

Campfire Session: Equitable Primary Care for Pain Care (Equip-PC) Study

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Where We Are Now: UG3 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	X	X	X	X	X		
1.3 Finalize outcome measures				X	X	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
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	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	X	X	X	X	X	X	X	X			
2.4 Conduct CAB meetings										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	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	X	X

EquiP PC: 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		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		X		
Collecting prospective data, including PROs			X			
Optimizing intervention sustainability and planning for sustainment					X	

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

Challenges So Far

- **Finalizing the Community Advisory Board members** - we took time to develop a thoughtful and staged approach to engagement and planning of activities that launch this month – we've just finished recruitment
- **Finalizing criteria for site selection** has been difficult to nail down due to challenges with defining criteria for where and what types of clinics to recruit without our partners' options of healthcare systems and prep for approach and materials to align engagement
- **EHR integration and extraction planning** has been delayed due to site selection taking longer; and we've increased scope to include an end of study data pull that we are planning for
- **Optimizing intervention sustainability and planning for sustainment** is always a challenge and particularly in these challenging times of federal changes and financial risks and funding cuts
- **Defining equitable and how to operationalize that concept throughout the project** has taken time and deliberation of thought and literature reviews that we're still wading through

Ongoing Issues

- Using community-centered research methods: patient recruitment and **sampling based only in the EHR is a biased approach** that could be improved with clinic engaged recruitment approaches, but feasibility is a challenge
- Weighing **whether to use a learning management system for provider training** materials vs traditional recorded didactics and written materials is a decision to be made
- **Selecting scope of digital therapeutics is still being decided**, namely, do we select only apps that directly claim to target chronic pain (e.g., pain self management, exercise and PT) vs. expand to some apps that don't market themselves for chronic pain but could be helpful interventions (e.g., mindfulness, relaxation, depression, anxiety)

Questions for the Group

- People with chronic pain may be vulnerable to experiences of injustice propagated by social factors including poverty, disability, poor social support, homelessness, isolation, and limited access to effective pain care – ***What examples, evidence or tools do you have for how to measure if our impact is reflective of the communities served by the clinics?***
- We want the intervention to sustain equity in access, treatment participation and completion, and outcomes. ***Are there comparator datasets to help us measure equity across the categories of access, treatment participation, and completion we can use to compare to?***
- Implementation strategies include instructions to create action plans for sustainment. ***What examples of implementation strategies that support sustainment has the group had good experience with?***