TAICHIKNEE Study

Chenchen Wang, MD, MSc – Tufts Medical Center
Eric Roseen, DC, PhD – Boston Medical Center
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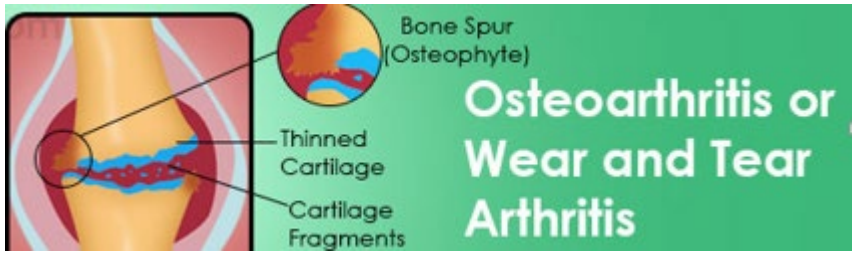
Osteoarthritis



- One of the most frequent disabling human disorders globally
- Major societal impact
  - Work loss
  - Medical costs, arthroplasty ($30b/y in the US)
- Major treatment gap
  - Pain
  - No disease modifying interventions

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Annals of Internal Medicine

ORIGINAL RESEARCH

Comparative Effectiveness of Tai Chi Versus Physical Therapy for Knee Osteoarthritis

A Randomized Trial

Chenchen Wang, MD, MSc; Christopher H. Schmid, PhD; Maura D. Iversen, SD, DPT, MPH; William F. Harvey, MD, MSc; Roger A. Fielding, PhD; Jeffrey B. Driban, PhD; Lori Lyn Price, MAS; John B. Wong, MD; Kieran F. Reid, PhD, MPH; Ramel Rones; and Timothy McAlindon, MD, MPH

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Tai Chi for Fibromyalgia

Chenchen Wang, M.D., M.P.H., Christopher H. Schmid, Ph.D., Ramel Rones, B.S., Robert Kalish, M.D., Janeth Yinh, M.D., Don L. Goldenberg, M.D., Yoojin Lee, M.S., and Timothy McAlindon, M.D., M.P.H.

REVIEW ARTICLE

The Effect of Tai Chi on Health Outcomes in Patients With Chronic Conditions

Chenchen Wang, MD, MSc; Jean Paul Collet, MD, PhD; Joseph Lau, MD

Effect of tai chi versus aerobic exercise for fibromyalgia: comparative effectiveness randomized controlled trial

Chenchen Wang,[1] Christopher H Schmid,[2] Roger A Fielding,[3] William F Harvey,[1] Kieran F Reid,[3] Lori Lyn Price,[4] Jeffrey B Driban,[1] Robert Kalish,[5] Ramel Rones,[6] Timothy McAlindon[1]

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 61, No. 11, November 15, 2009, pp 1545–1553

Tai Chi Is Effective in Treating Knee Osteoarthritis: A Randomized Controlled Trial

CHENCHEN WANG,[1] CHRISTOPHER H. SCHMID,[1] PATRICIA L. HIBBERD,[2] ROBERT KALISH,[1] RONENN ROUBENOFF,[3] RAMEL RONES,[4] AND TIMOTHY MCALINDON[1]

Clinical Practice Guidelines

Tai Chi now recognized as Core Treatment for Osteoarthritis

Review › Osteoarthritis Cartilage. 2019 Nov;27(11):1578-1589.

Epub 2019 Jul 3.

