

Brief and Digital Behavioral Innovations Across the Continuum of Care: Tools for right now

Beth Darnall, PhD

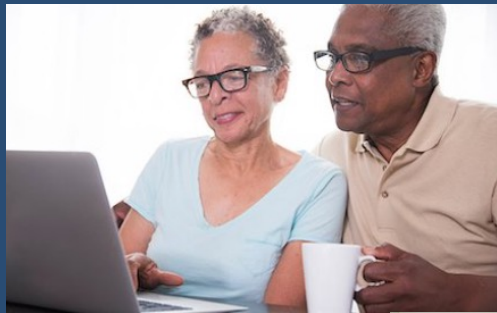
Christine Rini, PhD

Brennan M Spiegel, MD



Empowered Relief: A single-session intervention for chronic and acute pain

Scientific review of multiple randomized trials



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 [@BethDarnall](https://twitter.com/BethDarnall)

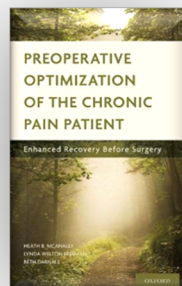
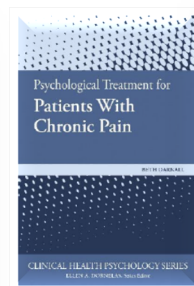
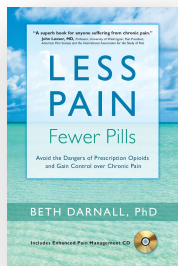
Disclosures

Chief Science Advisor: AppliedVR



Contracts and Grants

- NIH / NIDA Brief digital treatment for chronic pain
- PCORI Patient-Centered Opioid and Pain Reduction
- NIH / NCCIH Behavioral Treatment for Chronic Pain



Board of Directors

- American Academy of Pain Medicine
- Institute for Brain Potential

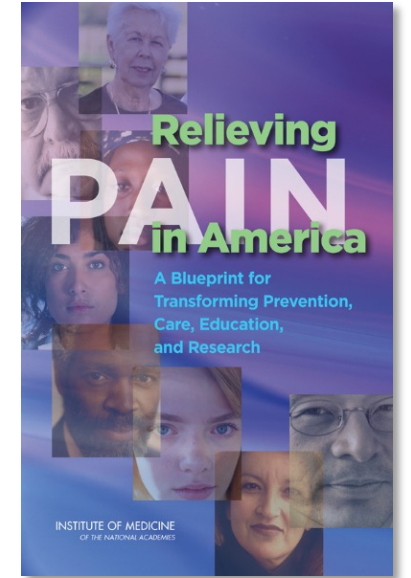
Scientific Member

- CDC Opioid Workgroup (2020-2021)
- NIH Interagency Pain Research Coordinating Committee (IPRCC)

The Call for Whole-Person Pain Care

100 million adults

- Institute of Medicine (2011)
- National Pain Strategy (2016)
- NASEM (2019)
- Center for Disease Control and Prevention (2019)
- HHS Interagency Task Force on Best Practices in Pain Management (2019) *Acute and chronic pain*



IAN MACKAY



To treat pain, study people in all their complexity

Clinical research needs to investigate not simply drugs, but the psychology of why and how individuals experience pain, says Beth Darnall.

Last month, the US National Institutes of Health (NIH) formally launched a multi-agency effort to combat the country's opioid-addiction crisis. Funds for research into controlling opioid misuse and treating pain will nearly double in 2018, to US\$1.1 billion.

The forces behind this epidemic extend beyond overprescription: most of the tens of thousands of deaths caused by opioid overdose in the United States each year result from illicit use. Still, an inadequate understanding about how to treat pain has certainly contributed. We need to characterize patients better, and we need more studies that incorporate non-drug treatments alongside any form of medication.

Consider this crucial question: what is the first treatment you should give a person for chronic pain, or even many acute injuries? Most clinicians now agree that the answer should not be opioids. Fewer recognize that the question is not which pill to use instead, but what system of interventions — including medication — and monitoring to implement.

Too often, pain is treated as a purely biomedical problem. It is a biopsychosocial condition. Psychological treatment can be combined with medication to equip people with the tools to better control their pain experience. Psychological therapies can also lower risks such as addiction, because the emphasis is on engaging patients in managing their daily actions to help themselves to feel better in the long run, rather than relying solely on passive medications. Yet a common clinical practice is to recommend such psychosocial strategies for pain only after all medications have failed.

