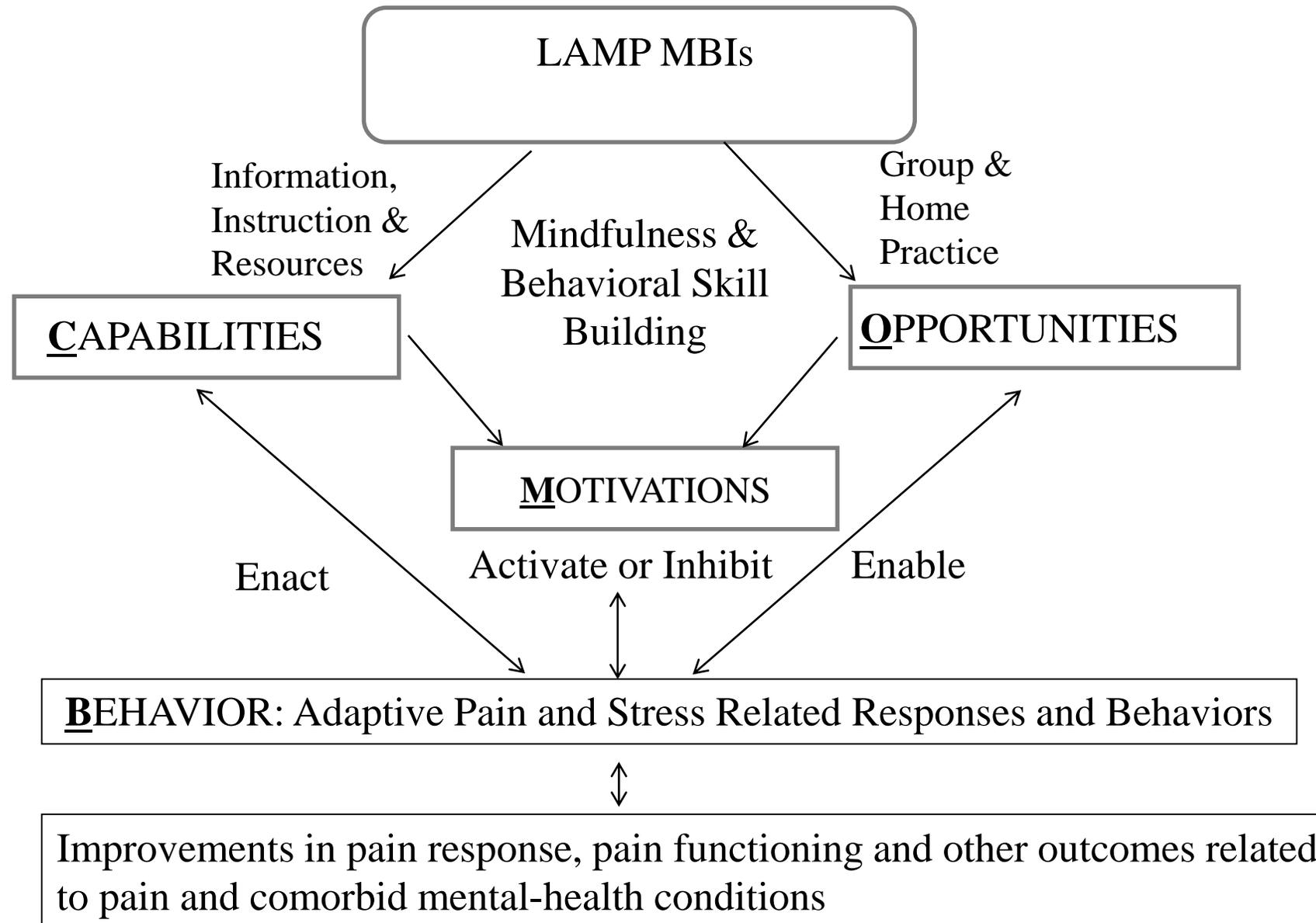
## Need for more attention to MBI intervention design & fidelity

- Effect sizes are modest & vary across studies (Jackson, 2019)
- MBIs: multifaceted interventions requiring systematic development
- **LAMP – uses evidence-based models to optimize MBIs to meet adaptive pain behavior goals**

## Iterative, stepped approach informed by Behavioral Change Wheel Model (Michie, Atkins & West, 2014)

- Synthesizes 19 behavior change frameworks
- Address components required to change behaviors: Capability, Opportunity, Motivation (COM-B)
- Maps intervention elements with patient needs & desired outcomes

# Conceptual Framework (COM-B; Michie, 2014)



**Examples**  
> **Adaptive:**  
Acceptance, unemotional problem solving, physical and social activities, stress reduction techniques

< **Maladaptive:**  
Catastrophizing, fear avoidance physical inactivity, social isolation, overuse and abuse of medications & substances

# LAMP: Designed to deliver MBIs to large number of Veterans (scalable)

- > 9 million patients in VHA
- VHA leaders & providers struggle to meet Veterans' demands for Complementary & Integrative Health treatments (Fletcher, 2016)
  - Lack of time, space, funding, staff training
- Mindfulness-Based Stress Reduction (MBSR) –Difficult to scale-up
  - Lack of certified MBSR instructors due to intensive & costly certification process
  - Time-intensive: 8 2.5 hr. sessions; daylong retreat

