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ASSOCIATION FOR UTAH COMMUNITY HEALTH



HEALTH

UNIVERSITY OF UTAH

BeatPain Utah

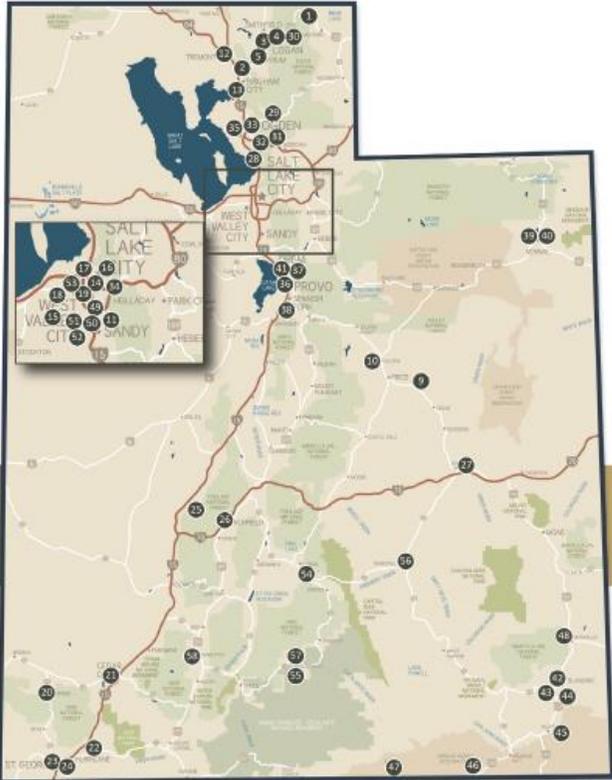
Nonpharmacologic Pain Management in FQHC Primary Care Clinics

UG3AT011297-01



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13 member organizations

58 primary care clinics

165,000 unique patients

- 66% below federal poverty level
- 47% Hispanic/Latino ethnicity



HEALTH

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Center for Clinical And
Translational Sciences



Center for Clinical Translational Science

College of Health

- Department of Physical Therapy

School of Medicine

- Department of Biomedical Informatics
- Department of Population Health Sciences



Center for Health Outcomes and
Population Equity



HUNTSMAN
CANCER INSTITUTE
UNIVERSITY OF UTAH

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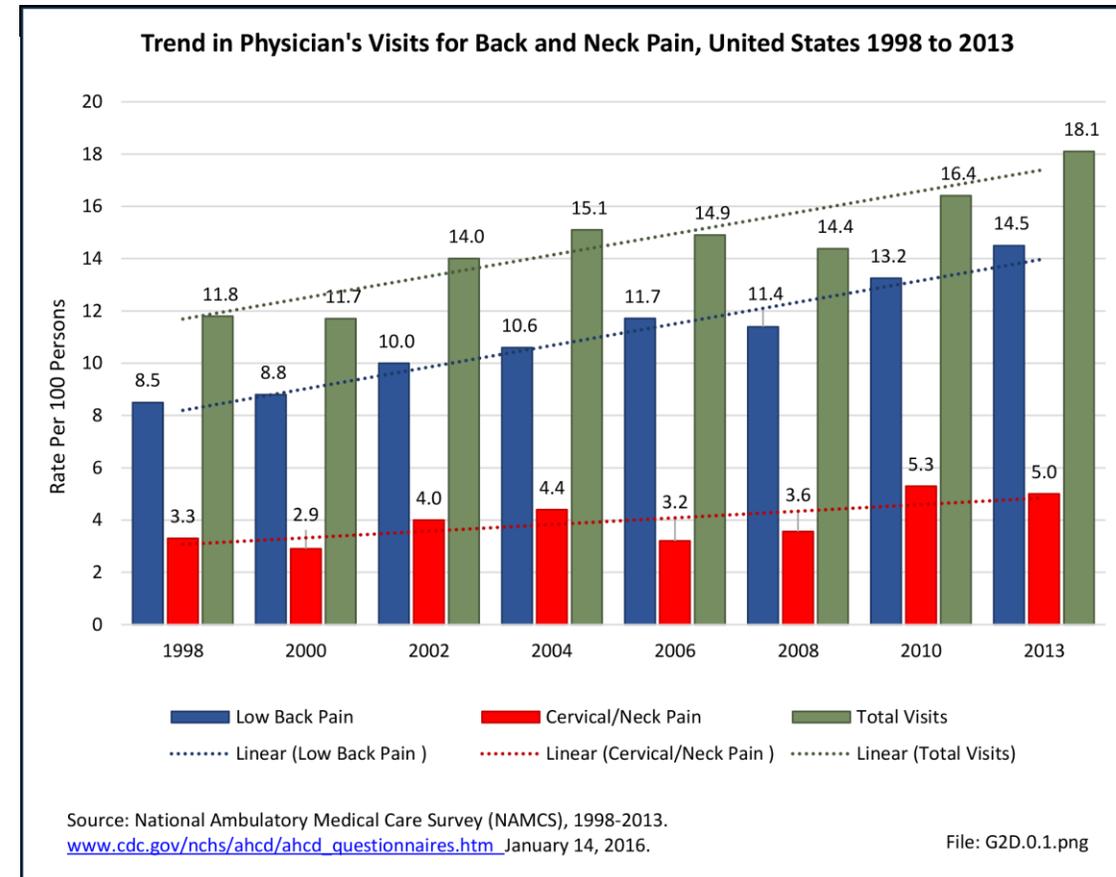
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Nonpharmacologic Pain Management in FQHC Primary Care Clinics

