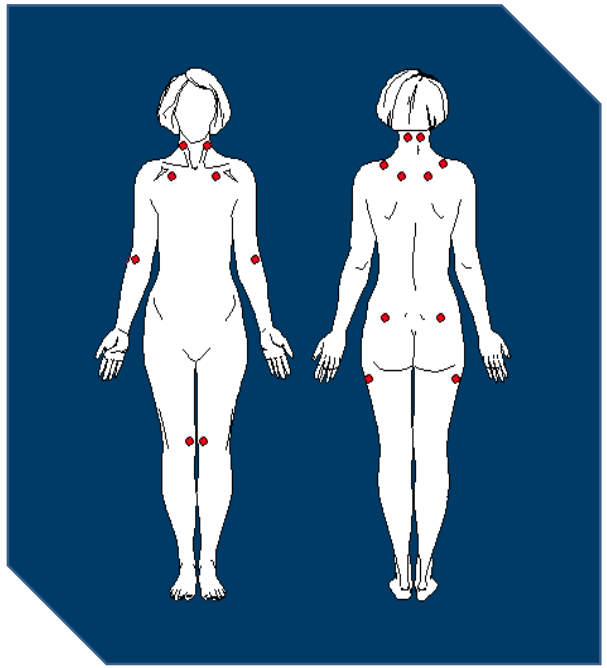
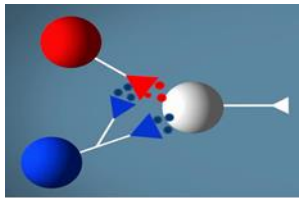
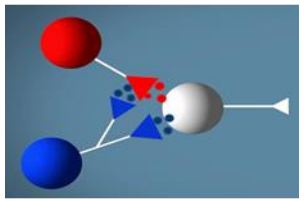
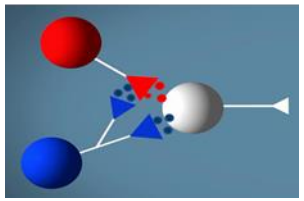
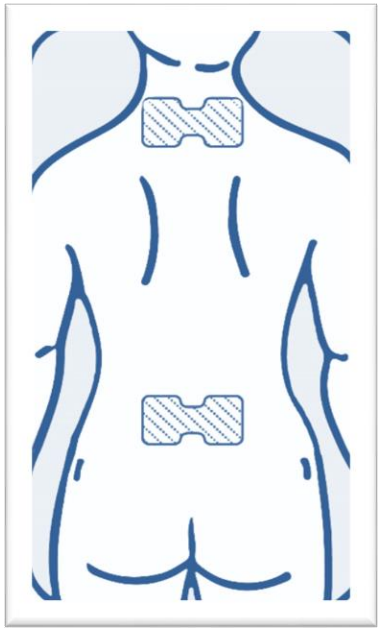










FIBROMYALGIA TENS IN PHYSICAL THERAPY STUDY (FM TIPS)

KICK OFF MEETING – NOVEMBER 19, 2019

The University of Iowa

Vanderbilt University

PARTNERSHIP BETWEEN THE COLLEGE OF PUBLIC HEALTH AND THE CARVER COLLEGE OF MEDICINE AT THE UNIVERSITY OF IOWA AND VANDERBILT UNIVERSITY

FM TIPS LEADERSHIP TEAM

Kathleen A. Sluka, PT, PhD, FAPTA

Professor

Leslie J. Crofford, MD

Professor

Dana Dailey, PT, PhD

Assistant Professor

Christopher Coffey, PhD

Director CTSDMC

Dixie Ecklund, RN, MSN, MBA

Director of Operations CTSDMC

Emine Bayman, PhD

Associate Director CTSDMC

M. Bridget Zimmerman, PhD

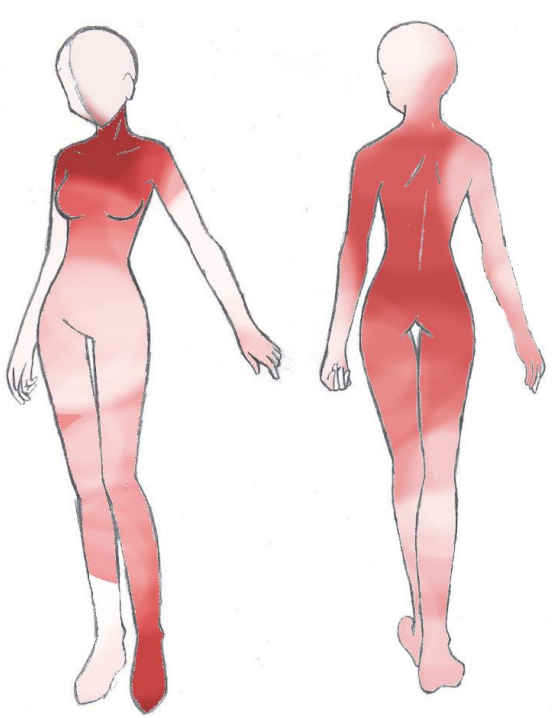
Clinical Professor

OTHER TEAM MEMBERS

- Regulatory and Protocol Development (Ecklund)
  - Michele Costigan
  - Carla Franck
  - Trevis Huff
  - Maxine Koepp
  - Tina Neill-Hudson
  - Leslie Crofford
  - Carol Vance
  - Dana Dailey
  - Bridget Zimmerman
  - Emine Bayman
- Site Team (Sluka)
  - Carol Vance
  - Kristin Archer
  - Bridget Zimmerman
  - Maxine Koepp
  - Michele Costigan
  - Carla Franck
  - Dixie Ecklund
  - Dana Dailey
- Clinical Teams