## LAMP: Designed to be “Veteran-Centric” & optimize engagement, adherence, and sustainability

- MBSR – patient-level barriers (Boggs, 2014; Martinez, 2015)
  - Intensive time commitment (33 hours, 45 min daily practice, travel time)
  - Access barriers (travel)
  - Aversion to group format (especially women Veterans; Martinez, 2015)
- Barriers – may contribute to high rates of drop-out, non-adherence & lack of sustainability

# LAMP programs

- **Group + Mobile Mindfulness:** Pre-recorded modules presented by MBSR instructor, viewed in group & interspersed with discussions led by a non-expert facilitator
  - Based in MBSR
  - Format developed by Co-Is Evans & Haley (R21#AT009110); adapted for Veterans with pain
  - Mobile app (with in-class and practice modules) & workbook
  - Incorporates specific behavioral change strategies
- **Mobile Mindfulness:** Same training and practice modules delivered via mobile app
  - Can examine added benefits of group component

## Specific Aims: Phase 1 (UG3: Years 1-2)

- **AIM 1.1**. Develop and implement an Engagement Plan to involve Veterans and stakeholders as partners.
- **AIM 1.2**. Use iterative user-centered design methods to adapt 2 MBIs to optimize Veteran engagement and sustainability.
- **AIM 1.3**. Conduct a 3-arm pilot RCT (N=48) to test data extraction, recruitment, intervention, and data collection protocols.

## Phase 2 (UH3 - Years 3-6):

### **AIM 2.1: 4-site 3-arm RCT (N = 750) to test effectiveness of Mobile+Group and Mobile MBIs compared to usual practice**

- Primary outcome: Improvement in Brief Pain Inventory total score assessed at 6 months
  - Outcomes also assessed directly after intervention and at 12 months
  - Examine the effectiveness separately by gender, as women Veterans experience elevated rates of chronic pain and mental health conditions
- Secondary outcomes:
  - Patient-reported measures related to pain, co-morbid mental health conditions and function
  - EMR (e.g., medication prescription/refills, health care visits for pain management)
- Will explore patient characteristics that may predict treatment response

## Phase 2 (UH3: Years 3-6)

- **AIM 2.2: IMPLEMENTATION** data collected & described, guided Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework
  - Multi-stakeholder, mixed methods process evaluation
  - Assess patient, staff, and health system leader perceived barriers and facilitators of intervention
  - Quantitative data to assess intervention application, adherence, fidelity, and inform cost estimate

# Innovations

- First to test scalable MBIs specifically for treating chronic pain in the VHA context
- First study statistically powered to examine the effects of MBIs on women with chronic pain
- Grounded in theoretical framework using behavioral change theory, informed by Veterans with chronic pain & key stakeholders
- Addresses implementation barriers to MBIs

### III. Intervention refinement process\*

- Phase I: Refine intervention & conduct pilot study (5/15/18 - 5/14/20)

*\*Evans R, Haley A, Burgess D, Kennedy D. A Mindfulness Based Intervention for Adaptive Pain Behaviors: Application of a Theory and Evidence Based Design Process. Poster to be presented at the International Forum for Back and Neck Pain Research in Primary Care, July 3, 2019, Quebec City, Canada.*