- Back pain is among the most common reasons for a physician office visit
- Back pain is the costliest health condition in the United States accounting for \$135 billion in 2016.

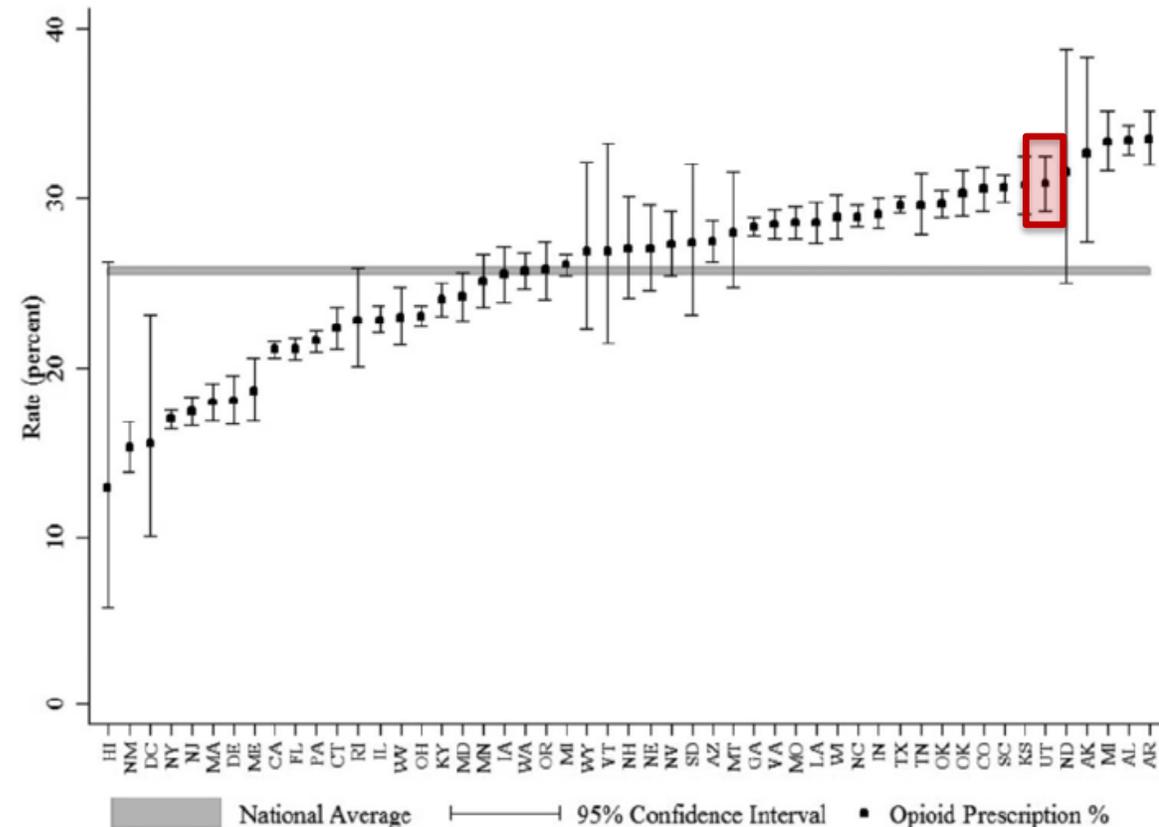
(Dieleman et al, JAMA 2020;323:863-884)

- Prevalence continues to increase



Nonpharmacologic Pain Management in FQHC Primary Care Clinics

- Back pain is the most common diagnosis for which opioids are prescribed.
- 20%-30% of new consultations for back pain result in an opioid prescription contrary to clinical guidelines. (Raad et al, JABFM 2020;33:138-142)
- Guidelines recommend nonpharmacologic treatments as first-line interventions for back pain.



