

Equitable Primary Care for Pain Care (Equip-PC) Project Kick-off Meeting

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Funding source: NIH HEAL

Date: September 17, 2025



Team Introductions



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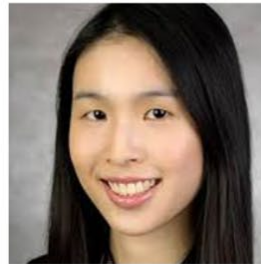
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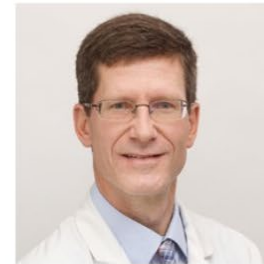
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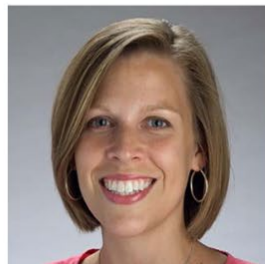
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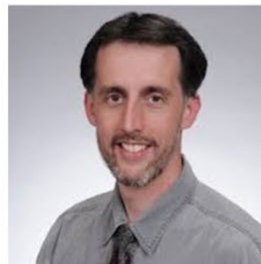
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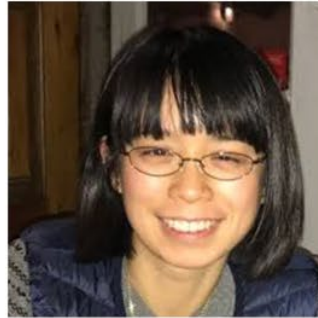


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Team Introductions



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Background and Rationale

- **Chronic pain (CP)** affects **25% of the U.S. population**, with nearly 50% of those individuals seeking treatment in **primary care** settings.
- **Equitable integrated team-based strategies** for chronic pain treatment within primary care are needed.
- **Cognitive Behavioral Therapy (CBT)** and **exercise therapy (ET)** can specifically target debilitating effects of chronic pain in primary care
- **Disparities** and lack of **PCP training** and **time** complicate delivery
- **Digital behavioral therapeutics (DTx)** can help extend and augment access to care

Project Overview

- *We aim to incorporate chronic pain treatment into multidisciplinary coordinated care in existing Integrated Behavioral Health (IBH) primary care teams to equitably improve patient outcomes.*
- *Our approach trains Behavioral Health Providers (BHPs) in chronic pain-specific Cognitive-Behavioral Therapy (CBT) and Exercise Therapy (ET) treatments, integrates evidence-based Digital Therapeutic (DTx) apps into care, and strengthens IBH capacity across practices.*

UH3 EquiP PC Study Aims

Aim 1: To determine effectiveness of the adapted 1) IBH-PC Toolkit + apps vs. 2) IBC-PC Toolkit only vs. 3) treatment as usual for improving pain interference and level of integration of IBH

Aim 2: Evaluate implementation of the interventions:

IBH-PC Toolkit + apps and IBH Toolkit only

Aim 3: Evaluate equity in access and outcomes of chronic pain care in primary care

Project Overview

- Study design:
 - Pragmatic, multi-site, 3-arm cluster randomized controlled trial (RCT)
- Frameworks:
 - Guided by **PRISM** - Pragmatic, Robust Implementation and Sustainability Model
 - Evaluated using **RE-AIM** - Reach, Effectiveness, Adooption, Implementation, and Maintenance
- Intervention:
 - Adaption of the **IBH-PC toolkit** (Integrated Behavioral Health in Primary Care) tailored **for chronic pain management**
 - Integration of **digital therapeutic apps** for home-based support

Study Design: Pragmatic Multi-site Cluster RCT

- **Three Arms:**

- **Arm 1:** Treatment as usual
- **Arm 2:** IBH-PC Toolkit only
- **Arm 3:** IBH-PC Toolkit + digital apps

- **Sites and populations:**

- **27 primary care practices** across 3+ health care systems (HCS)
- **75 patients per practice, N = 2,030** meeting the following criteria:
 - Age 18 or older
 - Chronic non-cancer pain currently and for ≥ 3 months
 - ≥ 2 primary care visits in the last 12 months at time of recruitment

