

Primary Care-Based Behavioral Treatment for Long-Term Opioid Users with Chronic Pain: Primary Results and Lessons Learned from the PPACT Pragmatic Trial

Lynn DeBar, PhD, MPH

Kaiser Permanente Washington Health Research Institute
Seattle, Washington

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It Takes a Village...

KP Northwest

Allison Bonifay

Charles Elder

Alison Firemark

Maura Gabriel

Inga Groß

Reesa Laws

Michael Leo

Meghan Mayhew

Carmit McMullen

Maureen O'Keefe-Rosetti

Nancy Perrin

Matthew Slaughter

David Smith

Lou Ann Thorsness

Alexandra Varga

Bill Vollmer

KP Georgia

Lee Cromwell

Kelley DeGraffenreid

Ashli Owen-Smith

Robbin Ryan

Musu Sesay

KP Hawaii

Casey Akana

Kristy Gabriel

Stacey Honda

Jonathan Lai

Jill Riggs

Pamela Roland

Sharin Sakurai

Connie Trinacty

Carmen Wong

Other Study Collaborators

Frank Keefe – Duke

Rick Deyo – OHSU

Lindsay Benes – Montana State

National Institutes of Health Partners

Linda Porter – NINDS (Project Officer)

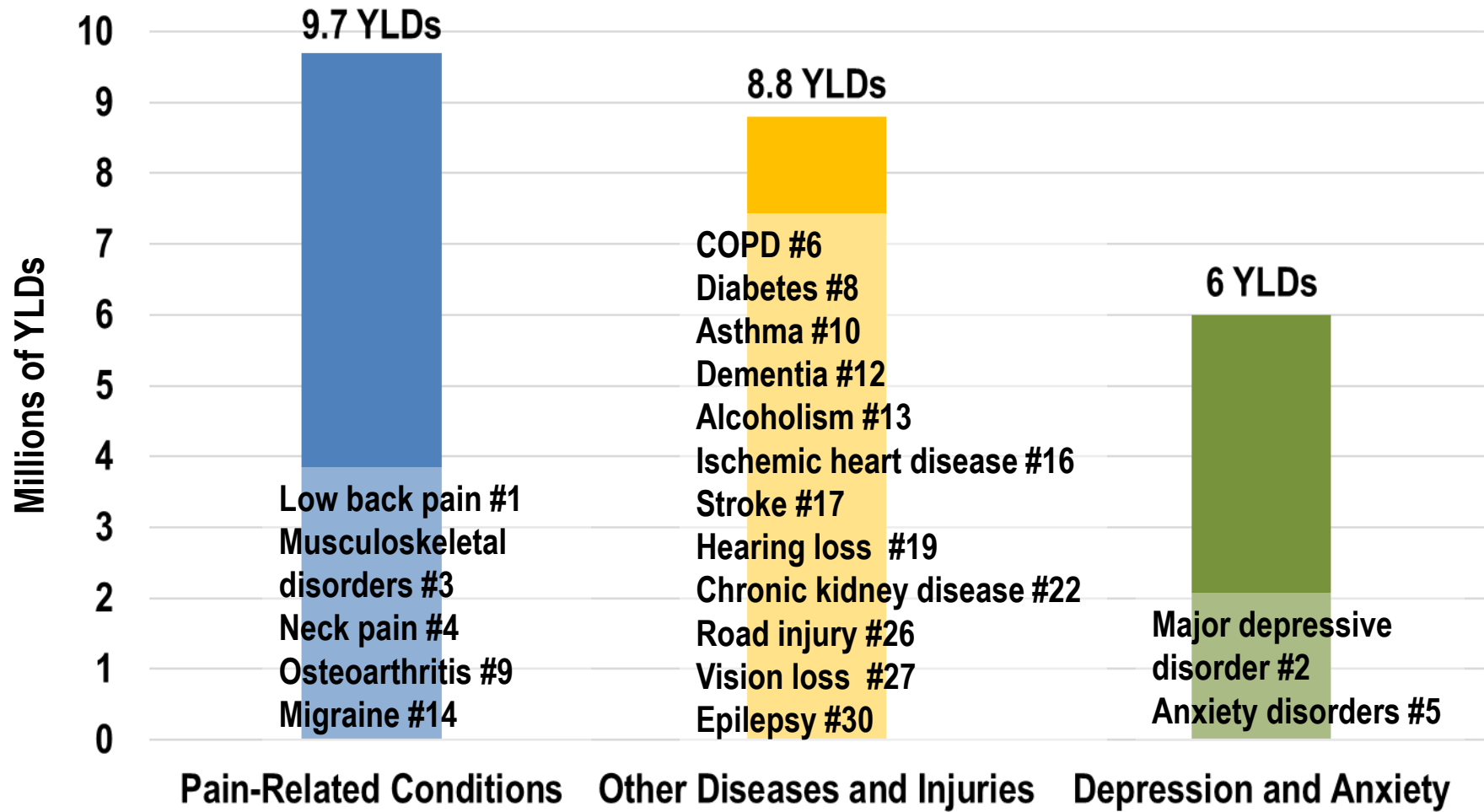
Sarah Duffy – NIDA (Project Scientist)

Road Map

- The Why and the What: Conditions that Motivated and Shaped PPACT Approach
- Getting to Go: Developing the Necessary Infrastructure & Responding to Patient Experience
- Main Study Outcomes
- Cost-Effectiveness Analyses
- Dissemination, Sustainability & Next Steps

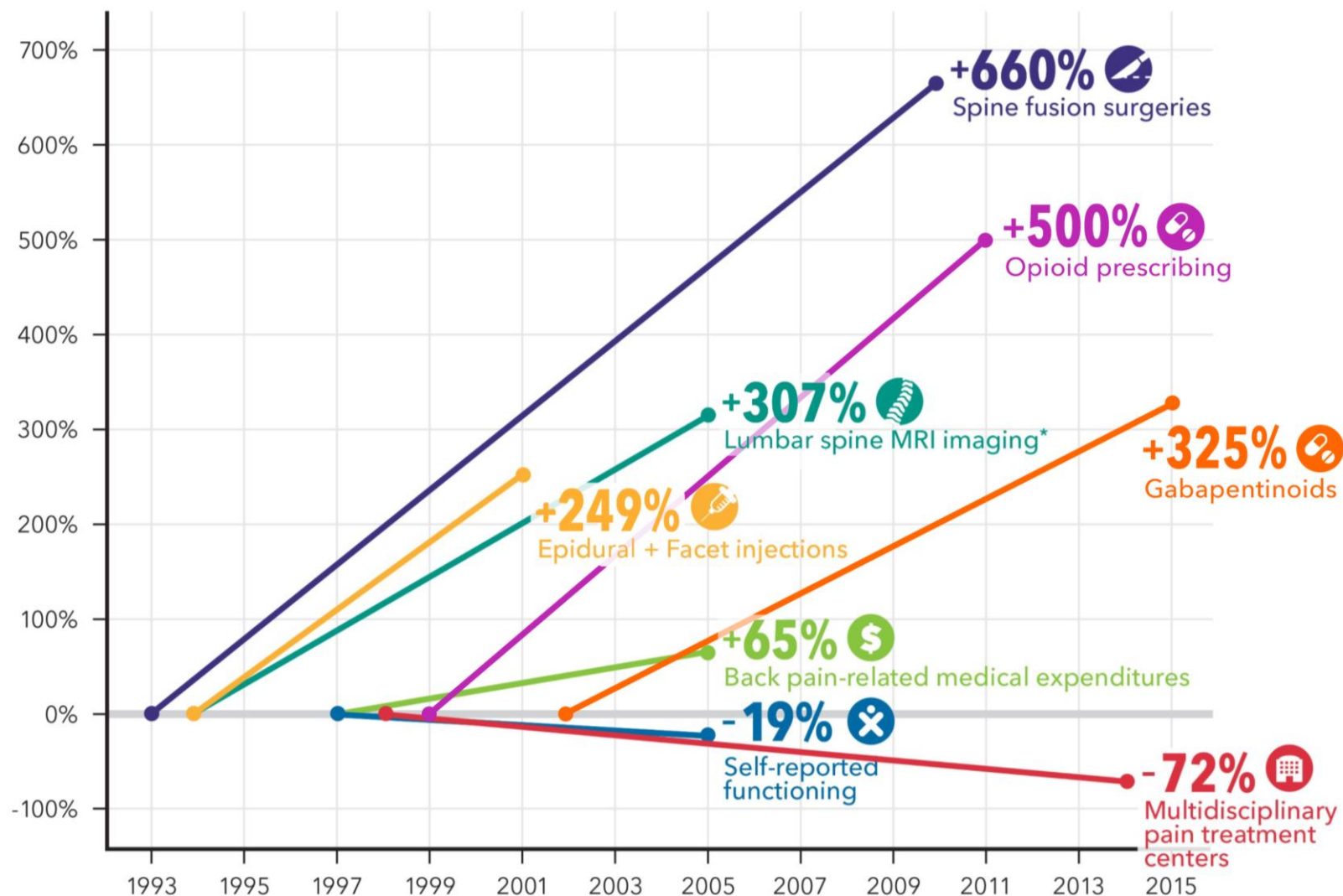
The Why and the What: Conditions that Motivated and Shaped PPACT Approach

Leading Diseases and Injuries Contributing to Years Lived with Disability (YLD) in U.S.