**Persistent low back pain
(>12 weeks)**

Education and self-care

Advice to remain active	First-line treatment, consider for routine use
Education	First-line treatment, consider for routine use

Superficial heat Insufficient evidence

Non-pharmacological therapy

Exercise therapy	First-line treatment, consider for routine use
Cognitive behavioural therapy	First-line treatment, consider for routine use

Spinal manipulation Second-line or adjunctive treatment option

Massage Second-line or adjunctive treatment option

Acupuncture Second-line or adjunctive treatment option

Yoga Second-line or adjunctive treatment option

Mindfulness-based stress reduction Second-line or adjunctive treatment option



“A major challenge will be to stop the use of harmful practices while ensuring access to effective and affordable health care for people with low back pain.”

Series on low back pain

THE LANCET

The best science for better lives

Nonpharmacologic Pain Management in FQHC Primary Care Clinics

- Disparities exist in pain prevalence and pain management.
 - Chronic back pain and HICP are more prevalent in communities with lower household income and rural communities.
 - Odds of receiving opioids for pain management are greater, and odds of nonpharmacologic care lower, in rural and Hispanic/Latino communities.
-

Federally-Qualified Health Centers

Qualify for funding under the Public Health Service Act.

Serve an underserved area or population

Provide services to all, Offer a sliding fee scale

Provide comprehensive services (either on-site or by arrangement with another provider)

80% increase in number of clinics and 62% increase in persons served from 2007-2014



2018

YEAR IN REVIEW



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UTAH HEALTH CENTERS SERVED:



1 IN EVERY 20 UTAHNS



1 IN 3 UTAHNS
LIVING IN POVERTY



1 IN 4 UNINSURED UTAHNS

166,860

TOTAL PATIENTS SERVED



120,434

ADULTS



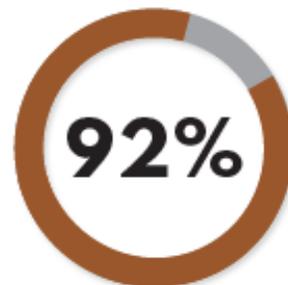
46,426

CHILDREN / ADOLESCENTS



7,126

INDIVIDUALS EXPERIENCING
HOMELESSNESS



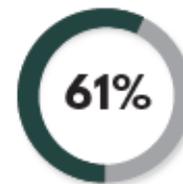
of patients are at
or below 200% of the
Federal Poverty Guidelines (FPG)

(e.g. annual income of \$25,750 for a family of four)

66% of patients are at or below
100% FPG



of patients are uninsured



identify as a racial or
ethnic minority

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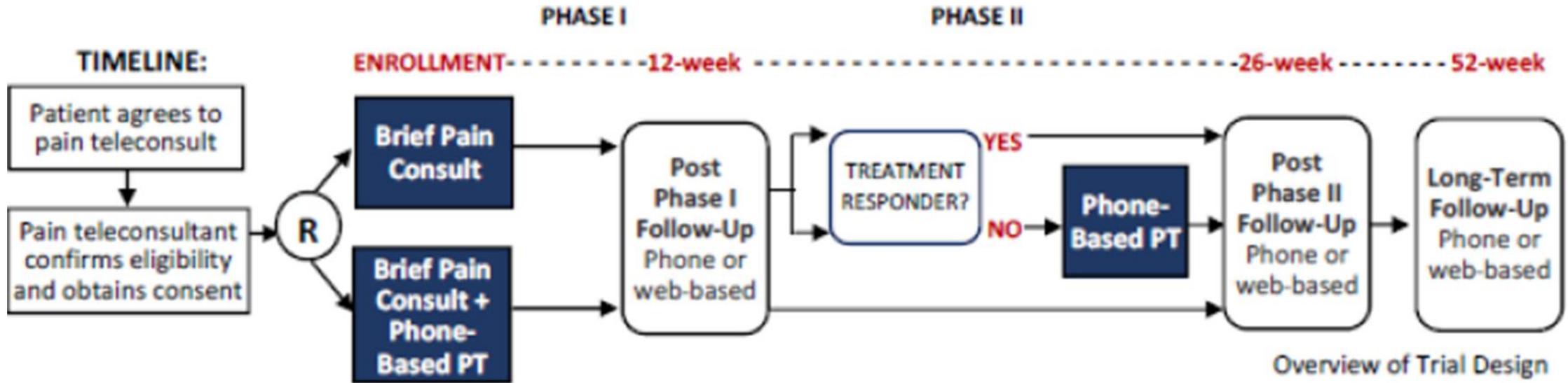
Goal: Improve pain management and reduce reliance on opioids for patients with chronic back pain in FQHCs in Utah.

