

Modification

Basic Info

Confirmation Number: **bjiebbaj**
Protocol Number: **812510**
Created By: **KESSLER, RONNI**
Principal Investigator: **IBRAHIM, SAID A**
Protocol Title: **African American Preference for Knee Replacement: A Patient-Centered Intervention**
Short Title: **ACTION**
Protocol Description: **We propose a randomized controlled trial to assess the effect of a patient-centered intervention on African-American (AA) patient preferences for and access to knee replacement.**
Submission Type: **Social and Biological Sciences**

PennERA Protocol Status

Resubmission*

No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Closed to subject enrollment (remains active)

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

197

Actual enrollment at participating centers

126

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination

If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed

change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant's continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject's willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date Expedited Review

Modification Summary

Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.

This modification is to remove Christina Nash and Francisca Bermudez and add Michael Kallan to the protocol to assist with data analysis for the study.

Risk / Benefit

Does this amendment alter the Risk/Benefit profile of the study?

No

Change in Consent

Has there been a change in the consent documents?

No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*

Yes

Study Personnel

Principal Investigator

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Training Expiration Date:	
Name of course completed :	

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Name of course completed :	

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HS Training Completed:	Yes
Training Expiration Date:	03/19/2017
Name of course completed :	CITI Protection of Human Subjects Research Training - ORA

Other Investigator

None

Responsible Org (Department/School/Division):

4239 - DM-General Internal Medicine

Key Study Personnel

Name:	KALLAN, MICHAEL
Department/School/Division:	EB-Biostatistical Analysis Core
HS Training Completed:	Yes
Training Expiration Date:	09/24/2016
Name of course completed:	CITI Protection of Human Subjects Research Training - ORA

Disclosure of Significant Financial Interests*

Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?

No

Certification

I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.

Yes

Social and Biological Sciences

Study Instruments

Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who

or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link [For oral histories or interviews provide the general framework for questioning and means of data collection](#). If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.

The study involves a baseline questionnaire, educational intervention, and follow-up questionnaire by phone 12 months after the intervention takes place. All eligible, consented patients will complete the baseline questionnaire, conducted by an ACTION research staff member. The baseline questionnaire (attached at end of protocol) will include the following instruments that have been field-tested by our team in previous and ongoing studies: 1.) Willingness to Consider Joint Replacement Question 2.) Knowledge Regarding Knee OA and Joint Replacement (developed by The Foundation for Informed Medical Decision Making) 3.) Hospital for Special Surgery Knee Expectations Survey 4.) Socioeconomic Survey 5.) Access to Health Care, Charlson Comorbidity Index 6.) Quality of Life SF-12v2. This survey can be done over the phone or in person. It should take approximately 30-40 minutes. At the completion of the baseline questionnaire, patients will be randomized into either study Decision Aid (DA) (hereafter referred to as DA intervention) arm or the attention control arm. Patient appointments for the DA intervention or attention control activity will be scheduled to occur 2 weeks prior to the patients appointment with an orthopedic specialist (up to the date of the appointment). The DA intervention (referred to as an information session in patient material) will be completed by an ACTION research study interventionist (the interventionist will not administer the baseline assessment). In the intervention arm, patients will be shown a decision aid video entitled, Treatment Choices for Knee Osteoarthritis. (A copy of the video transcript is attached at end of protocol). The patients are then given a brief education intervention called AskMe3, which is a brief communication skill-building intervention developed by the Partnership for Clear Health Communication. AskMe3 instructs patients 3 questions to ask their doctor: a) what is my main problem b) what do I need to do c) why is it important for me to do this? The completion time for the educational intervention will be approximately 1 hour. The attention control arm will be conducted by the ACTION research staff. Patients will be given written educational material adapted from the NIH/NIAMS publication Osteoarthritis to review at his/her leisure. (A copy of the information contained in the informational pamphlet is attached at end of protocol). The completion time for the attention control arm is approximately 10 minutes. Follow-up procedures will occur at the following time points: 1.) approximately 6 months after the participants intervention, an ACTION team staff member will review their medical chart to see if the participant had knee joint replacement surgery 2.) 12-months post intervention participants will be contacted to find out if they had knee joint replacement surgery and a medical chart assessment will occur at this time as well. All follow-up procedures will be administered by an ACTION research team member that was not involved in the educational intervention. Participants in both the DA intervention and the attention control will complete a 12-month follow-up (completed approximately 12 months post intervention) survey over the phone. The survey will be comprised of the following: Willingness to consider joint replacement, Hospital for Special Surgery Knee Expectations Survey, Knowledge Regarding Knee OA and Joint Replacement, and a survey regarding surgery for joint replacement. At the time of the 12-month follow-up, the patients medical record will be accessed to check for a joint replacement procedure.

