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

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Supported by NIH Common Fund within the Health Care Systems Research Collaboratory (U24AT009676) and NINDS (UH2AT007788 and UH3NS088731)
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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.

- Low back pain #1
- Musculoskeletal disorders #3
- Neck pain #4
- Osteoarthritis #9
- Migraine #14
- COPD #6
- Diabetes #8
- Asthma #10
- Dementia #12
- Alcoholism #13
- Ischemic heart disease #16
- Stroke #17
- Hearing loss #19
- Chronic kidney disease #22
- Road injury #26
- Vision loss #27
- Epilepsy #30
- Major depressive disorder #2
- Anxiety disorders #5

Millions of YLDs

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

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

- Addiction Medicine
- Social Work
- PT / OT
- Case Management
- Sleep Clinic
- Physiatry
- Pharmacy
- Neurology / Neurosurgery
- Chiropractic Services
- Behavioral Health
- Primary Care
- Pain Clinic
- Hospital
- Membership Services
- Rheumatology
- Occupational Medicine
- Emergency Department
- Acupuncture

Interdisciplinary Pain Management Embedded in Primary Care

- Behavioral Health Coach:
  - Goal setting & Lifestyle Changes
- Nurse:
  - Care Coordination
- Pharmacist:
  - Medication Review
- Physical Therapist:
  - Improved Movement
- 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

INTAKE

PCP referral/approval

Comprehensive Intake Evaluation by Interdisciplinary Team

PCP consult

PCP patient outreach

Care Management PCP Consultations (optional)

Group: CBT skills training & yoga based practice

Individual phone coaching

POST-PROGRAM

PCP consult

PCP patient outreach
## PPACT Outcomes

<table>
<thead>
<tr>
<th>Patient-Reported Outcomes (PROs)</th>
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<tbody>
<tr>
<td>PEG(S)</td>
<td>Primary</td>
</tr>
<tr>
<td>Roland Morris Disability Questionnaire (RMDQ)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Patient satisfaction (Pain Services, Primary Care)</td>
<td>Secondary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication-Related Outcomes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids dispensed</td>
<td>Secondary</td>
</tr>
<tr>
<td>Benzodiazepines dispensed</td>
<td>Secondary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes Related to Cost Analyses</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5D-5L</td>
<td>Secondary</td>
</tr>
<tr>
<td>Ambulatory care service use</td>
<td>Secondary</td>
</tr>
<tr>
<td>Telephone or email encounters</td>
<td>Secondary</td>
</tr>
<tr>
<td>Inpatient care</td>
<td>Secondary</td>
</tr>
<tr>
<td>Medications dispensed</td>
<td>Secondary</td>
</tr>
</tbody>
</table>
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)
What it **really** takes to collect PRO data in routine clinical care:

- **Eligible for PRO Collection** n = 831
- **Participants at 3 months**
- **20% of Total Completed**
  - Window for PHR 7 days
  - Completed PRO via PHR: 149
  - PRO Outreach via Personal Health Record (PHR) n = 676
  - Step Skipped n = 155
  - Participant Does Not Have PHR Account
- **47% of Total Completed**
  - Window for IVR 5 days
  - Completed PRO via IVR: 334
  - PRO Outreach via Interactive Voice Response (IVR) n = 647
- **33% of Total Completed**
  - Window for Clinical Support Staff 5 days
  - Completed PRO with Clinical Support Staff: 235
  - PRO Outreach via Clinic Support Staff n = 335

OVERALL: Total PROs Completed n = 718 (86%)

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

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEING IN THE STUDY</td>
<td>NOT BEING IN THE STUDY</td>
</tr>
<tr>
<td>New knowledge</td>
<td>Cost savings (Time &amp; money)</td>
</tr>
<tr>
<td>Support &amp; validation</td>
<td>No pressure to change</td>
</tr>
<tr>
<td>Hope for improvement</td>
<td>Discomfort avoided</td>
</tr>
<tr>
<td>Impact on research &amp; clinical practice</td>
<td>Hassle-free</td>
</tr>
<tr>
<td>Randomization process</td>
<td>Missed opportunity</td>
</tr>
<tr>
<td>Expectations</td>
<td>Status quo/No change</td>
</tr>
<tr>
<td>Time commitment</td>
<td>No contribution</td>
</tr>
<tr>
<td>Accountability</td>
<td>Health care management challenges</td>
</tr>
</tbody>
</table>

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

Main Study Outcomes
Participant Flow

9,998 EHR identified potentially eligible patients invited

5,283 Screened for eligibility (53% of invited)

Excluded:
- 2,706 Declined (51% of screened)
- 1,345 Barriers to in-person groups (25%)
- 121 Did not meet pain eligibility (2%)
- 260 Other ineligible (5%)

851 Enrolled (16% of screened)

433 Randomized to PPACT intervention
- Follow-up assessments:
  - 3 months – 86%
  - 6 months – 88%
  - 9 months 85%
  - 12 months – 84%

417 Randomized to usual care
- Follow-up assessments:
  - 3 months – 88%
  - 6 months – 87%
  - 9 months 86%
  - 12 months – 84%
## Select Patient Characteristics at Baseline* (n=850)

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

* 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

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

(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

<table>
<thead>
<tr>
<th></th>
<th>Cost</th>
<th>Incremental Cost</th>
<th>QALY</th>
<th>Incremental QALY</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual Care</td>
<td>$25,506</td>
<td></td>
<td>0.5459</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>$23,665</td>
<td>-$1,841</td>
<td>0.5695</td>
<td>0.0236</td>
<td>Intervention Dominant</td>
</tr>
</tbody>
</table>

Incremental Cost-Effectiveness Plane*

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

Cost-Effectiveness Acceptability Curve

Proportion of Bootstrap Replication with Highest Net Benefit

Willingness to Pay

Robustness of Cost Findings

Implementation, Sustainability & Next Steps
Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Karin E. Johnson1†, Gila Neta2*, Laura M. Dember3, Gloria D. Coronado4, Jerry Suls5, David A. Chambers3, Sean Rundell5, David H. Smith4, Benmei Liu6, Stephen Taplin7, Catherine M. Stoney7, Margaret M. Farrell7 and Russell E. Glasgow7

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.


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 in Integrated 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?