It is hard for clinicians to learn which treatments to use, because our research system shuns the very patients we need to understand. Pain-research trials often exclude adults who have depression, anxiety and other disorders, those who take other prescription medications and those over the age of 70, who tend to have multiple co-morbidities.

To treat pain better, we should attend to these complex patients, rather than exclude them. One effort to do so is the Collaborative Health Outcomes Information Registry, or CHOIR (<http://choir.stanford.edu>), which my colleagues developed with NIH support. The platform collects data on the patients we personally see in our pain clinic every

treatment that benefits them or expose them to a risky medication.

We know, for instance, that people who worry more about pain, or who report feeling helpless in the face of it, are at risk of prolonged pain and opioid use after surgery (M. M. Wertli *et al. Spine* 39, 263–273; 2014). My colleagues and I are currently assessing whether an online education app can help patients to manage their worries, decrease pain and limit opioid use after surgery.

More such pragmatic clinical trials are needed. So are accessible tools, such as CHOIR, to implement these trials. We are currently building a CHOIR network across the United States, Canada and Israel to integrate data and answer questions about which of several commonly used pain treatments works best, and in which individuals. Ideally, we will then use the results of these trials to inform clinicians continuously about the most safe and effective treatment to prescribe for their patients.

And we need to study how placebo effects could enhance pain treatment, by deliberately integrating them into clinical trials. I am not talking about sugar pills, but about a strategy called placebo optimization. Simple pain-science education, cognitive regulation and relaxation skills can help empower patients to reduce pain processing in the brain, gain better control over their symptoms and garner more benefit from medical treatments.

Patients can actually be primed for relief. For instance, placebo optimization could involve emphasizing to patients that we have evidence suggesting that various treatment plans — such as gently tapering opioid dosing — can be done without increased pain. Clinicians also need strategies for detecting and minimizing 'nocebo' effects: in this case, negative expectations and fears

about pain that can undermine the effectiveness of medical treatment.

We need to incorporate psychology and complexities into clinical trials and medical care. More funding for treating opioid addiction and misuse is welcome. But essential, too, are funds for investigating pain as a condition in itself.

In 2016, the Institute of Medicine estimated that up to one-third of the US population lives with ongoing pain. Chronic pain, the main

**TOO OFTEN,
PAIN IS
TREATED
AS A PURELY
BIOMEDICAL
PROBLEM.**

Darnall B.

Nature 2018, May 3, Vol 557:7.





International Association for the Study of Pain

IASP

Working together for pain relief

Pain Definition: A noxious sensory **and emotional experience**





Poor Descending Modulation of Pain



- Shapes neural functioning / patterns¹
- Shapes the brain at “rest”²⁻³
- Sets the stage for prolonged symptoms, chronic pain³⁻⁴
- Primes the nervous system for pain⁵

1. Seminowicz and Davis. Cortical responses to pain in healthy individuals depends on pain catastrophizing (2014).
2. Kucyi et al. Enhanced medial prefrontal DMN functional connectivity in chronic pain and its association with pain rumination (2014).
3. Jiang, Oathes, Hush, **Darnall**, Charvat, Mackey, Etkin. Perturbed amygdalar connectivity with the Central Executive and Default Mode Networks in Chronic Pain (*PAIN*®, 2016).
4. Picavet et al. Pain catastrophizing and kinesiophobia: predictors of chronic low back pain (2002).
5. Taub, **Darnall**, Johnson, Mackey. Effects of a pain catastrophizing induction on quantitatively measured pain perception in women with chronic low back pain (2017).



