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

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Acknowledgements and Disclosures

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- No conflicts of interest to disclose
- Many thanks to patients for participating
- Thank you also to PTs, Clinical Psychologists and Nurse interventionists.
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.

- Site clinical psychologist

- Team of 2 PTs trained in pain coping skills

- Monthly conference calls and as needed. Monthly calls with entire team, review of audiotapes by trainer
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

- Patients in the current trial had a mean PCS score of 30 ($sd = 9.3$).
- Typical scores for TKA samples $\approx 10$ ($sd = 10$)
Coping Skills for Patients fitting the Pain Catastrophizing Phenotype: An RCT of Persons Undergoing Knee Arthroplasty

(NCT01620983)
Participating Institutions

- Wake Forest University
- NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases
- Virginia Commonwealth University
- Duke University
- NYU School of Medicine
Key Team Members

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The knee - from normal to replaced
Estimated prevalence of TKA in US by age and sex

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

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%)
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
ORIGINAL ARTICLE

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


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kNational Institute for Health and Clinical Excellence, London, UK

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We prospectively designed the trial with PRECIS as a guide.
The steps to judging the P-E Continuum

Table 1
Summary of the 10 PRECIS domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Eligibility criteria for trial participants</td>
</tr>
<tr>
<td>2</td>
<td>Extent of flexibility in application of the experimental intervention</td>
</tr>
<tr>
<td>3</td>
<td>Degree of practitioner expertise in applying and monitoring the experimental intervention</td>
</tr>
<tr>
<td>4</td>
<td>Extent of flexibility in application of the comparison intervention(s)</td>
</tr>
<tr>
<td>5</td>
<td>Degree of practitioner expertise in applying and monitoring the comparison intervention(s)</td>
</tr>
<tr>
<td>6</td>
<td>Intensity of follow-up of trial participants</td>
</tr>
<tr>
<td>7</td>
<td>Nature of the primary outcome</td>
</tr>
<tr>
<td>8</td>
<td>Intensity of measurements of participants’ compliance to study protocol and whether compliance improving strategies are used</td>
</tr>
<tr>
<td>9</td>
<td>Intensity of measurements of practitioners’ adherence to study protocol and whether adherence-improving strategies are used</td>
</tr>
<tr>
<td>10</td>
<td>Specification and scope of analysis of primary outcome</td>
</tr>
</tbody>
</table>
### Criteria from PRECIS – 2 Examples

<table>
<thead>
<tr>
<th>Domain</th>
<th>Pragmatic Trial</th>
<th>Explanatory Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant eligibility criteria</td>
<td>All participants who have the condition of interest are enrolled, regardless of anticipated risk, responsiveness, co-morbidity, or past compliance.</td>
<td>Stepwise selection criteria applied to restrict study individuals to just those who are thought likely to be highly responsive to the intervention</td>
</tr>
<tr>
<td>Primary trial outcome</td>
<td>The primary outcome is an objectively measured, clinically meaningful outcome to the study participants, assessed under usual conditions.</td>
<td>The outcome is known to be a direct consequence of the intervention. May be a surrogate marker of another downstream outcome</td>
</tr>
</tbody>
</table>
Highly pragmatic and highly explanatory trials
How did we do?
The basic study design – The 3-arm trial

- Screening
- Baseline
- PCST Recruitment
- Educational Control Recruitment
- Usual Care Recruitment
- Surgery (1 to 8 weeks after randomization)
- Year 2, 6, and 12 month follow-up
- Today
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

Independent Variable: 3 Treatment Arms

- Pain Coping Skills Training
- Arthritis Education
- Usual Care

Mediator

- Pain Catastrophizing Scale
- Depression Scale (PHQ-8)

Potential confounders

Outcome Variable

- WOMAC Pain Scale
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.
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