Strategy: Hybrid type I effectiveness-implementation trial.

Compare the effectiveness of first-line nonpharmacologic pain treatments using phone-based telehealth to overcome access barriers, improve patient-centered outcomes and reduce opioid use.

Collect implementation outcomes for EHR-based, e-referral process and phone-based telehealth.

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UG3 Study Aims

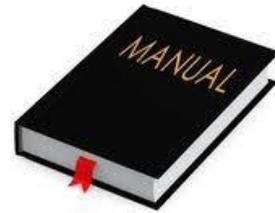
1. Finalize procedures for interventions; develop protocols, procedure manuals and fidelity assessments.
 2. Conduct sociotechnical assessment at FQHC sites to assess current EHR reminder and e-referral workflow
 3. Implement EHR reminders for e-referrals to teleconsult services in the FQHCs.
 4. Finalize study outcomes, data collection methods and data analysis plan.
 5. Train pain teleconsultants and FQHC staff.
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UG3 Aim 1

Finalize procedures for interventions



Gather community input
through interviews/focus
groups



Finalize intervention
manuals



Complete training manuals
for providers

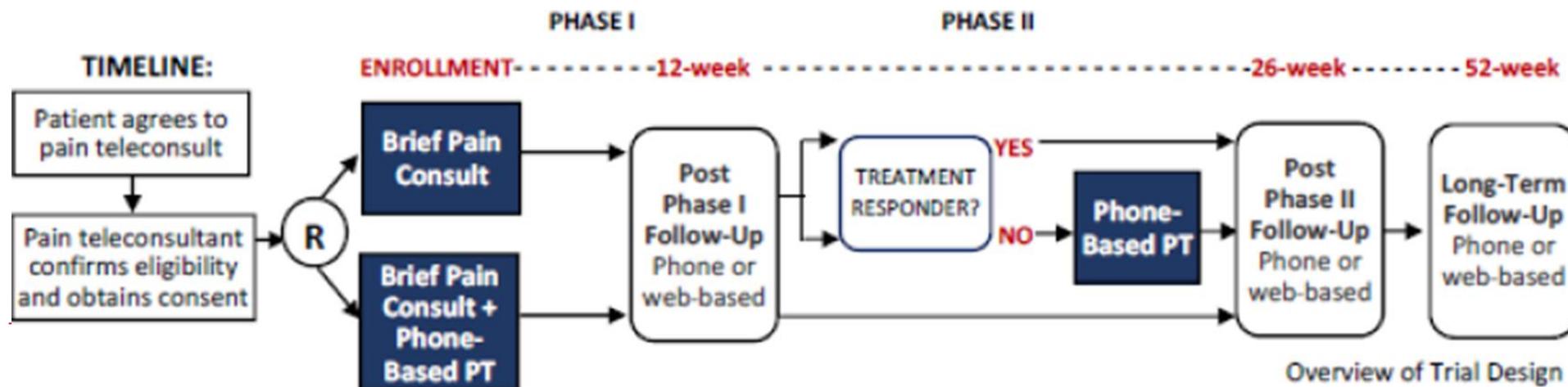
Interventions

Brief Pain Teleconsult

- Two sessions provided in ~1 week
- Provided to all participants and non-participant referrals as standard of care
- Cognitive-behavioral approach to reduce maladaptive pain perceptions and increase physical activity