Intervention – IBH-PC Toolkit

- Integrated Behavioral Health in Primary Care (IBH-PC) Toolkit supports complex change to improve behavioral health integration
 - 12- month practice-centric intervention
 - Adapted version of the existing IBH-PC Toolkit:
 - (1) structured, team-based, ***practice redesign*** and implementation set of workbooks to guide a quality improvement (QI) team
 - (2) ***online educational curriculum*** that will be streamlined to include online trainings for BHPs that teach Cognitive Behavioral Therapy (CBT) and Exercise Therapy (ET) treatment skills adapted from the pilot tested CBT 1-2-3 training
 - (3) ***remote QI coaching / practice facilitation services***, providing practice-specific support for a QI team and facilitator by experts in IBH, QI and workflow redesign
 - (4) ***online learning community*** that will be adapted to support BHPs in learning and sustaining CBT CP skills

Intervention – Digital Therapeutics

- **FDA approved mobile apps** that address chronic pain and/or related issues
- **Training for BHPs** to offer digital therapeutics (DTx) apps
- Apps that address both CBT and ET will be chosen from an up-to-date review of available DTx apps

Recruitment – Primary Care Clinics

- 9 Primary care clinics from 3 recruitment sites (N=27): 1) University of Washington Medicine Primary Care (UWMPC), 2) Duke Primary Care Research Consortium (PCRC), and 3) American Academy of Family Physician's National Research Network (NRN)
- 0.5 FTE Behavioral Health Provider present / part of the clinic services with shared EHR
- Ability to recruit 75 patients (have at least 375 eligible patients)
- Serve underserved populations (e.g., BIPOC, lower income, rural) who have disparities in access to chronic pain care
- Agree to be randomized and willing to engage the interventions
- Willing to share data and complete governance agreements

Clinic Randomization

- Clinics (n=9) within each of the 3 sites will be randomized equally to 3:3:3 across the 3 arms
- Randomizing clustered by sites will attempt to mediate balancing randomization across size, geography, and type of clinic
- Patients within each clinic will be randomized based on the clinic's randomization

Recruitment - Patients

- 75 from each of the 27 clinics N=2,030
- ≥ 18 years
- Have current chronic non-cancer related pain and clinically significant level of pain interference (PEG ≥ 4) AND ≥ 1 ICD code related to chronic pain condition
- Currently engaged in care at the clinic (≥ 2 visits in last year)
- No dementia
- Not receiving palliative, hospice care or living in a controlled setting
- EHR data will be used to solicit to patients
- eConsent will be used via REDCap

Outcomes

Effectiveness
Outcomes at:

1. Baseline

2. Post intervention

3. Follow-up at 6 mos
(12 months after baseline)

TABLE 5: IMPLEMENTATION OUTCOMES FOR UH3 EQUIP CP STUDY			
PRISM RE-AIM IMPLEMENTATION	OUTCOMES	MEASURE	DATA SOURCE
Reach	Patients approached	Proportion of patients eligible and enrolled	Enrollment data
	Patients treated by BHP and PCP	Proportion of patients seen by BHP and PCP	Patient report / EHR data
Effectiveness & Maintenance	Patient Outcomes		
	Pain interference	PEG	Patient report
	Pain intensity	PEG	Patient report
	Physical function	PROMIS Physical Functioning Short Form 6b	Patient report
	Quality of life	WHOQOL-2	Patient report
	Satisfaction with treatment	PGIC	Patient report
	Substance use screening	TAPS-1	Patient report
	Depression	PHQ-9	Patient report
	Anxiety	GAD-7	Patient report
	BHP Provider Outcomes		
	Self-efficacy treating chronic pain	BHP rating	BHP report
	Practice Outcomes		
	Level of integrated behavioral health	PIP	Practice report
What will persist after the study	Processes and structures changed	Practice champion interview	
Adoption	Practice engagement	Proportion of practices engaged in the study; descriptives of personnel engaged in the toolkit use	Practice characteristics
	Staff/provider engagement	Proportion of BHPs engaged in trainings	BHP training report
	Patient engagement in BHP care and app use	Proportion of patients engaged in BHP and apps	BHP report; Patient report
	Toolkit tactics used	Individual and total tactics used in intervention toolkit	Practice champion interview; practice champion survey; coaching notes
Implementation	Feasibility: intervention toolkit completion rate	Stages completed	Practice champion interview, coaching notes, practice champion survey
	Feasibility: BHP training completion rate	Completion rates for training modules and attendance	Training tracking report
	Fidelity: BHP clinical delivery	Proportion of visits BHP used CBT or ET	BHP report
	Fidelity: BHP delivery of apps	Proportion of patients recommended to use an app	BHP report
	Fidelity: planned vs executed changes	Fidelity practice survey	Practice champion report
	Cost	Time and financial cost estimates of intervention	Practice champion report
	Adaptations: Implementation challenges, adjustments made	Qualitative interview	Practice champion interview

