



JOHNS HOPKINS
M E D I C I N E

Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)

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Overview

Low Back Pain (LBP)

- Most common cause of disability in the US
- Largest driver of US healthcare spending growth
- Number one reason for opioid prescriptions

Physical Therapy (PT)

- First line treatment
- Cost-effective in reducing disability and pain
- Decreased risk of opioid use
- 7-13% of patients attend PT
 - Barriers surrounding travel, missed work time, etc.

Overview

Rural Communities

- 40% fewer therapists per capita
 - Longer distance to travel
- Fewer patients attend PT within 30 days of onset
- Higher rates of opioid use

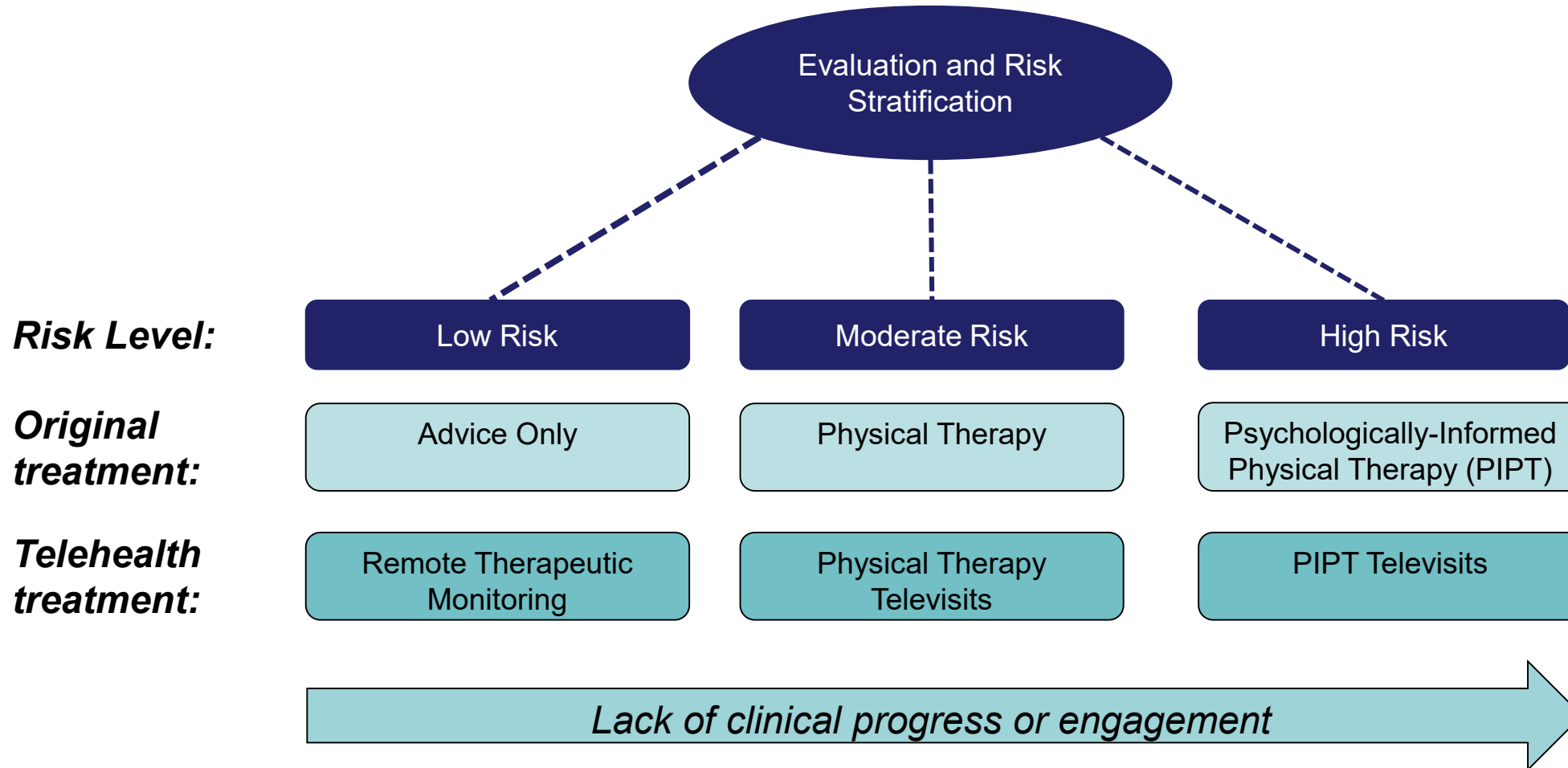
Telehealth

- PT provided by televisits for first time during pandemic
- Reimbursed by CMS and most commercial insurances
- New code for remote therapeutic monitoring (RTM)
 - Asynchronous telerehabilitation using mobile application