# MBI Refinement

## Intervention Mapping

### 1. Needs Assessment

2. Matrices (of determinants, performance, outcomes)

3. Theory-based methods and practical application (COM-B, Behavioral change wheel)

4. Intervention (themes, prototype, feedback, etc.)

5. Adoption and Implementation Plan

6. Evaluation Plan

### Implementation

*(Bartholomew et al., 2011)*

## Project Management Tools & Process

Mind Map

**Intervention Spreadsheet**

**Intervention Assets**

**“Learnings”**

## Design & Development Process

Structure & Format Options

**Topics & Themes**

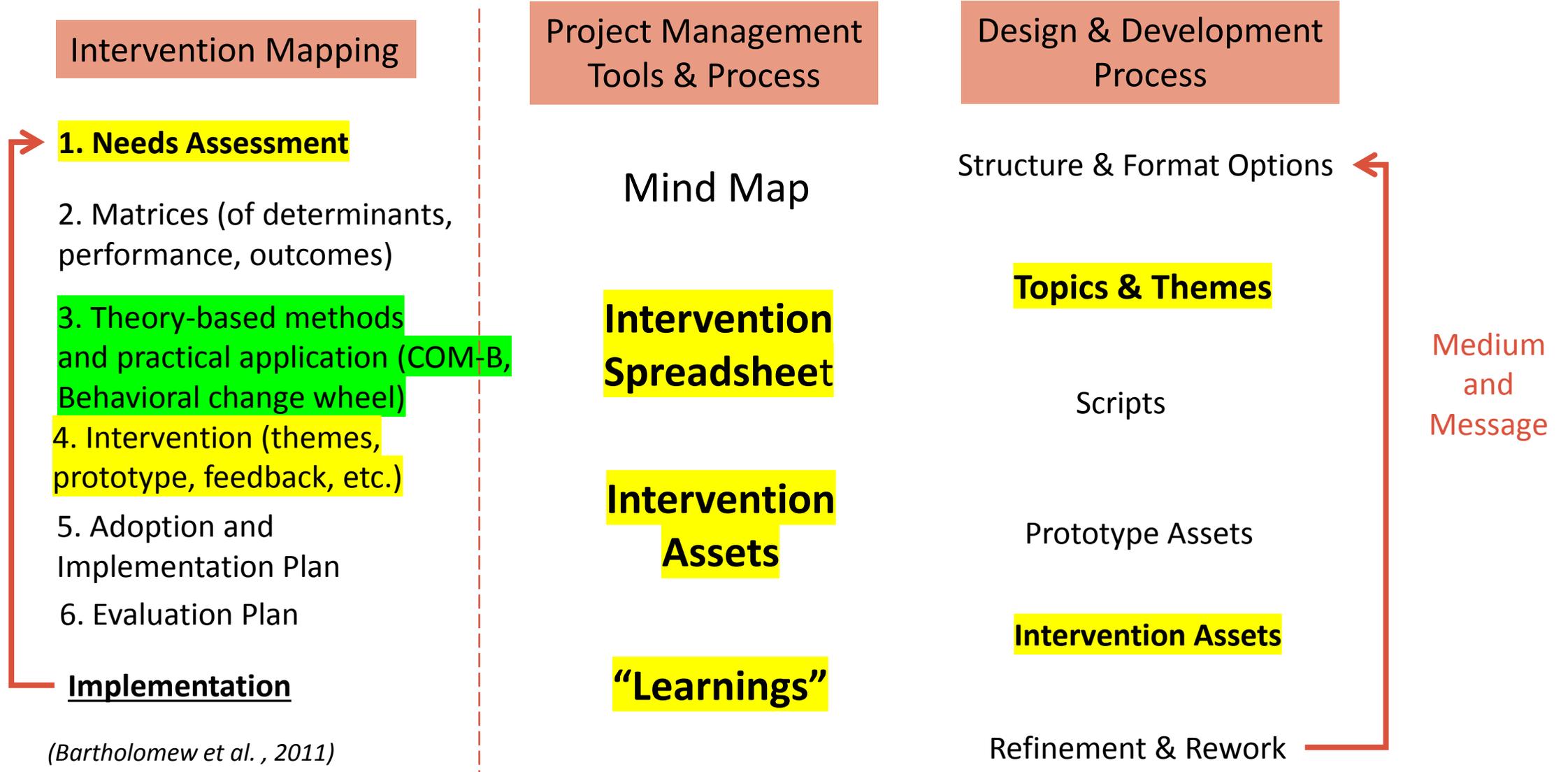
Scripts

Prototype Assets

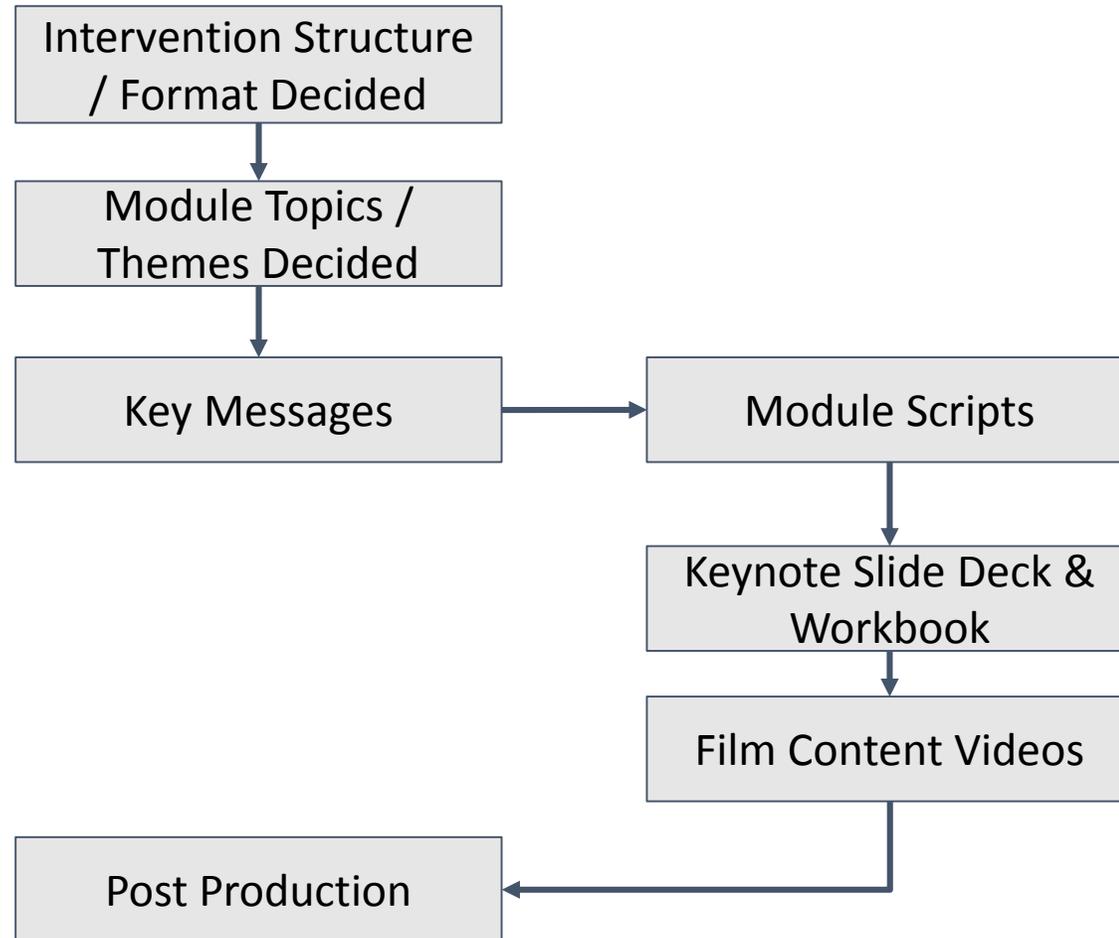
**Intervention Assets**

Refinement & Rework

Medium and Message



# Intervention Development Process Diagram



# Veteran and stakeholder engagement input throughout process

- Veteran Engagement Panel (VEP): Racially diverse, mixed-gender group of Veterans with chronic pain
  - Partners – not participants
  - In-depth (2 to 3 hr.) meetings to provide input
- Stakeholder Advisory Panel (SAP):
  - VA leaders in Integrative Health, Women's Health, Pain Management, Women Veterans;