Phone-Based Physical Therapy

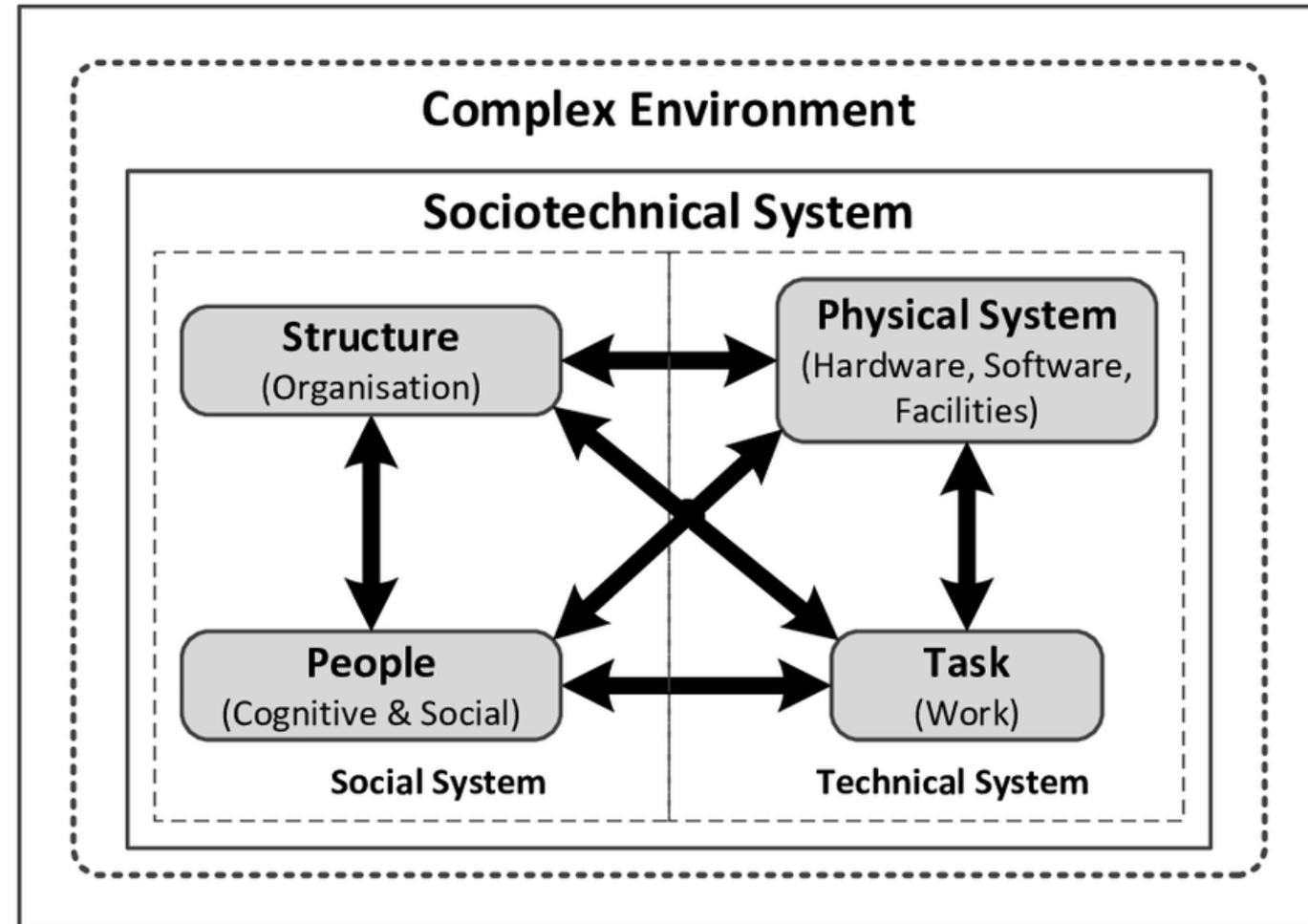
- 10 weekly sessions
- Provided in Phase I or Phase II (non-responders) for enrolled participants
- Cognitive-behavioral approach including education, pain coping strategies, physical activity and back-specific exercise instruction



