

1) Study Title:

Promoting Physical Activity via Physical Therapist Following Knee Replacement – The PATH Study

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Study Site:

Palmetto Health – USC Orthopedic Center

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Funding:

University of South Carolina ASPIRE-I

NCT:

NCT03768206

Date:

3/17/2020

2) Background / Justification For Study

More than 4 million adults over the age of 50 years are living with a total knee replacement (TKR).¹ TKR utilization in the US continues to dramatically increase across all ages, with over 615,000 TKR completed annually.² The number of *new* TKR's is expected to approach 3.48 million by 2030.³ TKR substantially increases lifetime medical costs and accounts for 61% of osteoarthritis-related direct medical costs.⁴ Hospital-based costs of TKR exceed \$16 billion.⁵ With the dramatic expected rise of TKR utilization over the next 20 years³ and substantial burden on the economy, it is imperative to identify approaches to maximize the benefits of the costly treatment.

TKR is effective at improving health-related quality of life,⁶ pain,⁷ and physical function⁸ with more than 75% of patients experiencing improvements.⁹ Despite the improvements in preoperative symptoms, corresponding post-operative changes in physical activity are not typically observed, with physical activity levels at 1 year after surgery remaining similar to pre-operative levels.^{10,11} Less than 5% of patients reach recommended physical activity guidelines after knee replacement.^{12,13} The continued low levels of physical activity are concerning because inactivity is associated with increased risk of mortality¹⁴ and chronic disease,^{15,16} as well as lower quality of life¹⁷ and poorer physical function.^{18,19} Even though improvements are observed in pain and function, it is unknown why patients continue to maintain their pre-operative low levels of physical activity.

Following TKR, patients receive physical therapy either at home or at a skilled nursing rehabilitation facility and then transition to outpatient rehabilitation for 4-6 weeks.²⁰ The primary objective of therapy is to help the patient regain strength and mobility after surgery by strength and mobility exercises and functional training.²¹ Improved function is reported by 70-80% of patients and decreased pain is reported by 85-90% of patients receiving physical therapy.²² While physical therapists are effective at enhancing function and strength outcomes via rehabilitation exercises following TKR, encouraging patients to engage in the recommended 150 minutes/week of moderate-to-vigorous intensity physical activity during and after therapy is outside of their focus and not typically discussed.¹³

To date, only a few studies have focused on increasing overall physical activity levels in TKR patients; however, the increases in activity observed have been modest compared to changes observed in non-TKR populations and interventions were costly or resource intensive.²³⁻²⁵ Due to the high volume of contact time outpatient physical therapists have with TKR patients (2-3 times/week for 4-6 weeks) and the sense of rapport that is established between the therapist and patient,²¹ physical therapists may be a promising avenue to deliver a physical activity intervention. Given the success of physical therapists to achieve patient strength, mobility, and range of motion goals following TKR, it is likely that they could help patients increase their overall physical activity levels. TKR requires rehabilitation; thus, having physical therapists deliver a physical activity intervention during the required rehabilitation is a novel and efficient approach to reach patients and promote physical activity. *This research is significant because it is the first step towards building a progressive line of research targeting the development of a low-additional cost and translatable physical activity intervention that will have the ability to*

be widely disseminated by physical therapists providing rehabilitation, both in home or outpatient, to TKR patients.

Preliminary Studies:

The PACE study (AHRQ K12HS023011) compared weight loss programs that started either before knee replacement (PACE) or started 12 weeks after surgery (Delayed PACE). Sixteen patients were randomized (63.3±7.5 years old, 69% female, 69% White, BMI of $36.5 \pm 5.1 \text{ kg/m}^2$) to PACE or Delayed PACE. Primary outcomes from 11 participants were objectively assessed at 26 weeks after surgery. Nine participants provided self-reported outcomes at approximately 12.78±1.5 months after knee replacement. Participants in Delayed PACE lost significantly more weight (-7.6±5.9kg, -7.9±5.9%) than PACE (-2.5±2.7kg, -2.6±2.6%) at 26 weeks ($P=0.03$). Delayed PACE maintained greater weight loss outcomes than participants in PACE at one year post-operatively. Pain intensity decreased ($P<0.001$) and function improved ($P=0.001$) significantly, but no significant changes were observed in physical activity (Table 1).