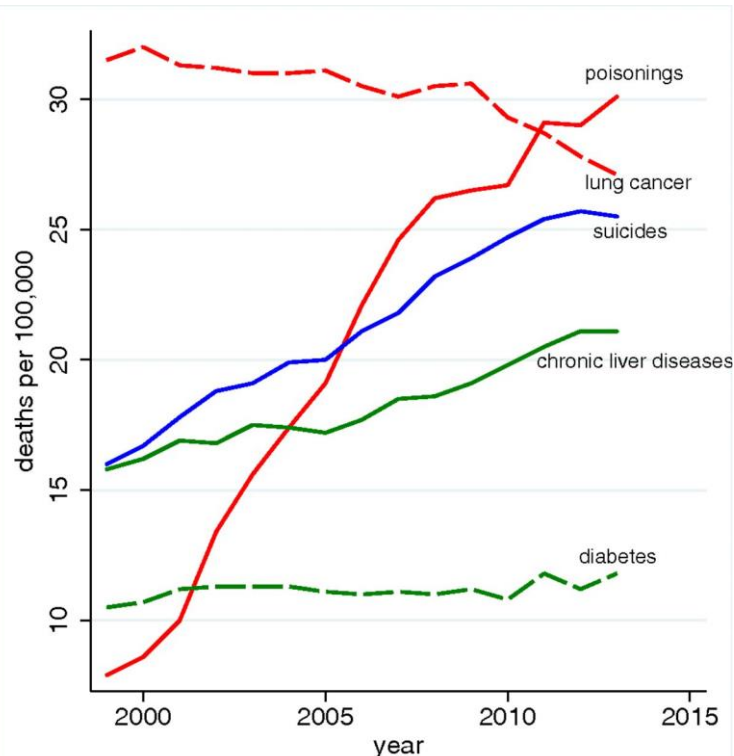
Source: U.S. Burden of Disease Collaborators. The state of US health, 1990-2010: burden of diseases, injuries, and risk factors. *JAMA*. 2013 Aug 14;310(6):591-608.

An Acute Care Model for a Chronic Condition?



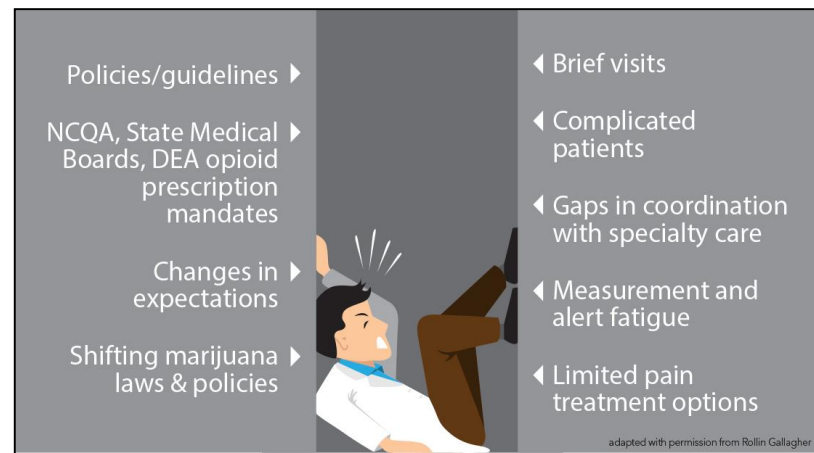
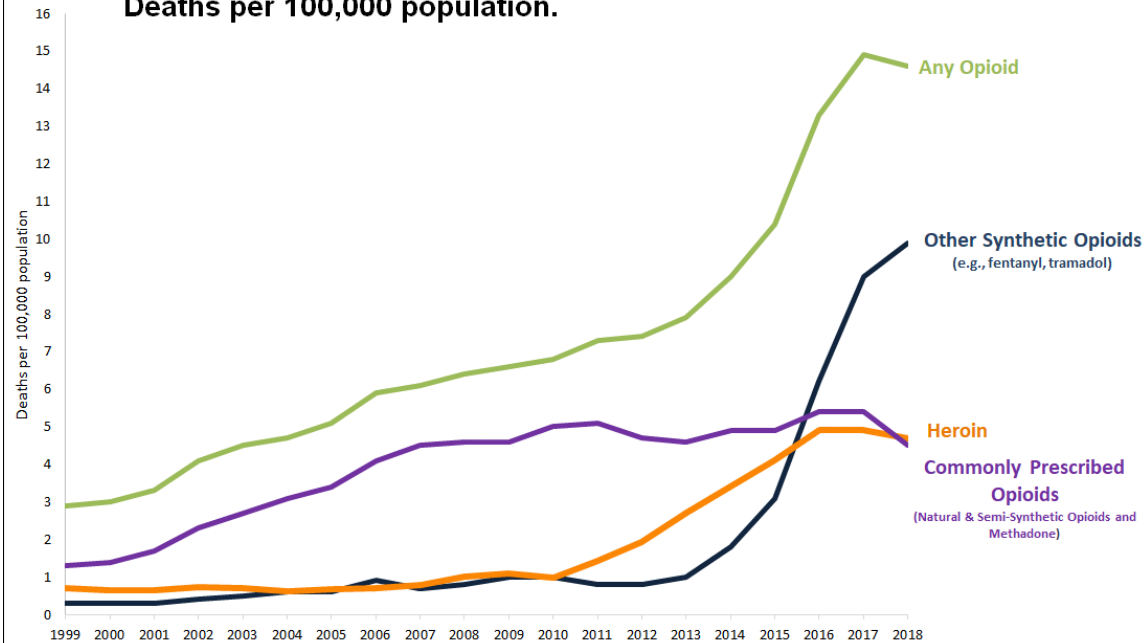
The U.S. Opioid Epidemic and Resulting Pressures on Health Care Providers...

**Mortality by Cause, White non-Hispanics
Ages 45–54**



Source: Case A, Deaton A. Rising midlife morbidity and mortality, US whites. *Proceedings of the National Academy of Sciences*. Dec 2015; 112 (49) 15078-15083

Overdose Death Rates Involving Opioids, by Type, United States, 1999-2018
Deaths per 100,000 population.

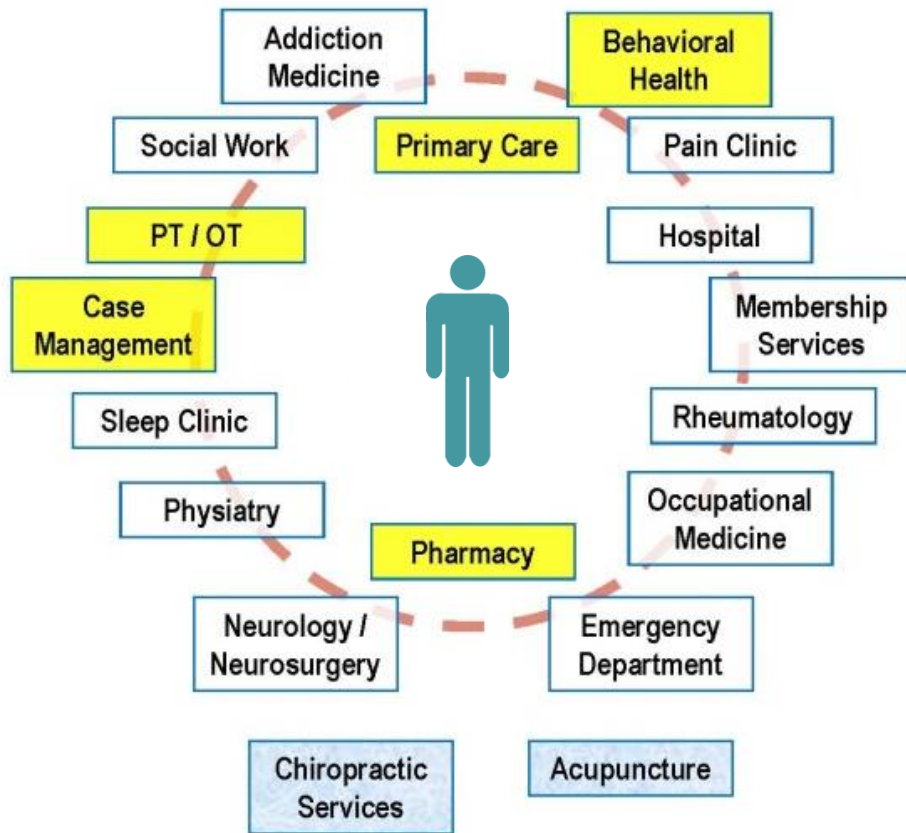


The “Ask” from Kaiser Permanente Clinical and Health Plan Leadership...