Cognitive Behavioral Therapy for Chronic Pain

Topics and Skills

- Pain and the brain
- Mood and pain
- Sleep and pain
- Pleasant activities
- Goal setting
- Problem solving
- Movement
- Social connection
- Diaphragmatic Breathing
- Relaxation Response
- Cognitive Restructuring
- Mindfulness
- Meditation



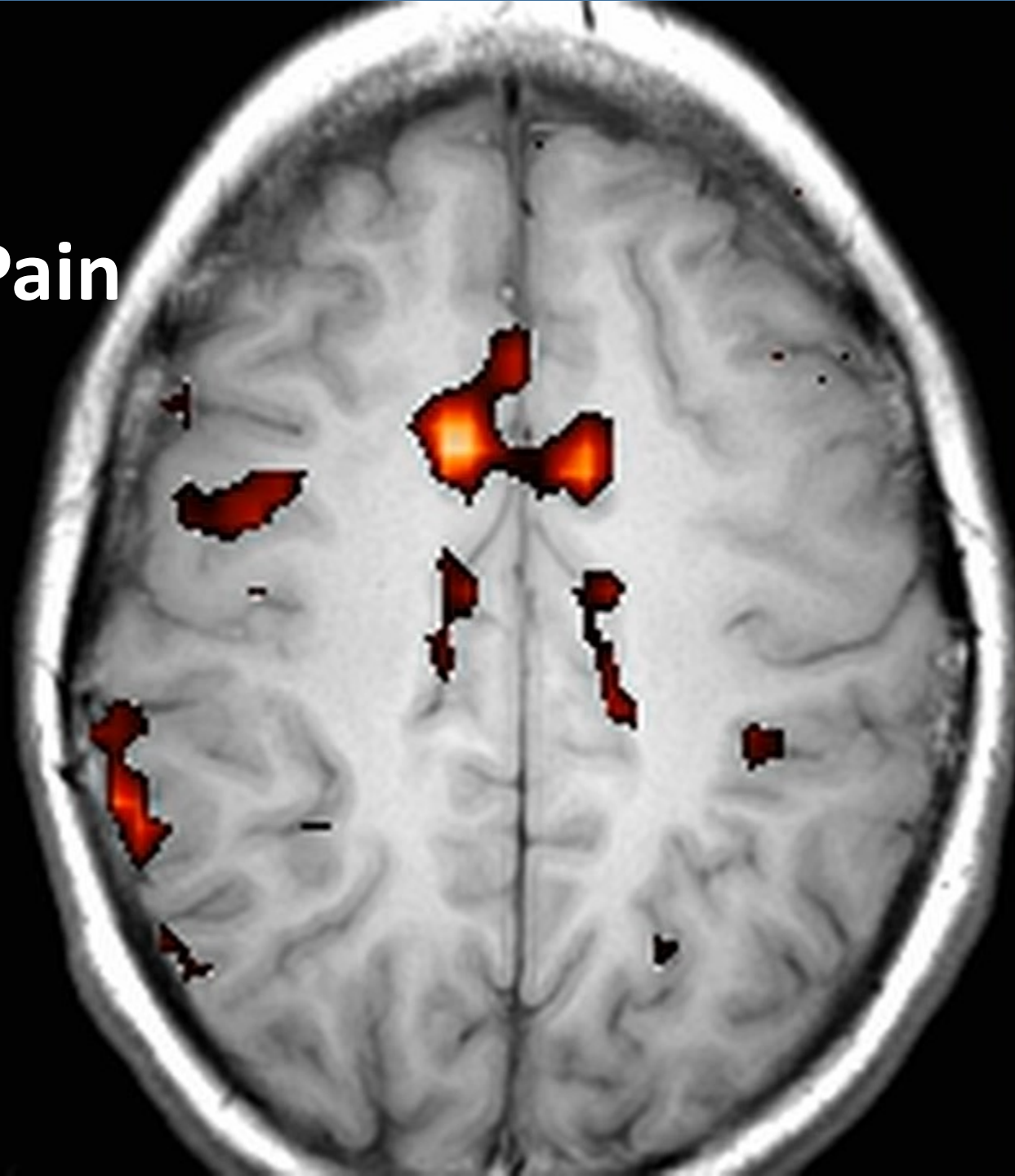
**There's nothing I
can do about my
pain. It is only going
to get worse!**



There are several things I can do right now to soothe myself and feel better.