  - Non-VA & Veteran experts (chronic pain, women's health, mindfulness)

## Needs Assessment

- Literature review
- Input from:
  - Subject matter experts
  - Veteran Engagement Panel (VEP)
  - Stakeholder Advisory Panel (SAP)
- Veteran “Personas” (VHA Human Factors Engineering, 2017)

# Veteran Personas

- Developed by VHA Human Factors Engineering program
- Representative users from 4 key groups: Vietnam Era Veterans, WWII and Korean War Veterans, Post 9/11 Era Male Veterans, and Post 9/11 Era Female Veterans



<https://veteransaffairsuxguide.com/wp-content/uploads/2017/10/VA-Veteran-Personas-V1.6.pdf>

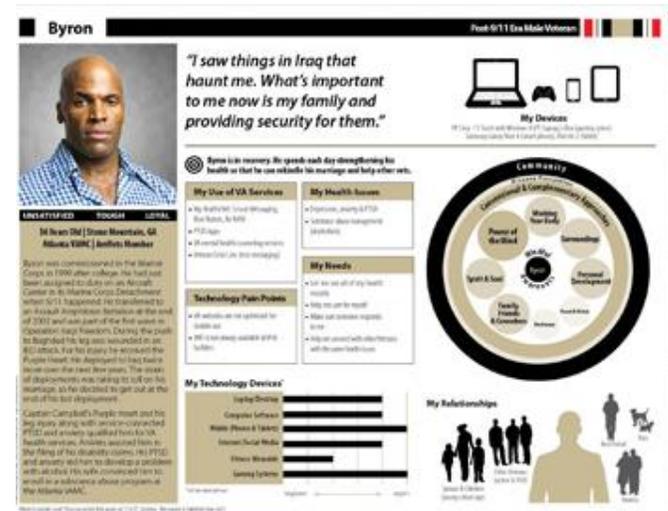
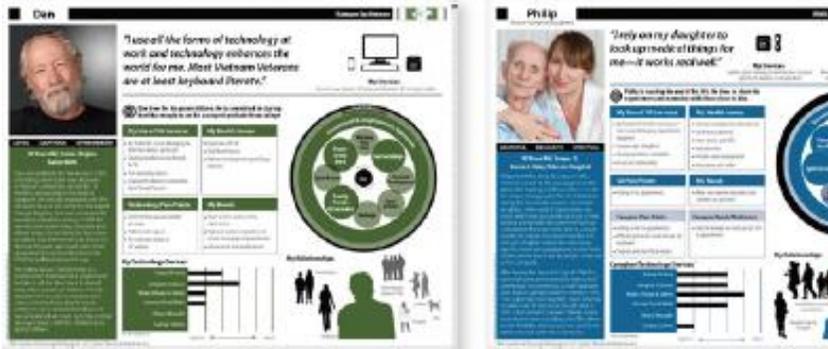
VETERAN\* PERSONAS

September 2017



\*Veterans  
Who Use  
VHA Services

# Veteran Personas



## Meghan Post-9/11 Era Female Veteran



*"I want to be a career person and I want to accomplish things and feel like I'm contributing to society, my community and my family."*



**My Devices**  
iPhone 7 plus (smart phone- health & productivity apps), Apple MacBook with Tiger OS (Mac Laptop), iPad Mini (tablet-lots of kid apps), Fitbit Charge (fitness tracker wristband)