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis

For the first time, mind-body exercises (Tai Chi and Yoga) are recommended as Core Treatment options for individuals with knee OA, highlighting the importance of the holistic wellbeing of the individuals. Panel members also made the difficult decision to

Arthritis & Rheumatology
Vol. 0, No. 0, Month 2020, pp 1–14
DOI 10.1002/art.41142

AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee

	HAND	KNEE	HIP
MIND-BODY APPROACHES		Exercise*	
		Self-Efficacy and Self-Management Programs	
		Weight Loss	
		Tai Chi	
		Cane	
	1st CMC Orthosis	TF Knee Brace**	

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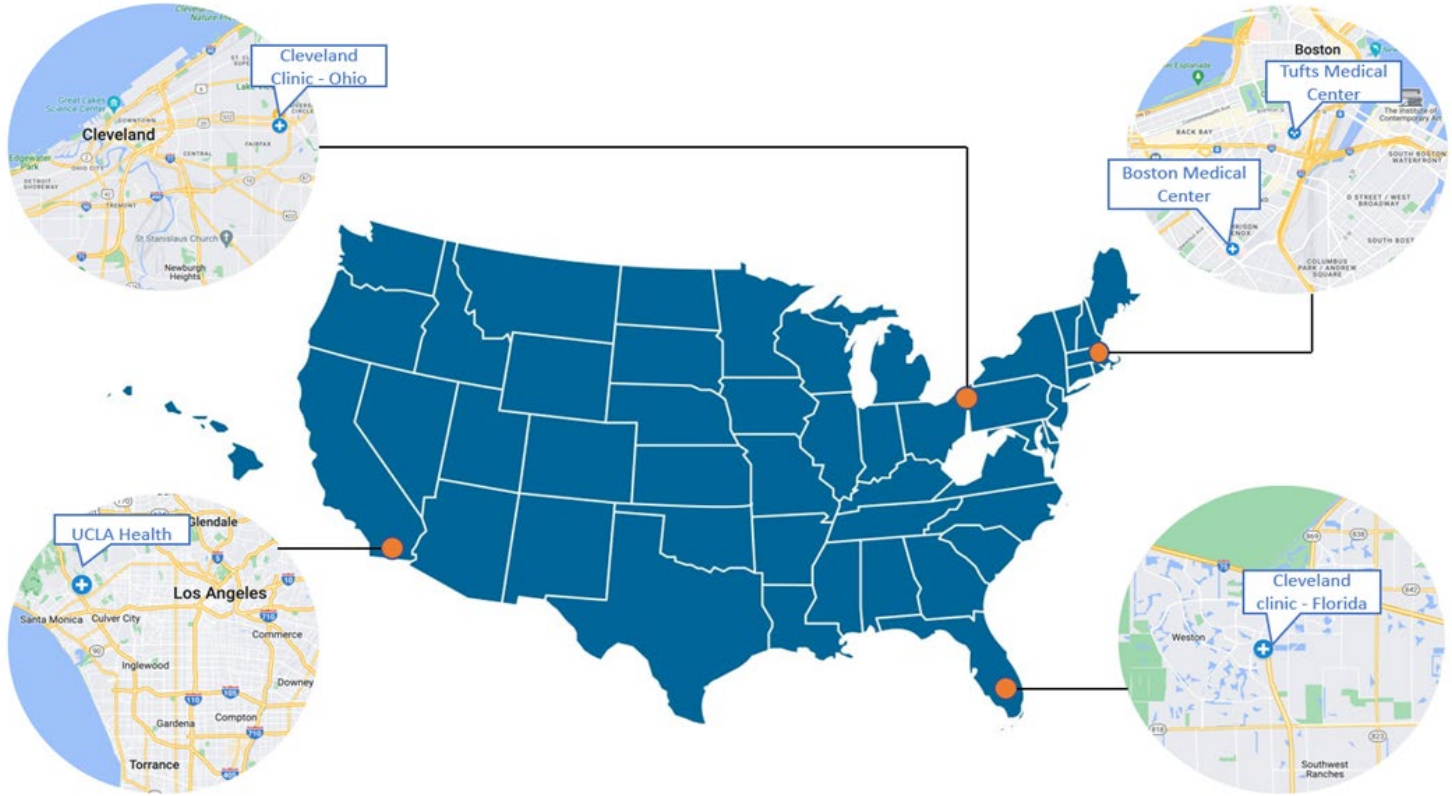
Large and diverse population in four geographic regions



Major Goal: To study "real world" effectiveness and implementation of Tai Chi versus routine care for Knee Osteoarthritis Pain across four US Health Care Systems.