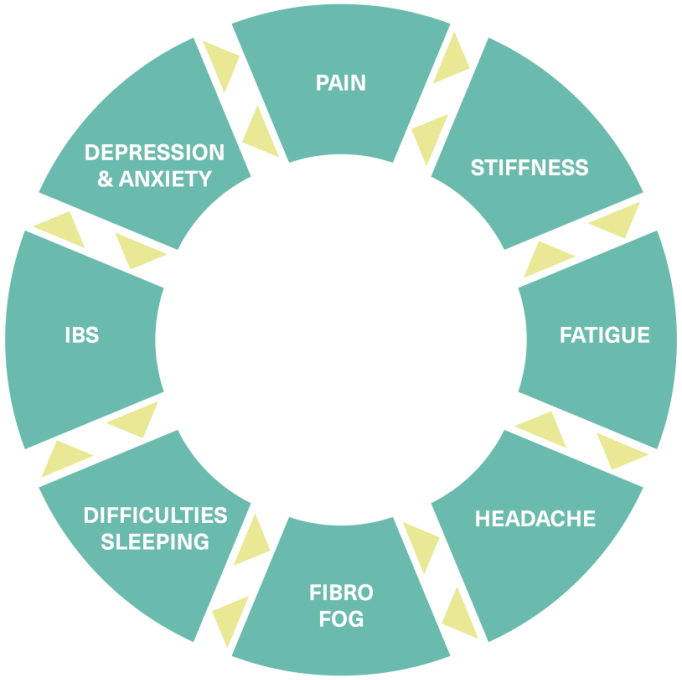
  TENS (Vance), Logistics (Dailey), PRO and Data Collection(Crofford)
  - Kathleen Sluka
  - Ruth Chimenti
  - Dana Dailey
  - Michele Costigan
  - Maxine Koepp
  - Kristin Archer
  - Carla Franck
  - Sandra Mostaert
  - Emine Bayman
  - Richard Peters
  - Trevis Huff
  - Andrew Post
  - Carol Vance
  - Bridget Zimmerman
- Design and Analysis Team (Bayman and Zimmerman)
  - Janel Fedler
  - Jon Yankey

FIBROMYALGIA IS ASSOCIATED WITH WIDESPREAD PAIN, CO-MORBID SYMPTOMS, AND CENTRAL SENSITIVITY



Fibromyalgia Diagnostic Criteria 2016[2]

1. Generalized pain
2. >3 months
3. Fibromyalgia Severity
   a. Widespread pain index
   b. symptom severity scale score



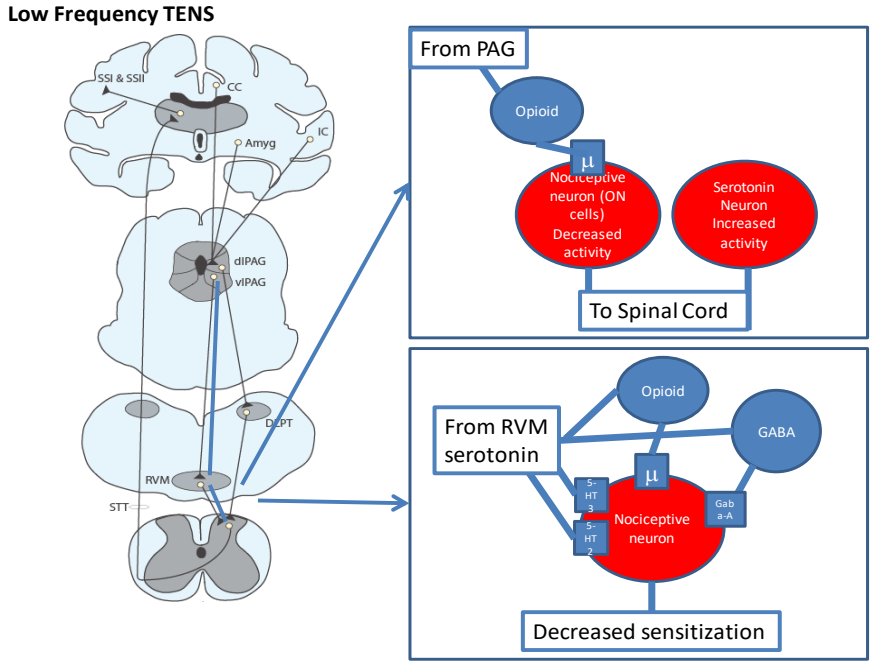
FIBROMYALGIA PAIN CYCLE

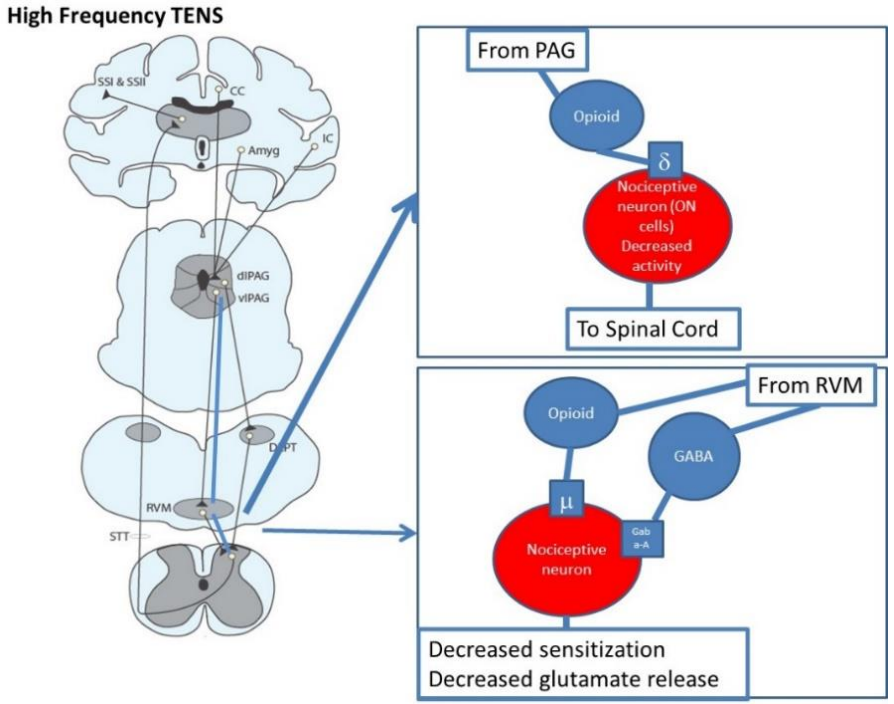
[1]Mansfield 2016, [2]Wolfe 2016

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS)