**Meghan strives to make a difference. She wants to be healthy so that she can accomplish her life goals.**

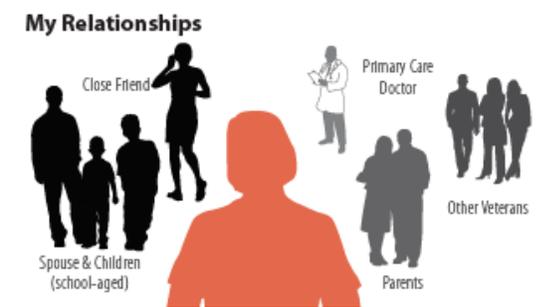
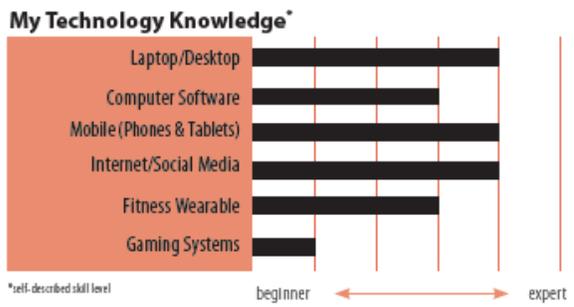
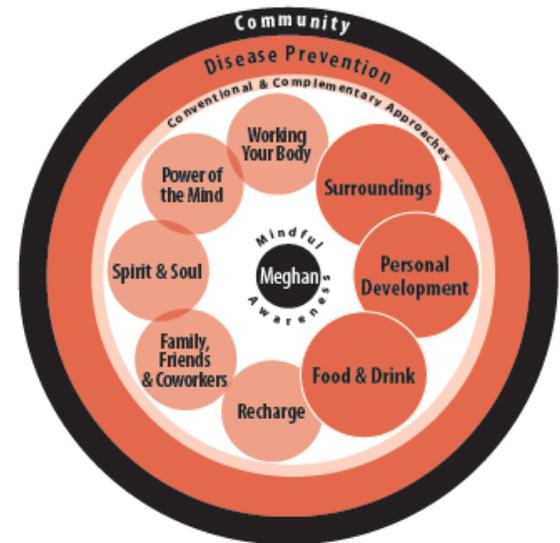
### INDEPENDENT DETERMINED CARING

**35 Years Old | Virginia Beach, Hampton VAMC, Virginia Beach CBOC**

Meghan joined the Navy after graduating high school in the summer following 9/11. She deployed to Afghanistan as an individual augmentee with the Combined Forces Command Afghanistan. It was there that she suffered a head injury when the truck in front of hers in a convoy was struck by an RPG, the resulting explosion causing her truck to flip. However, her best friend was not as lucky and died in the attack.