UG3 Aim 2

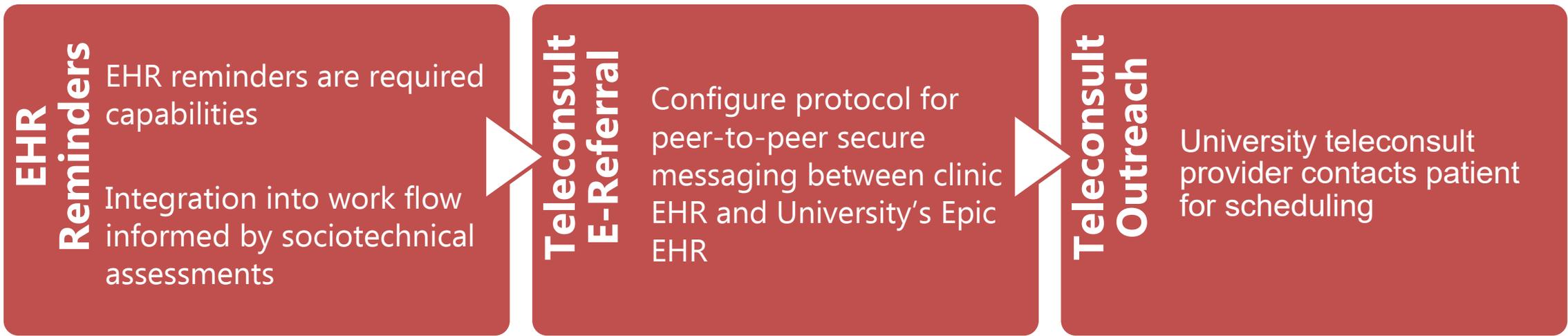
Conduct sociotechnical assessments

- Structured assessment of social and technical aspects of in-clinic work processes
- In-clinic observations
- Qualitative evaluations with providers and staff
- Findings inform implementation planning for e-referral

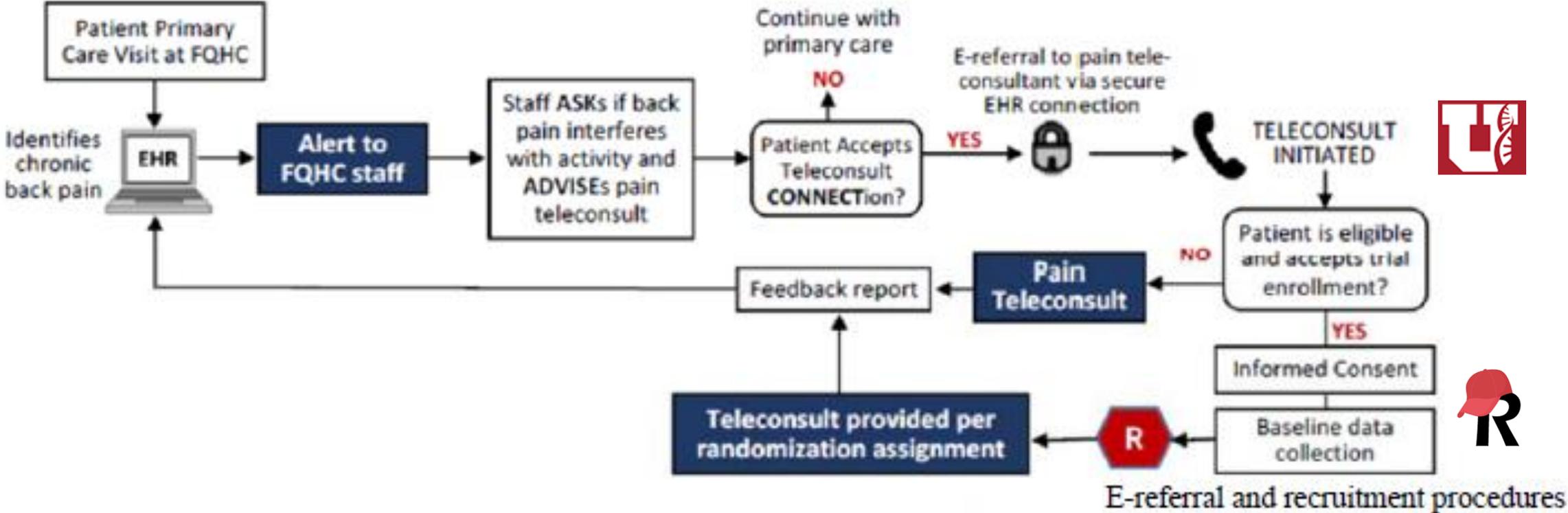


UG3 Aim 3

Implement EHR reminders for e-referrals to teleconsult services



We will use scalable automated EHR reminders for electronic referral to teleconsult services based at University of Utah.