Analytic Plan – Aim 1 Effectiveness

- Linear mixed models with random effect at practice level to compare individual PEG scores post-randomization at 9 months after baseline (post-intervention) between practices that are assigned to different intervention groups
- Intention to treat (ITT) approach
- Individual and practice-level precision variables such as baseline PEG scores will be included in the model, together with indicator variables for the treatment arms
- Treatment effect estimates, two-sided 95% confidence intervals, and the joint significance test of a null treatment effect at 5% significance level will be reported
- Test if the mean PEG score is different between any 2 of the 3 treatment arms, using a conservative 1.7% significance level to correct for multiple comparisons
- For BHP, practice level, and secondary patient outcomes measured at post-intervention, we will use generalized linear mixed models with identity, logit and logarithm links for continuous, binary and count outcomes
- Bonferroni and the Benjamini-Hochberg procedure to correct for multiple comparisons
- Secondary analysis for longitudinally collected outcomes to study the potential change of treatment effects over time
- Missing data: use multiple imputation which is recommended for trials, imputed 10 times and statistical analyses will be repeated on each of the datasets and combined using the Rubin's rule

Analytic Plan – Aim 2 Implementation

- ***Reach***: Proportion of patients who we reach out to, who agree to participate in our study, and who receive services from the behavioral health provider (BHP) or primary care provider.
- ***Effectiveness***. See Aim 1.
- ***Adoption***: 1) compute the proportion of practices we reach out to and proportion who agree to participate, 2) describe the type of personnel at the practices who engage in the toolkit, 3) compute the proportion of BHPs who engage in the trainings, 4) compute the proportion of patients who engage in at least 1 and >1 BHP visit, 5) compute the proportion of patients who use a DTx app that were offered one and describe usage rates of the apps, and 6) describe the type and total tactics used from the Toolkit.
- ***Implementation***: Feasibility related descriptive statistics describing total Toolkit stages completed across practice sites, rates of BHP training completion, rates of BHP use of CBT 1-2-3 skills in visits, and rates of BHP recommending use of DTx apps. Practice changes targeted and completed will be documented and summarized. Implementation costs will be quantified by close estimates of time-effort related to implementing the adapted IBH-PC Toolkit. Descriptions of challenges and adjustments made during implementation will be described.
- ***Maintenance***. Change at 6-months post-intervention in our effectiveness outcomes and description of which changes practices made to IBH that remained in place 6-months post-intervention.
- ***Key informant interview analyses***. Interview transcripts will be analyzed using content analysis approach

Analytic Plan – Aim 3 Equity in Access and Outcomes

Variations in rates of access to BHP care and engagement in treatment and heterogeneity of treatment effect across outcomes for subgroups of patients:

- **Examine demographic data to determine equity in access and rates of access to CP care by BHPs in PC.** T-tests or ANOVA will be used to assess whether the access is the same across subgroups.
- **Analyze the outcomes data to determine equity in CP care by BHPs by examining heterogeneity of treatment effect across patient primary and secondary outcomes.** Subgroup analyses will be considered exploratory to study the heterogeneity of treatment effect (HTE) using features and patient characteristics (X) at baseline (e.g. race/ethnicity, gender identity, comorbidities, degree of rurality, and insurance status). HTE will be assessed through both a traditional regression approach testing interactions one-modifier at a time, and a contemporary nonparametric estimation of the CATE (conditional average treatment effect) using honest causal forest.