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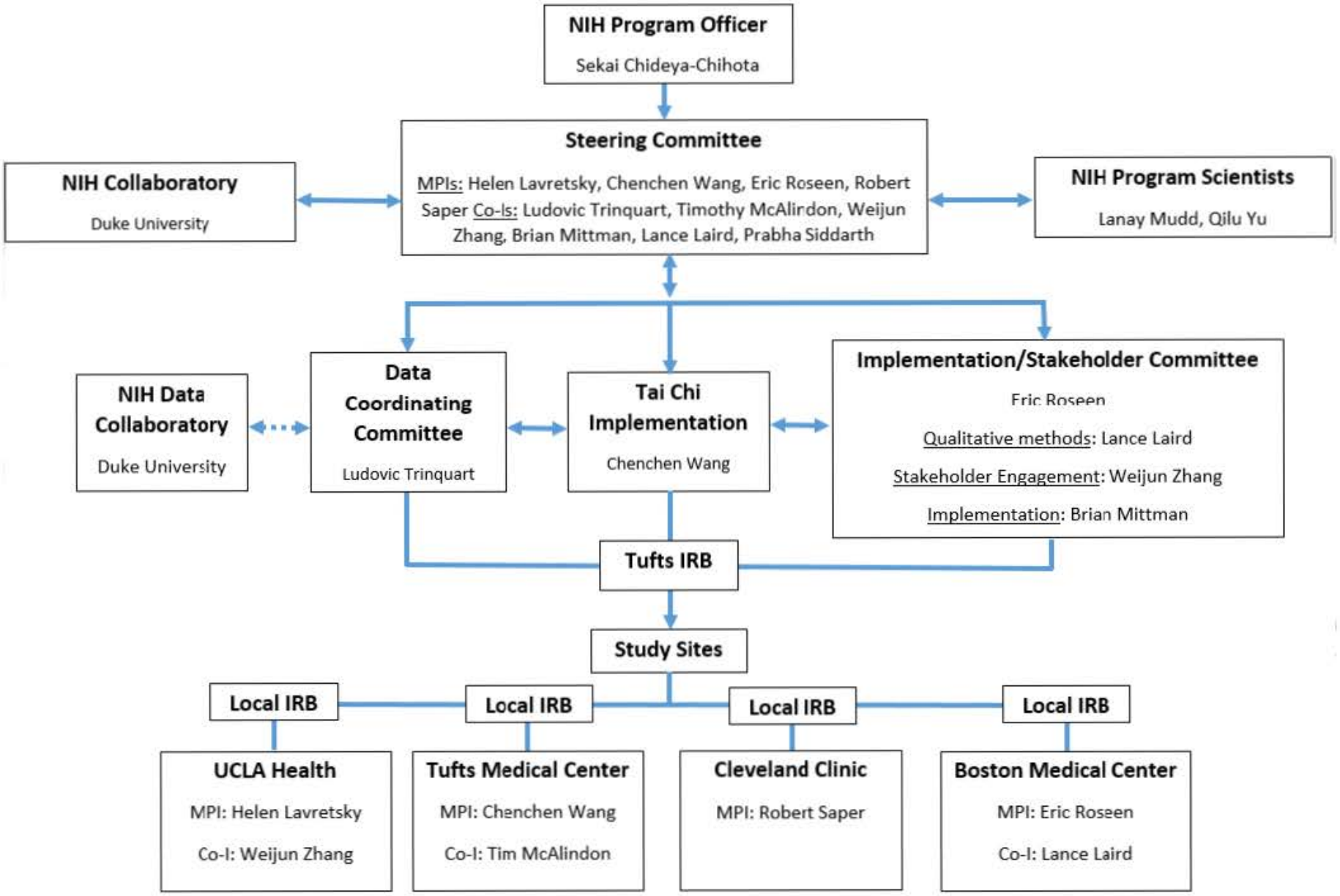
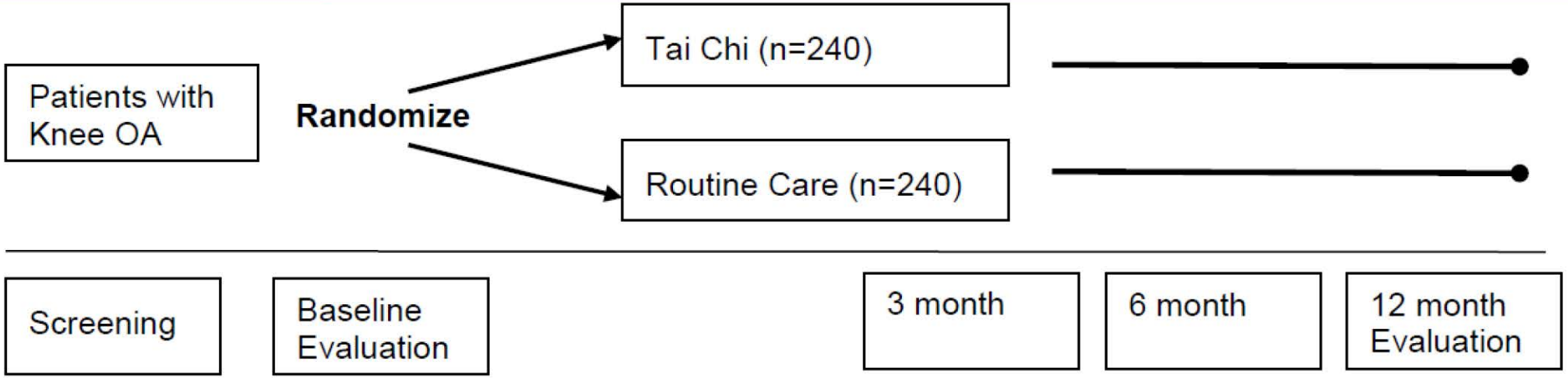
TAICHIKNEE Trial Organization Chart