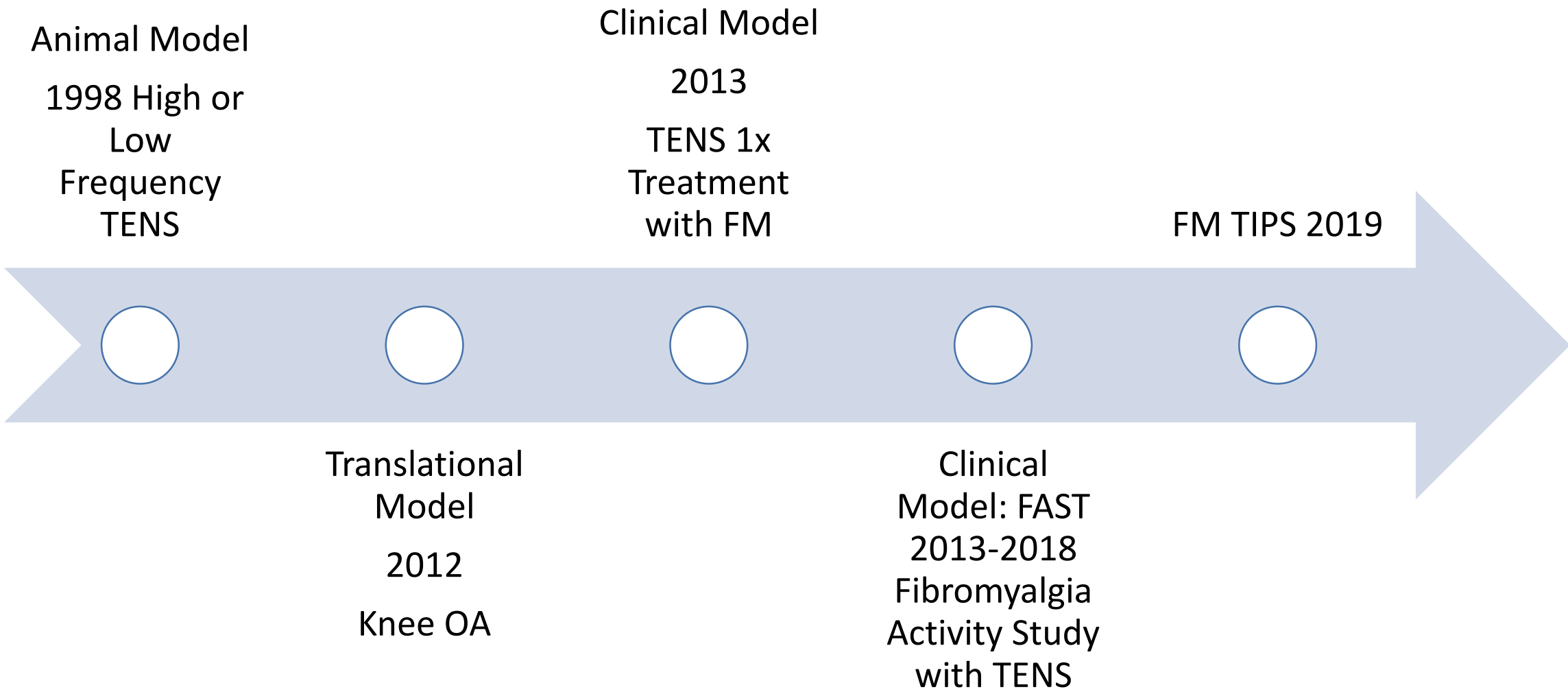
- Application of electrical stimulation to the skin for pain control (APTA 1990)

TENS USES ENDOGENOUS INHIBITORY MECHANISMS TO PRODUCE ANALGESIA





PATH TO FM TIPS:



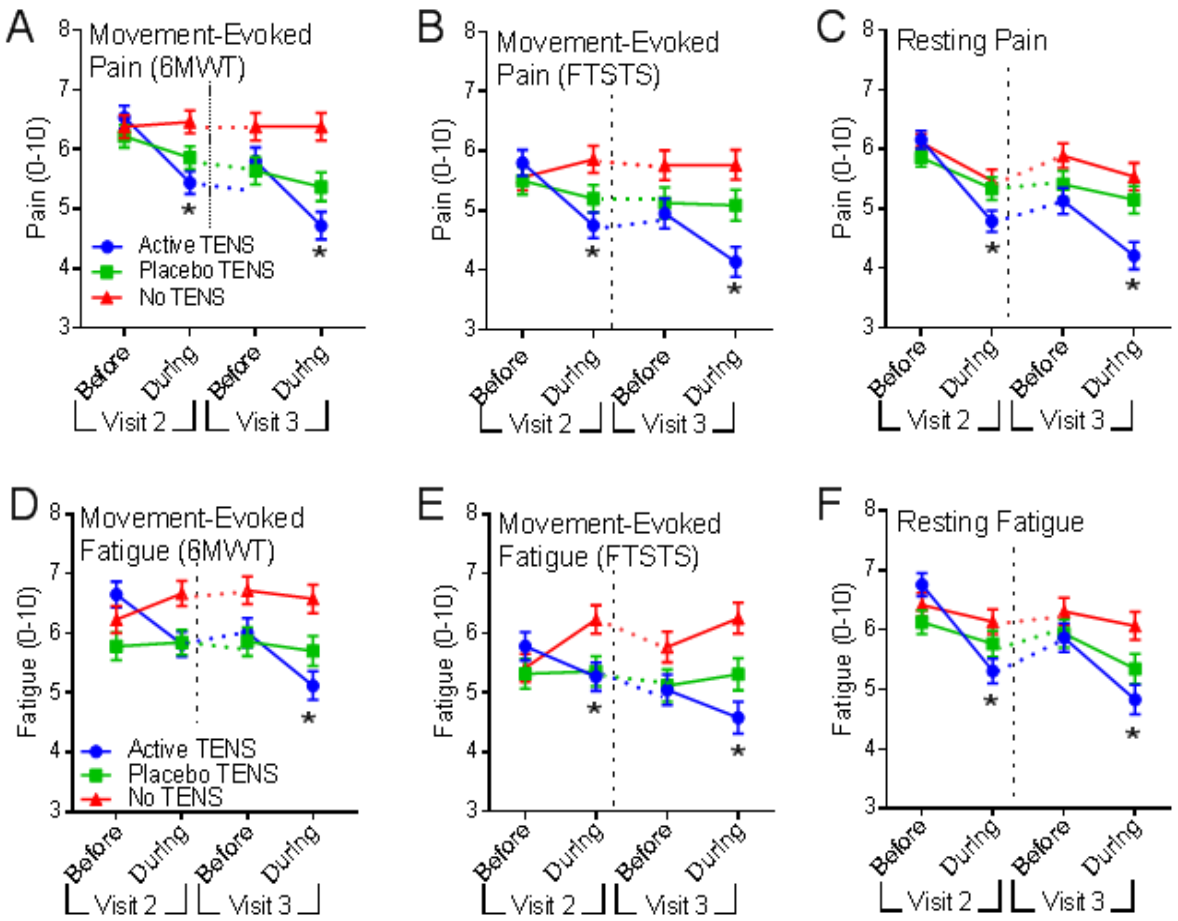
TENS DOSING IS CRITICAL TO EFFECTIVENESS