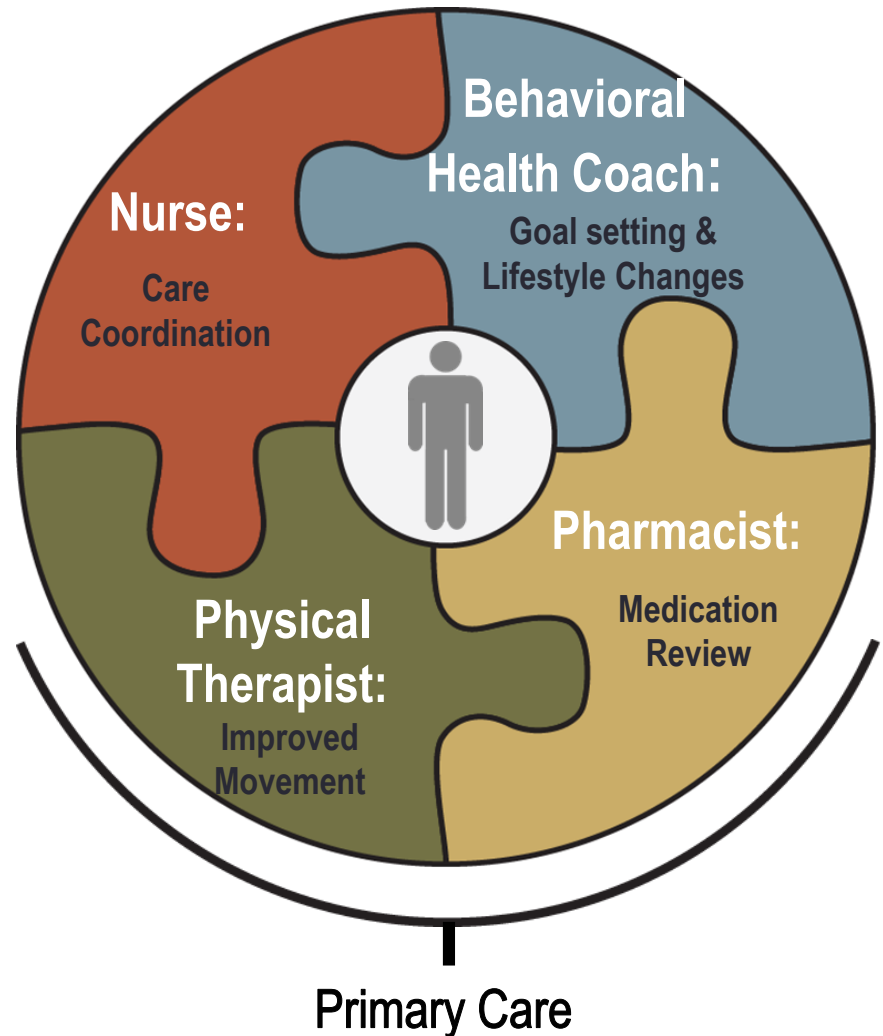
How do we keep our primary
care providers from burning out
and leaving the health care
system?

What do we do with the
patients with complex pain who
“belong to everyone and no
one”?

Pain Management in Usual Care



Interdisciplinary Pain Management Embedded in Primary Care



PPACT Overview

AIM: Integrate interdisciplinary services into primary care to help patients adopt cognitive behavioral therapy (CBT) based self-management skills to:

- Manage chronic pain (decrease pain severity / improve functioning)
 - Limit use of opioid medication
 - Identify exacerbating factors amenable to treatment

Focus on feasibility and sustainability

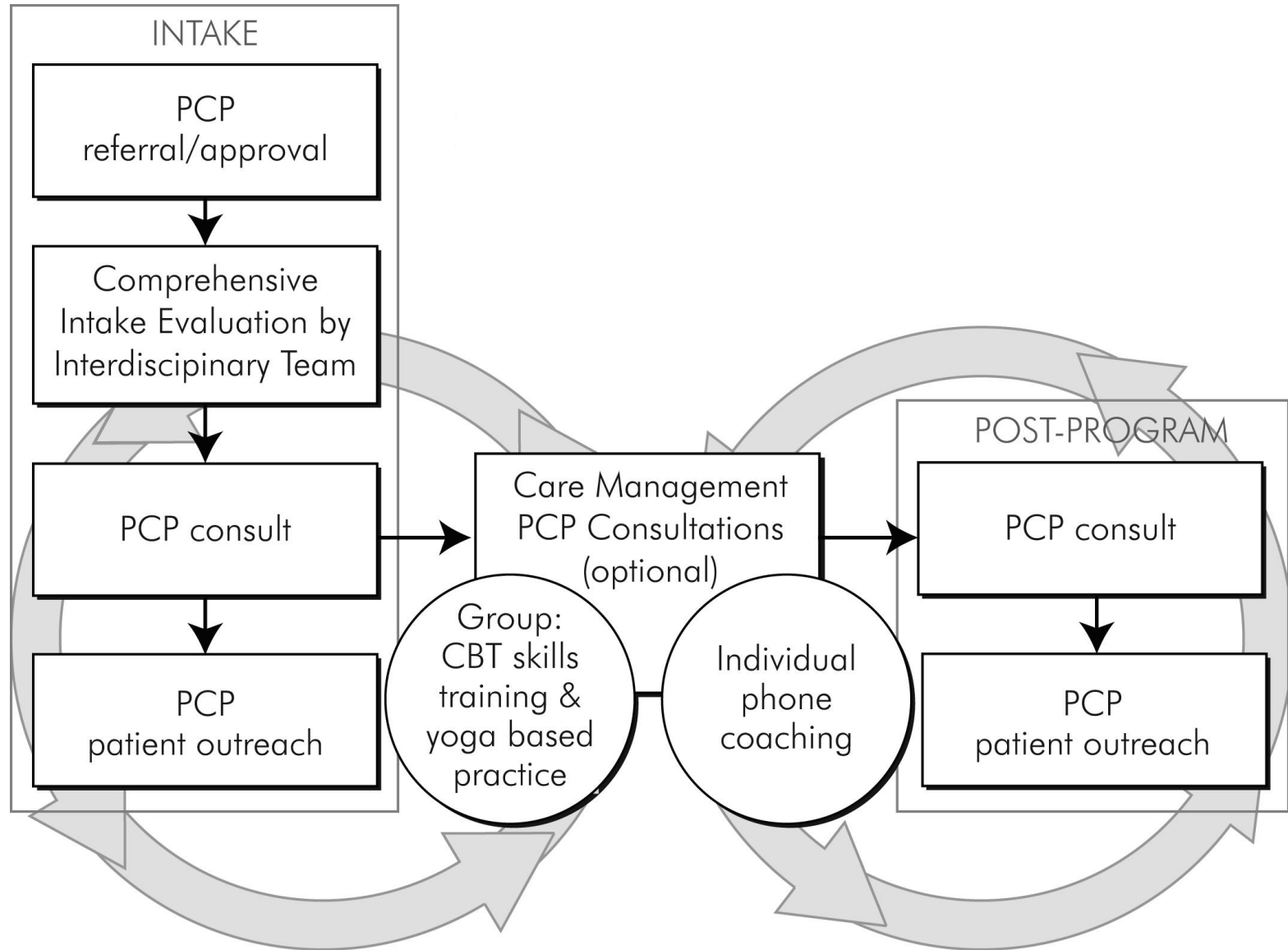
DESIGN: Cluster (PCP)-randomized PCT (106 clusters, 273 PCPs, 850 patients)

SETTINGS: KP Georgia, KP Hawaii, KP Northwest

ELIGIBILITY: Mixed chronic pain conditions, long-term opioid tx (prioritizing ≥ 90 MME, benzodiazepine co-use, high utilizers [≥ 12 visits in 3 months])

INTERVENTION: Core 12-week CBT + yoga-based adapted movement groups led by behavioral specialist / nurse case manager, 2 physical therapy patient consultations (intake & mid-treatment), pharmacist medication review; PCP support

PPACT Intervention Overview



PPACT Outcomes

Patient-Reported Outcomes (PROs)		
PEG(S)	Primary	Study assessment
Roland Morris Disability Questionnaire (RMDQ)	Secondary	Study assessment
Patient satisfaction (Pain Services, Primary Care)	Secondary	Study assessment
Medication-Related Outcomes		
Opioids dispensed	Secondary	EHR
Benzodiazepines dispensed	Secondary	EHR
Outcomes Related to Cost Analyses		
EQ-5D-5L	Secondary	Study survey
Ambulatory care service use	Secondary	EHR
Telephone or email encounters	Secondary	EHR
Inpatient care	Secondary	EHR
Medications dispensed	Secondary	EHR

Getting to Go: Developing the Necessary Infrastructure and Responding to Patient Experience

What does it take to collect Patient Reported Outcome (PRO) data within routine clinical workflow?