TAICHIKNEE Trial Overview

Population	Adults over 45 years with Symptomatic knee OA (ACR Criteria)
Setting	Primary care clinics in four healthcare systems
Design	An embedded, pragmatic, randomized trial
Intervention	Remote tai chi (3-month twice weekly)
Control	Routine Care
Clinical outcomes	Pain interference (primary) Knee Pain and Function, Pain medication, Quality of life (secondary)
***Anticipated* Implementation Strategies**	Internal facilitation, educational meeting, development and distribution of educational materials
Implementation outcomes	Feasibility of implementation strategies



UG3 planning phase aims

- **AIM 1:** Establish a collaborative and effective Project Governance and Organizational Structure among the four Health Care Systems, the NIH Collaboratory Coordinating Center and Collaborators through assembly of Working Groups, Study Teams and Panels including Stakeholder Committees and Data and Safety Monitoring Board.

- **AIM 2:** Identify multilevel (patient, provider, and health system leadership) barriers and facilitators of embedding a web-based Tai Chi intervention.

- **AIM 3:** Finalize the study design, implementation strategies, study materials, data capture systems, informed consent materials, ethical oversight structure, and quality control procedures.

Milestones

1. Finalize organizational chart and regular video call meeting cadence for study team and subcommittees **(Tufts)** ***Done June 19th***
2. Finalize representatives from Study Team to join and engage with NIH Collaboratory Work Groups **(Cleveland Clinic)** ***Done June 19th***
3. Complete an overarching stakeholder engagement plan that defines specific advisory groups, their purpose, and their meeting cadence **(BMC)** ***Done June 30th***
4. Convene a Team to oversee the design and implementation of the Tai Chi intervention **(Tufts)** Convene a Team to oversee the design and implementation of the Tai Chi intervention **(Tufts)** ***Done June 30th***