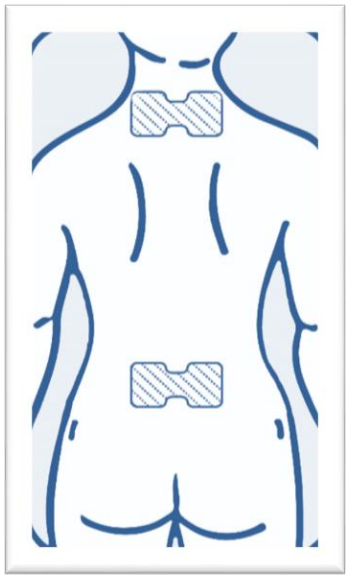
Clinical Message

1. Intensity set as "strong but comfortable"

2. Give instructions to increase as able

TENS REDUCES *MOVEMENT* AND RESTING PAIN





Mixed Frequency

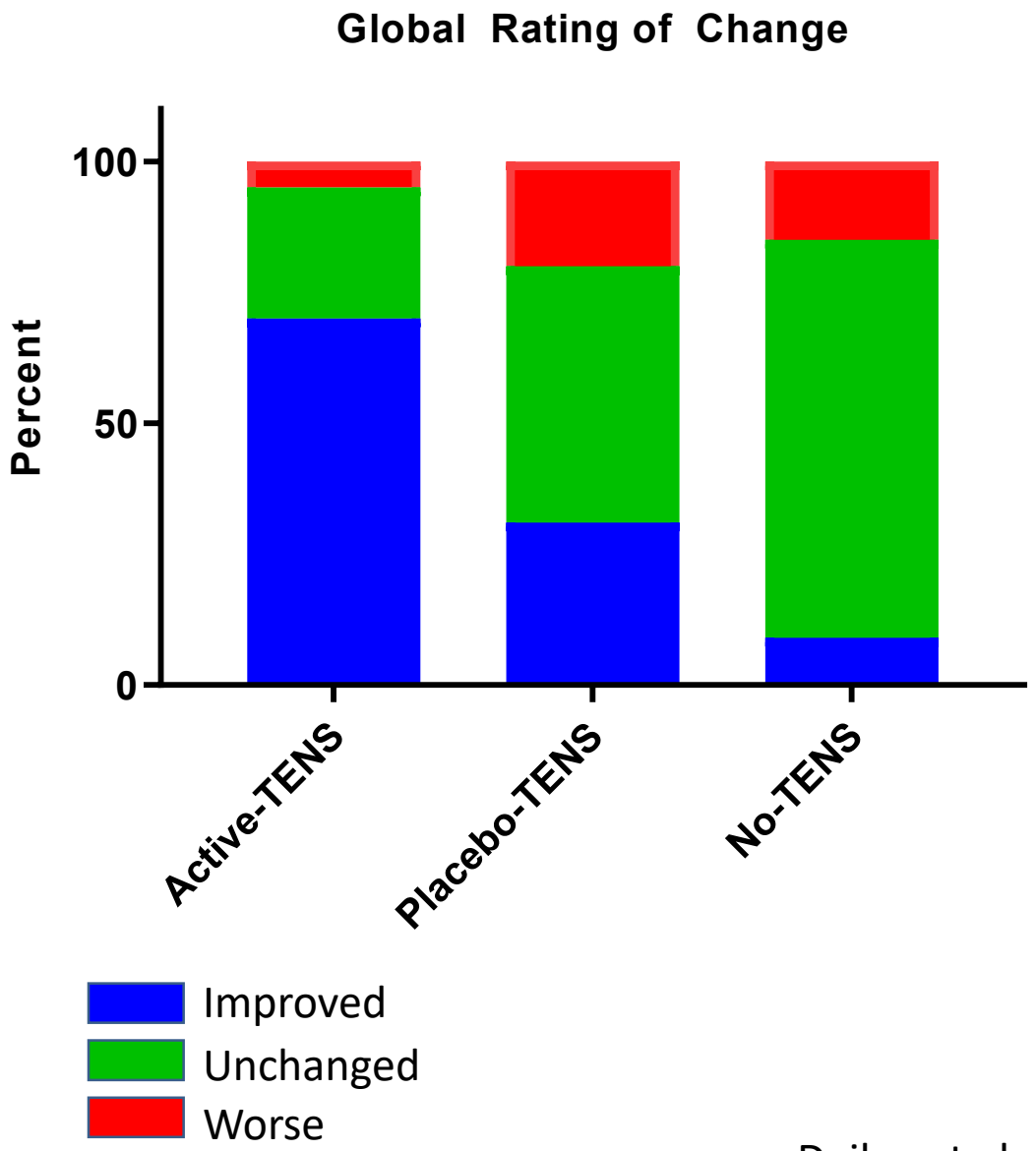
Active-TENS, n=103
Placebo-TENS, n=99
No-TENS, n=99

