An Integrated Approach to Peri-Operative Management for Prevention of Chronic Pain

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Acknowledgements and Disclosures

- Funded by NIAMS – 1UM1AR062800
- No conflicts of interest to disclose
- Many thanks to patients for participating
- Thank you also to PTs, Clinical Psychologists and Nurse interventionists.

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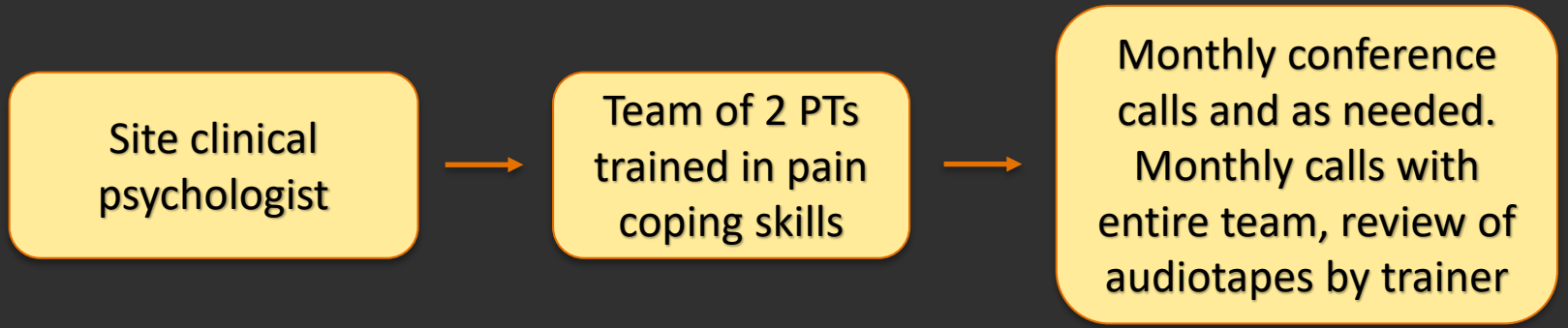
The integrated care model of interest

- Collaborative care between physical therapists and clinical psychologists with an interest in pain, providing pain coping skills training via in-person and telephone sessions to persons scheduled for TKA.



Pain Coping Skills Training

- Traditionally a CBT-related care approach
- Traditionally delivered in RCTs as an “all-comers” intervention
- We studied a specific phenotypic subgroup: patients scheduled for TKA with moderate to high pain catastrophizing

The pain catastrophizing phenotype

- Pain catastrophizing scale scores of ≥ 16, predicting poor pain outcome in patients with TKA (Riddle et al, 2010, Dave et al, 2016, Sullivan et al, 2011).
- Patients in the current trial had a mean PCS score of 30 (sd = 9.3).
- Typical scores for TKA samples ≈ 10 (sd = 10)

Coping Skills for Patients fitting the Pain Catastrophizing Phenotype: An RCT of Persons Undergoing Knee Arthroplasty

(NCT01620983)

1UM1AR062800

NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases

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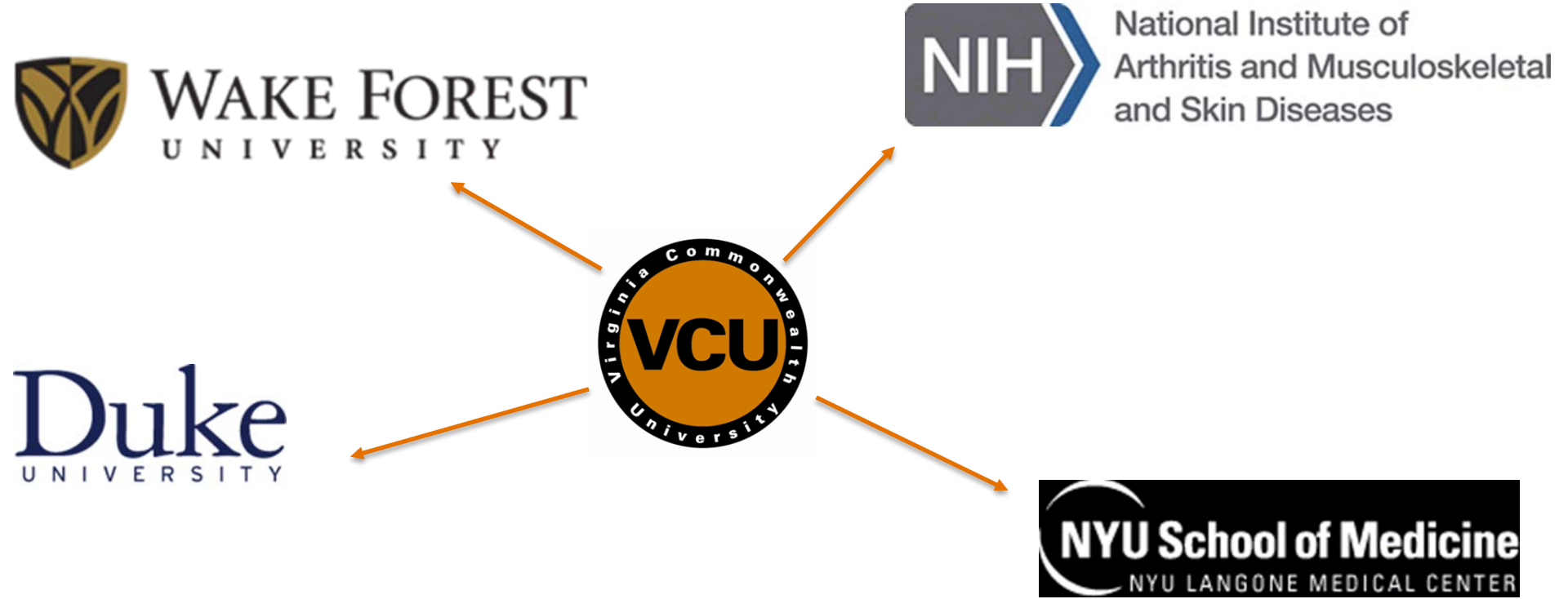
Participating Institutions



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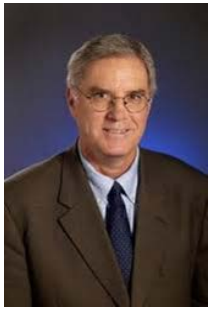