Table 1. Physical Activity Pre- and Post-Surgery in PACE (n=6) & Delayed PACE (n=7)

	Baseline	12 Weeks	26 Weeks
Bouted MVPA, min/week			
PACE	81.2±141.8	3.5±5.4	33.3±76.4
Delayed PACE	37.6±85.7	62.1±135.8	78.1±108.0
Steps/day			
PACE	5715.7±3098.0	4255.6±1687.8	4991.8±2910.2
Delayed PACE	6062.4±2817.6	4943.6±1653.2	6324.4±2201.3

The research team has experience with recruitment of TKR patients in the Columbia, SC area. Currently, we have recruited 12 patients who underwent a TKR to participate in an ongoing study examining the use of Fitbits and social support on physical activity over a 4-month period. To date, 73% of patients recruited for this study are from the Columbia, SC region. Additionally, across the 5 orthopedic surgeons within the Palmetto Health USC Orthopedic Center, an average of 21.8 TKR are completed each week.

3) Objectives / Research Aims

The purpose of this proposed project is to conduct a pilot randomized controlled trial to examine the feasibility and preliminary efficacy of a physical therapist led physical activity intervention on physical activity levels in TKR patients after surgery. The specific aims of the project are:

Aim 1: To examine the feasibility and acceptability of conducting a randomized controlled trial examining a physical therapist led physical activity intervention for TKR patients within an outpatient physical therapy facility. Specifically, enrollment, retention, session attendance and duration, treatment fidelity, and patient and physical therapist satisfaction will be examined.

Aim 2: To examine the effect of a physical therapist led physical activity intervention on the changes in physical activity, physical function, and pain in TKR patients.

4) Setting

The study procedures will be performed at Palmetto Health USC Orthopedic Centers. Potential patients will be identified and recruited after they attend their first physical therapy appointment by physical therapists participating in the study. Patients who are interested in participating will complete the informed consent process with the Principal Investigator or study research assistants. Study data and consent forms will be stored in a locked office at Palmetto Health USC Orthopedic Centers and the University of South Carolina Technology Center to Promote Healthy Lifestyles.

5) Resources Available

The purpose of this study is to examine the feasibility of conducting a physical therapist led physical activity intervention in a clinical setting. We will strive to recruit a total of 50 patients. If recruitment efforts are slow, we will plan to recruit additional physical therapists to participate in the study and assist with recruitment over the 15 month granted funded period of time.

Dr. Christine Pellegrini, the Principal Investigator and Assistant Professor in the Department of Exercise Science at USC, will oversee all study related procedures, included but not limited to recruitment, behavioral intervention, and data collection and analysis. Dr. Pellegrini has extensive experience overseeing behavioral clinical trials.

Debbie Brown, Co-Investigator and Senior Physical Therapist, will help recruit patients at Palmetto Health USC Orthopedic Centers and will coach participants as part of the intervention during standard physical therapy appointments.

Dr. Sara Wilcox, Co-Investigator and Clinical Psychologist, will serve as the mentor to Dr. Christine Pellegrini as well as oversee delivery and treatment fidelity of the behavioral intervention. Additionally, Dr. Wilcox serves as a PI for another study through Palmetto Health (Pro00033131 Promoting Health in Pregnancy and Postpartum).

All members of the study team will have a copy of the study protocol and know their respective research duties.

6) Prior Approvals

NA

7) Study Design

a. Recruitment Methods

Patients will be recruited from Palmetto Health USC Orthopedic Center. After completing the first outpatient physical therapy appointment, potentially eligible patients

identified by Palmetto Health Physical Therapists will be provided information about the study verbally by a USC research staff member. Interested patients will be able to ask questions and read the consent form. They will have the opportunity to complete the informed consent process either at the first or second outpatient physical therapy appointment.

b. Inclusion and Exclusion Criteria

After initial identification of potential patient participants by physical therapists, research staff will screen patients for eligibility criteria in-person or over the telephone.

Inclusion criteria:

Eligible participants will 1) be 40-79 years of age, 2) have had a knee replacement in the last 2 months, 3) be willing to wear an accelerometer for 7 days during assessments, and 4) be English speaking.

Exclusion criteria:

As all patients will be under physicians' supervision post-TKR, participants will only be excluded if they (1) have any contraindications to activity, (2) have a mobility limiting comorbidity (e.g. spinal stenosis), or (3) have a scheduled surgery (i.e., TKR on contralateral knee) within the next 6 months.

c. Local Number of Subjects

We will aim to randomize 50 patients that had a knee replacement within the last 2 months and are attending outpatient physical therapy at the Palmetto Health USC Orthopedic Center. We anticipate that we will need to approach and screen approximately 75 patients to enroll our goal of 50 patients.

d. Study-Wide Number of Subjects

NA

e. Study Timelines

Subject participation will last 12 weeks. We estimate it will take 15 months to complete the study, which will include finished study enrollment, data collection and data analysis (See Figure 1).