Dailey et al., 2019

TENS IMPROVES GLOBAL RATING OF CHANGE

NNT=3

To decrease movement pain



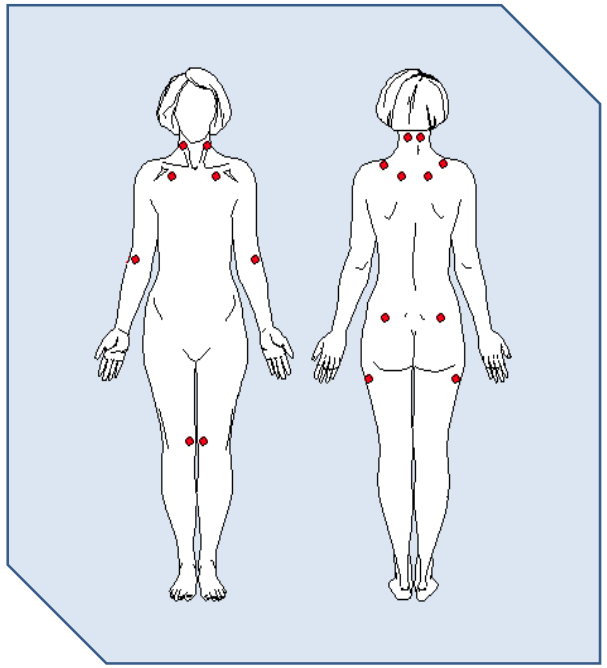
Dailey et al., 2019

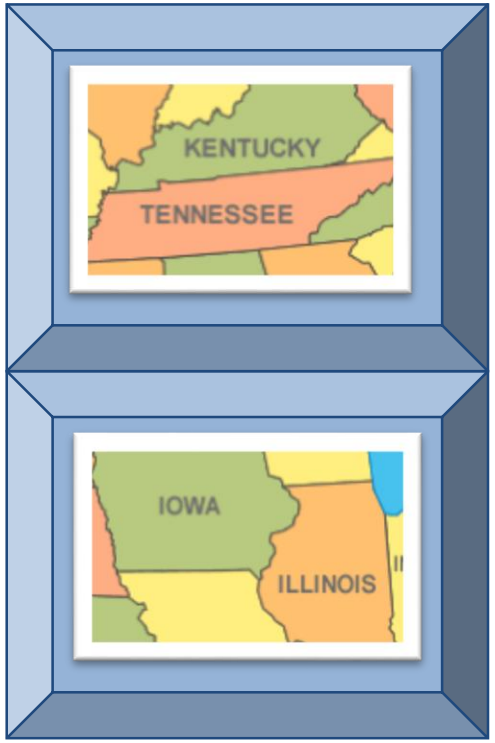
RESPONDER ANALYSIS

Responder Definitions	% Responder (95% CI)			Risk difference (adjusted 95% CI) Adjusted P-value	
	Active-TENS n=103	Placebo-TENS n=99	No-TENS n=99	Active-TENS vs Placebo-TENS	Active-TENS vs No-TENS
≥30% reduction in pain	44% (34, 53)	22% (15, 31)	14% (9, 22)	22 (6, 37) 0.004	30 (15, 44) <0.001
≥20% reduction in fatigue	45% (35, 54)	26% (19, 36)	23% (16, 33)	19 (3, 34) 0.019	22 (6, 37) 0.004
≥20% improved function	38% (29-48)	36% (28, 46)	28% (20, 38)	2 (-15, 18) 0.974	10 (-6, 25) 0.319
≥30% reduction in pain and ≥20% reduction in fatigue	29% (21-39)	13% (8, 21)	13% (8, 21)	16 (3, 29) 0.018	16 (3, 29) 0.018

Dailey et al., 2019

FIBROMYALGIA TENS IN PHYSICAL THERAPY STUDY (FM TIPS)





The University of Iowa

Vanderbilt University

STUDY OVERVIEW

- **Goal**:
  - Demonstrate the feasibility of adding TENS to treatment of patients with FM in a real-world *Physical Therapy* practice setting **and**
  - Determine if addition of TENS to standard *Physical Therapy* for FM reduces pain, increases adherence to PT and allows patients with FM to reach their specific functional goals with less drug use.
- **Hypothesis**
  - Using TENS in a *Physical Therapy* setting is feasible and that FM patients using TENS are more likely to reach their therapeutic goals.

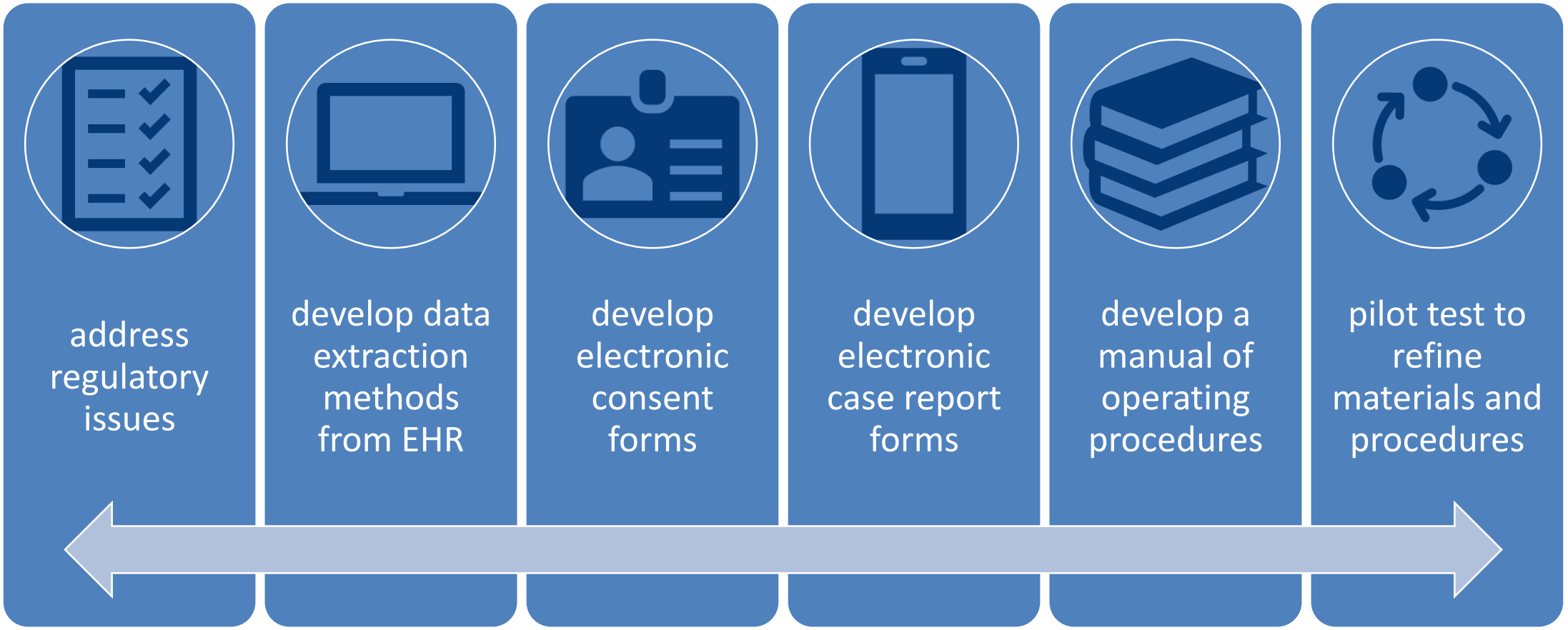
UG3 AIM 1: PLANNING YEAR

RECRUIT PHYSICAL THERAPY PRACTICES AS RESEARCH SITES FOR AN EMBEDDED PRAGMATIC CLINICAL TRIAL, UNDERSTAND USUAL PT PRACTICE FOR PATIENTS WITH FM TO INFORM TRIAL PROCESSES, AND DEVELOP IMPLEMENTATION PROCEDURES