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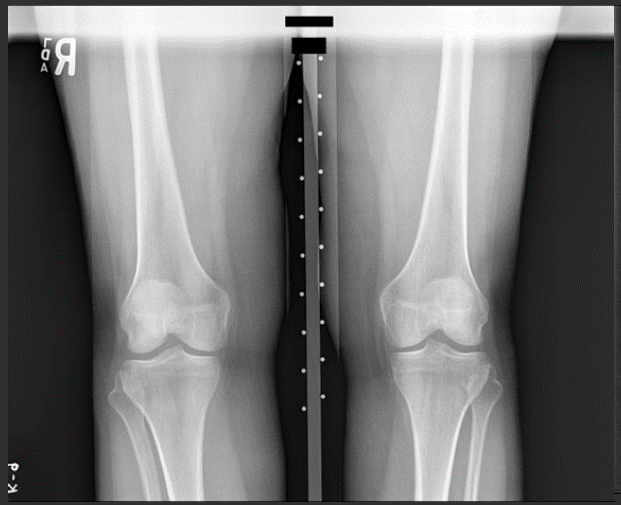
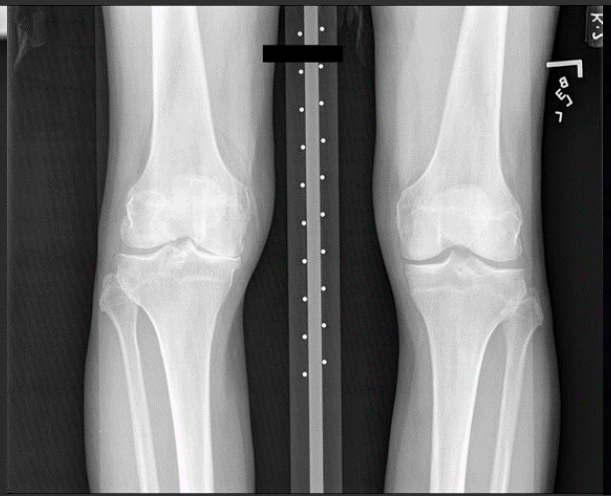
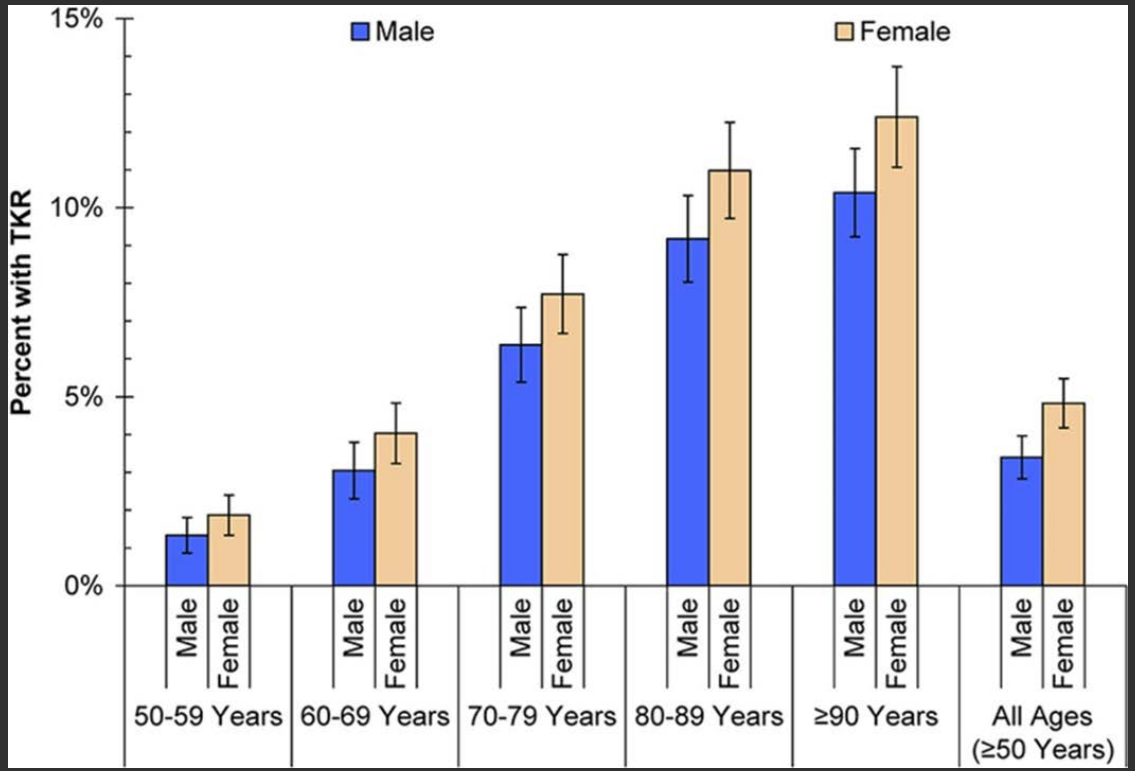
The knee - from normal to replaced



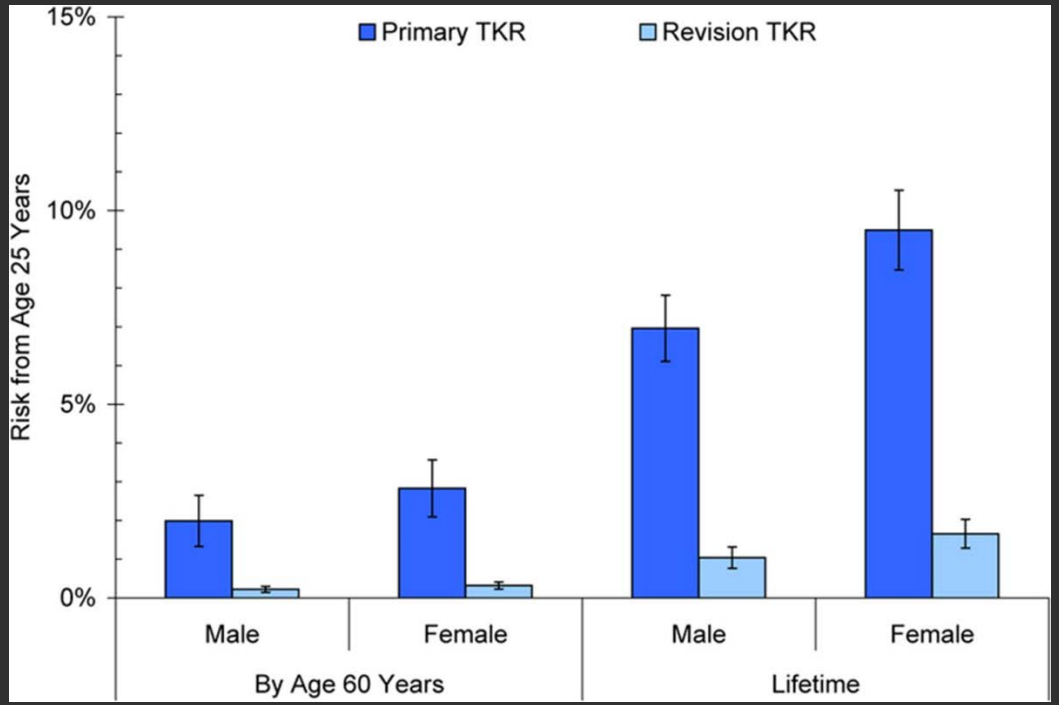


Estimated prevalence of TKA in US by age and sex



Weinstein et al, J Bone Joint Surg AM. 2013;95:385-392.

Estimated risk of 1° and revision TKA from 25 yrs by sex



Weinstein et al, J Bone Joint Surg AM. 2013;95:385-392.

Why is the pain catastrophizing phenotype an important group to study?