Sustainability

- ***Continued BHP Co-location in PC:*** Embedded BHPs co-located with in PC practices
- ***Adapted IBH-PC Toolkit:*** Easily accessible to the public on a ***newly developed up-to-date website*** built during the UG3 Phase
- ***DTx Apps for Continued BHP Training & Patient Home Use:*** Practices and HSCs will be encouraged to continue access to DTx apps for patients as part of their continued CP care; FDA approval allows these apps to be prescribed by providers and potentially covered by insurance
- ***Creation of a BHP for CP Online Forum:*** BHPs will be encouraged to set up a chatroom where they can share experiences, challenges, and comment on their continued treatment of CP patients; they will also be invited to participate in the UW TelePain, a free weekly service funded by Washington State Legislature ECHO program, free to providers treating patients with chronic pain to increase knowledge and confidence

Data Sharing Plans

Informed consent will not be waved

Types of data (N)	Metadata and associated documentation	Repository
<ol style="list-style-type: none">1. Participant surveys (2,030)2. EHR data to facilitate recruitment and outcome evaluation data (TBD)3. Practice champion and behavioral health provider (BHP) surveys (27)4. Post-intervention key informant interview data (36)5. Mobile app usage data (1,350)	<ol style="list-style-type: none">1. Comprehensive data dictionary will provide definitions for all data variables2. Detailed study protocol that includes measure definitions and references	<p>Inter-university Consortium for Political and Social Research (ICPSR) https://www.icpsr.umich.edu/web/pages/about/</p> <p>All PHI/PII removed</p> <p>Available for at least 7 years</p>

Data Sharing Plans – Risks and Mitigation

Risks to providers or health systems	Data sharing structure	Steps to mitigate risks to providers or health systems
Data regarding baseline patient characteristics and study outcomes could be used for biased or inappropriate comparisons of care in participating facilities.	Inter-university Consortium for Political and Social Research (ICPSR) archive will be used and managed by study team as restricted-use data	De-identified patient level data will be provided, with priority given to research that will effect primary care systems nationwide and Collaboratory investigators.

UG3 Planning Phase

Project Aims – UG3

Aim 1: Finalize outcome measures, recruitment processes, and establish centralized data infrastructure

Aim 2: Recruit 27 PC practices and create a Community Advisory Board (CAB)

Aim 3: Refine the IBH-PC Toolkit for chronic pain care, select digital therapeutics for homecare use, and adapt the BHP training materials

UH3 Milestones

Table 4: UG3 Milestones	FY1												
	Month	1	2	3	4	5	6	7	8	9	10	11	12
AIM 1: Finalize outcome measures, practice and patient recruitment processes, and establish a centralized data coordinating infrastructure.													
1.1 Establish participation in NIH Collaboratory Workgroups	X	X	X	X	X	X	X	X	X	X	X	X	X
1.2 Obtain IRB approval across sites	X	X	X	X	X	X							
1.3 Finalize outcome measures				X	X	X	X	X					
1.4 Finalize patient recruitment strategies across HCSs and practices							X	X	X	X			
1.5 Develop data collection processes and infrastructure (i.e., EHR extraction specifications, survey builds)							X	X	X	X	X	X	X
AIM 2: Recruit 27 practices and create a Community Advisory Board (CAB) from the practices.													
2.1 Assess practices for feasibility to participate (i.e., clinic characteristics, readiness for intervention)				X	X	X	X	X					
2.2 Recruit and randomize 27 practices across 3 partners							X	X	X	X	X	X	X
2.3 Establish CAB membership	X	X											
2.4 Conduct CAB meetings			X	X	X	X	X	X	X	X	X	X	X
AIM 3: Refine the IBH-PC Toolkit for CP care, choose digital therapeutics/apps for CP homecare use, and adapt the BHP training materials.													
3.1 Finalize adaptations to the IBH-PC Toolkit		X	X	X	X	X	X	X	X	X	X	X	X
3.2 Finalize digital therapeutics / apps and contracts				X	X	X	X						
3.3 Refine and finalize BHP training materials for CBT and ET for chronic pain				X	X	X	X	X	X	X	X	X	X
3.4 Finalize website and digital resources for adapted IBH-PC Toolkit and trainings										X	X	X	X