UG3 Aim 4

Finalize outcomes and data analysis plan

Effectiveness Outcomes		Baseline	12 weeks	26 weeks	52 weeks	Domain	HEAL Core Instrument
Domain	Measure						
Pain interference	PROMIS 8-item short form*	X	X	X	X	Pain interference	PEG-3
Additional mental and physical health domains	PROMIS-29 v.2**	X	X	X	X	physical function, sleep, anxiety depression, catastrophizing, self-efficacy	PROMIS short forms, PCS-6, PSEQ-4
Pain Self-Efficacy	Pain Self-Efficacy Questionnaire	X	X	X	X		
High Impact Chronic Pain	Graded Chronic Pain Scale – Revised	X	X	X	X	High Impact Chronic Pain	
Treatment Responder Status	Single-item PASS		X	X	X	Responder Status	PGIC
Opioid Use	Categorization based on EHR data as short-term, episodic or long-term	X^			X	Opioid Use	Single-item current opioid use
Opioid misuse, abuse, and related events	SR-MAD		X	X	X	Opioid MARE	
Implementation Outcomes (assessed at conclusion of recruitment)							
Acceptability	PATIENT LEVEL - Percentage of individuals with chronic pain asked about a pain teleconsult during a clinic visit who accept the consult.						
Adoption	PROVIDER LEVEL - Percentage of patients asked about a pain teleconsult (i.e., provider asks patient and does not opt out) during a clinic visit out of all back pain patients.						
Feasibility	PATIENT LEVEL – Percentage of brief pain teleconsult and phone-based physical therapy sessions completed out of number specified in intervention protocols,						
Fidelity	PROVIDER LEVEL – Percentage of core treatment components provided at of brief pain teleconsult and phone-based physical therapy sessions out of the total number of sessions provided for each treatment group (brief teleconsult with or without phone-based PT.						

Target Patient Population

~600 participants

- Adults age 18-70
 - English or Spanish-speaking
 - FQHC clinic visit associated with back pain as chief complaint or relevant diagnostic code in past 6 months
 - Chronic back pain based on NIH Back Pain Research Task Force definition
-

Key UG3 Milestones

MONTH	1	2	3	4	5	6	7	8	9	10	11	12
Finalize outcome measures and data elements												
Finalize statistical analysis plan and sample size												
Conduct sociotechnical assessments at FQHC clinic sites												
Conduct community member focus groups												
Finalize FQHC clinic sites for UH3 clinical trial												
Submit protocol to University of Utah IRB												
Finalize clinical trial protocol												
Complete and test EHR reminder/e-referral												
SUBMIT TRANSITION REPORT												
Finalize Manual of Operating Procedures												
Register UH3 trial with clinicaltrials.gov												
Train FQHC clinic staff at participating sites												
Train phone-base PT and teleconsult providers												