Figure 1. Project Timeline

	Project Month														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Finalize protocol & IRB approval	X	X	X												
Recruit TKA patients (n=50)				X	X	X	X	X	X	X	X	X	X		
Intervention				X	X	X	X	X	X	X	X	X	X		
Completing 12 week assessments				X	X	X	X	X	X	X	X	X	X	X	
Data Analysis														X	X
Prepare manuscript & presentations														X	X
Draft & submit NIH R21 or R01														X	X

f. Study Endpoints

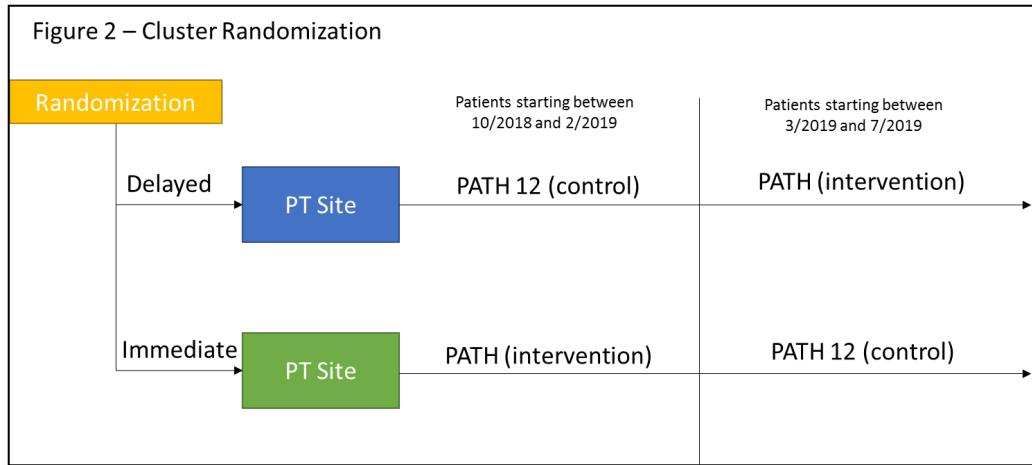
Assessments will be completed before the second outpatient therapy session (baseline) and at 12 weeks after TKR. Detailed descriptions and a timeline of outcomes are provided below in the text and Table 2. Briefly, at both assessments, participants will be asked to complete surveys (demographics, brief medical history, KOOS, PROMIS, self-identification), which should take approximately 20 minutes to complete. Based on participant preferences, surveys will be able to be completed on paper or online via RedCAP, with the exception of the PROMIS surveys which are computer adaptive surveys. Participants will also be given an Actigraph Link accelerometer and ActivPAL monitor to wear for 7 days at each assessment. These monitors will be provided at the in-person assessment or mailed to the participants. At the end of the 7 days, these monitors will be returned to the PT clinic or participants will be provided with a prepaid padded envelope to return the monitor. Only at 12 weeks will participants complete functional tests and the Surgery and Medication Questionnaire, which will take approximately 15 minutes to complete. In the event participants are unable to complete the function tests at the in-person assessment, we will ask participants to complete the chair stand test at home and self-report the outcomes. Participants will not be asked to complete the 6-minute walk or timed up and go at home. Participants will receive \$20 for completing the 12-week assessment.

Measure	Baseline	12 Weeks
Participant Demographics	X	
Participant height and weight	X	X
Brief Medical History	X	X
Knee Injury and Osteoarthritis Outcome Score (KOOS)	X	X
PROMIS Pain Intensity, Pain Interference, & Mobility	X	X
WOMAC Pain and Stiffness	X	X
Physical Function		
6-minute walk		X
Timed up and go		X
Chair stands		X
Physical activity (Actigraph)	X	X
Sedentary time (ActivPAL)	X	X
Self-Reported Exercise Identity	X	X
PATH Study Survey		X

Primary Outcomes: The feasibility and acceptability of conducting a randomized controlled trial within an outpatient physical therapy setting is the primary endpoint. Specifically, we will examine the number of participants enrolled vs. approached, participant retention, number of therapy sessions attended, session duration, and treatment fidelity. Further, participants will complete a PATH Study Survey at the 12 week assessment. Physical therapists will complete a brief evaluation about delivering the PATH program.