Group Modifications

Describe necessary changes that will or have been made to the study instruments for different groups.

No Group Modifications will or have been made.

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

At the completion of the baseline questionnaire, patients will be randomized into either study Decision Aid (DA) (hereafter referred to as DA intervention) arm or the attention control arm.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting,

describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

The duration of screening questionnaire (which is attached) is approximately 10-15 minutes and can be conducted on the phone or in person. Visit 1 (the baseline questionnaire attached) last about 30 - 40 minutes and can be conducted on the phone or in person. Visit 2 (the information session, MUST take place in person and before the visit with the orthopedic doctor, preferable within a 2 week period) last from 10 to 60 minutes. At 6 months after the intervention, an ACTION team staff member will review the participant's medical record for knee joint replacement surgery. The final Follow Up occurs 12 months after the information session. An ACTION team staff member will ask participants to complete a survey (this survey is attached). This will take approximately 10-20 min and can be conducted by phone or in person. At this time the participants medical record will be reviewed again for knee joint replacement surgery.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

The Clinical Research Computing Unit (CRCU) will be responsible for data management and trial quality assurance. The CRCU is a UPENN Core Research facility that provides the full range of services essential for clinical research, including support of multi-center clinical trials conducted consistent with all applicable federal guidelines and will work with Dr. Ibrahim and the team through all phases of the trial. CRCU activities will include development of a Data Management Plan (DMP) and data management tasks. Participants will be screened using paper forms that will then be entered manually into an Access database. The DMP will cover topics such as case report form (CRF) refinement and retrieval; tracking of study participants to ensure proper enrollment, randomization, and follow-up; screen design and database development; backup procedures; disaster recovery; user manuals and training; data flow and quality control; data entry and validation; secure handling and transfer of electronic data; data coding; database lock; and approval and transfer. All study procedures will be explicitly documented in the Manual of Procedures (MOP). Data Management System (DMS) software will be used for tracking of participants, CRFs, data validation, and study milestones.

Radiation Exposure*

Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?

No

Human Source Material*

Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?

No

CACTIS and CT Studies*

Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?

No

CAMRIS and MRI Studies*

Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?

No

Cancer Related research not being conducted by an NCI cooperative group*

Does this protocol involve cancer-related studies in any of the following categories?

No

Medical Information Disclosure*

Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?

Yes

CTRC Resources*

Does the research involve CTRC resources?

No

If the answer is YES, indicate which items is is provided with this submission:

Request for HIPAA Waiver of Authorization

Use of UPHS services*

Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?

No

Primary Focus*

Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

- Sociobehavioral (i.e. cognitive or behavioral therapy)
- Drug
- Device - therapeutic
- Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
- Surgical
- Diagnostic test/procedure (research-related diagnostic test or procedure)
- Obtaining human tissue for basic research or biospecimen bank
- Survey instrument
- None of the above

The following documents are currently attached to this item:

HIPAA Waiver of Authorization (vahipaaconsentapproved.pdf)

HIPAA Waiver of Authorization (vawaiverofindividualauthorizationandapproval.pdf)

Sponsors

Business Administrator

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Funding Sponsors

Name:	NATIONAL INSTITUTES OF HEALTH
Type:	UPENN Federal

Funding sponsors billing address

If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/commercial, this information is not necessary to provide with your application.