- Recruit community PT clinics willing to offer TENS as an adjunct to usual care for FM
- Perform interviews with front-line providers to evaluate PT-interventions for FM
- Evaluate potential barriers to TENS use during routine PT practice

UG3 AIM 2: PLANNING YEAR

ENSURE ADEQUACY OF INFRASTRUCTURE AT POTENTIAL STUDY SITES TO COMPLETE A PT EMBEDDED PRAGMATIC TRIAL

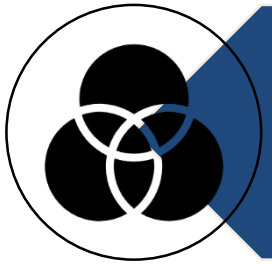


UH3: PRAGMATIC TRIAL AIMS

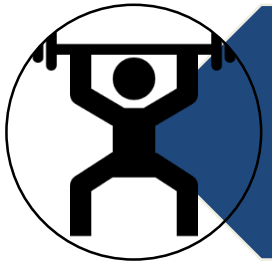
UH3 AIM 1: *DETERMINE IF ADDITION OF TENS TO ROUTINE PT IMPROVES MOVEMENT-EVOKED PAIN*

UH3 AIM 2: *DETERMINE IF ADDITION OF TENS TO ROUTINE PT IMPROVES 1) DISEASE ACTIVITY, 2) LIKELIHOOD OF MEETING PATIENT-SPECIFIC FUNCTIONAL GOALS, 3) ADHERENCE TO PT, AND 4) MEDICATION USE*

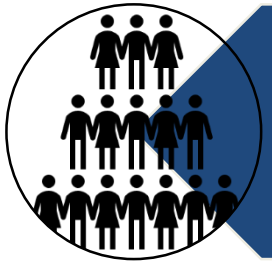
UH3 AIM 3: *EXAMINE FEASIBILITY OF IMPLEMENTING TENS INTO ROUTINE PT CARE FOR FM USING SEMI-STRUCTURED EXIT INTERVIEWS OF PATIENTS AND PTS*



cluster-randomized pragmatic trial



routine PT with or without TENS for FM



enroll ~600 people with FM

MILESTONE: SELECTION OF CLINICS (=20 CLINICS)

Kepros Physical Therapy and Performance – Iowa, local

Carla Franck, a PT with Kepros Physical Therapy will be part of the study team to help develop outcomes and training procedures for implementation of the trial

Genesis Healthcare Systems - Quad Cities, Iowa and Illinois

15 outpatient PT practices which see 200-300 FM patients per year

Vanderbilt University Physical Therapy Services - Nashville, TN

2 clinics that see approximately 100 people with FM per year

BenchMark Physical Therapy- Tennessee and Kentucky

regional network identified (approximately 10-15 sites)