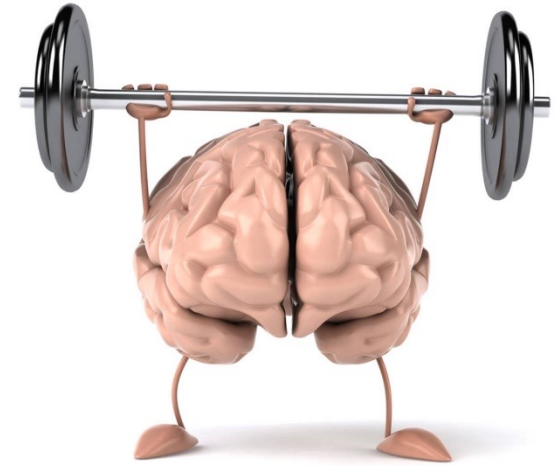
**Unhelpful Pain
Coping**



Pain Relief Skills

Regular skills use:

- Dampens pain processing
- Reduces physiological hyperarousal
- Reduces cognitive and emotional responses that amplify pain
- Entrain positive neural patterns
- Alters the function and structure of the brain



CBT increases prefrontal gray matter in patients with chronic pain

Seminowicz DA, Shpaner M, Keaser ML, Krauthamer MG, Mantegna J, Dumas JA, Newhouse PA, Filippi C, Keefe FJ, Naylor MR. *J Pain*. 2013 Dec; 14(12):1573-84



- Insurance coverage
- Time
- Co-pays
- Travel
- Work / family obligations
- Pain / health
- Proximity (rural settings)
- No psychologists nearby who are trained to treat pain
- Surgical patients need asynchronous treatment

Original Research Article

**Pain Psychology: A Global Needs Assessment
and National Call to Action**

Beth D. Darnall, PhD,^{*,a} Judith Scheman, PhD,^{†,a}
Sara Davin, PhD,^{†,b} John W. Burns, PhD,^{‡,b}
Jennifer L. Murphy, PhD,^{§,b} Anna C. Wilson, PhD,^{¶,b}
Robert D. Kerns, PhD,^{||} and
Sean C. Mackey, MD, PhD,^{*,a}

Design. Prospective, observational, cross-sectional.

Methods. Brief surveys were administered online to six stakeholder groups (psychologists/therapists, individuals with chronic pain, pain physicians, primary care physicians/physician assistants, nurses

Pain Medicine 2016; 17: 250–263
doi: 10.1093/pm/pnv095

An evidence-based, single-session pain class
that rapidly equips patients with pain
management skills



Empowered ReliefTM

Train your brain away from pain

For patients with acute and chronic pain and their families



Original Investigation | Physical Medicine and Rehabilitation

Comparison of a Single-Session Pain Management Skills Intervention With a Single-Session Health Education Intervention and 8 Sessions of Cognitive Behavioral Therapy in Adults With Chronic Low Back Pain

A Randomized Clinical Trial

Beth D. Darnall, PhD; Anuradha Roy, MSc; Abby L. Chen, BS; Maisa S. Ziadni, PhD; Ryan T. Keane, MA; Dokyoung S. You, PhD; Kristen Slater, PsyD; Heather Poupore-King, PhD; Ian Mackey, BA; Ming-Chih Kao, PhD, MD; Karon F. Cook, PhD; Kate Lorig, DrPH; Dongxue Zhang, MS; Juliette Hong, MS, MEd; Lu Tian, PhD; Sean C. Mackey, MD, PhD

Abstract

IMPORTANCE Chronic low back pain (CLBP), the most prevalent chronic pain condition, imparts substantial disability and discomfort. Cognitive behavioral therapy (CBT) reduces the effect of CLBP, but access is limited.

OBJECTIVE To determine whether a single class in evidence-based pain management skills (empowered relief) is noninferior to 8-session CBT and superior to health education at 3 months after treatment for improving pain catastrophizing, pain intensity, pain interference, and other secondary outcomes.

DESIGN, SETTING, AND PARTICIPANTS This 3-arm randomized clinical trial collected data from May 24, 2017, to March 3, 2020. Participants included individuals in the community with self-reported CLBP for 6 months or more and an average pain intensity of at least 4 (range, 0-10, with 10 indicating worst pain imaginable). Data were analyzed using intention-to-treat and per-protocol approaches.

INTERVENTIONS Participants were randomized to (1) empowered relief, (2) health education

Key Points

Question Is a single-session pain relief class noninferior to 8 sessions of cognitive behavioral therapy (CBT) at 3 months after treatment?

Findings In this 3-arm randomized clinical trial that included 263 adults with chronic low back pain, a single-session pain management skills class was noninferior to 8 weeks of CBT and superior to a health education class for pain catastrophizing and multiple secondary outcomes at 3 months after treatment.