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Milestones (cont)

5. Convene advisory groups **(All)** ***July 31st***
6. Select and finalize with NCCIH approval Protocol Review Committee & DSMB **(UCLA)** ***August 31st***
7. Complete FWAs for all sites and reliance agreements for single IRB **(Tufts)** ***August 31st***
8. IRB approval for qualitative study using semi-structured interviews and study documents with stakeholders to understand barriers and facilitators of embedding Tai Chi exercise into routine care and health system **(BMC)** ***August 31st***

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

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Participation in working groups

Work Group	Members
Regulatory/Ethics	Chenchen Wang, Helen Lavretsky
Electronic Health Records	Robert Saper, Ludovic Trinquart
Biostatistics and Study Design	Ludovic Trinquart, Prahaba Siddarth
Health Care Systems Interactions	Weijun Zhang, Timothy McAlindon
Implementation Science	Eric J. Roseen, Brian Mittman
Health Equity	Robert Saper, Lance D. Laird
Patient-Centered Outcomes	Helen Lavretsky, Chenchen Wang
Publications Committee	Helen Lavretsky, Chenchen Wang

Embed Remote Tai Chi into Four Health Care Systems

- Convene a team to oversee the implementation of Tai Chi
- Complete implementation plan to understand barriers and facilitators of embedded remote Tai Chi in four health care systems informed by stakeholders and qualitative data
- Develop and finalize intervention training materials.
- Finalize a list of Tai Chi instructors at each site and conduct Tai Chi Instructor Training: two four-hour sessions for two weeks.
- Conduct a total of six interactive grand rounds/lunch seminars distributed across the 4 health care systems about TAICHIKNEE study.

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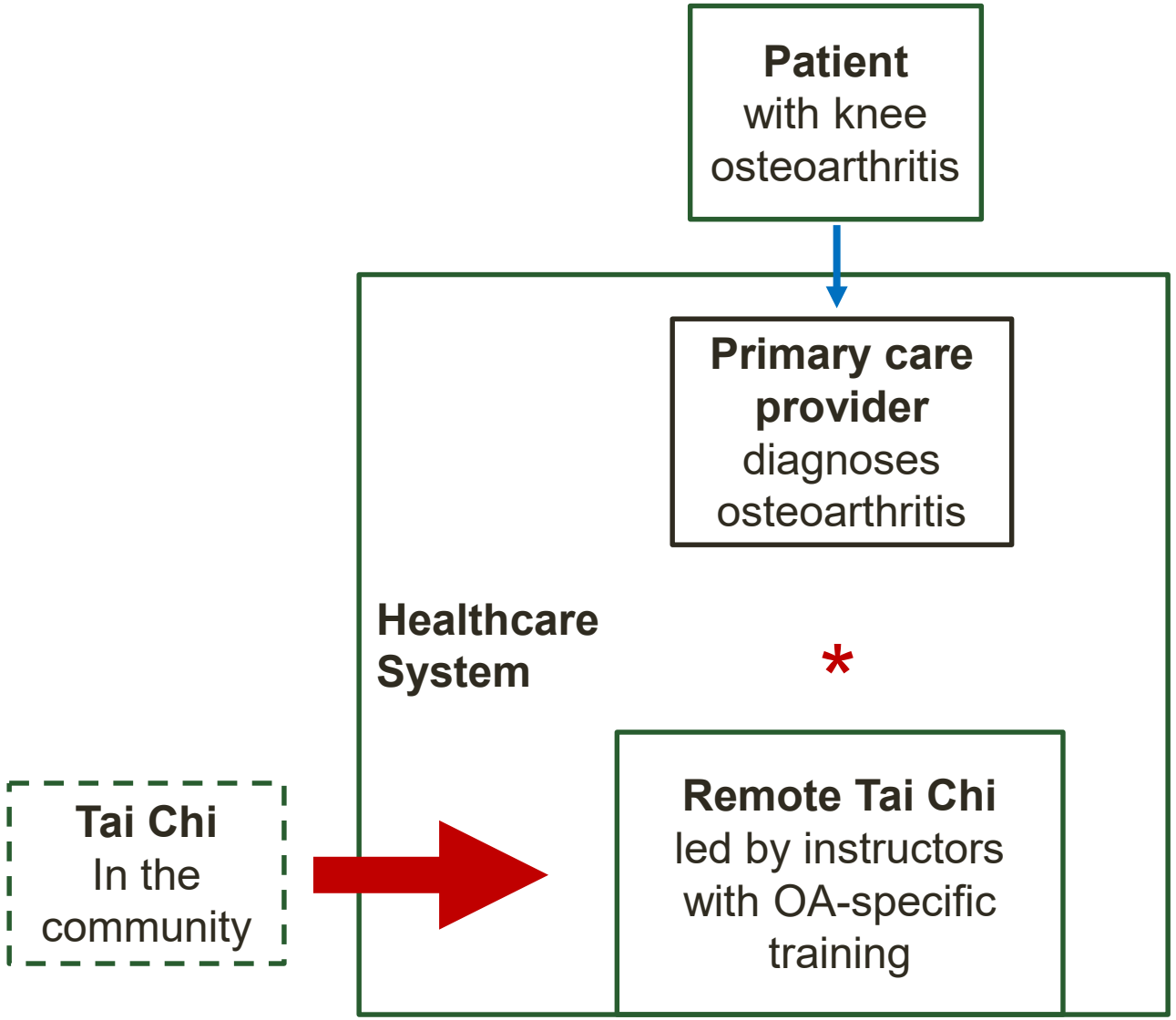
Stakeholder engagement