**Transition
Request Due
6/31/21**

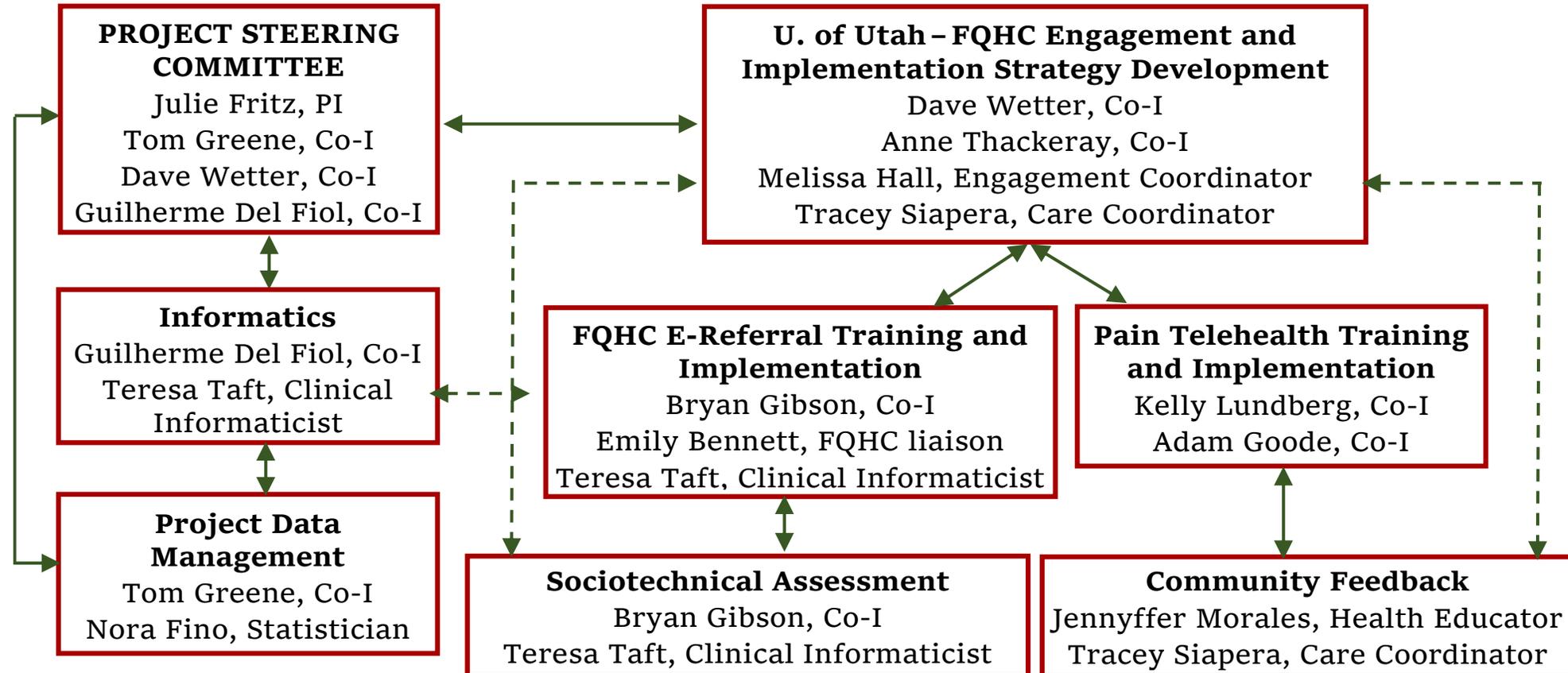
STUDY ORGANIZATION

Pragmatic and Implementation Studies for the Management of Pain

STEERING COMMITTEE

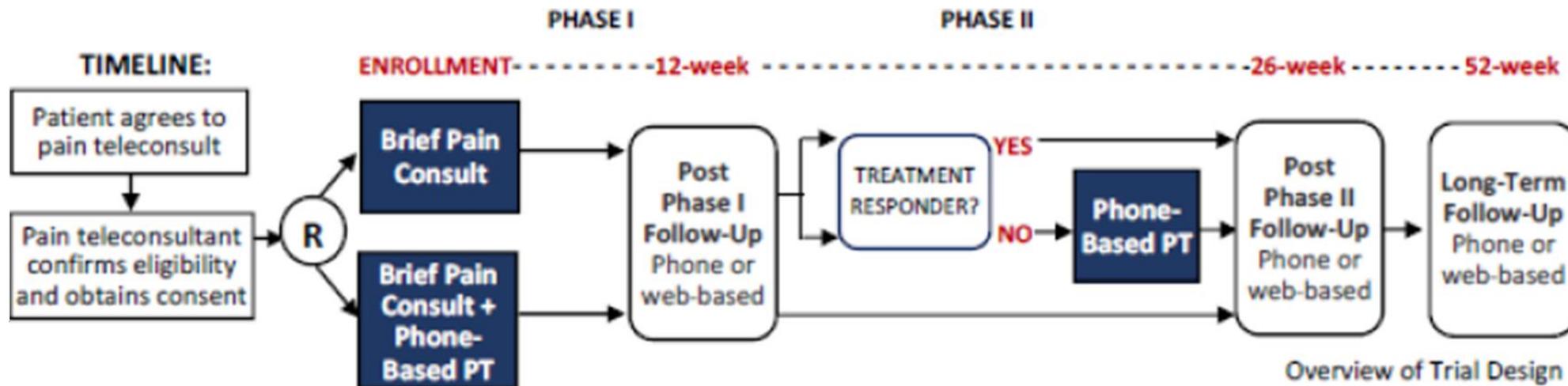
Julie Fritz

Biostats/Study Design Work Group Tom Greene	Electronic Health Record Work Group Guilherme Del Fiol	Healthcare Systems Work Group Julie Fritz	Patient-Reported Outcomes Work Group Anne Thackeray	Regulatory/Ethics Work Group Bryan Gibson
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UH3 Study Aims

1. Compare the effectiveness of brief pain teleconsult with or without phone-based PT (pain interference as primary outcome; opioid use as a secondary outcome).
2. Compare the effectiveness of phone-based PT as a first-line vs. a stepped care strategy as second-line care for patients do not respond to brief pain teleconsult.
3. Examine effectiveness results of Aims 1 & 2 in pre-defined patient phenotypes based on gender, presence of HICP and current opioid use.
4. Explore implementation outcomes for teleconsult services (acceptability, adoption, feasibility and fidelity).



Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems			X		
Data collection and merging datasets		X			
Regulatory issues (IRBs and consent)		X			
Stability of control intervention		X			
Implementing/delivering intervention across healthcare organizations		X			

*Your best guess!

1 = little difficulty

5 = extreme difficulty

Data Sharing UG3

- *What is your current data sharing plan and do you foresee any obstacles?*
 - Publish findings in peer-review journals
 - Comply with NIH HEAL Initiative Public Access and Data Sharing requirements
- *What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?*
 - We will not waive informed consent
- *What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?*
 - Individual level data