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

<table>
<thead>
<tr>
<th>Patient Themes Over the Course of the Study</th>
<th>Paraphrased Examples of Related Patient Concerns</th>
<th>Primary Coping Skills*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Themes during the preoperative period</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Uncertainty about outcomes of surgery</strong></td>
<td>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</td>
<td>Coping thoughts; communicating with health care providers; goal setting</td>
</tr>
<tr>
<td><strong>Worries and practical concerns about functional limitations</strong></td>
<td>I just feel like I am such a burden to my family</td>
<td>Coping thoughts; communicating with family members and friends</td>
</tr>
<tr>
<td></td>
<td>I am the only one available for housework</td>
<td>Problem solving; activity-rest cycling; communicating with family members and friends</td>
</tr>
<tr>
<td></td>
<td>I can't drive myself to all of these appointments, but I don't want to ask my family to drop everything for me.</td>
<td>Problem solving; communicating with family members and friends</td>
</tr>
<tr>
<td><strong>Pain and pain management</strong></td>
<td>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.</td>
<td>Progressive muscle relaxation; mini-practices; coping thoughts; activity-rest cycling; distraction/refocusing</td>
</tr>
<tr>
<td><strong>Sleep</strong></td>
<td>The pain is keeping me up nights</td>
<td>Coping thoughts; progressive muscle relaxation; distraction/refocusing; communicating with health care providers</td>
</tr>
<tr>
<td><strong>Themes during the immediate postoperative period (up to 2wk after surgery)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pain, swelling, and fatigue</strong></td>
<td>I never thought the pain would continue like this after surgery</td>
<td>Coping thoughts; progressive muscle relaxation; mini-practices; distraction/refocusing</td>
</tr>
</tbody>
</table>
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)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>63.2 (8.0)</td>
</tr>
<tr>
<td><strong>Sex (female)</strong></td>
<td>66%</td>
</tr>
<tr>
<td><strong>Body mass index (Kg/m²)</strong></td>
<td>32.2 (6.2)</td>
</tr>
<tr>
<td><strong>Race (African American)</strong></td>
<td>35%</td>
</tr>
<tr>
<td><strong>Current Income</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; $10,000</td>
<td>9%</td>
</tr>
<tr>
<td>$10,000 to $24,999</td>
<td>20%</td>
</tr>
<tr>
<td>$25,000 to $49,999</td>
<td>23%</td>
</tr>
<tr>
<td>$50,000 to $99,999</td>
<td>24%</td>
</tr>
<tr>
<td>$100,000 or &gt;</td>
<td>14%</td>
</tr>
<tr>
<td>Declined</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Current work status</strong></td>
<td></td>
</tr>
<tr>
<td>Work for pay</td>
<td>33%</td>
</tr>
<tr>
<td>Unpaid work for family business</td>
<td>0.3%</td>
</tr>
<tr>
<td>Not working in part due to health problems</td>
<td>25%</td>
</tr>
<tr>
<td>Not working for other reasons</td>
<td>42%</td>
</tr>
<tr>
<td>Declined</td>
<td>0.2%</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>6%</td>
</tr>
<tr>
<td>High school graduate</td>
<td>23%</td>
</tr>
<tr>
<td>Some college</td>
<td>26%</td>
</tr>
<tr>
<td>College degree or higher</td>
<td>45%</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>49%</td>
</tr>
<tr>
<td>Separated</td>
<td>5%</td>
</tr>
<tr>
<td>Divorced</td>
<td>20%</td>
</tr>
<tr>
<td>Never Married</td>
<td>12%</td>
</tr>
<tr>
<td>Widowed</td>
<td>12%</td>
</tr>
<tr>
<td>Member of an unmarried couple</td>
<td>2%</td>
</tr>
<tr>
<td>Declined</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Current smoker (yes)</strong></td>
<td>12%</td>
</tr>
</tbody>
</table>
Some preliminary baseline findings

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

<table>
<thead>
<tr>
<th>Category</th>
<th>N (%)</th>
<th>Median Milligram Dosage (range)</th>
<th>Median Daily Frequency (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tramadol</td>
<td>48 (40.0%)</td>
<td>50 (10 to 100)</td>
<td>2 (1 to 6)</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>44 (36.7%)</td>
<td>5 (5 to 50)</td>
<td>2 (1 to 4)</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>34 (28.3%)</td>
<td>7.5 (1 to 30)</td>
<td>2 (1 to 6)</td>
</tr>
<tr>
<td>Codeine with acetaminophen</td>
<td>5 (4.2%)</td>
<td>30 (5 to 30)</td>
<td>1 (1 to 4)</td>
</tr>
<tr>
<td>Morphine</td>
<td>3 (2.5%)</td>
<td>15 (5 to 50)</td>
<td>3 (2 to 3)</td>
</tr>
<tr>
<td>Methadone</td>
<td>3 (2.5%)</td>
<td>10 (10 to 20)</td>
<td>3 (2 to 4)</td>
</tr>
<tr>
<td>Other*</td>
<td>3 (2.5%)</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
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.
Characterizing the pain catastrophizing phenotype (scales set to 0 to 100)

Distress and Appraisal Median Ratings
PCS = 16-28

Pain Catastrophizing

80

60

40

20

0

Depressive symptoms

16.7

14.3

Generalized Anxiety

Moderate Catastrophizing

Distress and Appraisal Median Ratings
PCS = 29-52

Pain Catastrophizing

80

60

40

20

0

Depressive symptoms

25

28.6

Generalized Anxiety

High Catastrophizing
Pain in other body regions (% for each region)

Trunk Pain Ratings
- Low back
- Neck
- Upper back
- Chest

Contralateral Lower Extremity Pain Rating
- Hip
- Upper leg
- Lower leg

Index Lower Extremity Pain Ratings
- Hip
- Upper leg
- Lower leg
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.