Community Advisory Board

- Patients, providers and administrators from the HCSs, including at least three members drawn from each of the three partners organizations
- Dr. Jill Vanwyk, family medicine physician who leads a behavioral health forward chronic pain service to provide safer opioid prescribing at University of Colorado in Family Medicine
- Dr. Joey Nelson, family medicine physician, Director of Diversity, Equity and Inclusion for UW Family Medicine Residency, and an enrolled member of the Confederated Tribes and Bands of the Yakama Nation
- Dr. Mari Yamamoto, psychologist and interim Director of Behavioral Health at UW Family Medicine
- Meet 10 times over the UG3 Phase and work together with the investigative team to advise on the adaptation of the IBH-PC Toolkit, processes related to recruitment and retention, and outcomes.

Challenges Scorecard

Challenge	Level of Difficulty*					
	NA	1	2	3	4	5
Regulatory issues (e.g., IRBs, consent)		X				
Study design issues (e.g., ICC, power, sample size, confounders)			X			
Using community-centered research methods				X		
Engaging with patient partners to inform the study		X				
Engaging with clinicians and health systems to identify or recruit participants		X				
Engaging with clinicians and health systems to deliver the intervention				X		
Data access (e.g., approval, privacy, security) and data management planning		X				
EHR integration and/or data extraction, including data management and quality assessment		X				
Collecting prospective data, including PROs			X			
Optimizing intervention sustainability and planning for sustainment					X	

*Your best guess: 1 = little difficulty; 5 = extreme difficulty

Q&A

- What other studies and resources are there for setting up our REDCap recruitment and data capture system for participants?
- What regulatory examples or resources are there for establishing DUAs, DTAs, and publication committees exist?
- What are best practices with respect to recruitment of population representative sample vs oversampling to allow for more statistically robust evaluation of subgroups?
- What resources are there for sustainability of the intervention at the clinics – i.e., any best practices for helping clinics maintain an intervention set of changes and resources?

Appendix Slides

UG3 specific milestones

UG3 Aim 1 Milestones

Aim 1: Finalize outcome measures, recruitment processes, and establish centralized data infrastructure

Milestone	Criteria for Success
Establish participation in NIH Collaboratory Working Groups (WG)	Identify member(s) to attend each of the six WGs; ≥70% attendance in WG meetings
Finalize outcome measures	Final set of outcome measures (including HEAL CDEs) identified; CAB feedback incorporated
Coordinated IRB approval in place	Single IRB approval by UW Finalized consent plans DSMP plan approved ≥80% reliance agreements executed Protocol finalized and IRB-approved
Establish patient recruitment strategies	Recruitment plans finalized across health care systems (HCS) EHR identification methods tested and validated
Develop data collection processes and infrastructure	Data dictionary, CRFs, and REDCap build Validated EHR extraction and harmonization across sites QA processes, analysis methods, and NIH-compliant DMS plan

UG3 Aim 2 Milestones

Aim 2: Recruit 27 PC practices and create a Community Advisory Board (CAB)

Milestone	Criteria for Success
Assess practices for feasibility	Define clinical characteristics Design and distribute readiness questionnaires Collect responses
Recruit and randomize 27 practices	9 sites per health care system partner 27 participation agreements executed ≥1 backup site per partner identified
Establish CAB membership and meetings	At least 9 members (3 per HCS) Payment system in place CAB meets monthly (9 meetings over Year 1)

UG3 Aim 3 Milestones

Aim 3: Refine the IBH-PC Toolkit for chronic pain care, select digital therapeutics for homecare use, and adapt the BHP training materials

Milestone	Criteria for Success
Complete adaptations to IBH-PC Toolkit	Toolkit updated to streamline content Reflect PCORI approach and address IBH care for chronic pain Finalized toolkit ready for implementation
Finalize digital therapeutics/apps and prepare contracts	Review evidence and feasibility Rationale for selection documented Plans for onboarding and support in place Vendor contracts prepared for UH3
Refine and finalize BHP training materials	Adapt CBT-123 to include exercise therapy and digital therapeutics CAB feedback incorporated iteratively
Finalize website and digital resources	Training website created, accessibility tested, and ready for champions and BHPs at UH3 launch