Secondary Outcomes:

- Physical activity will be measured using Actigraph Link accelerometers owned by the TecHealth Center at the University of South Carolina. During assessments, participants will be asked to wear the Actigraph on their waist for 7 days. Non-wear time will be defined as ≥ 90 minutes with zero activity counts, allowing for up to 2 minutes of <100 counts/min.²⁶ Physical activity will be categorized as light (100-2019 counts/min) and moderate-to-vigorous (MVPA) (≥ 2020 counts/min).²⁷ Total MVPA over the week will be calculated. Steps/day will also be obtained. A valid day will be considered if participants wore the accelerometer for at least 10 hours/day. Participants will also be asked to complete a log indicating times the accelerometer was worn and taken off over the 7-day assessment period.
- Sedentary time will be measured using ActivPAL™ (PAL Technologies Ltd, Glasgow, UK), a small lightweight (15 g) uni-axial accelerometer. The time spent sitting/lying, standing, and walking, transitions and step counts will be determined. The ActivPAL summarizes data in 15 second intervals over 24 hours at a sampling frequency of 10 Hz.²⁸ During assessments, participants will be asked to wear the ActivPAL on their thigh for 7 days. Participants will also be asked to complete a log indicating times the ActivPAL was worn and taken off over the 7-day assessment period.
- Physical function measures will include the chair stand, timed up and go, and 6-minute walk test. All physical function tests will be completed following Osteoarthritis Research Society International (OARSI) recommendation procedures.²⁹ During the chair stand test, patients are asked to complete as many chair stand repetitions as possible during a 30-second period. The Timed Up and Go Test assesses the time in seconds taken to rise from a chair, walk 3-meters, turn, walk back to the chair, and sit down. The Six Minute Walk Test evaluates the maximal distance a patient can cover during a 6-minute period.
- Patient-Reported Outcomes will be assessed using two methods: 1) Patient-Reported Outcomes Measurement Information System (PROMIS)³⁰ utilizes a computer adaptive test via RedCap.³¹ We will assess pain intensity, pain interference, and mobility; 2) Western Ontario and McMaster Universities Arthritis Index (WOMAC) is a 15-item survey assessing pain and stiffness over the last 48-hour on a 5-point Likert scale.³²
- Self-reported exercise identity will be assessed at baseline and 12-week assessments using the Self-Reported Exercise Identity Scale.³³ Participants will rate on a scale from 1 (strongly disagree) to 5 (strongly agree) their feelings relating to exercise identity. Examples include, “I would feel a real loss if I were forced to give up exercising” and “I need exercise to feel good about myself.”



g. Procedures Involved

Design Overview: We propose to conduct a pilot two-arm cluster randomized controlled trial with patients attending outpatient physical therapy following TKR. The proposed project was developed in collaboration with Debbie Brown, Senior Physical Therapist at Palmetto Health USC Orthopedic Center. Over 9 months, TKR patients (n=50) attending outpatient physical therapy at Palmetto Health USC Orthopedic Center will be recruited and randomized to either 1) PATH-12 (control), or 2) PATH. Due to potential contamination of the intervention between patients in PATH-12 and PATH during typical open, group-like physical therapy settings, we have opted to randomize physical therapy sites instead of individual patients. Specifically, physical therapy sites will be randomized to either Immediate or Delayed. The first phase of the study will take place starting in November and end after 25 participants have been recruited. During this time, those sites randomized to Immediate will receive the PATH intervention and those sites randomized to Delayed will receive the PATH-12 intervention. There will then be a “wash out period” to allow for all the participants to finish their current PT. After this “wash out period”, the second phase of the study will begin and will end after 25 participants have been recruited. During this time, those sites randomized to Immediate will receive the PATH-12 intervention and those sites randomized to Delayed will receive the PATH intervention.”

Screening: Participants will be required to complete a brief screening after the first physical therapy appointment. Research staff will administer the screening in-person or over the telephone. The screening will assess eligibility criteria and willingness to participate. Following the completion of the screener, eligible and interested participants will be invited to complete the informed consent process.