Rock Valley Physical Therapy – Iowa and Illinois

>50 sites in rural and city environments

Results Physical Therapy – Tennessee

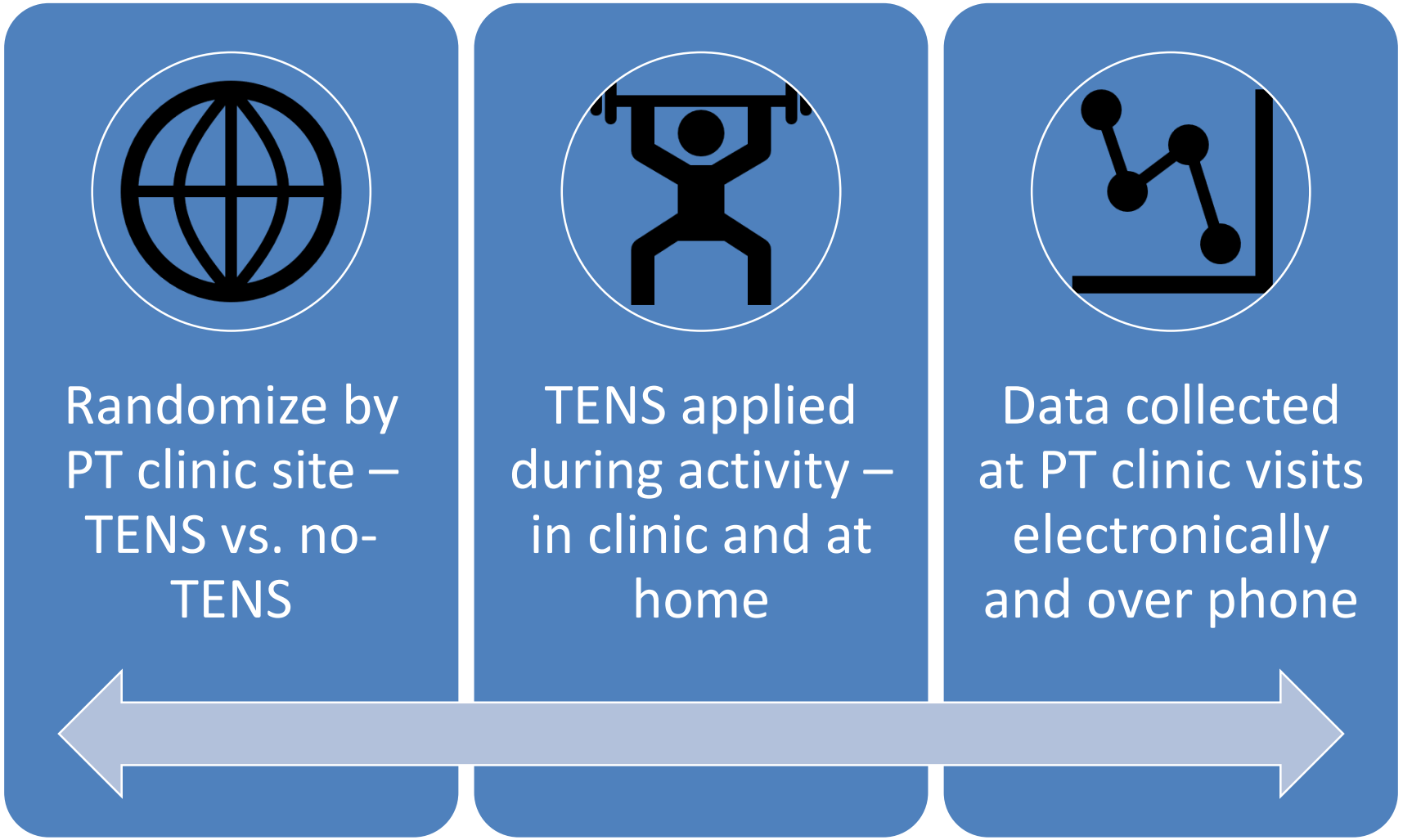
>50 sites rural and city environments

MILESTONE: DRAFT PROTOCOL

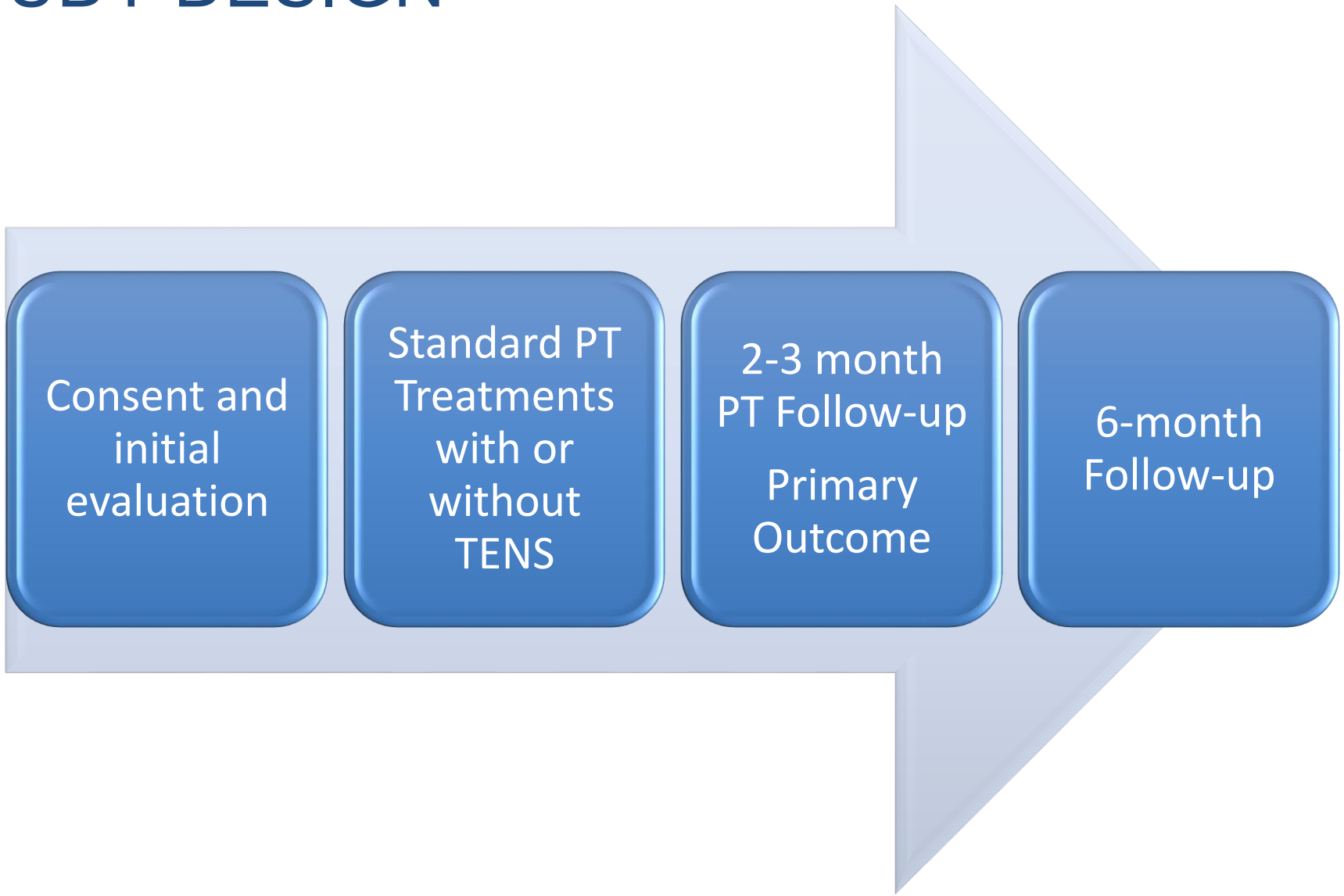
Participants

- Inclusion:
  - Individuals referred for land-based PT who have been diagnosed by a physician with FM
  - Primary diagnosis prompting referral or referred for axial pain
- Exclusion
  - Unwilling to use TENS
  - TENS contraindications
- NOTE: FM Diagnosis will be confirmed using instruments filled out by participants

STUDY OVERVIEW



STUDY DESIGN



MILESTONE: OUTCOMES

Pain. Pain during activity (movement-pain, primary outcome), and at rest (secondary outcome) using a 0-10 NRS

Patient-Specific Functional Scale (PSFS) - patient identifies 2-5 functional goals for the treatment plan, and rates their ability to do these on an 11-point scale: 0 unable to perform activity and 10 able to perform at the same level as before problem

Patient-Reported, Validated
Fibromyalgia Impact Questionnaire (FIQR), 21-item disease specific questionnaire that is divided into 3 domains: function, overall impact, and symptoms.

The FM 2016 diagnostic criteria is a simple assessment that the patient can self-report and allows for determination of a Widespread Pain Index, Symptom Severity Scale, and Fibromyalgia Severity Score.
PROMIS modules

HEAL common dataset - BPI, MOS-Sleep, PCS, Depression PHQ-2, Anxiety GAD-2, PGIC, TAPS.