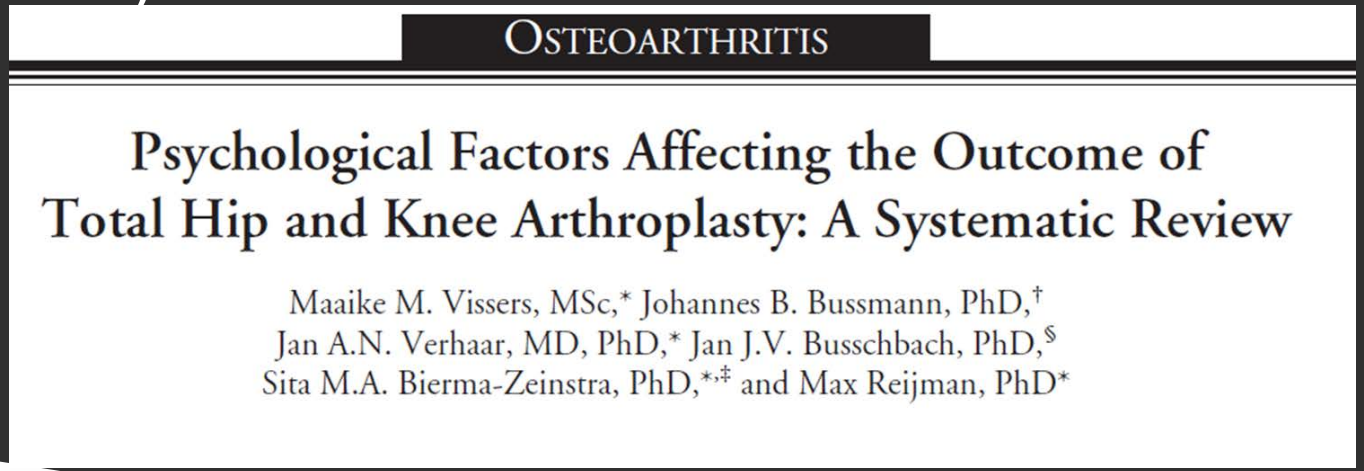
- Report more severe pain, worse function
- Demonstrate more pain behavior (critical for TKA recovery)
- Report higher rates of mental health and coping challenges
- Greater use of analgesics
- Elevated Pain Catastrophizing is a known risk factor for poor outcome in TKA.

The essence of pain catastrophizing

- A multidimensional pain appraisal construct including
  - Rumination (I worry whether the pain will end)
  - Helplessness (Nothing I can do to reduce the pain)
  - Magnification (I wonder if something serious may happen)

In the context of a challenging TKA surgery and recovery….

- Pain catastrophizing may explain a large proportion of those with persistent pain following technically sound surgery (≈ 20%)



OSTEOARTHRITIS

Psychological Factors Affecting the Outcome of Total Hip and Knee Arthroplasty: A Systematic Review

Maaike M. Vissers, MSc,* Johannes B. Bussmann, PhD,†
Jan A.N. Verhaar, MD, PhD,* Jan J.V. Busschbach, PhD,§
Sita M.A. Bierma-Zeinstra, PhD,*,‡ and Max Reijman, PhD*

Seminars in Arthritis and Rheumatism, 2012

Our trial planning process

- The R34 and UM1 funding mechanism at NIAMS
- Pre-trial investigator meeting for planning
- Use of the PRECIS instrument

Key steps in finalizing design

- To what extent should the trial be pragmatic or explanatory?
  - Historically, cognitive behavioral trials have been highly explanatory
  - We were bringing together a multidisciplinary team with both pragmatic and explanatory biases
  - The PRECIS was needed to sort out and reveal biases in order to directly address them when designing the trial

ELSEVIER

Journal of Clinical Epidemiology 62 (2009) 464–475

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers

Kevin E. Thorpe[a,*], Merrick Zwarenstein[b], Andrew D. Oxman[c], Shaun Treweek[d], Curt D. Furberg[e], Douglas G. Altman[f], Sean Tunis[g], Eduardo Bergel[h], Ian Harvey[i], David J. Magid[j], Kalipso Chalkidou[k]

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Accepted 13 December 2008

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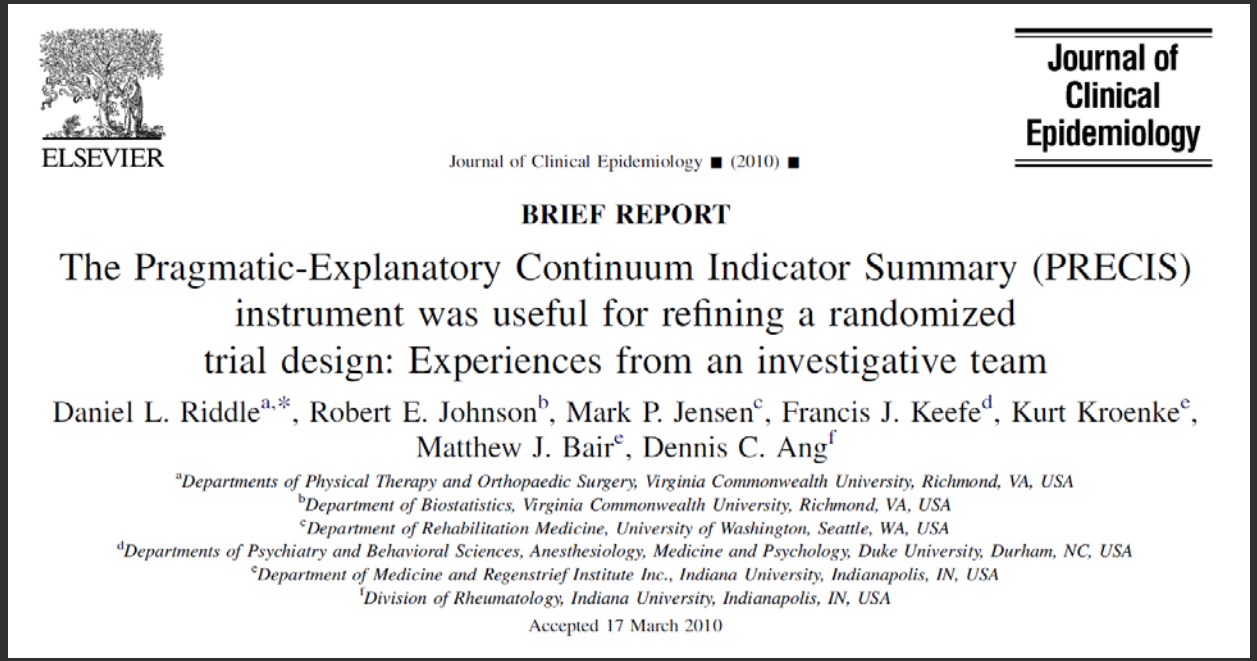
We prospectively designed the trial with PRECIS as a guide



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Journal of Clinical Epidemiology ■ (2010) ■

Journal of Clinical Epidemiology

BRIEF REPORT

The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) instrument was useful for refining a randomized trial design: Experiences from an investigative team

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Accepted 17 March 2010

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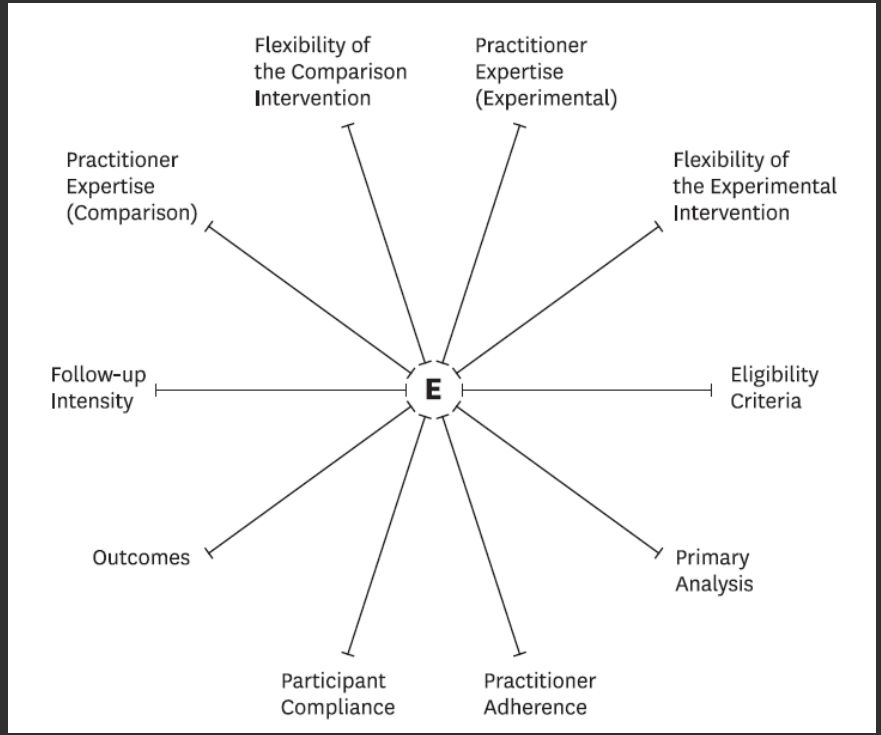
The steps to judging the P-E Continuum