Meaning For patients with chronic low back pain, a single-session pain relief skills class showed comparable efficacy

N = 263

Health Education
2 hours



Empowered Relief™
2 hours

8-session CBT
16 hours





Empowered Relief™ was similar
to 8-session CBT for improving:

- Pain intensity
- Pain interference
- Pain catastrophizing

Secondary outcomes:

- Pain self-efficacy
- Pain bothersomeness
- Sleep disturbance
- Depression
- Anxiety
- Fatigue

Study Details:

- Chronic low back pain study (N=263)
- Half had 2+ chronic pain conditions
- ***Results at 3 months post-treatment***

JAMA
Network | **Open™**

NIH National Center for
Complementary and
Integrative Health

Darnall BD et al. JAMA Network Open. AUG 2021;4(8):e2113401.

Cited by the 2019 HHS Best Practices Pain Management
Task Force as a promising and scalable treatment option





Empowered Relief™

6-month post-treatment results

- Continued non-inferiority to 8-session CBT for reducing pain intensity and pain interference
- New superiority for ER vs. CBT for reducing pain catastrophizing, anxiety, and pain bothersomeness

Darnall BD, Roy A, Hong J, Tian L, Mackey SC. Comparison of a Single-Session Pain Management Skills Intervention With a Single-Session Health Education Intervention and 8 Sessions of Cognitive Behavioral Therapy in Adults With Chronic Low Back Pain: 6-Month Results for a Randomized Trial. (in review)



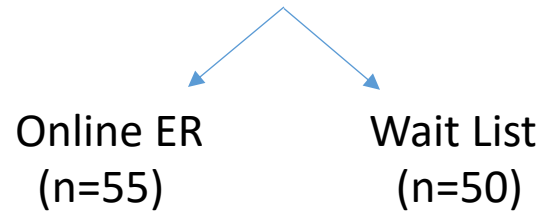
Original Paper

Efficacy of a Single-Session “Empowered Relief” Zoom-Delivered Group Intervention for Chronic Pain: Randomized Controlled Trial Conducted During the COVID-19 Pandemic

Maisa S Ziadni¹, MS, PhD; Lluvia Gonzalez-Castro¹, BS; Steven Anderson¹, PhD; Parthasarathy Krishnamurthy², PhD; Beth D Darnall¹, PhD

Online ER Study

Randomized Controlled Study (N=105)



- No in-person visits
- Occurred during COVID
- Enrolled 100 people in first 11 days
- Mixed etiology chronic pain
- Minimal enrollment criteria
- Follow-up at 3 months post-treatment

Ziadni MS, Anderson SR, Gonzalez-Castro L, Krishnamurthy P, Darnall BD. Efficacy of a Single-Session "Empowered Relief" Zoom-Delivered Group Intervention for Chronic Pain: Randomized Controlled Trial Conducted During COVID-19. (*JMIR*. 2021. Vol 23, No 9 (2021): September)

Between group results at 3 months

Variable	Time (Months)	ER Mean (SE)	Wait List Mean (SE)	Difference Mean (SE)	p-value	95% CI*	Effect Size*
Pain Catastrophizing	0	20.64 (1.53)	20.22 (1.52)	0.42 (2.16)	0.844	-3.81 — 4.66	0.04
Pain Catastrophizing	3	11.92 (1.39)	17.97 (1.39)	-6.05 (1.97)	0.0023	-9.92 — -2.18	0.62
Anxiety (PROMIS)	0	59.57 (1.23)	60.41 (1.22)	-0.84 (1.73)	0.6263	-4.24 — 2.56	0.10
Anxiety (PROMIS)	3	54.85 (1.28)	59.99 (1.28)	-5.14 (1.81)	0.0048	-8.7 — -1.58	0.57
Pain Intensity (PROMIS)	0	62.24 (0.98)	62.53 (0.97)	-0.28 (1.39)	0.8379	-3.01 — 2.44	0.04
Pain Intensity (PROMIS)	3	57.26 (1.18)	61.07 (1.2)	-3.81 (1.68)	0.0245	-7.12 — -0.49	0.45
Pain Bothersomeness	0	5.78 (0.29)	6.3 (0.29)	-0.52 (0.4)	0.198	-1.31 — 0.27	0.26
Pain Bothersomeness	3	4.62 (0.35)	5.92 (0.36)	-1.3 (0.5)	0.0102	-2.29 — -0.31	0.52
Anger (PROMIS)	0	54.64 (1.57)	55.48 (1.57)	-0.84 (2.22)	0.7054	-5.21 — 3.53	0.08
Anger (PROMIS)	3	50.54 (1.33)	56 (1.35)	-5.47 (1.89)	0.0041	-9.19 — -1.75	0.58
Sleep Disturbance (PROMIS)	0	56.28 (1.25)	59.5 (1.25)	-3.22 (1.77)	0.0694	-6.69 — 0.26	0.37
Sleep Disturbance (PROMIS)	3	53.46 (1.38)	61.19 (1.4)	-7.74 (1.97)	0.0001	-11.61 — -3.87	0.79