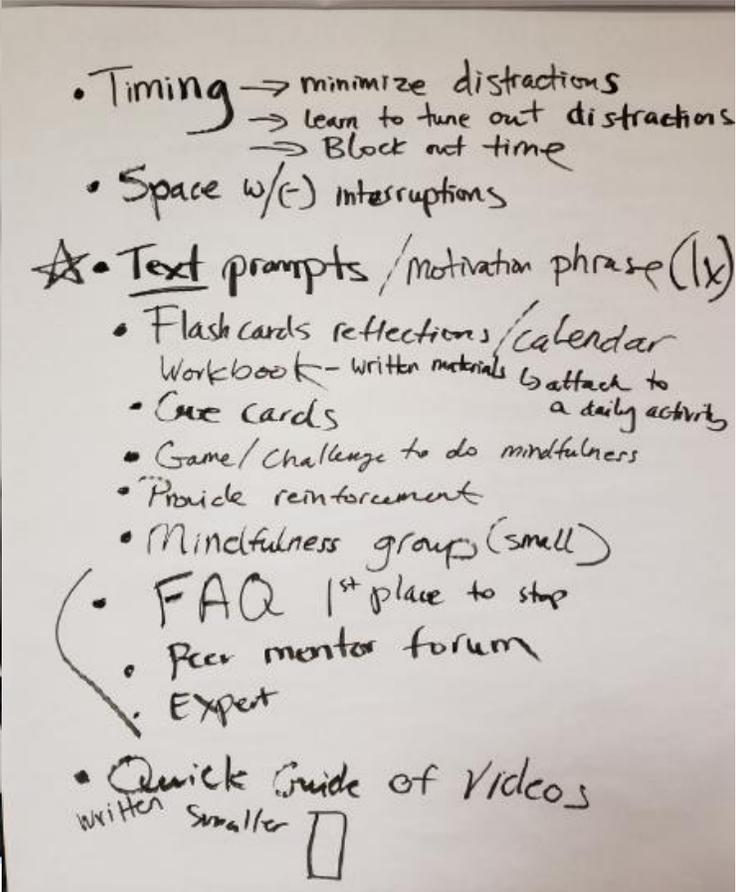
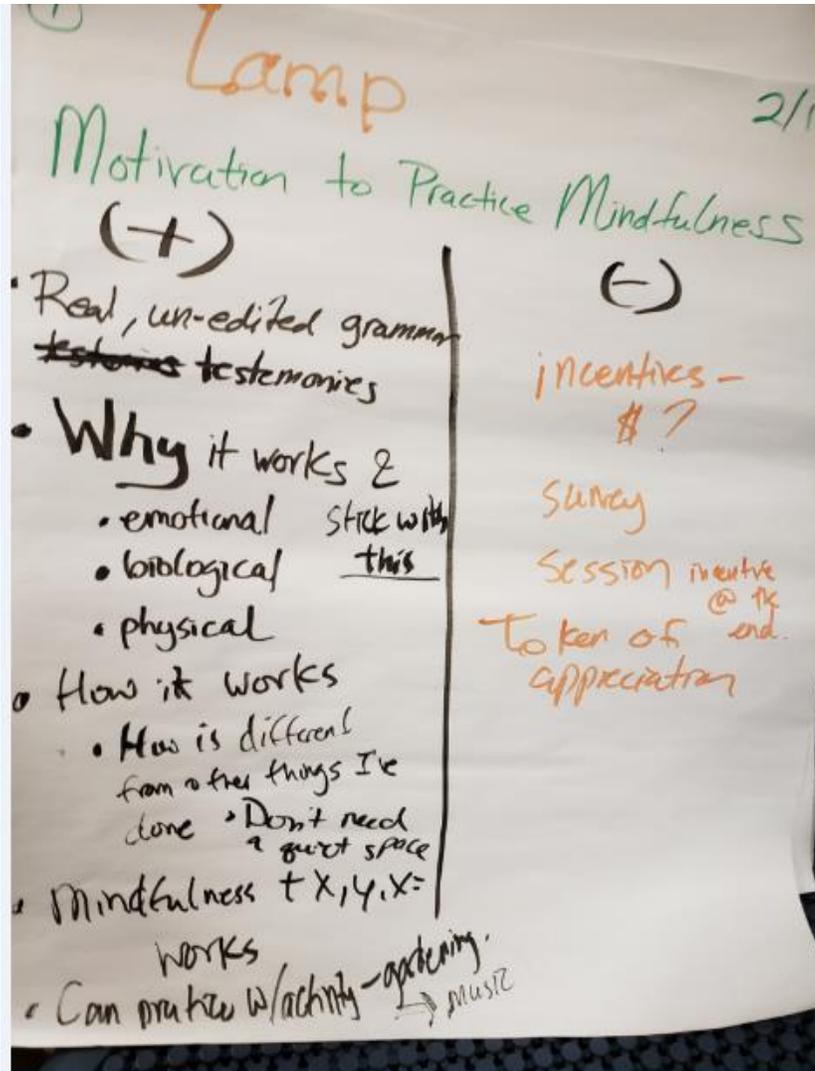
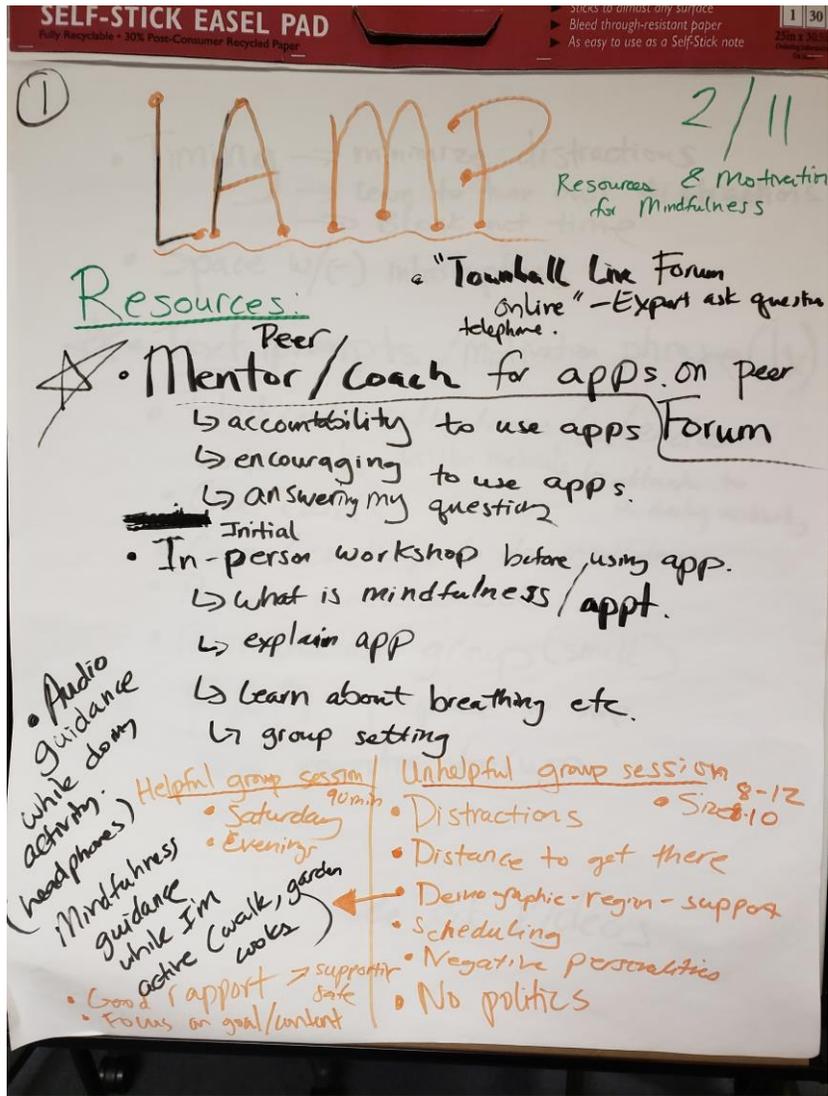
Meghan advanced to the rank of Yeoman First Class before leaving the service; she and her first husband divorced near the end of her second enlistment. After a couple of years, she married a Navy Senior Chief who is stationed at Oceana Naval Air Station. They live in Virginia Beach, Virginia where she works as a legal secretary. Still haunted by seeing her best friend killed, she sees a Mental Health Counselor at the Virginia Beach Outpatient Clinic. Her new husband loves her and her children. She is pregnant with her third child.