- Opioid therapy plans (OTP) required for patients on long-term opioids
- BPI administration specifies semi-annually or quarterly depending on risk of opioid use disorder
- Panel support tool reminds clinicians of care gaps, included needed actions for OTP care plan
- 12-item BPI resisted by clinicians (too long, focused on pain intensity)
- Shifted national KP EHR-embedded standard to PEG(S) (Pain Intensity and Interference with Enjoyment of Life, General Activity and Sleep)

PST - PATIENT

Print Preview

DM	CVD	CHF	HTN
Y			
CKD	Asth		Gap
	Y		8

Consider Dx refresh: Address condition during an office encounter and enter dx code in HealthConnect during 2011. If Dx is no longer active, click X? to exclude it.
X2 205.01 ACUTE MYELOID LEUKEMIA IN REMISSION Source: KPHC Date: 12/11/09

Utilization Profile
 Last Discharge: 10/27/08
 MYALGIA AND MYOSITIS NOS
 Last ER Visit:
Preventive Care
 Last Flu Date:
 Last H1N1 Date:
 Last Pnuemo: 7/22/08
 Last Td:
 Last Tdap: 7/22/08
 Last Mamm: 12/20/10
 Last Pap: 5/19/10
 Last Flex Sig: 5/6/08

Opiate Therapy Plan
 OTP on PL: 2/22/10
 Last APAP dispense:
 Last OTP order:
 Last Brief Pain Inventory: 8/29/11
 Last PCP visit w PAIN Dx:
 Last urine drug test: 1/13/11

Panel Support Tool Caregaps:

Therapeutic Care Gaps:
 Statin - START at min.Simva 40. Last LDL 224 24-NOV-10 Possible interaction:

Chronic Condition Monitoring Care Gaps:
 OTP order REQUIRED by current PCP
 Qtrly pain Dx DUE with PCP ofc visit, Last Visit On:
 OTP yellow/red: QTRLY Urine Drug Screening DUE
 DM eye screen OVERDUE, previous 24 months findings unknown
 HBA1C DUE SOON Last: 7.1 05-APR-11.

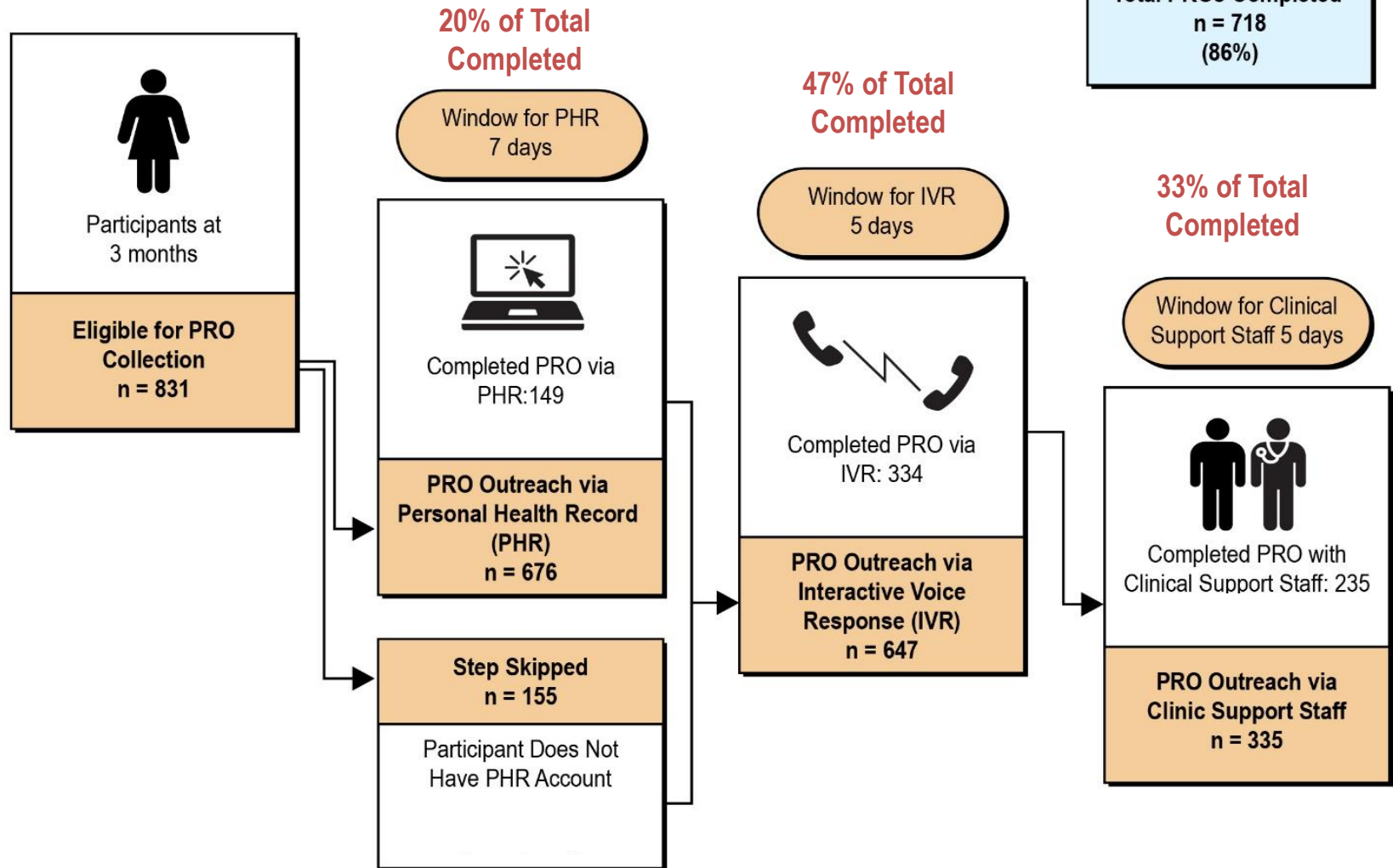
Preventive Care Gaps:
 Active Tobacco Use: Advise quitting today

Ob/Gyn: REED, SANDRA
Ob/Gyn Care Gaps:
 COTEST OVERDUE. Last result: PAP N / EC- 19-MAY-10. (no endocervical cells)

** LDL	224	11/24/10
HDL	56.0	11/24/10
TRI	212	5/6/08
CHOL	297	11/24/10
** A1C	7.1	4/5/11
FBG	71	4/23/10
ALT	28	4/23/10
** CRE	0.8	4/5/11
BUN	19	4/5/11
** GFR	98.0	4/5/11
** ALB/CRE	24	10/8/10
** PRO/CRE		
HGB	13.6	9/29/10
HCT	41.5	9/29/10
NA	139.0	4/5/11
K	4.1	4/5/11
TSH	2.94	8/29/11
** PSA		

**Hover over the result to see trended results if available

What it really takes to collect PRO data in routine clinical care:



The health care experience of patients with chronic pain – aligning study approach and expectations

Patient experiences with long-term opioid treatment and PCPs

- Report debilitating physical side effects, significant emotional distress, negative impact on patient/provider relationship
- YET, often positive appraisal of PCP despite low satisfaction with pain treatment
- What patients hope from their PCP?:
 - Maintaining communication, taking time
 - Having a trusted access point to comprehensive pain care
 - Providing an honest assessment of benefits of such care

Addressing ambivalence / addressing retention

	BEING IN THE STUDY	NOT BEING IN THE STUDY
PROS	<ul style="list-style-type: none">• New knowledge• Support & validation• Hope for improvement• Impact on research & clinical practice	<ul style="list-style-type: none">• Cost savings (Time & money)• No pressure to change• Discomfort avoided• Hassle-free
CONS	<ul style="list-style-type: none">• Randomization process• Expectations• Time commitment• Accountability	<ul style="list-style-type: none">• Missed opportunity• Status quo/No change• No contribution• Health care management challenges

Enhanced enrollment process improved intervention adherence and data collection (without bias) but resulted in fewer enrolled patients