Funding sponsors gift

Is this research being funded by a philanthropic gift?

No

Regulatory Sponsor

Name:	NATIONAL INSTITUTE OF ARTHRITIS & MUSCULOSKELETAL & SKIN DISEASES/NIH/DHHS
Type:	UPENN Federal

IND Sponsor

none

Industry Sponsor

None

Project Funding*

Is this project funded by or associated with a grant or contract?

Yes

Selected Proposals

Proposal No	Title
10028587	Behavioral & Social Science Research on Understanding and Reducing Health Dispart

Sponsor Funding

Is this study funded by an industry sponsor?

No

Status of contract

The following documents are currently attached to this item:

Grant Application (ro1grantapplication.doc)

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract

A randomized, controlled design will be utilized to examine and compare the effectiveness of the proposed educational intervention, which includes an educational decision aid with attention control on select key patient-centered and process of care outcomes. The study sample will consist of approximately 350 African-American patients with osteoarthritis of the knee. Patients will be recruited from Pennsylvania Presbyterian Medical Center, the Philadelphia VA Medical Center and Temple Orthopaedics & Sports Medicine and will be randomized to one of the two study arms.

Objectives

Overall objectives

The immediate goal of this randomized controlled trial is to assess the effect of a high-quality, evidence-based, patient-centered educational intervention on African American patient preferences, expectations, and the likelihood of receiving a recommendation for knee joint replacement surgery when clinically indicated. The long-term goal of this research is to implement effective strategies to improve minority patients' access to joint replacement and ultimately eliminate racial disparities in the utilization of this effective treatment for knee OA.

Primary outcome variable(s)

Study Aim: To examine the effect of the DA intervention on the likelihood of receiving a recommendation for knee joint replacement when clinically indicated. Hypothesis: The DA intervention will lead to higher rate of treatment recommendation within 6 months. .

Secondary outcome variable(s)

Secondary Aim: To examine the effect of the DA intervention on the rate of knee replacement receipt within 12 months. Hypothesis: Patients randomized to receive the intervention will undergo knee replacement within 12 months at a higher rate than those in the attention control group.

Background

1) Osteoarthritis, epidemiology and impact on health: Osteoarthritis (OA) is the most prevalent form of arthritis and is among the most prevalent chronic conditions in the US. It is estimated that nearly 70 million Americans, about one of every three, are impacted by arthritis or musculoskeletal disease. 2) Knee joint replacement, an effective treatment option for end-stage knee OA: The evidence base for joint replacement as a treatment option for end-stage knee or hip OA has been the subject of several National Institutes of Health (NIH) consensus statements and evidence-based systematic reviews by the Agency for Healthcare Research and Quality (AHRQ). The 2003 NIH consensus statement touted the effectiveness of knee joint replacement.(20) The most recent AHRQ systematic review of over 129 studies found that the evidence supports the effectiveness of joint replacement as the primary surgical option for end-stage knee OA. 3)Evidence of racial/ethnic disparities in the utilization of joint replacement: Numerous studies have documented the existence of racial/ethnic differences in the utilization of knee or hip joint replacement over the past 10-15 years. Most of these studies have utilized Medicare data where access to the procedure based on insurance status is not a significant issue. Wilson and colleagues studied Medicare hospital claims data from 1980 to 1988 and found that compared to AA men, white men were 3.0 to 5.1 times more likely to undergo knee replacement. Escarce and colleagues examined 1989 Medicare data and found that whites underwent hip replacement three times more often than AAs and were twice as likely to receive knee replacement. McBean and Gornick used the 1992 Medicare database to report an AA to white odds ratio of 0.64 for undergoing knee replacement. 4)Race: A social construct in this research: In this proposal we will use patient self-reported data to determine race, while being consistent with the US Federal government proposed categories of race. However, we recognize the potential problems with the use of racial categories in research and the ongoing scientific debate about the definition of race. We posit that race, as it relates to this area of research, is a social construct and a marker of patient-level cultural and psychosocial factors. Findings from our earlier work in this area support this conceptualization of race. For instance,