<b>My Use of VA Services</b> <ul style="list-style-type: none"> <li>My HealtheVet: Secure Messaging, Blue Button, Rx Refill</li> <li>PTSD App &amp; VA Moms App</li> <li>eBenefits</li> <li>VA mental health counseling services</li> <li>Veterans Crisis Line (text msg)</li> <li>Neurology</li> </ul>	<b>My Health Issues</b> <ul style="list-style-type: none"> <li>Depression, anxiety &amp; PTSD</li> <li>TBI with seizures</li> <li>Headaches</li> <li>Lower back/extremities pain</li> <li>Weight management</li> <li>Pregnancy</li> </ul>
<b>Technology Pain Points</b> <ul style="list-style-type: none"> <li>VA websites are not optimized for mobile use</li> <li>Wifi is not always available at VHA facilities</li> <li>Can't upload my personal health data to the VA</li> </ul>	<b>My Needs</b> <ul style="list-style-type: none"> <li>Make it easy for me to send my provider information</li> <li>Time management (help me with my appointments and don't waste my time)</li> <li>Coordination with neurology and OB/ GYN</li> </ul>



<http://www.digitalsocialmedia.com>

# Example: Input from Veteran Engagement Panel (VEP)



# Intervention spreadsheet\* (56 activities)

## Columns: Weekly Sessions (1-8) – Topic

- **Activity (1 – 7)**

- Learning Objective(s)
- COM (Capabilities Opportunities Motivation)/Intervention Function
- Format
- Time (min)
- Behavior Change Technique(s)

Week	TOPIC	Learning Objective	COM/Intervention Function 1	Format	Time (min)	BCTs
	<b>Mindfulness &amp; Pain</b>	Welcome; congratulate for taking effort to be in program. Orient: provide introduction to program, guidelines for participation	--	In-Person Facilitator Presentation OR Narrated Presentation	10	Education -Information (Inquritor)  Incentivization -Social reward for effort of participation
		Script Link	YES			
		Presentation/Slide	YES			
		Video Link	NO			
		Workbook Link	YES			

\*37 columns X 50 rows

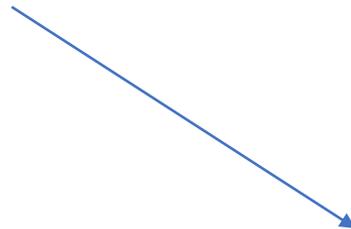
# Intervention spreadsheet (56 activities)

Columns: Weekly Sessions (1-8) - Topic

- Activity (1 – 7)
  - Learning Objective(s)
  - COM/Intervention Function
  - Format
  - Time (min)
  - Behavior Change Technique(s)

Rows (assets)

- Script Link
- Presentation/Slide Link
- Video Link
- Workbook Link



Activity 1-Session Introduction (5-10 min)						
Week	TOPIC	Learning Objective	COM/Intervention Function	Format	Time (min)	BCTs
	Mindfulness & Pain	Welcome; congratulate for taking effort to be in program Orient: provide introduction to program, guideline for participation	--	In-Person Facilitator Presentation OR Narrated Presentation	10	Education -Information (Inquiry)  Incentivation -Social reward for effort of participation
	Script Link	YES				
	Presentation/Slide	YES				
	Video Link	NO				
	Workbook Link	YES				

# Example: Week 1 – Mindfulness and Pain; Activity 3-Educational Video

Learning Objectives [Primary Behavior Change Techniques]	COM- (TDF)/Intervention Function 3	Format	Time	Behavioral Change Techniques by Intervention Function
<p>1. Provide information that engaging in healthy behaviors, like pain can be difficult and stressful for anyone; physical and psychological discomfort, is part of being human and is normal (prevalence of pain, impacts of pain) [INFORMATION]</p> <p>2. Provide information about what mindfulness is, related terms (attention, intention, attitude--IAA), and why it matters for wellbeing and pain [INFORMATION] Provide information about what it means to be non-judgmentally aware of present moment experiences in relationship to pain, and why it is important [INFORMATION]</p> <p>3. Provide information about the consequences (emotional, health) of mindfully approaching pain (can lead to new perspective about pain; new feelings about one's own ability/self-efficacy related to pain; new positive/adaptive ways to manage some of the challenges/barriers to pain); versus not being mindful when approaching/dealing with pain [INFORMATION EMOTIONAL, HEALTH CONSEQUENCES];[SALIENCE OF HEALTH CONSEQUENCES]</p> <p>4. Provide information on common barriers/facilitators to learning mindfulness skills--course has been designed to provide strategies, tools to overcome the barriers, but like any skill, need to practice (will get out of it, what you put into it) [INFORMATION]</p> <p>5. Provide information on human capacity for mindfulness...within everybody's reach; individual has capacity for mindfulness; is a skill that can be developed with practice, through meditation, mindful movement,</p>	<p>Address: C-Psychological Capability (Knowledge) using Education M-Reflective Motivation using Persuasion</p>	<p>Educational Video</p>	<p>12</p>	<p>Education -Information about what mindfulness is in relation to pain -Information about health and emotional consequences (e.g. information about health impacts, emotional impacts related to being/not being mindful in daily life, related to pain)</p> <p>Persuasion -Verbal persuasion about capability--mindfulness is within everyone's reach; how mindfulness can help with tuning into body's cues, making helpful pain choices; how program can help overcome barriers/challenges to learning mindfulness -Salience of health consequences (e.g. story about health consequences about being/not being mindful in daily life, pain)</p>