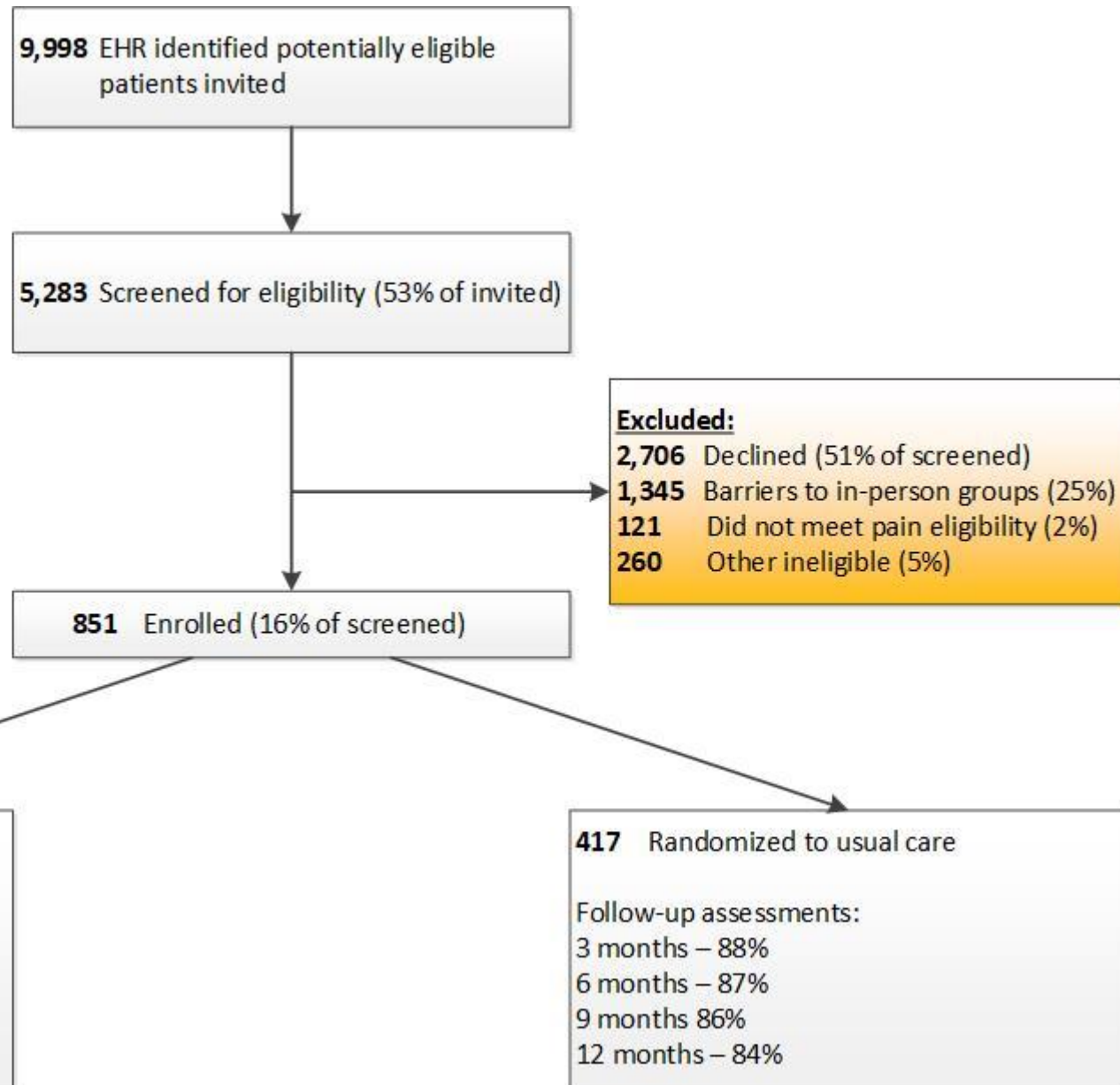
Mayhew M, et al. *Contemp Clin Trials Commun*. 2020 Jan 21;17:100527.

Gruß I, et al. *J Gen Intern Med*. 2020 Jan;35(1):190-197.

Gruß I, et al. *Int J Drug Policy*. 2019 Dec;74:62-68.

Main Study Outcomes

Participant Flow



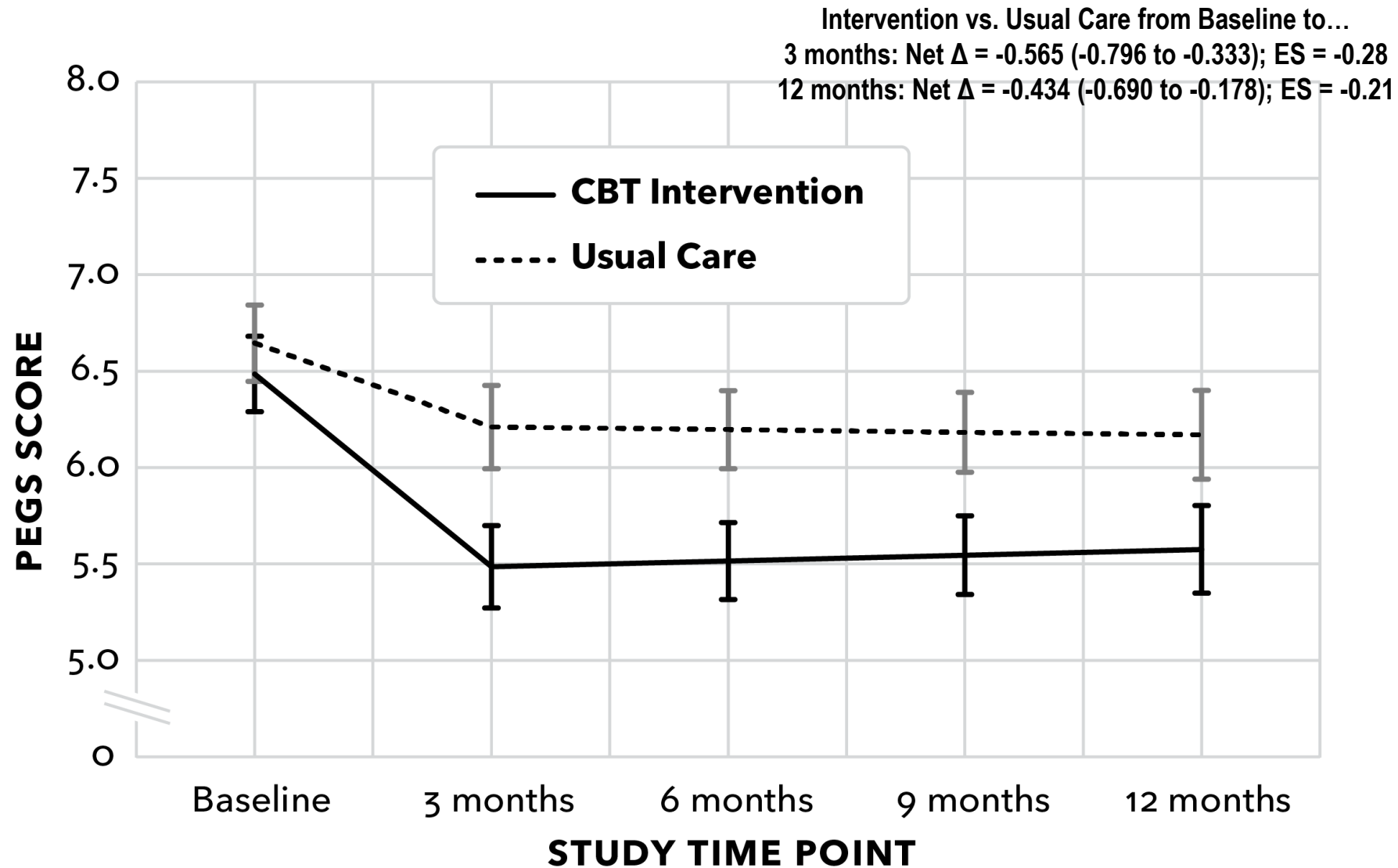
Select Patient Characteristics at Baseline* (n=850)

	Mean (SD) or N (%)
Age	60.3 (12.2)
Female	573 (67.4%)
Black or African American	110 (12.9%)
Asian or Native Hawaiian / Pacific Islander	46 (5.4%)
Receives disability benefits	215 (25.3%)
≥ 2 chronic medical conditions (diabetes, cardiovascular disorders, hypertension, chronic obstructive pulmonary disease)	304 (35.8%)
Median nonmalignant chronic pain types** (IQR)	4.0 (3.0-5.0)
Any mental health diagnosis	374 (44.0%)
Median average dose of opioids (IQR), MME	29.6 (16.0-62.0)
90 or higher morphine equivalent daily opioid dose, MME	155 (18.2%)
Benzodiazepines dispensed	227 (26.7%)
High use of primary care services (≥ 12 contacts in 3-month period)	42 (4.9%)

