Introduction to Tai Chi for Knee Osteoarthritis: Educational materials for the TAICHIKNEE Hybrid Type 1 Implementation Effectiveness Pragmatic Trial

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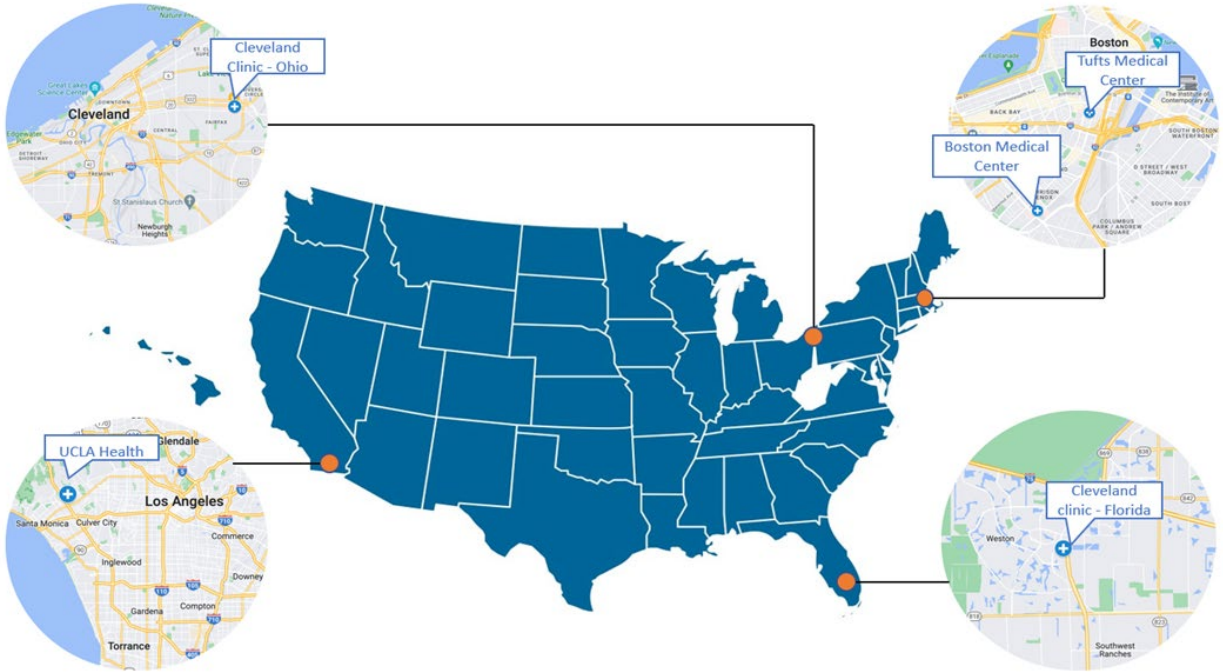
UCLA Health

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.**

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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Yang et al. Systematic Reviews (2022) 11:260
https://doi.org/10.1186/s13643-022-02100-5

Systematic Reviews

RESEARCH Open Access

Determining the safety and effectiveness of Tai Chi: a critical overview of 210 systematic reviews of controlled clinical trials

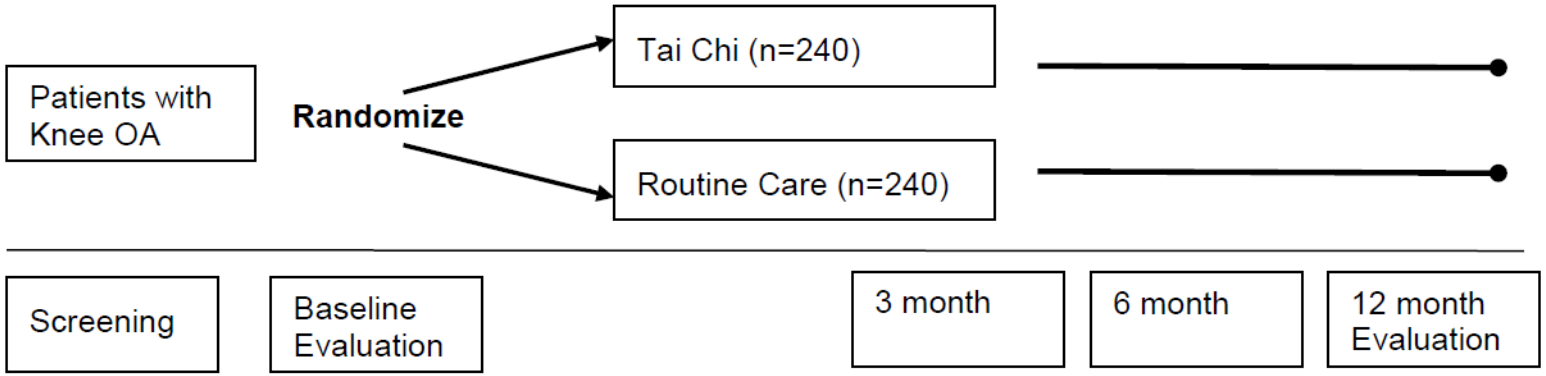
Guo-Yan Yang[1*†], Jennifer Hunter[2†], Fan-Long Bu[3], Wen-Li Hao[4], Han Zhang[5], Peter M. Wayne[6] and Jian-Ping Liu[7,8]

- Serious adverse events are unlikely after Tai Chi
- Tai chi practice associated with occasional soreness, transient pain
- Poor/inconsistent reporting limit conclusions that can be made.