*between group

N/S: Depression, Pain Interference, Social Isolation



Empowered Relief™

Train your brain away from pain



Stanford
HEALTH CARE



MASSACHUSETTS
GENERAL HOSPITAL

Clinician Certification Workshops

- 350 certified ER instructors
- Delivered in 12 countries
- Available in 7 languages
- 11-hour CME workshop



McGill
UNIVERSITY



Intermountain®
Healthcare

<https://empoweredrelief.com/>

New \$11.1M Research Award!

Comparative Effectiveness of 8-Session Online Cognitive Behavioral Therapy vs. Online Single-Session Pain Relief Skills Class for Chronic Pain

- PI: Darnall
- National study; 6 study sites
- 1200 adults, mixed-etiology chronic pain
- Fully online – *no in-person visits required*
- Enrollment begins Fall 2022

**Community-based
MSK chronic pain**

Humana®

Spine Surgery



Cleveland Clinic









Welcome to *My Surgical Success*®!

We are very excited to present you our pain psychology package called My Surgical Success®. My Surgical Success® provides you with education and specific mind-body skills to use in order to prepare for your surgery. We hope to teach you to better control pain and distress without additional medication; Research shows that regular use of these skills helps with healing after surgery. We aim to get you on the road to recovery, and back to doing the things you love as quickly as possible!

Step 1:
Print personal plan

Step 2:
Watch video &
complete personal plan

Step 3:
Click to download audio

Step 4:
Tell us what you think!

A video thumbnail for "My Surgical Success" featuring Beth Darnall, PhD. The video title is "My Surgical Success" in red, with the subtitle "Mind – Body Medicine for Health & Recovery" in purple. Beth Darnall, PhD, is shown in a yellow top, smiling. To her right is a blue and red illustration of a human head and neck, showing the brain and spinal cord. A subtitle at the bottom of the video reads "And welcome to My Surgical Success." The Stanford University logo is visible in the bottom right corner of the video frame.