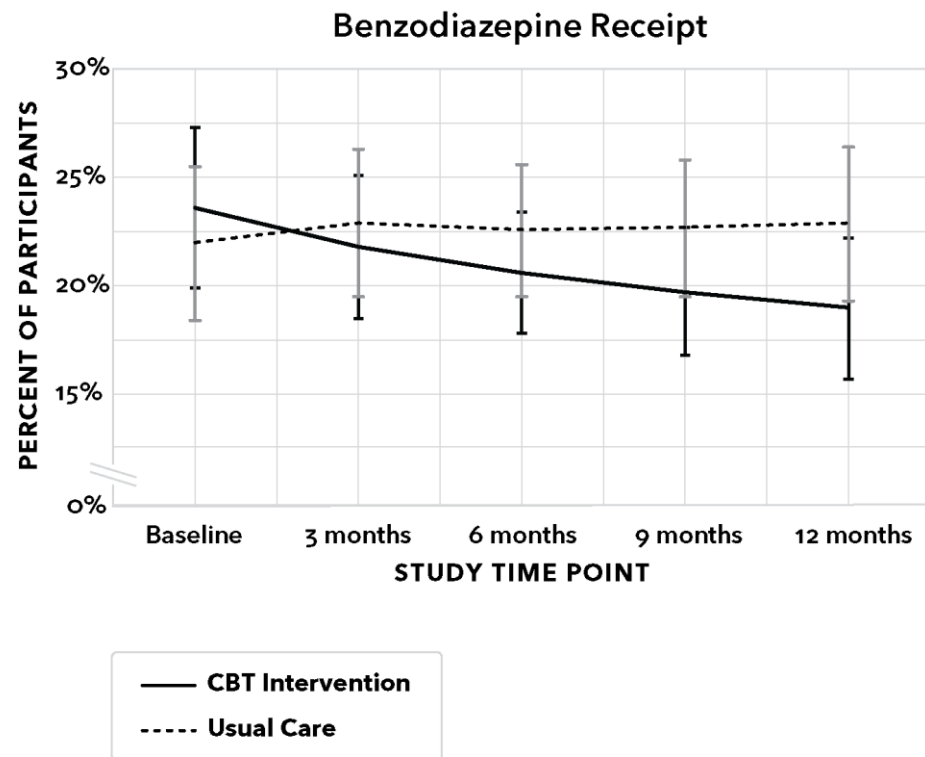
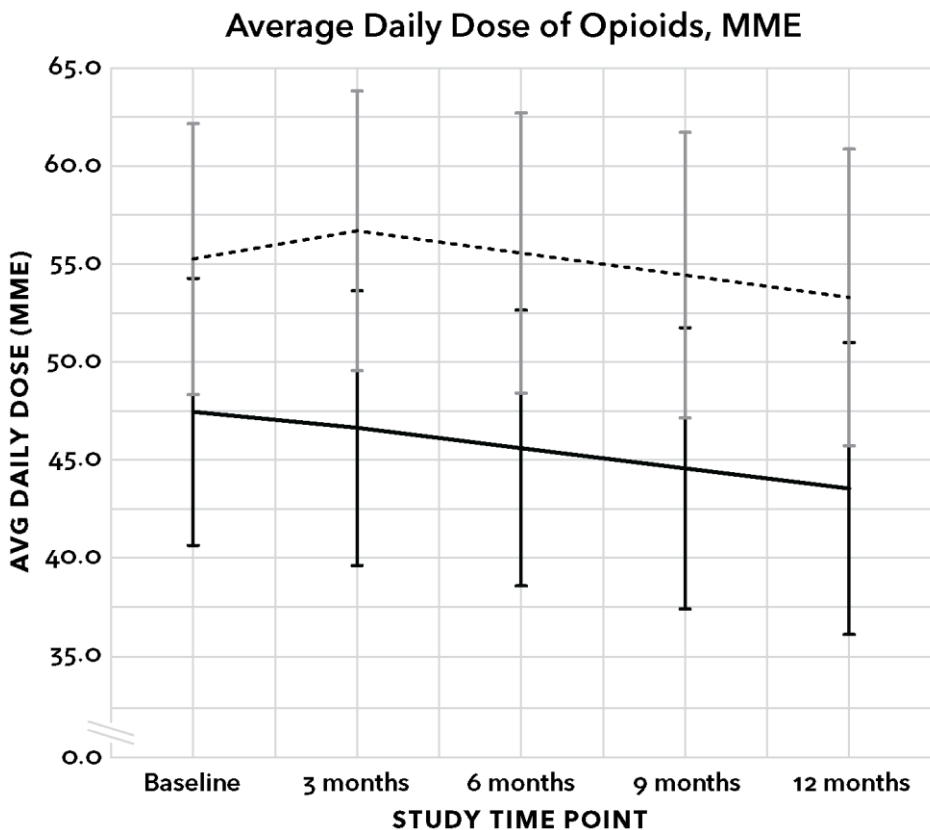
* From KP EHR in 6 months preceding enrollment in the trial

**Pain types (by prevalence/ ≥ 20% of sample) arthritis/join/extremity, back/neck, general widespread, abdominal/bowel, neuropathy, headache, fibromyalgia, musculoskeletal chest pain (Mayhew et al, J Pain 2019)

Primary Outcome (PEGS) by Treatment Group



Medication Outcomes by Treatment Group



Other Secondary Outcomes

Outcome	Baseline to Post-Tx Net Δ (95% CI)	Baseline to 12 months Net Δ (95% CI)	Effect Size (Post-Tx, 12 mo.)
Pain-Related			
PEG	-0.607 (-0.846 to -0.369)	-0.434 (-0.695 to -0.172)	-0.29, -0.21
RMDQ	-0.043 (-0.064 to -0.021)	-0.060 (-0.084 to -0.035)	-0.20, -0.28
Tx Responder ($\geq 30\%$ PEGS improv)	RR = 1.92 (1.48 to 2.50) 26.1% (Int) vs. 11.5% (UC)	RR = 1.42 (1.11 to 1.81) 25.4% (Int) vs. 16.8%(UC)	N/A
Patient Satisfaction			
Primary care services	0.230 (0.053 to 0.406)	N/A	0.21
Pain services	0.336 (0.129 to 0.543)	N/A	0.27

(Why) Does It Matter?

Modest effect size of pain-related outcomes (0.20-0.29) but:

- Comparable to other nonpharmacological trials
- Focused on patients deemed highest need by PCPs:
 - Receiving long-term opioid treatment
 - High multimorbidity (medical and mental health) and disability (25%)
 - Not limited to one pain type
- Delivered by frontline staff (nurses, behavioral specialists) w/o prior pain expertise
- Effect sustained well past active 3-month treatment
 - Longer duration of effect and similar magnitude compared to opioid and nonopioid medication effects
- Favorable safety profile

Cost-Effectiveness Analyses

PPACT Intervention Cost per Person

- Payer / health plan perspective
- Cost components include both labor and non-labor inputs (e.g., patient identification, patient materials, intervention delivery, training)

‘As-Delivered’ Cost: \$2,574

- Removed costs incurred because intervention is part of a research study (e.g., IRB, randomization)

Replication Cost: \$2,145

- Assumes intervention is to be implemented in health plan as part of clinical care

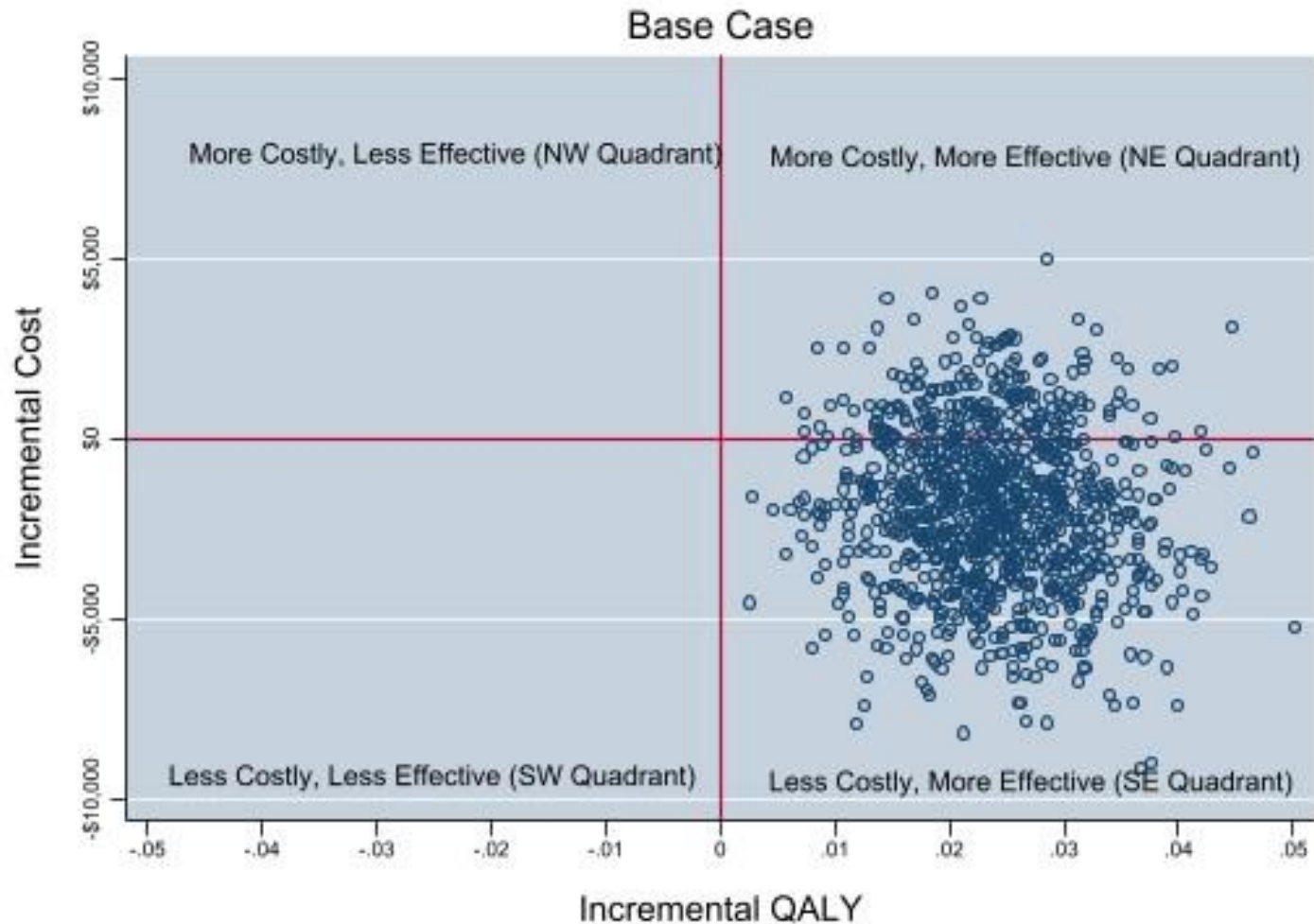
Incremental Cost-Effectiveness Ratio (ICER)