Yang 2022

TAICHIKNEE Trial Overview

Population	Adults over 50 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, Function, Pain medication, Quality of life (secondary)
Anticipated Implementation Strategies	Population health approaches, Internal facilitation, educational meeting, development and distribution of educational materials.
Implementation outcomes	Feasibility of implementation strategies



TAICHIKNEE Study Design

- Hybrid type 1 embedded, pragmatic trial
- Individually randomized group-treatment trial
  - individual randomization 1:1 to remote Tai Chi (3-month twice weekly)+Routine Care vs. Routine Care alone
  - Tai Chi delivered to small groups of ~10 participants through instructors
- Primary Endpoint
  - WOMAC (VAS 0-100 version) pain score at 3 months after randomization
- Key Secondary Endpoints
  - PROMIS Pain Interference at 3 months
  - SF-12 at 3 months
  - Number of knee joint injections at 12 months

TAICHIKNEE Eligibility Criteria

Inclusion

- Age 50 years or older
- Treating clinician diagnosis of Knee OA
- ≥40 on ≥ 1 of 5 WOMAC pain questions (VAS 0-100)
- Able to provide informed consent
- If randomized to Tai Chi, willing to comply with Tai Chi program (twice-a-week remote sessions for 12 weeks)
- If randomized to Routine Care, willing to abstain from Tai Chi until completion of the study
- Has access to home device that will allow telehealth (bidirectional audio and video) delivery of the intervention
- Is an active patient at one of the 4 participating HCS

Exclusion

- Currently practicing Tai Chi
- Serious medical conditions limiting ability to practice Tai Chi safely
- Unable to walk without a cane or other assistive device
- Any previous or scheduled knee replacement
- Reports severe depression (BDI-II≥29)
- Reports suicidal ideations (BDI-II #9 2 or 3).
- Not English speaking
- Enrollment in any other clinical trial within the last 30 days

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Recruitment Goal

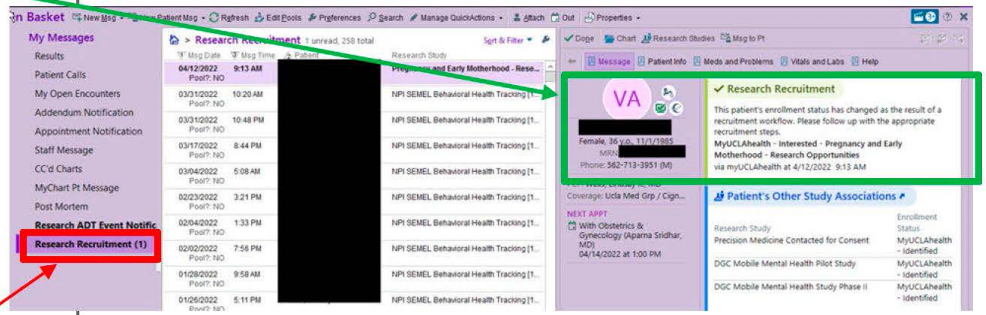
- Target sample size of 480 participants attained by recruiting 6 consecutive cohorts of 80 participants each
- At least 10 participants from each HCS in each cohort
- Randomization 1:1 after recruitment of 80 participants
  - ensures same zero time and randomization as close as possible to intervention
  - stratified by HCS and sex
- 4 instructors will teach Tai Chi for each cohort
  - for every other cohort, we will alternate between instructors A/B/C/D and instructors E/F/G/H.
- Participants randomly allocated to Tai Chi will choose preferred class day/time
  - encouragement of always attending the selected class
  - option to make up a class at another day/time if necessary
  - participants in a given class can be from different HCS
  - class size between 6 and 14

UCLA Recruitment Strategy

- Use CareConnect Research Tool for screening and recruitment
  - MyChart research recruitment
  - BPA-physician alerts in CareConnect to assist with referral
- Recruitment through UCLA Health, including Primary care clinics and Rheumatology clinics
  - Flyers and educational materials for clinics
  - Grand rounds or short meetings in relevant departments
  - Reach out to minority clinics- Hispanic and Asian
- Concentrate on partnering primary care physicians in integrative medicine
  - Educational meetings with providers at UCLA integrative medicine collaborative providers with periodic reminders
  - Educational materials and flyers at clinics
- Advertising approaches
  - Social media: UCLA Facebook, craig's list
  - Wellness UCLA staff newsletter adverting the study
  - local publications and radio