Overall Objective

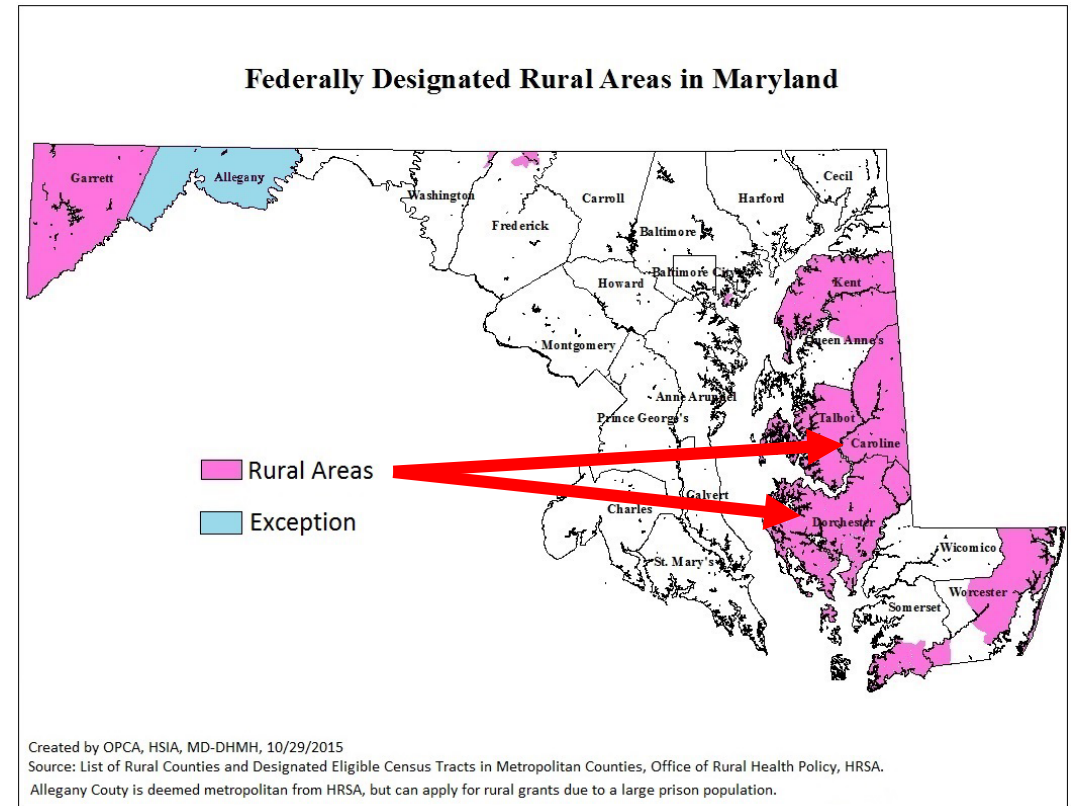
- To compare the effectiveness of a risk-stratified telerehabilitation model to patient education to improve outcomes in patients with chronic low back pain in rural communities

RiSC Telerehabilitation Model*



Study Design

- Randomized clinical trial
 - RiSC Telerehabilitation
 - Delivered by TidalHealth
 - Patient Education
 - Delivered via website
- Patients
 - 434 with chronic LBP
 - No spine surgery past 12m
 - Primary care office visit
 - Offset broadband access cost



Study Team

- Johns Hopkins
 - Richard L. Skolasky, Sc.D. (MPI)
 - Kevin McLaughlin, D.P.T. (MPI)
 - Elizabeth Colantuoni, Ph.D.
 - Stephen Wegener, Ph.D.
 - Tricia Kirkhart
- MHRI
 - Kisha Ali, Ph.D.
- TidalHealth
 - Robert Joyner, Ph.D.
 - Jill Stone, D.P.T.
 - Melanie Smith
 - Mary Chance
 - Megan Brimer
- Maryland Rural Health Association

Study Outcomes

Outcome	Measure	Data Source
Pain-Related Disability	ODI	Patient Report
Physical Function	PROMIS-26, v2.0 Physical Function	Patient Report
Pain Intensity	PEG	Patient Report
Quality of Life	PROMIS-29, v2.0 Profile	Patient Report
Opioid Use	Recent use for LBP	EHR and/or Patient Report
Health Care Use	Physical therapy (external to trial), Physician/ED visit, Imaging, Pain interventions, Medications, Back surgery	EHR and/or Patient Report
Implementation	Acceptability, Adoption, Feasibility, Fidelity	Patient Report
Safety	Adverse Events	Patient Report

UG3 Specific Aims

- Aim 1: Examine effectiveness of telerehabilitation in reducing pain and disability
 - Oswestry disability index, PROMIS-29
- Aim 2: Examine effectiveness of telerehabilitation in reducing opioid use
- Aim 3: Examine implementation of the RiSC telerehabilitation model
 - RE-AIM Framework

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

Date Sharing UG3

- *What is your current data sharing plan?*
 - All de-identified individual level data, with supporting documentation, will be made publicly available in compliance with NIH, Collaboratory, and institutional guidelines
- *Do you foresee any obstacles?*
 - We may be limited in sharing data on an un-restricted access registry from the UG3 phase, as this data will be collected under a waiver of informed consent (this will not be an obstacle in the UH3 Clinical Trial, as we will obtain informed consent from all participants)
- *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 be applying for a waiver of informed consent in order to conduct Model Recruitment (identifying likely eligible patients seen in the past 12 months from the EHR and performing data check on a random sample of 250 patients via medical chart abstraction)

Date Sharing UG3

- *What data you are planning to share from **your** project (individual-level data, group-level data, specific variables/outcomes, etc.)?*
 - Data generated will include observational data, statistical and programming code, derived and compiled metadata, analytic documentation.
 - Data will include, but may not be limited to:
 - Diagnostic and encounter data from the EHR
 - Self-reported patient-reported outcome measures and healthcare use
 - Technical and practical knowledge regarding risk stratification and implementation of the intervention
 - Metadata, such as data collection instruments, protocols, and data dictionaries

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QUESTIONS?