Table 1
Summary of the 10 PRECIS domains

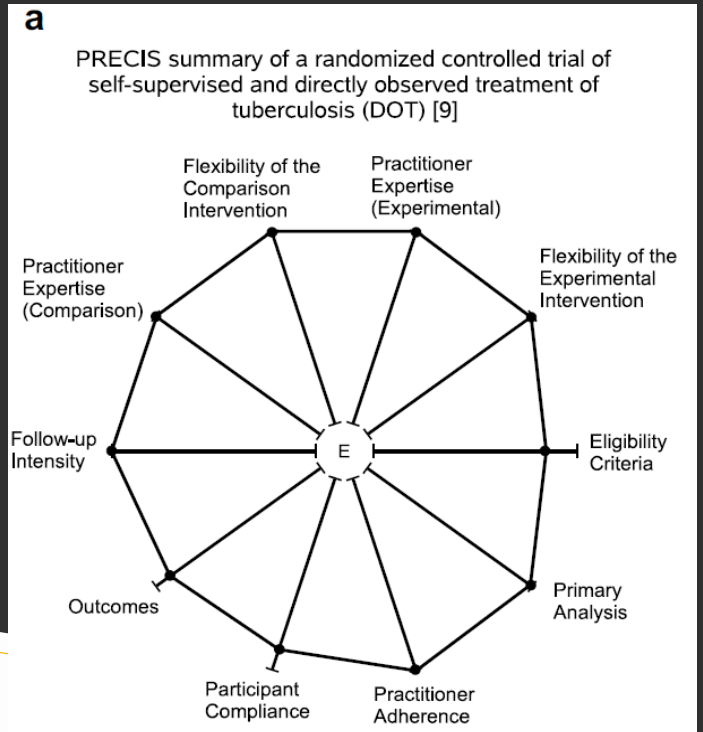
Domain	Description
1	Eligibility criteria for trial participants
2	Extent of flexibility in application of the experimental intervention
3	Degree of practitioner expertise in applying and monitoring the experimental intervention
4	Extent of flexibility in application of the comparison intervention(s)
5	Degree of practitioner expertise in applying and monitoring the comparison intervention(s)
6	Intensity of follow-up of trial participants
7	Nature of the primary outcome
8	Intensity of measurements of participants' compliance to study protocol and whether compliance improving strategies are used
9	Intensity of measurements of practitioners' adherence to study protocol and whether adherence-improving strategies are used
10	Specification and scope of analysis of primary outcome

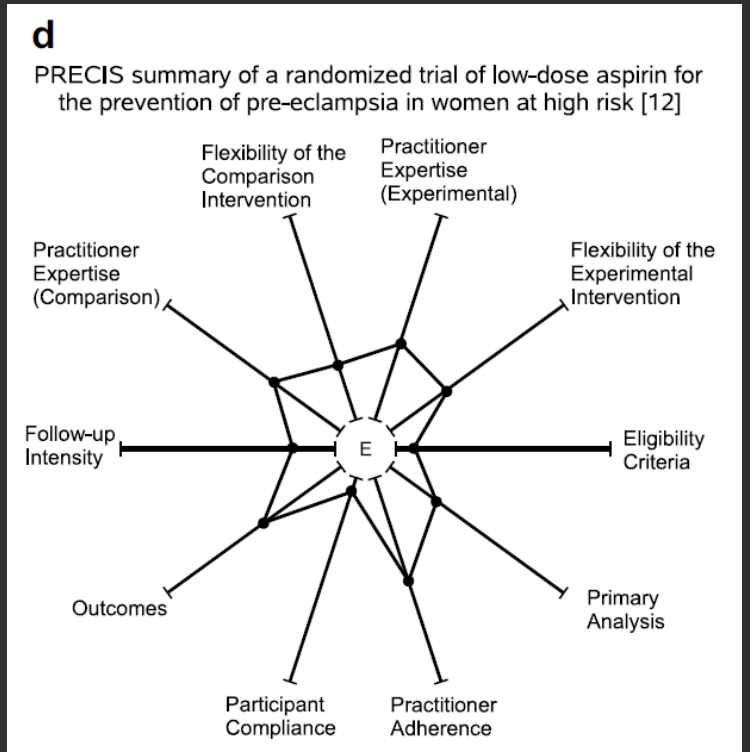


Criteria from PRECIS – 2 Examples

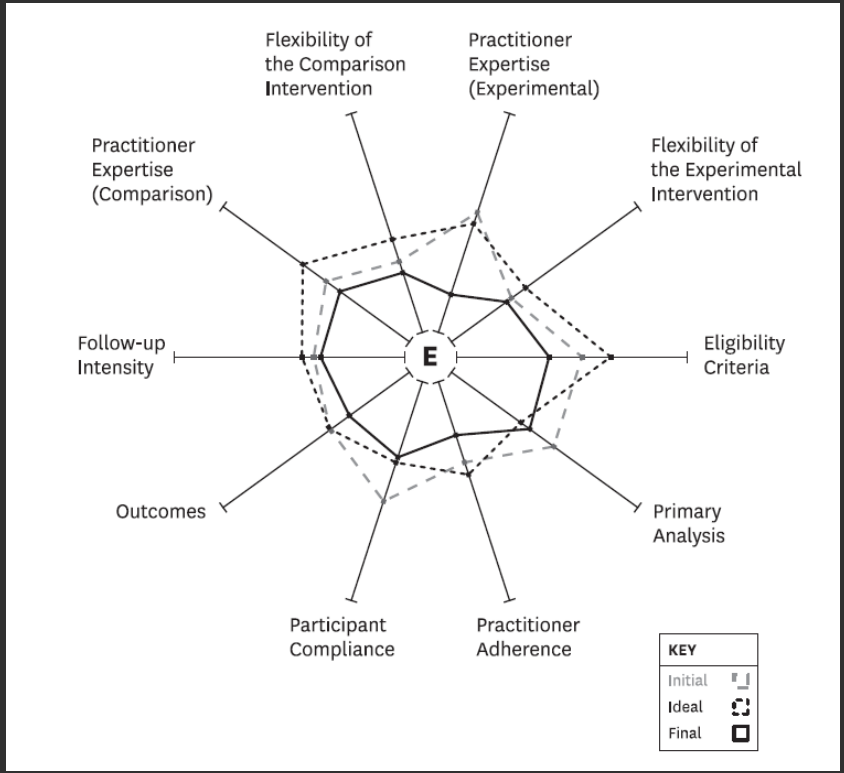
Domain	Pragmatic Trial	Explanatory Trial
Participant eligibility criteria	All participants who have the condition of interest are enrolled, regardless of anticipated risk, responsiveness, co-morbidity, or past compliance.	Stepwise selection criteria applied to restrict study individuals to just those who are thought likely to be highly responsive to the intervention
Primary trial outcome	The primary outcome is an objectively measured, clinically meaningful outcome to the study participants, assessed under usual conditions.	The outcome is known to be a direct consequence of the intervention. May be a surrogate marker of another downstream outcome