Randomized Conditions:

PATH-12 (control). Patients randomized to receive PATH-12 will undergo the standard physical therapy following TKR. The study will not change any treatment patients typically receive and instead will just document how long sessions occur and if any aerobic activity goals were set. In addition to the standard physical therapy received and to enhance retention in the study, all participants who receive PATH-12 will be given a brief physical activity coaching session led by a trained USC research staff member at 12 weeks following the completion of the assessment. Participants will receive all materials

provided to PATH and the session is expected to last approximately 1 hour. In the event this cannot be completed in-person, it will be completed over the telephone.

PATH. Patients randomized to receive PATH will undergo the standard physical therapy following TKR. In addition, physical therapists will briefly discuss lifestyle and moderate-to-vigorous physical intensity activity at each session. At least once/week, physical therapists will help patients set a SMART (Specific, measurable, attainable, realistic, timely) goal related to overall aerobic physical activity and identify strategies that will help them achieve their goal. Physical therapists will use motivational interviewing techniques and check in on patients' progress towards goals at each session. Physical therapists will be encouraged to engage in physical activity coaching and goal setting during down time while patients are completing aerobic warm up, rehabilitation exercises, or during ice, manual therapy, neuromuscular electrical stimulation, or scar management to ensure these discussions do not add additional time to the regular therapy session.

Intervention Data Collection. Physical therapists for both randomized conditions will document the session start and end times as well as any goals that are set during the sessions. Physical therapists can document the session information on a paper form

Treatment Fidelity. Due to the open, group-like nature of physical therapy and patient confidentiality, we are unable to audio record treatment sessions. Therefore, to monitor treatment fidelity to ensure intended session content for both conditions is delivered and that unintended session content (i.e., contamination such as goal setting on physical activity levels with a patient randomized to PATH-12) is not delivered, physical therapists will complete a session checklist. In addition, random observations will occur by USC research staff. The physical therapist and observation fidelity checklists will monitor session duration, goals set, and indication if aerobic physical activity was discussed.

h. Data and Specimen Banking

NA

i. Statistical Analysis

Descriptive statistics will be used to describe baseline characteristics, establish recruitment and retention rates, and examine intervention intensity (session frequency, duration, and fidelity) and patient and therapist satisfaction. Mixed ANOVA or ANCOVAs, if appropriate adjustments are required based on baseline characteristics, will examine the changes in physical activity levels (MVPA/week, steps/day), and pain (PROMIS and WOMAC) across time between PATH and PATH-12. Additionally, differences between PATH and PATH-12 in physical function (chair stands, Timed Up and Go, 6-minute walk) will be examined at 12 weeks. Although the proposed study may not be powered to detect significant differences, the results will allow us to collect feasibility and acceptability data, refine the intervention, if necessary, and determine effect sizes for future grant submissions.

j. Data Management

All surveys will be administered either on paper or online via REDCap (secure, web application for building and managing online surveys and databases – managed by the University of South Carolina). Paper surveys will be stored in a locked filing cabinet at Palmetto Health-USC Orthopedic Center or the TecHealth Center at University of South Carolina. All computer files will be password protected. Only the study team will have access to the data.

k. Confidentiality

A number will be assigned to the participant who agrees to be a part of the study. This number will be used on the project records rather than their name, and no one other than the study team will be able to link the data with the name. Study records/data will be stored in locked filing cabinets and protected computer files at Palmetto Health USC Orthopedic Center and the University of South Carolina's TecHealth Center.

l. Provisions to Monitor the Data to Ensure the Safety of Subjects

Patient enrollment numbers, consent documents, the data collection sheet and any reportable events will be monitored by the Study Coordinator every month.

Any issues found will be rectified as appropriate and preventative actions, as needed, will be taken in efforts to eliminate the issue in the future.

m. Withdrawal of Subjects

Participants will be informed they can leave the research at any time without penalty. If a participant decides to withdraw, no more information will be collected. The participants will be made aware of this during the consent process.

Any data collected during their participation may be used by the investigators for the purposes described above. Choosing not to be in the study will not result in any penalty or loss of benefit to which participants are entitled. Specifically, the choice not to be in this study will not negatively affect a participant's right to any present or future medical treatment or his/her present or future employment.

8) Risks to Subjects

The risks of participating in this study are minimal. Participants may experience:

1. Feelings of muscle soreness and fatigue during physical function tests or engaging in physical activity. Although participants will be experiencing muscle soreness and fatigue from the surgery, we will attempt to minimize any additional symptoms. Participants will be allowed to take breaks at any time during function

tests and the physical activity goals will be tailored specifically based on the participants progress after surgery. The physical therapist will work with the participant to ensure a safe and reasonable goal is set to minimize additional symptoms following surgery. Participants will be encouraged to stop engaging in physical activity immediately if at any time they are injured or are encouraged to stop engaging in physical activity from their physical therapist/physician/medical professional.