Study Coordinator Workflow – research Template

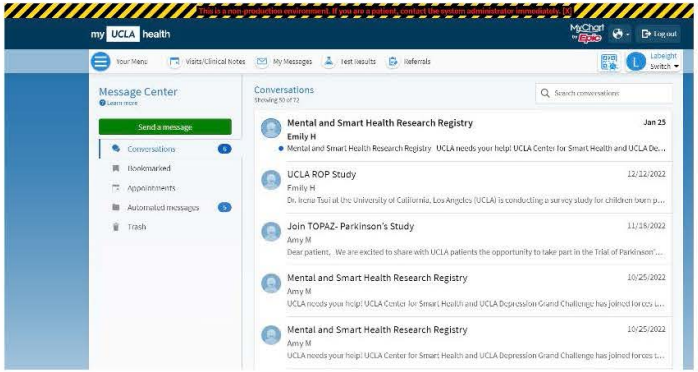
- If patient selects *'Interested'* the study team will get an in-basket with:
  - the patient name
  - phone number
  - age
  - D.O.B.
  - and the study they are replying to.

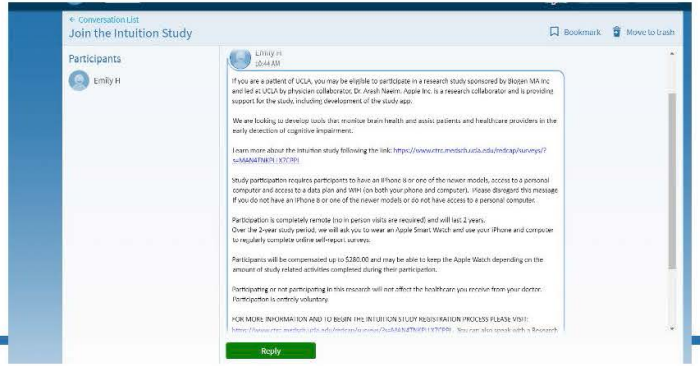


- A research label will appear in study team CC in-basket and replies will go in there.

CareConnect Research Tool(s): MyChart Direct Inbox Message

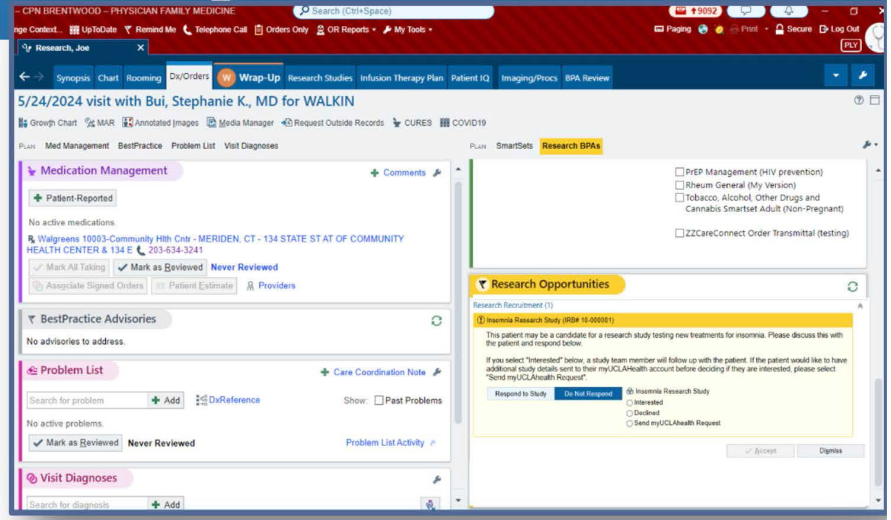
- Build the same as Recruitment template, based on study criteria (only smart data fields for inclusion/exclusion criteria)
- The message template needs are like the research recruitment template but can be more expanded.
- Eligible patients will be sent a direct MyChart inbox message.
- This tool is suitable for studies that require only one-time survey completion. Or studies that have a study website where the patient can be routed to a webpage and they are able to enroll, consent, or fill out pre-screening information without needing a coordinator to follow-up.

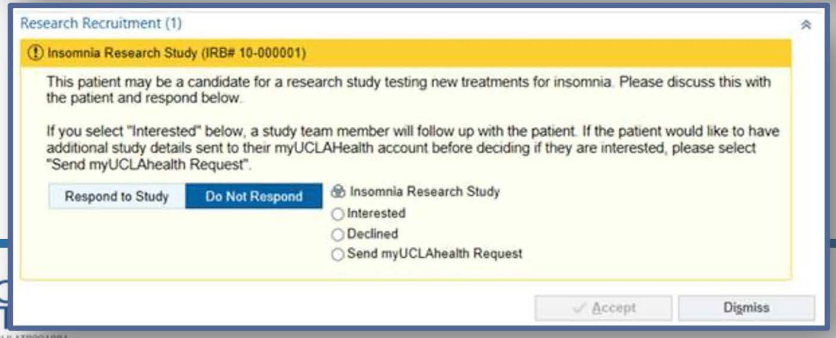




CareConnect Research Tool(s): Provider-Facing BPA in Care Connect

- Alert physicians of eligible patients during clinic visit in CareConnect.
- Physicians can then talk to patient about the study and select within the alert if patient says they are interested.
- The research coordinator then receives access to those interested and can contact patient with next steps.





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THANK YOU!

QUESTIONS?

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