My Surgical Success
Mind – Body Medicine for Health & Recovery

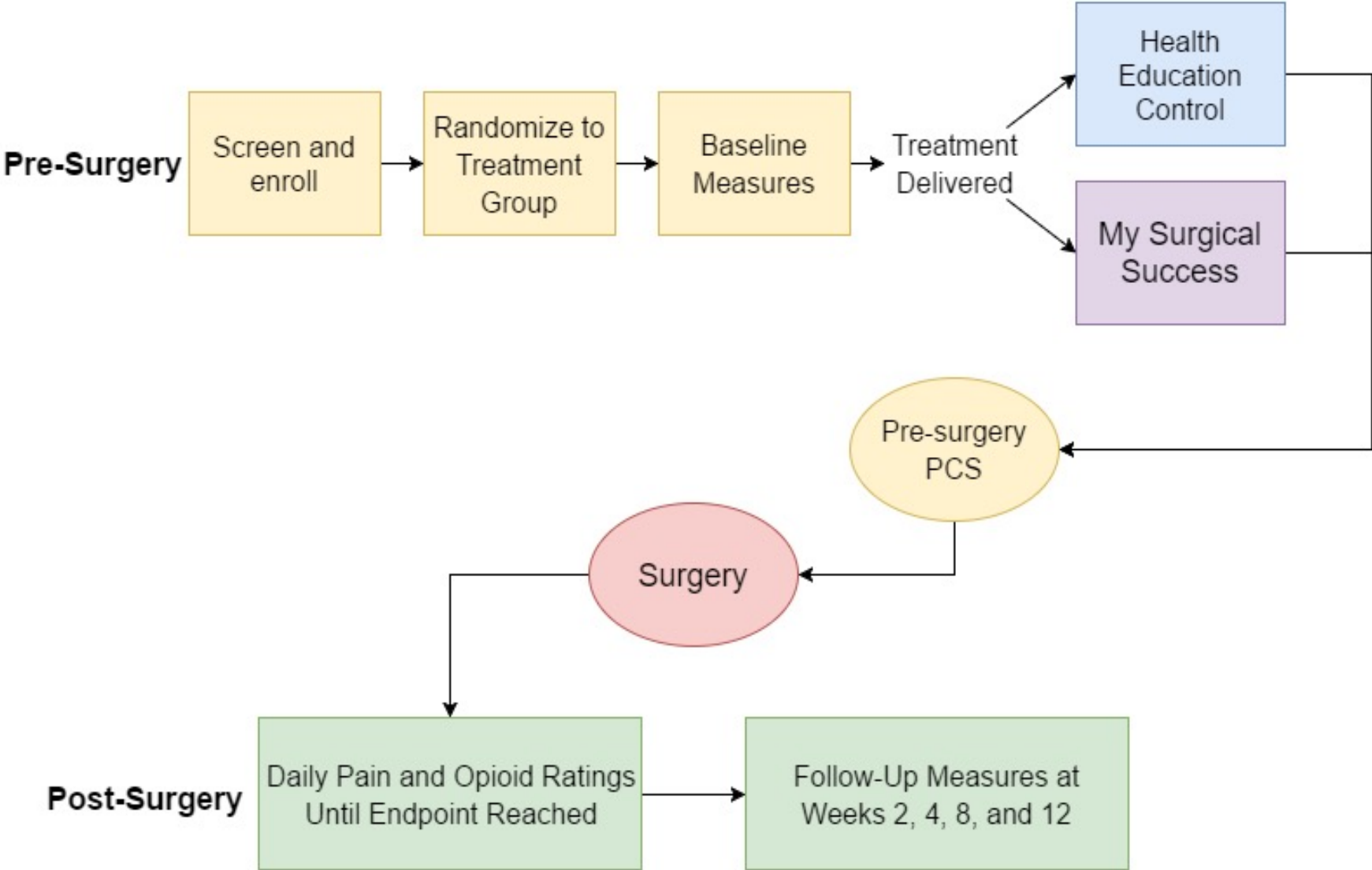
Beth Darnall, PhD
Clinical Professor
Stanford University
Anesthesiology, Perioperative, and Pain Medicine
Division of Pain Medicine
Stanford Systems Neuroscience & Pain Research Center

And welcome to My Surgical Success.