- **UG3 AIM 2:**
  - Identify multilevel (patient, provider, and health system leadership) barriers and facilitators of embedding a web-based Tai Chi intervention.

- **UH3 AIM 3:**
  - Examine facilitators and barriers of implementing remote Tai Chi mind body therapy into the four large Health Care Systems using semi-structured exit interviews of patients, clinicians, and staff.



*Any mechanism/strategy to recruit patients into intervention

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UG3 key-informant interviews and focus groups

Category	Group
Patient	Patients with Knee Osteoarthritis
Tai Chi	Instructors
Primary care Provider	General Internal Medicine Family Medicine
Health system	Health system leaders IT/Population health staff

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Biostatistics and Study Design

- Design allows for correlation in experimental group
  - Individuals receive intervention with other participants through instructors
  - Individually Randomized Group-Treatment (IRGT) trial
- ANCOVA comparing mean PROMIS PI score between groups
- 240 subjects per group gives 90% power to detect effect size of 0.333
  - Within-participant correlation between baseline and 3-month T score = 0.5
  - ICC in experimental group 0.03
  - Average cluster size of 10 individuals for tai chi classes
  - 30% drop out (missing outcome data at 3 months)
- With T score SD of 6, effect size of 0.333 corresponds to Minimal Important Clinical Difference, a between-group difference of 2 T score points

Data Collection & Merging Datasets

- Data use agreements between the DCC and sites: 20-25 clinics across 4 Health Care Systems -- Tufts Medical Center, Boston Medical Center, University of California Los Angeles Health, and Cleveland Clinic Ohio/Cleveland Clinic Florida
- 4 main data sources
  - Data from sites collected by coordinators through REDCap
  - Patient-reported outcome measures by HIPAA-compliant surveys via REDCap and MyCap
  - Resource utilization assessed through Electronic Medical Record interrogation & patient survey
  - Qualitative interviews
- No anticipated problem with merging of de-identified datasets from sites, but multisite EHR harmonization might be a challenge

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Data Sharing UG3

- Current data sharing plan: All de-identified individual-level data & supporting documentation will be made publicly available to the widest possible audience. Exception for PHI, none of the data associated with this proposal will be subject to any restrictions to data sharing
- We do not foresee any obstacles
- Waiver of informed consent NOT applicable

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