2. Skin irritation from wearing the physical activity monitors. Participants will be asked to wear two physical activity monitors, one on their waist, and one on their thigh for 7 days. The waist-worn monitor will only be worn during waking hours to minimize discomfort. The ActivPAL will be securely taped with water proof sealing on the participants thigh and be worn 24 hours for 7 days. In the event the participant experiences discomfort, the participant will be asked to remove the tape. Participants will be provided with additional tape and asked to reapply the monitor once the skin irritation resolves.

9) Potential Benefits to Subjects

Participants may or may not experience any benefits from participating in this study. If participants modify activity behaviors, they may experience positive changes to health and mood. Additionally, this research will help us understand if a physical therapist led physical activity intervention can help to increase activity after knee replacement.

10) Provisions to Protect the Privacy Interests of Subjects

The research study will be explained to potential subjects in a private manner. Consenting will be done also in a private room, away from other subjects or Palmetto staff. Participants will have the option to not answer any question that they do not feel comfortable answering.

11) Compensation for Research-Related Injury

NA

12) Economic Burden to Subjects

NA

13) Consent Process

Informed consent will be obtained either after the first outpatient physical therapy appointment or before the second appointment by a USC research team member. Full details of the study will be discussed, and participants will be reminded that participation is voluntary. Disclosure will be made of the nature and potential risks of participating and all participants will be asked if they have any questions about their

participation to ensure they understand the procedures. We estimate it will take approximately 15 minutes to complete the consent process. The paper consent form has been developed according to the requirements of Palmetto Health and the University of South Carolina Institutional Review Boards. Additionally, the consent process with each participant will be documented on the informed consent checklist. A copy of all signed IRB-approved consent forms will be provided to the participant.

14) Process to Document Consent in Writing

Interested participants will provide written informed consent on an informed consent document approved by the IRB. Date, time, and the research staff member obtaining consent will be documented for each participant.

15) Vulnerable Populations

NA

16) Drugs or Devices

NA

17) Multi-Site Research

NA

18) Community-Based Participatory Research

NA

19) Sharing of Results with Subjects

At the end of the trial, a results presentation will be given for interested participants. If participants are unable to attend, the presentation will be provided via email or letter.

20) Bibliographic References

1. Weinstein AM, Rome BN, Reichmann WM, et al. Estimating the burden of total knee replacement in the United States. *The Journal of bone and joint surgery American volume*. 2013;95(5):385-392.
2. Losina E, Thornhill TS, Rome BN, Wright J, Katz JN. The Dramatic Increase in Total Knee Replacement Utilization Rates in the United States Cannot Be Fully Explained by Growth in Population Size and the Obesity Epidemic. *The Journal of bone and joint surgery American volume*. 2012;94(3):201-207.

3. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030. *The Journal of bone and joint surgery American volume*. 2007;89(4):780-785.
4. Losina E, Paltiel AD, Weinstein AM, et al. Lifetime Medical Costs of Knee Osteoarthritis Management in the United States: Impact of Extending Indications for Total Knee Arthroplasty. *Arthritis care & research*. 2015;67(2):203-215.
5. Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. In: *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*. Rockville (MD)2006.
6. Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster J-Y. Health-Related Quality of Life in Total Hip and Total Knee Arthroplasty: A Qualitative and Systematic Review of the Literature. *JBJS*. 2004;86(5):963-974.
7. Vina ER, Hannon MJ, Kwoh CK. Improvement following total knee replacement surgery: Exploring preoperative symptoms and change in preoperative symptoms. *Semin Arthritis Rheum*. 2016;45(5):547-555.
8. Mizner RL, Petterson SC, Clements KE, Zeni JA, Jr., Irrgang JJ, Snyder-Mackler L. Measuring functional improvement after total knee arthroplasty requires both performance-based and patient-report assessments: a longitudinal analysis of outcomes. *J Arthroplasty*. 2011;26(5):728-737.
9. Vina ER, Hannon MJ, Kwoh CK. Improvement following total knee replacement surgery: Exploring preoperative symptoms and change in preoperative symptoms. *Seminars in Arthritis and Rheumatism*. 2016;45(5):547-555.
10. Arnold JB, Walters JL, Ferrar KE. Does Physical Activity Increase After Total Hip or Knee Arthroplasty for Osteoarthritis? A Systematic Review. *Journal of Orthopaedic & Sports Physical Therapy*. 2016;46(6):431-442.
11. Harding P, Holland AE, Delany C, Hinman RS. Do activity levels increase after total hip and knee arthroplasty? *Clin Orthop Relat Res*. 2014;472.
12. Kahn TL, Schwarzkopf R. Does Total Knee Arthroplasty Affect Physical Activity Levels? Data from the Osteoarthritis Initiative. *The Journal of Arthroplasty*. 2015;30(9):1521-1525.
13. US Department of Health and Human Services. *2008 Physical Activity Guidelines for Americans*. 2008.
14. Nocon M, Hiemann T, Müller-Riemenschneider F, Thalau F, Roll S, Willich SN. Association of physical activity with all-cause and cardiovascular mortality: a systematic review and meta-analysis. *European Journal of Cardiovascular Prevention & Rehabilitation*. 2008;15(3):239-246.