Highly pragmatic and highly explanatory trials

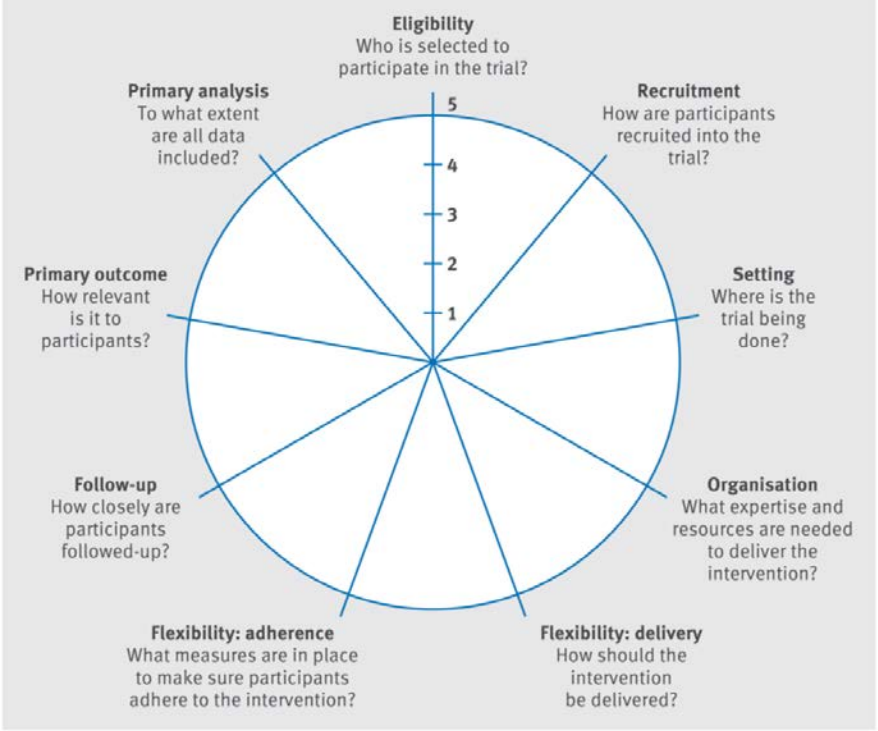




How did we do?

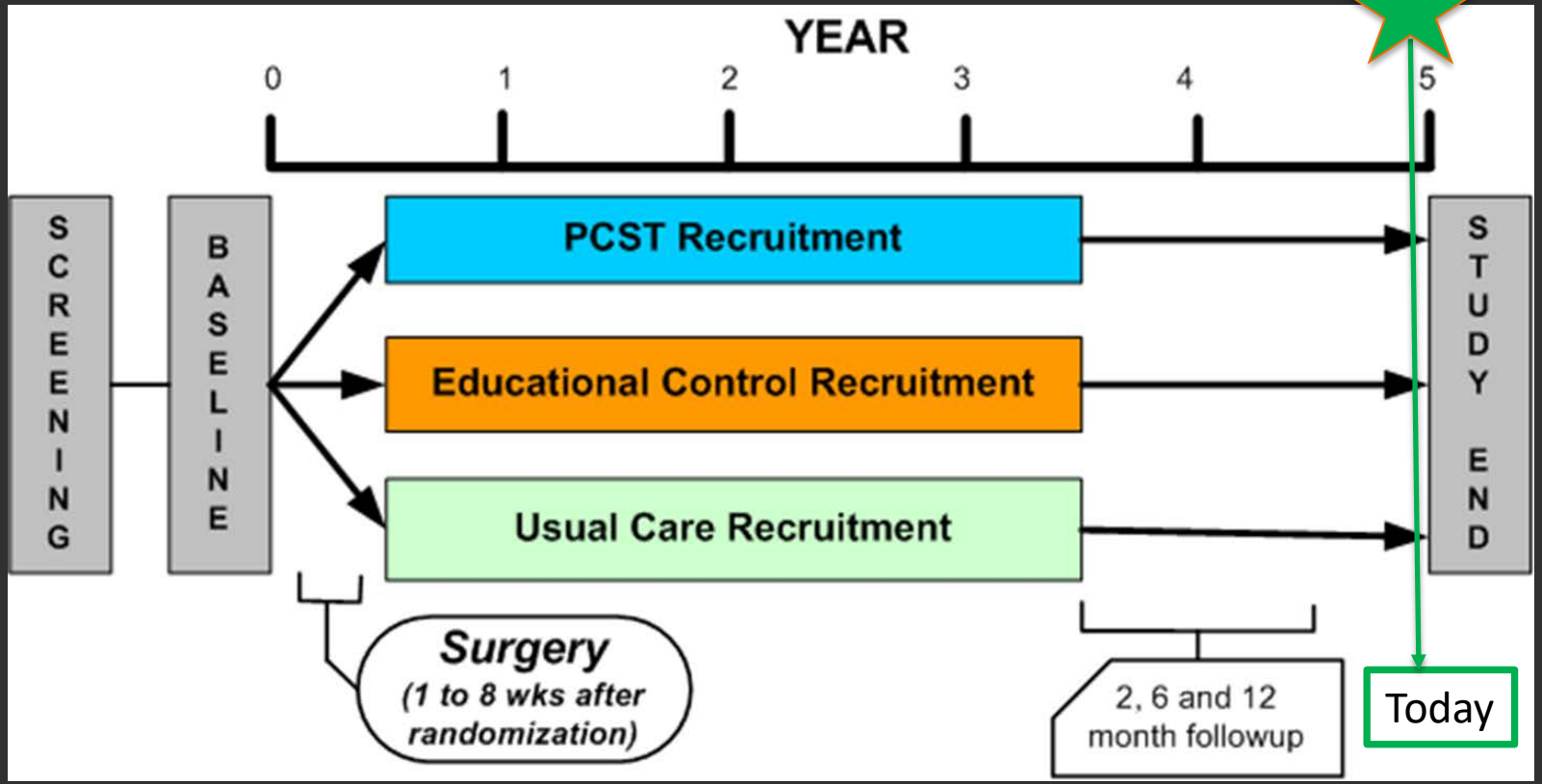

Flexibility of the Comparison Intervention
Practitioner Expertise (Experimental)
Practitioner Expertise (Comparison)
Flexibility of the Experimental Intervention
Follow-up Intensity
E
Eligibility Criteria
Outcomes
Primary Analysis
Participant Compliance
Practitioner Adherence
KEY
Initial
Ideal
Final

New and improved version: PRECIS-2 (Loudon et al, BMJ 2015;350:h2147)



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

The basic study design – The 3-arm trial



Aim 1 of the Trial – Our effectiveness aim

- Specific Aim 1. To assess the effectiveness of pain coping skills training in reducing knee pain and improving function. Our hypothesis:
  - Pain coping skills training is more effective than arthritis care education or usual care in decreasing knee pain during functional activities.