Patient Adherence Indicators. EHR queries of data recorded at follow-up visits: Record if the patient used TENS, attended PT, or performed their home exercise program.

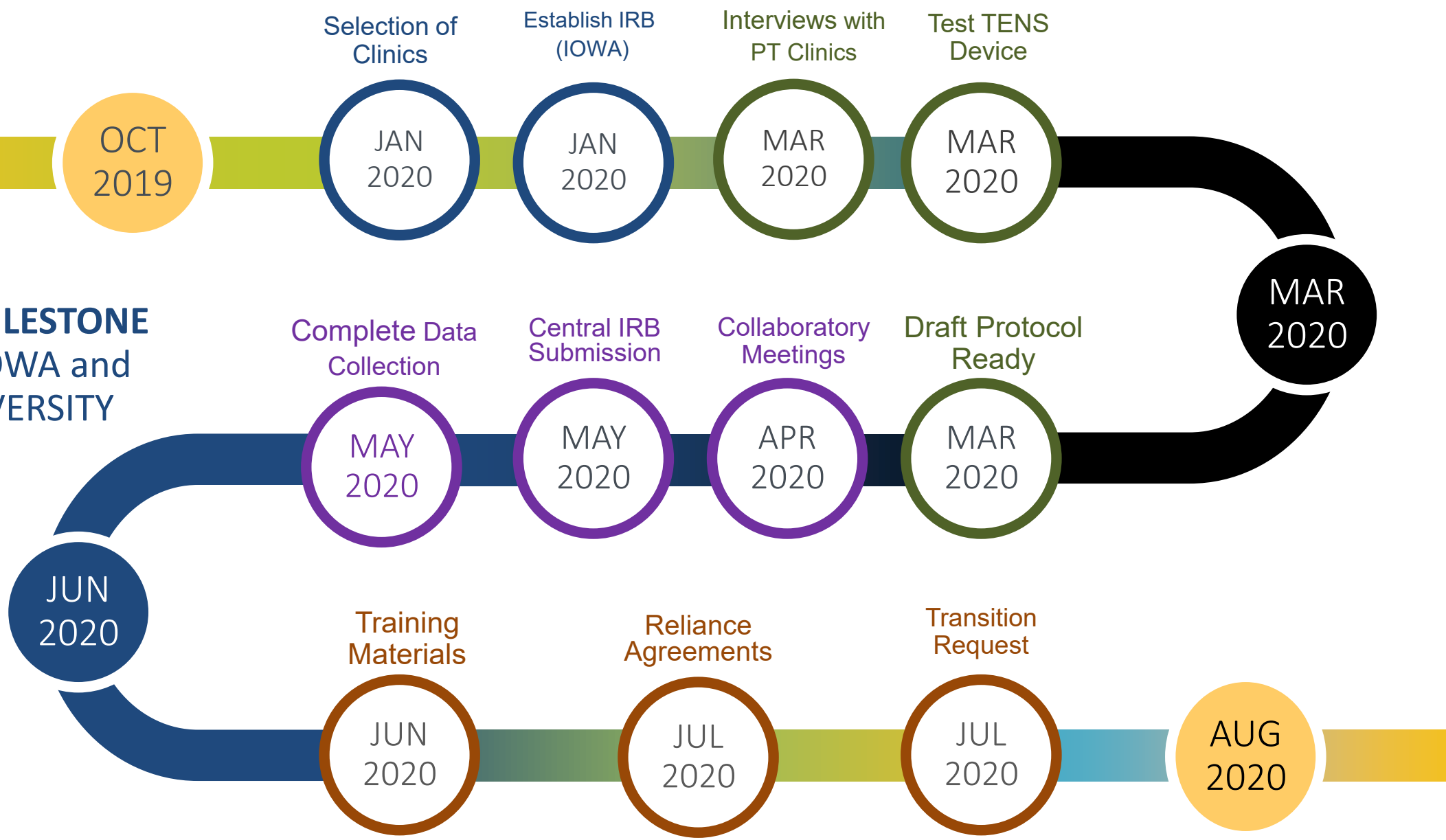
Medications collected through the EHR and patient report. We will ask both FM medication and doses, and prn medications and usage (opioids, NSAIDs, Tylenol).

Additional questions for patients at the follow-up visit will include ease of TENS use, barriers to TENS use, and general perceptions about TENS for pain control

Exit interview questions of all PT providers about use of TENS in PT practice for FM and chronic pain to assess likelihood of continued use, provider perceptions on usefulness of TENS for patients, barriers to TENS use in the clinic, perceived barriers to TENS use by patients

FM TIPS
OVERVIEW OF MILESTONE
UNIVERSITY OF IOWA and
VANDERBILT UNIVERSITY

2019-2020



Executive	Regulatory & Protocol Development	Clinical			Site
		TENS	Logistics	PRO/Data Collection	
Sluka*	Ecklund*	Vance*	Dailey*	Crofford*	Sluka *
Crofford*	Neill Hudson	Chimenti	Archer	Bayman	Vance
Ecklund	Costigan	Sluka	Franck	Koepp	Archer
Archer	Crofford	Koepp	Post	Franck	Zimmerman
Bayman	Vance		Costigan	Huff	Koepp
Dailey	Dailey		Koepp	Peters	Costigan
	Zimmerman			Zimmerman	Ecklund
	Bayman				# Ad Hoc: Dailey, Franck
Monthly/Bi-Monthly	*Weekly*	*Weekly*	*Weekly*	*Weekly*	*Weekly*
Tasks to achieve Milestones					
Oversee operations	MOP	Evaluate TENS unit	Instrument Administration	Instrument selection	Clinic Interviews
	NIAMS Protocol	Test units in people	Contacting sites	Data management	Site Selection
	Operational Training Materials	Evaluate cost of units	MOP development	Statistical analysis Plan	Recruitment Strategy
	CIRB	Develop education and training materials for TENS	Training materials	Power analysis	Site Training- CITI and protocol
	Site selection and contracts	Protocol for ordering and tracking TENS units	Pilot Test Protocol in Clinics		Interviews with selected PT's
					Recruitment

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	

1=easy, 5=difficult

DATA SHARING UG3

- ***What is your current data sharing plan and do you foresee any obstacles?***
  - *Publish data in peer-reviewed journal*
  - *Post final data set on central server at University of Iowa*

- ***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 are not waiving 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*