- Cost per Quality Adjusted Life Year (QALY) Gained Based on Intervention Replication Costs and Total Medical Care Costs

	Cost	Incremental Cost	QALY	Incremental QALY	ICER
Usual Care	\$25,506		0.5459		
Intervention	\$23,665	-\$1,841	0.5695	0.0236	Intervention Dominant

Smith DH, O'Keefe-Rosetti M, Leo MC, Mayhew M, Benes L, Bonifay A, Deyo RA, Elder CR, Keefe FJ, McMullen C, Owen-Smith A, Trinacty CM, Vollmer WM, DeBar L. Economic evaluation: A randomized pragmatic trial of a primary care-based cognitive behavioral intervention for adults receiving long-term opioids for chronic pain. Medical Care, in press

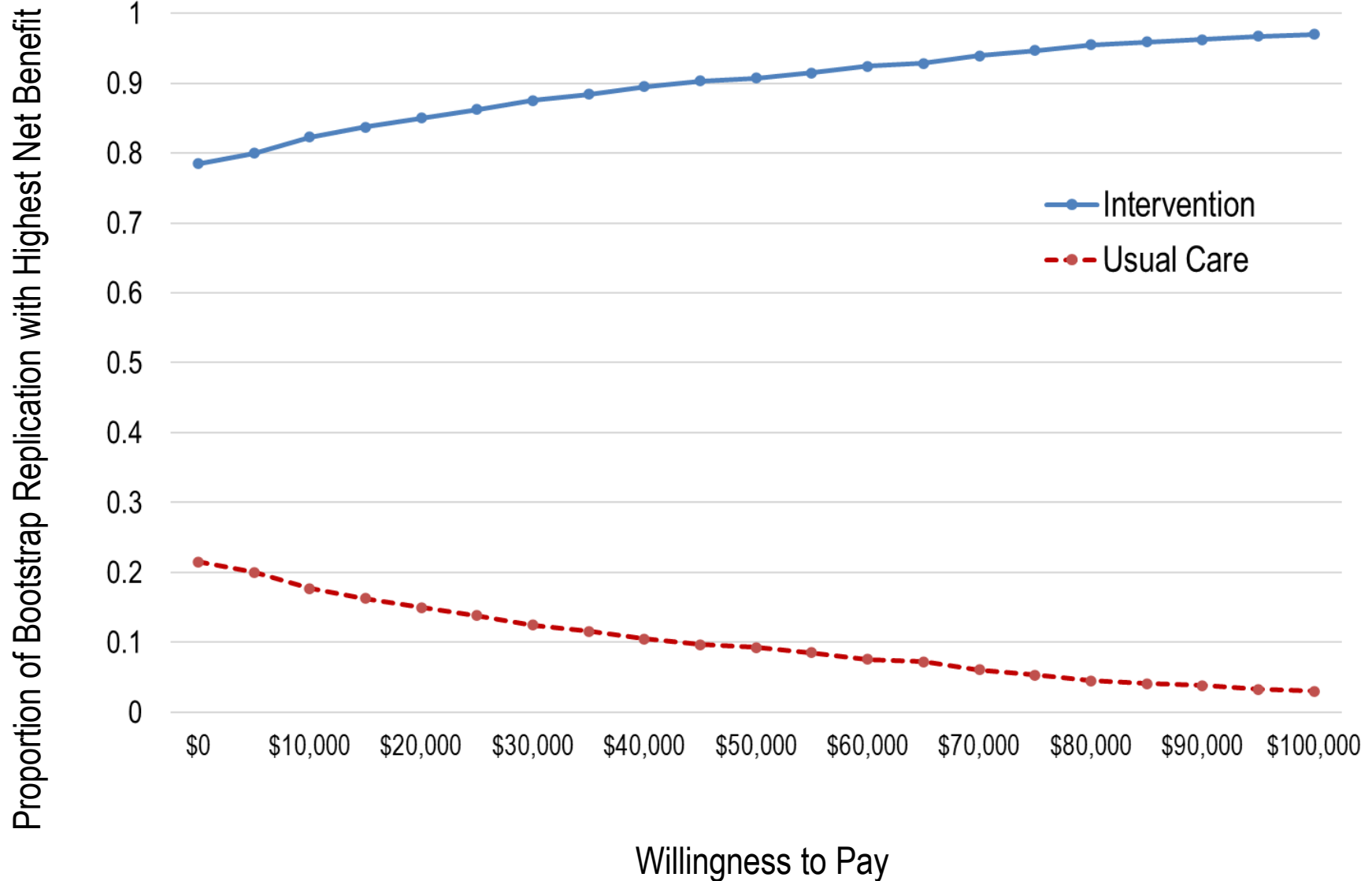
Incremental Cost-Effectiveness Plane*



* Cost per QALY Gained Based on Intervention Replication Costs and Total Medical Care Costs

Smith DH, O'Keefe-Rosetti M, Leo MC, Mayhew M, Benes L, Bonifay A, Deyo RA, Elder CR, Keefe FJ, McMullen C, Owen-Smith A, Trinacty CM, Vollmer WM, DeBar L. Economic evaluation: A randomized pragmatic trial of a primary care-based cognitive behavioral intervention for adults receiving long-term opioids for chronic pain. Medical Care, in press

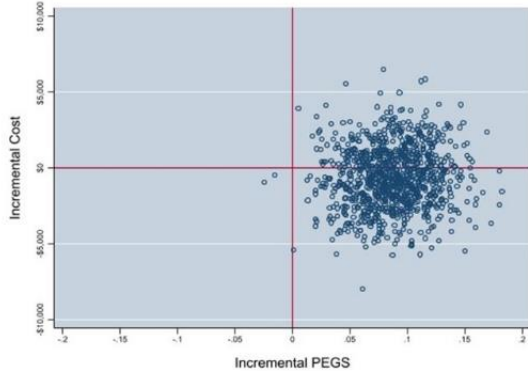
Cost-Effectiveness Acceptability Curve



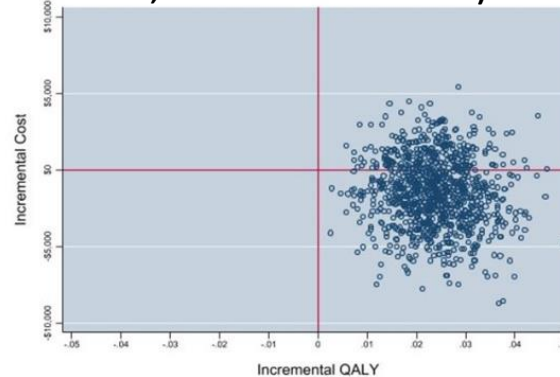
Smith DH, O'Keefe-Rosetti M, Leo MC, Mayhew M, Benes L, Bonifay A, Deyo RA, Elder CR, Keefe FJ, McMullen C, Owen-Smith A, Trinacty CM, Vollmer WM, DeBar L. Economic evaluation: A randomized pragmatic trial of a primary care-based cognitive behavioral intervention for adults receiving long-term opioids for chronic pain. Medical Care, in press

Robustness of Cost Findings

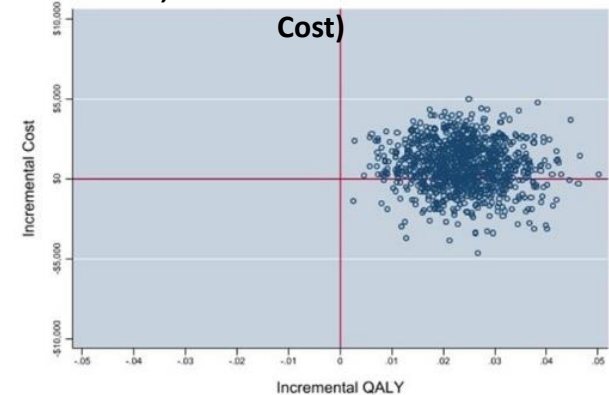
Treatment Responder (Intervention Replication Cost, Total Medical Care Cost)