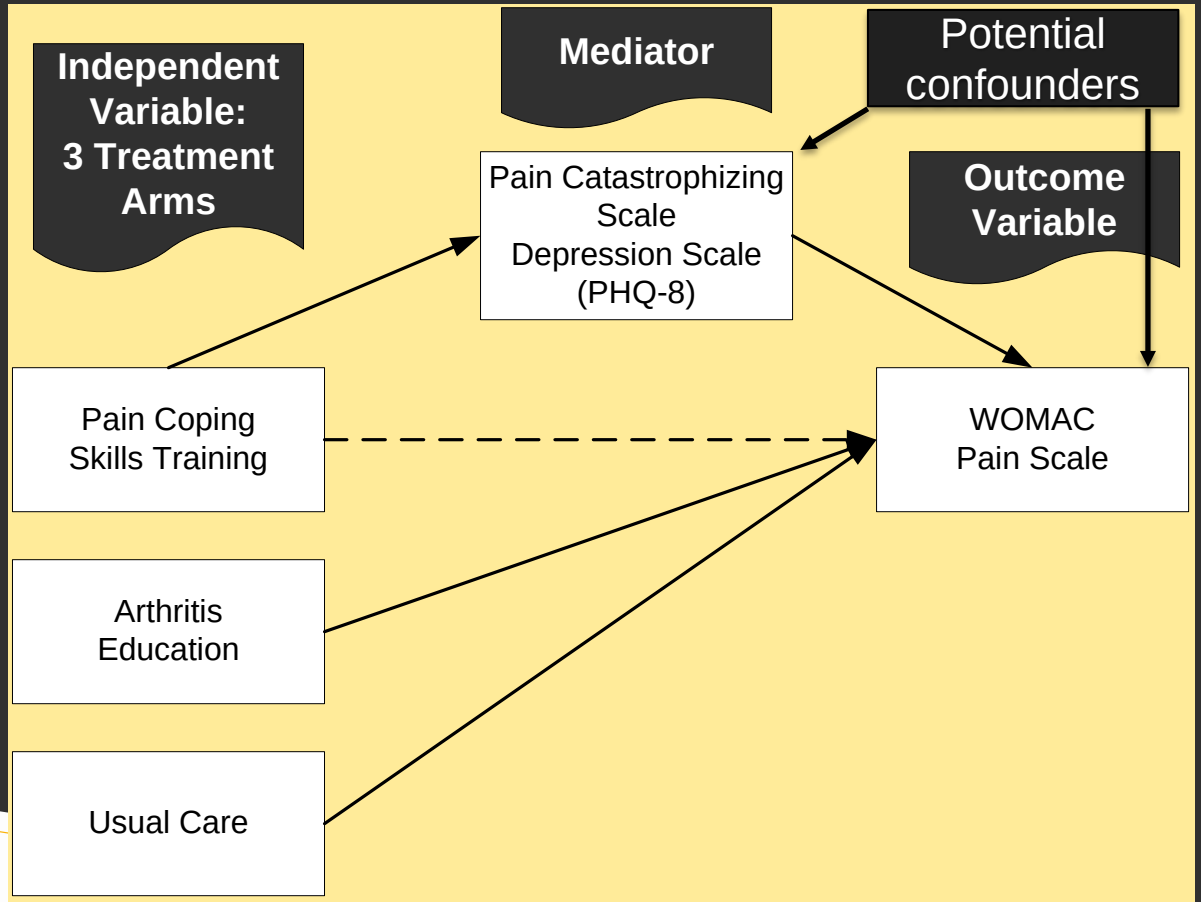
Aim 2 of the Trial – Our cost effectiveness aim

- Hypothesis: Pain coping skills training will reduce direct medical costs and indirect (i.e. patient time) costs relative to arthritis care education and usual care.

Aim 3 of the Trial – Our mechanistic aim

- Treatment-related changes in pain catastrophizing mediate treatment-related improvements in pain and self-reported function during recovery.

A look at mechanism – Causal Mediation



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The Pain Coping Intervention

- Pain coping skills training intervention developed by Keefe and colleagues and customized for patients with TKR
- Telephone based delivery - perioperative with pre- and post-surgery sessions
- 1 in-person, 7 telephone-based over 2 months (≈ 8 hrs)
- Delivered by physical therapists, supervised by clinical psychologists

Why choose PTs for care delivery?

- 200,000 PTs in healthcare versus 35,000 Psychologists. (Bureau of Labor Stats, 2012)
- PTs on the “front line” of knee arthroplasty care
- “The Potential BENEFIT” - PTs optimally aligned to deliver this care efficiently in clinical practice
- “The CHALLENGE” - PTs not currently trained to deliver psychologically based care. Patients with moderate to high levels of catastrophizing can be difficult to manage.

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Pain coping skills included

- Progressive muscle relaxation
- Relaxation and mini-practices
- Guided imagery
- Distraction techniques
- Pleasant/valued activities
- Activity-rest cycling
- Coping thoughts
- Cognitive-restructuring
- Maintenance

Some illustrative applications

Archive Phys Med Rehab. 2011, 92(6):859-65

Table 2: Summary of Types of Patient Concerns Reported During the Preoperative Period, the Immediate Postoperative Period, and the Later Postoperative Period Along With the Primary Coping Skills Taught to Deal With the Reported Concerns

Patient Themes Over the Course of the Study	Paraphrased Examples of Related Patient Concerns	Primary Coping Skills*
Themes during the preoperative period		
Uncertainty about outcomes of surgery	I've had so many shots, manipulations, pills, and physical therapy attempts, I just don't know if this surgery is going to do the trick	Coping thoughts; communicating with health care providers; goal setting
Worries and practical concerns about functional limitations	I just feel like I am such a burden to my family	Coping thoughts; communicating with family members and friends
	I am the only one available for housework	Problem solving; activity-rest cycling; communicating with family members and friends
	I can't drive myself to all of these appointments, but I don't want to ask my family to drop everything for me.	Problem solving; communicating with family members and friends
Pain and pain management	I'm so frustrated, I can't plan on anything because I don't know when the pain is going to hit, or how bad it is going to be.	Progressive muscle relaxation; mini-practices; coping thoughts; activity-rest cycling; distraction/refocusing
Sleep	The pain is keeping me up nights	Coping thoughts; progressive muscle relaxation; distraction/refocusing; communicating with health care providers
Themes during the immediate postoperative period (up to 2wk after surgery)		
Pain, swelling, and fatigue	I never thought the pain would continue like this after surgery	Coping thoughts; progressive muscle relaxation; mini-practices; distraction/refocusing

The comparison groups

- Arthritis education control group
  - To control for possible attention effects
  - Same amount of time (≈ 8 hrs) with nurse
  - Telephone delivered educational content regarding OA (no coping skills)
- Usual care group
- Relatively pragmatic approach to estimate real life effects of surgery relative to interventions

Study Flow

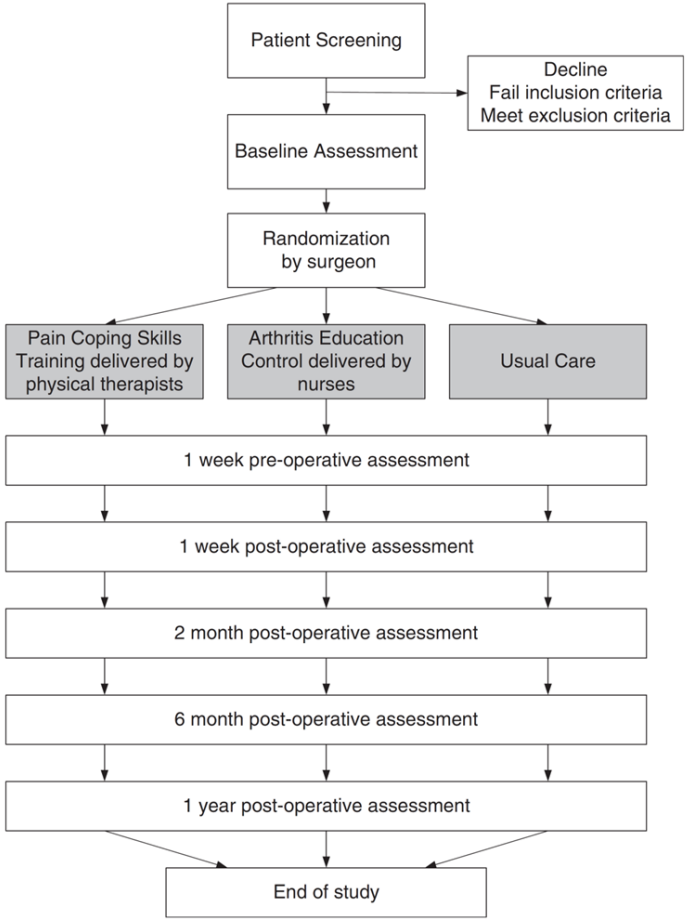


Figure 1 Legend: The figure illustrates the flow of subjects through the trial.