Stanford University

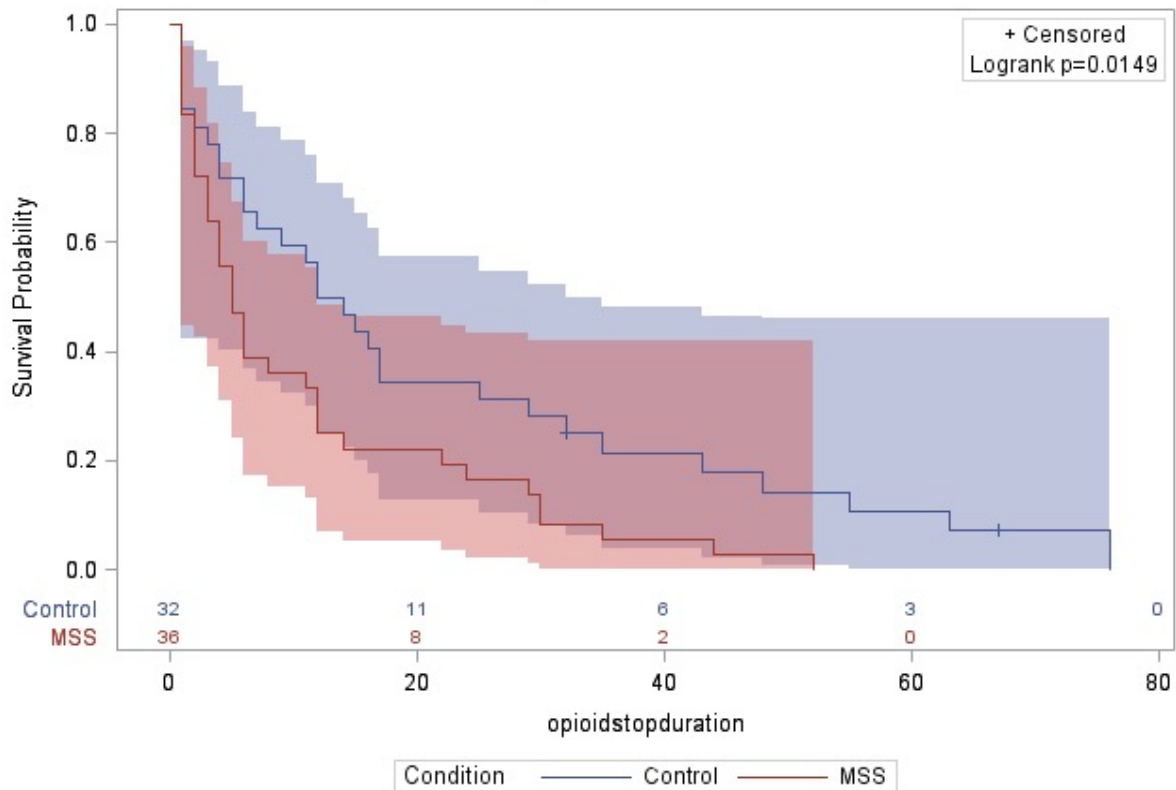
Darnall BD, Ziadni MS, Krishnamurthy P, Mackey IG, Heathcote L, Taub CJ, Flood P, Wheeler A.

“My Surgical Success”: Impact of a digital behavioral pain medicine intervention on time to opioid cessation after breast cancer surgery (May 2019, *Pain Med*).



Product-Limit Survival Estimates

With Number of Subjects at Risk and 95% Hall-Wellner Bands



N = 68 (MSS, n = 36; HE, n = 32)

Effects of My Surgical Success (MSS) vs HE Control in Unadjusted and Adjusted Model on Opioid Cessation

Model	Effect	HR Estimate	Lower 95% CI	Upper 95% CI	z Value	Pr > z
Unadjusted Model						
	MSS versus HE	1.8623	1.1205	3.0952	2.40	0.0164
Adjusted Model						
	MSS versus HE	1.7405	1.0276	2.9478	2.06	0.0393
	PROMIS Anger	0.9734	0.9374	1.0107	-1.4	0.1601
	PROMIS Fatigue	1.0081	0.9749	1.0426	0.47	0.6357
	PROMIS Physical	0.998	0.9575	1.0403	-0.09	0.9256

Ziadni MS, You DS, Tanner R, Salazar B, Jaros S, Ram J, Roy A, Tanner N, Salmasi V, Gonzalez-Castro L, Gardner M, Darnall BD. “My Surgical Success”: Impact of a Digital Behavioral Pain Medicine Intervention on Pain After Orthopedic Trauma Surgery – A Randomized Trial (in review).

MSS associated with reduced pain after surgery and 3 months after surgery



Switzerland



Stanford
MEDICINE

Department of Orthopaedic Surgery



Empowered Relief™

*For people with chronic pain and **comorbid opioid misuse***

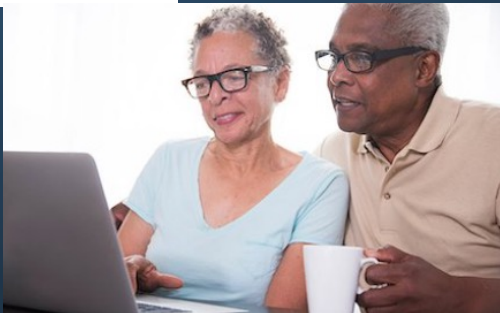
- PI: Darnall
- National RCT
- N=600
- *We are testing a fully automated on-demand version of Empowered Relief that includes interactive learning*
- Primary outcome is 3 months post-treatment
- Enrollment begins Summer 2022



National Institute
on Drug Abuse

Treating the full
definition of pain:

Access is everything



A single-session skills-based intervention

- improves access to pain treatment
- has durable and clinically meaningful outcomes

Colleagues and Collaborators

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