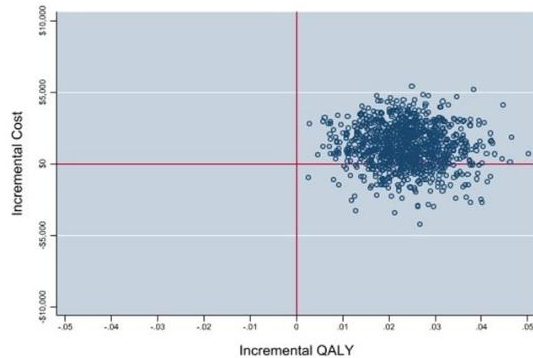
QALY (Intervention As-Delivered Cost, Total Medical Care Cost)



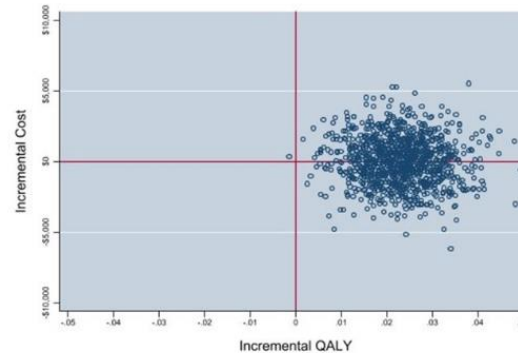
QALY (Intervention Replication Cost, Pain-related Medical Care Cost)



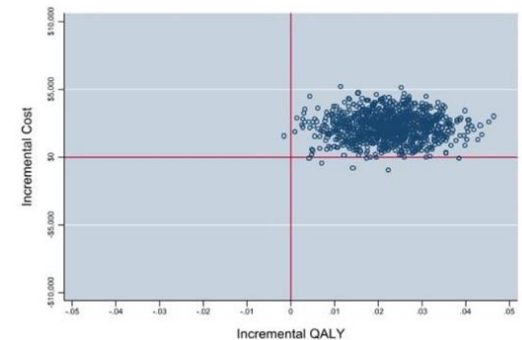
QALY (Intervention As-Delivered Cost, Pain-Related Medical Care Cost)



QALY - Baseline Cost Outliers Excluded (Intervention Replication Cost, Total Medical Care Cost)



QALY - Follow-up Cost Outliers Excluded (Intervention Replication Cost, Total Medical Care Cost)



Smith DH, O'Keefe-Rosetti M, Leo MC, Mayhew M, Benes L, Bonifay A, Deyo RA, Elder CR, Keefe FJ, McMullen C, Owen-Smith A, Trinacty CM, Vollmer WM, DeBar L. Economic evaluation: A randomized pragmatic trial of a primary care-based cognitive behavioral intervention for adults receiving long-term opioids for chronic pain. Medical Care, in press

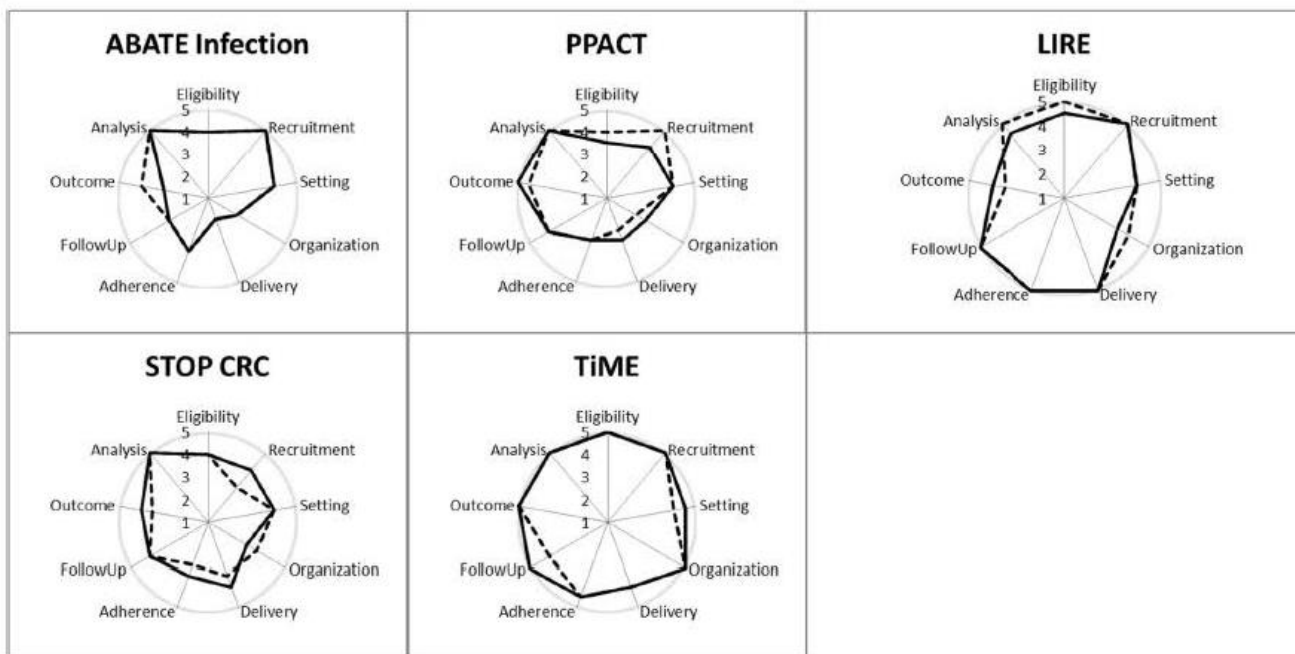
Implementation, Sustainability & Next Steps



Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Trials

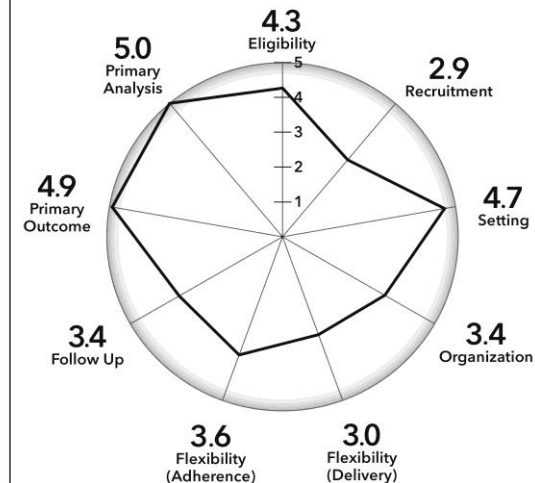
Karin E. Johnson^{1†}, Gila Neta^{2*†}, Laura M. Dember³, Gloria D. Coronado⁴, Jerry Suls², David A. Chambers², Sean Rundell⁵, David H. Smith⁴, Benmei Liu², Stephen Taplin², Catherine M. Stoney⁶, Margaret M. Farrell² and Russell E. Glasgow⁷



--- Planning phase
— Implementation phase

Fig. 1 PRECIS wheels as assessed by raters for each of the five trials at two time points. Ratings on a 1 – 5 scale indicate more explanatory to more pragmatic ratings. The dashed line indicates the planning phase. The solid line indicates the implementation phase

Figure 3. PPACT PRECIS-2 Scoring



DeBar LL, et al. *Contemporary Clinical Trials*. 2018 Apr;67:91-99.

Sustaining PPACT

KPNW (and WA) – Uptake of shorter variant

- 4 sessions delivered by primary care-integrated behavioral health providers
- Challenge: Adequate therapist training / support

KP Hawaii – Malama Ola adaptation

- 6-week variant with whole health / wellness focus housed Physical Rehabilitation Dept.

KP Georgia – No direct uptake

- Regional focus on restructuring at study conclusion



Broad psychoeducation approaches with brief / limited contacts are common

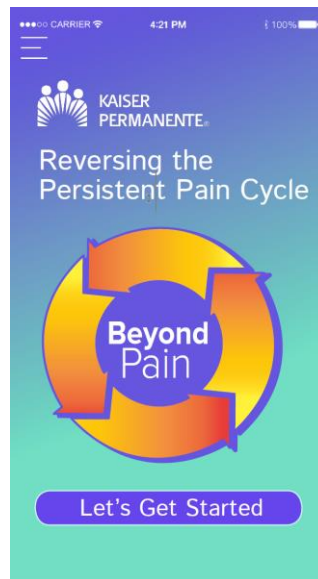


HEAL NIA-funded PCT comparing
2 telehealth CBT interventions
among 2,300+ (50% rural) with
high impact chronic pain
*Staff centralization, for whom does
live touch matter?*



HEAL NIMH-funded Zelen RCT to
evaluate primary care-based collaborative
care for OUD, depression (& chronic pain)
*Addressing stigma, systematic approach
to treating multiple chronic conditions
(addiction/mental health/pain)*

Building on PPACT



KP-funded App designed to
connect patients with behavioral
skills training on the front-end of
health care journey

PPACT Summary

CBT-focused multidisciplinary primary care-based treatment showed a modest but sustained effect on functioning among patients with chronic pain on long-term opioid treatment

Intervention cost offset by savings in health care utilization; robust across a range of assumptions

Even integrated delivery systems are not “ready” to implement and sustain such programs

QUESTIONS?