15. Sullivan PW, Morrato EH, Ghushchyan V, Wyatt HR, Hill JO. Obesity, Inactivity, and the Prevalence of Diabetes and Diabetes-Related Cardiovascular Comorbidities in the U.S., 2000–2002. *Diabetes Care*. 2005;28(7):1599-1603.
16. Lee IM, Shiroma EJ, Lobelo F, Puska P, Blair SN, Katzmarzyk PT. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. *The Lancet*. 2012;380(9838):219-229.
17. Brown DW, Balluz LS, Heath GW, et al. Associations between recommended levels of physical activity and health-related quality of life Findings from the 2001 Behavioral Risk Factor Surveillance System (BRFSS) survey. *Preventive medicine*. 2003;37(5):520-528.
18. Dunlop DD, Song J, Semanik PA, Sharma L, Chang RW. Physical activity levels and functional performance in the osteoarthritis initiative: a graded relationship. *Arthritis and rheumatism*. 2011;63(1):127-136.
19. Dunlop DD, Semanik P, Song J, et al. Moving to Maintain Function in Knee Osteoarthritis: Evidence From the Osteoarthritis Initiative. *Archives of Physical Medicine and Rehabilitation*. 2010;91(5):714-721.
20. Westby MD. Rehabilitation and total joint arthroplasty. *Clin Geriatr Med*. 2012;28(3):489-508.
21. APTA. Guide to physical therapy practice. *Phys Ther*. 2001;81:9-744.
22. Jones CA, Voaklander DC, Suarez-Alma ME. Determinants of function after total knee arthroplasty. *Phys Ther*. 2003;83(8):696-706.
23. Losina E, Collins JE, Deshpande BR, et al. Financial incentives and health coaching to improve physical activity following total knee replacement: a randomized controlled trial. *Arthritis care & research*. 2017:n/a-n/a.
24. Piva SR, Almeida GJ, Gil AB, DiGioia AM, Helsel DL, Sowa GA. A comprehensive behavioral and exercise intervention improves physical function and activity participation after total knee replacement – a pilot randomized study. *Arthritis care & research*. 2017:n/a-n/a.
25. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC public health*. 2011;11(1):119.
26. Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of Accelerometer Wear and Nonwear Time Classification Algorithm. *Medicine and science in sports and exercise*. 2011;43(2):357-364.

27. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Medicine and science in sports and exercise*. 2008;40(1):181-188.
28. Ryan CG, Grant PM, Tigbe WW, Granat MH. The validity and reliability of a novel activity monitor as a measure of walking. *British journal of sports medicine*. 2006;40(9):779-784.
29. Dobson F, Hinman RS, Roos EM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. *Osteoarthritis and Cartilage*. 2013;21(8):1042-1052.
30. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): Progress of an NIH Roadmap Cooperative Group During its First Two Years. *Medical care*. 2007;45(5 Suppl 1):S3-S11.
31. Obeid JS, McGraw CA, Minor BL, et al. Procurement of shared data instruments for Research Electronic Data Capture (REDCap). *Journal of Biomedical Informatics*. 2013;46(2):259-265.
32. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988;15(12):1833-1840.
33. Anderson DF, Cychosz CM. Development of an exercise identity scale. *Percept Mot Skills*. 1994;78(3 Pt 1):747-751.