Subject recruitment

No RA, IA

No revision TKA

PCS ≥ 16

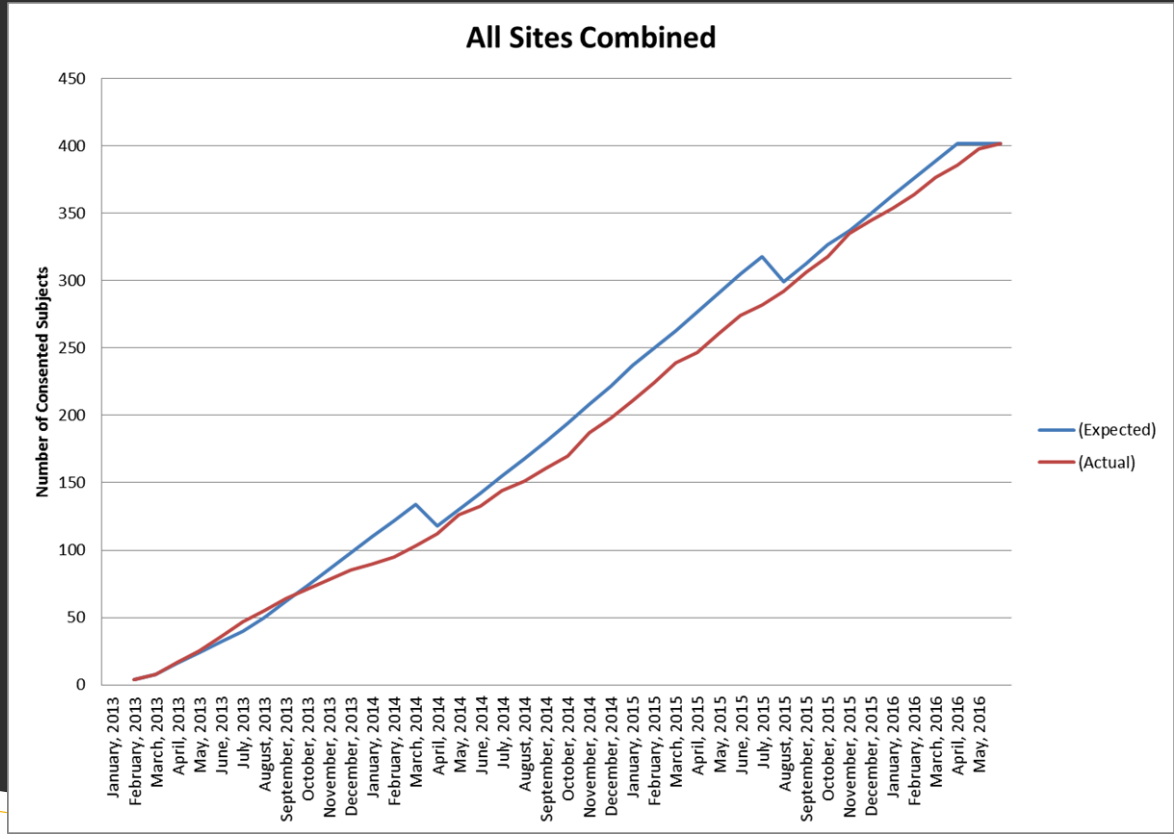
PHQ-8 ≤ 20

Passed cognitive screen

No THA or TKA pre/post 6 mos

Consented = 402

Screened = 4,043



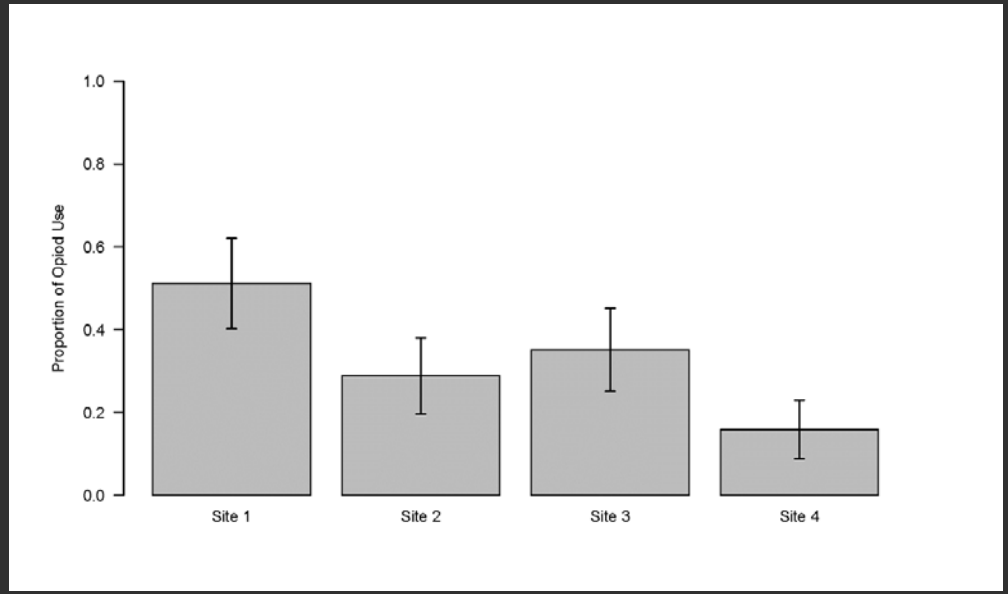
Characteristics of the sample (n = 402)

Variable	Mean (SD) or %
Age	63.2 (8.0)
Sex (female)	66%
Body mass index (Kg/m^2)	32.2 (6.2)
Race (African American)	35%
Current Income	
< $10,000	9%
$10,000 to $24,999	20%
$25,000 to $49,999	23%
$50,000 to $99,999	24%
$100,000 or >	14%
Declined	10%
Current work status	
Work for pay	33%
Unpaid work for family business	0.3%
Not working in part due to health problems	25%
Not working for other reasons	42%
Declined	0.2%
Education	
Less than high school	6%
High school graduate	23%
Some college	26%
College degree or higher	45%
Marital Status	
Married	49%
Separated	5%
Divorced	20%
Never Married	12%
Widowed	12%
Member of an unmarried couple	2%
Declined	0.5%
Current smoker (yes)	12%

Some preliminary baseline findings

- Opioid use at baseline: 31.7% varied across sites from 15.9% to 51.2%

Category	N (%)	Median Milligram Dosage (range)	Median Daily Frequency (range)
Tramadol	48 (40.0%)	50 (10 to 100)	2 (1 to 6)
Oxycodone	44 (36.7%)	5 (5 to 50)	2 (1 to 4)
Hydrocodone	34 (28.3%)	7.5 (1 to 30)	2 (1 to 6)
Codeine with acetaminophen	5 (4.2%)	30 (5 to 30)	1 (1 to 4)
Morphine	3 (2.5%)	15 (5 to 50)	3 (2 to 3)
Methadone	3 (2.5%)	10 (10 to 20)	3 (2 to 4)
Other*	3 (2.5%)	--	--



Independent predictors of opioid use

- After accounting for patients nested within surgeon, and surgeons nested within site, younger age ($p = 0.01$), African American race ($p = 0.02$), higher self-efficacy ($p = 0.02$) and higher comorbidity score ($p < 0.001$) increased the probability of opioid usage.