Script Link

Presentation/Slide Link

Video Link

Workbook Link

# Weekly Activities

1. Introduction
2. Individual Reflection or Reflection/Group Discussion
3. Educational Video
4. Guided Meditation Practice Video
5. Guided Mindful Movement Practice Video
6. Individual Reflection or Reflection/Group Discussion
7. Session Close

# Weekly Topics

1. Mindfulness and Pain
2. Working with the Body Mind Connection
3. Being Kind to Yourself
4. Thoughts & Feelings
5. Power of Perspective
6. Finding the Positive
7. Connecting & Communicating

# “Learnings” - example from VEP

## Video 1 Reactions

	A : Liked picture (connection)	B : Liked stated what mindfulness is not	C : Mindfulness doesn't get rid of my pain	D : Not sure what I'm being asked to do with mindfulness--how can it make my pain better	E : Addressing all ways px affects life was affirming	F : Like experiential learning	G : Liked definition of pain	H : Need more practice
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## Video 1 Suggestions

A : Allow more time for silence in mindfulness practice	B : Animated graphic for mind-body connection	C : Expand on what happens during pause, as well as outcome	D : Finger injury trivial..use back/pain, or knee pain	E : Information in writing as well	F : Likes seeing big picture...how it all fits together	G : More realistic scenario and outcome	H : Smile
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## Video 2 Suggestions

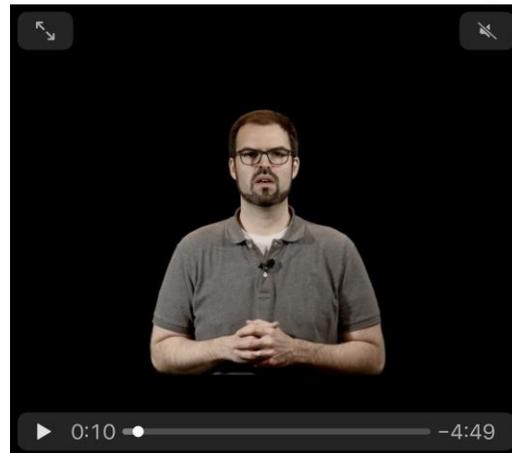
A : Be more clear on point of Body Scan, how it relates to mindfulness	B : Bring back gently out of scan--wobble fingers, etc	C : End videos with 'teasers' so want to watch next one	D : Provide examples of judgemental thoughts	E : Soft white noise in background	F : Use one male, one female for Vet Stories
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## Intervention Assets

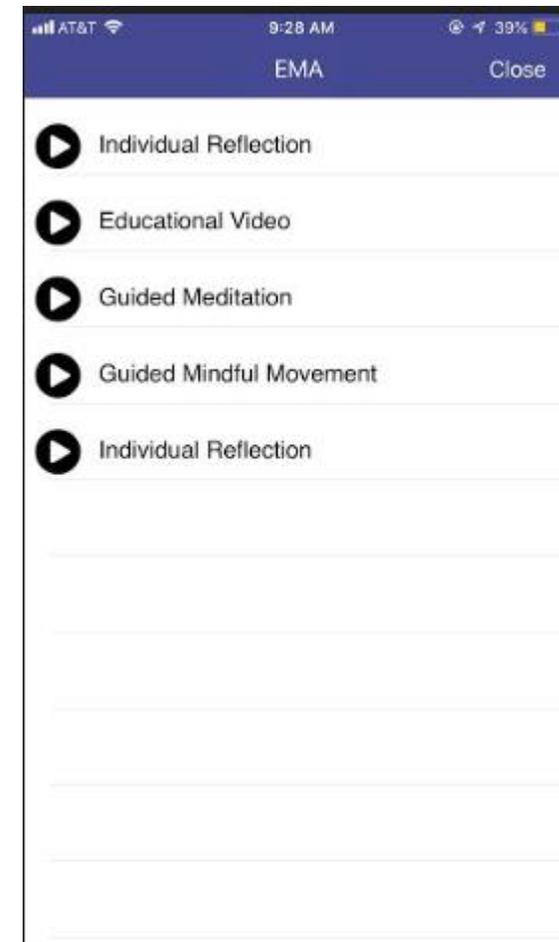
- Video & audio lessons
  - Delivered in group setting & on mobile app
- Facilitator training manual & presentation slides
- Patient workbook

# Mobile app refinement (in-process)

- Part of intervention refinement
- Customizing existing platform designed for behavioral researchers; data collection capability
- Made compliant with VA standards
- Usability testing & fixing bugs
- Optimization interviews with Veterans



Close Window



# Questions & Discussion

- Forthcoming methods posters to be presented at the International Forum for Back and Neck Pain Research in Primary Care, July 3, 2019, Quebec City, Canada.
- Email me if interested in receiving a copy: [diana.burgess@va.gov](mailto:diana.burgess@va.gov)

Evans R, Haley A, Burgess DJ, Kennedy D. A Mindfulness Based Intervention for Adaptive Pain Behaviors: Application of a Theory and Evidence Based Design Process.

Burgess DJ, Allen K, Bangerter A, Bronfort G, Cross L, Ferguson J, Haley A, Matthias M, Meis L, Polusny M, Taylor B, Taylor S, Evans R. Learning to Apply Mindfulness to Pain (LAMP): A pragmatic, randomized clinical trial of two mindfulness-based interventions for chronic musculoskeletal pain.

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