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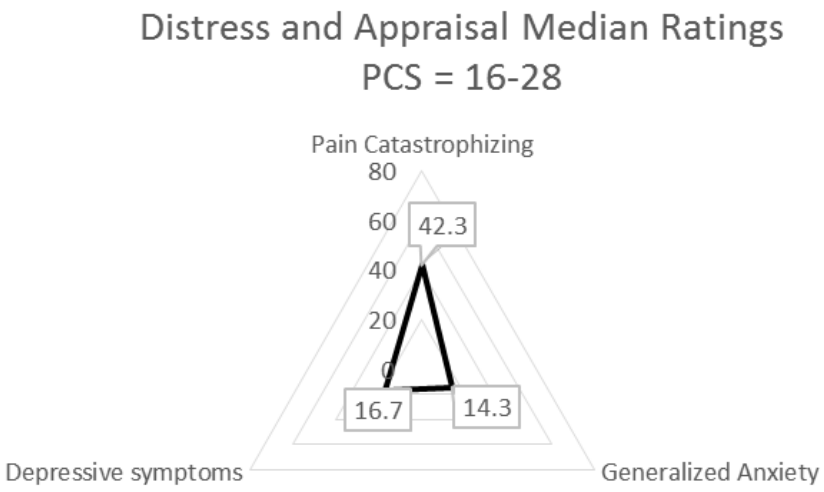
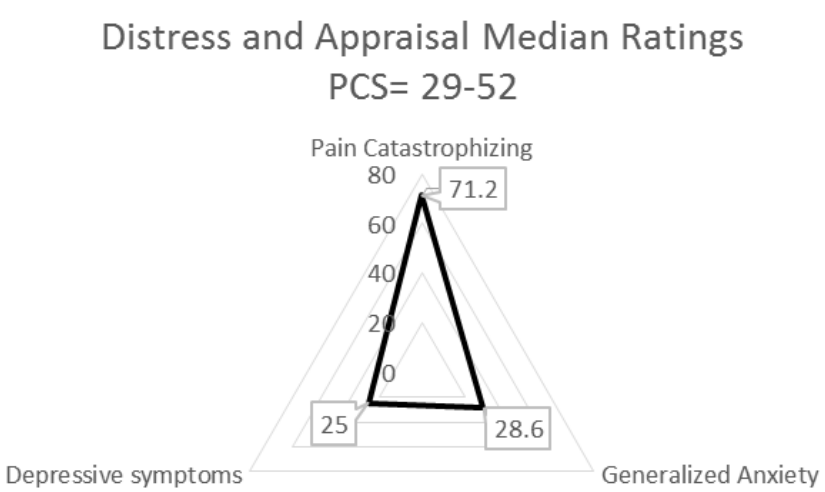
Characterizing the pain catastrophizing phenotype (scales set to 0 to 100)

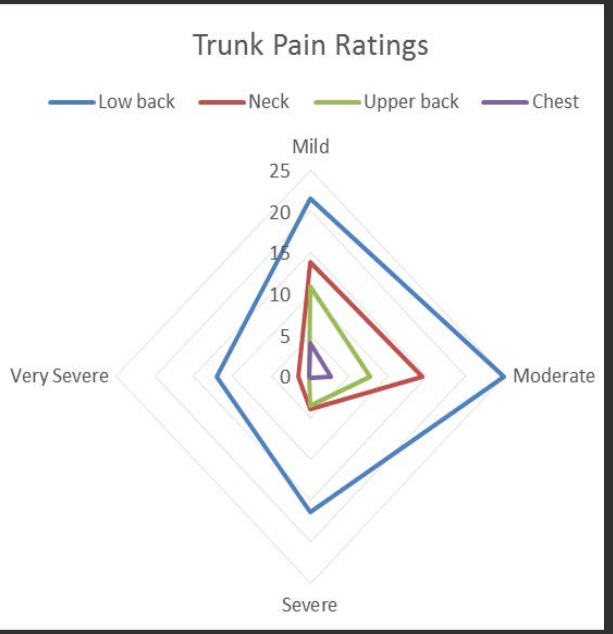


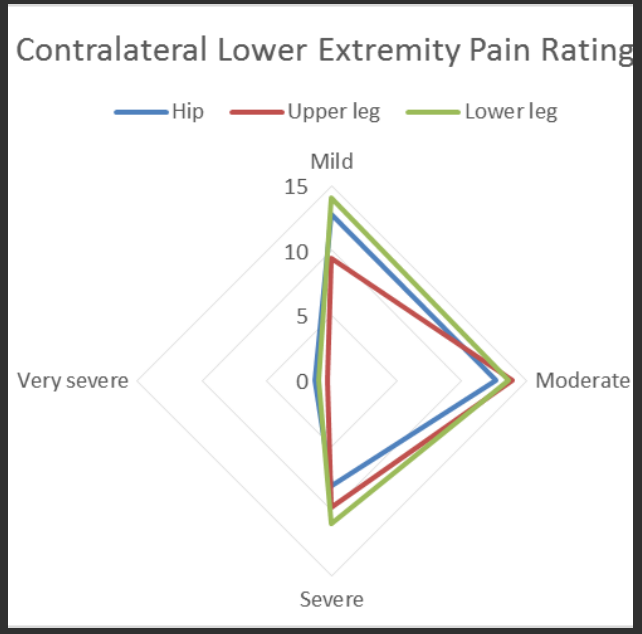
Moderate Catastrophizing

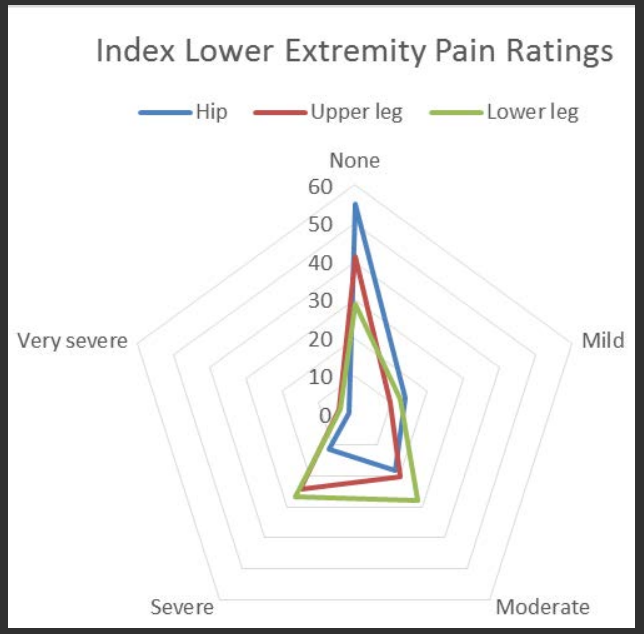


High Catastrophizing

Pain in other body regions (% for each region)







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Conclusions

- The pain catastrophizing phenotype demonstrates substantial variability in a variety of domains
- With some supervision, physical therapists are capable of delivering pain coping skills training to a challenging population of patients.
- Results will determine whether pain coping skills training, as delivered collaboratively with clinical psychologists, is effective and cost effective in this challenging phenotype.

Thank you.

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