we found that among potential candidates for joint replacement, AA patients hold different cultural views about knee or hip arthritis care. They also perceive a greater role of religiosity and prayer in knee and hip pain management, and are less knowledgeable about the benefits and risks of joint replacement compared to white patients. In focus group studies of older AA patients with chronic knee or hip arthritis, we also found that AA patients hold culturally-based expectations regarding knee or hip pain and joint replacement.

5) Conceptual framework for this proposal - A theory-based framework for the role of patient preference in treatment seeking: A central hypothesis of this proposal is that cultural and psychosocially based attitudinal factors in combination with contextual factors (i.e., clinical factors) shape patient preferences regarding knee joint replacement, and consequently, the likelihood of seeking and undergoing this procedure if offered. The impact of attitudes on intention (a correlate of preference), and consequently behavior, has been well studied. Most studies that have examined the link between attitudes and intentions and subsequent action (behavior) have been conducted within the framework of the Theory of Planned Behavior and its predecessor, the Theory of Reasoned Action. According to these theories, people act or behave in accordance with their intentions and perceptions of control over their behavior (i.e., self-efficacy). Intentions (e.g., articulated preference for knee joint replacement) are influenced by attitudes toward the behavior or goal (e.g., knee joint replacement as a treatment option) in addition to subjective norms regarding the object or behavior and perception of behavioral control. Examples of practical applications of these theories in public health include use of condoms, smoking cessation, use of hormone replacement therapy, compliance with medications, and use of dental floss.

6) Framework for the proposed intervention: Although the aforementioned theoretical framework provides the scientific basis for the relationship between preference, knowledge and expectancies and how they influence behavior, the intervention component of this proposal operationalizes the conceptual framework. It tests the hypothesis that the knee OA DA will lead to a change in preference by altering patient knowledge and expectancies about joint replacement thus leading to patient empowerment and consequently increasing the likelihood of receiving a recommendation for knee joint replacement when clinically indicated.

Study Design

Phase*

Phase I

Design

Design: A randomized, controlled 2 arm design will be utilized to examine and compare the effectiveness of the proposed intervention, a knee OA decision aid (DA) to attention control on select key patient-centered and process of care outcomes. Methods: We will recruit and conduct the study arm intervention with approximately 350 African-American primary care patients who meet clinical indications for osteoarthritis and randomize them into 1 of the 2 study arms. We will assess patient expectations, willingness and recommendation for knee joint replacement.

Study duration

This study will last 5 years. We anticipate the study to be completed June 30, 2015. Recruitment is to end approximately June 2014. Participants will be in the study for 1 year.

Resources necessary for human research protection

Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

Personnel training will be considered to be of the highest priority and will be addressed prior to the start of the trial and on an ongoing basis; it will include training of the Research Assistants, Research Coordinators, and Project Manager on how to interface with the CRCU. The CRCU will train these project personnel to ensure that all processes and procedures for data collection are correctly applied and utilized. All ACTION research staff will complete Human Subjects Training and have been well informed of the procedures and contents of the protocol. In addition, persons who will have access to patient medical records are HIPAA certified. The research staff will have access to subject population at Pennsylvania Presbyterian Medical Center, the Philadelphia VA Medical Center and Temple Orthopaedics & Sports Medicine. Potential participants will be identified with the assistance of Penn's Office of Human Research (PICARD) and with the help of a data manager at the VA's Center for Health

Equity Research and Promotion (CHERP). We are requesting a waiver of HIPAA authorization from the IRB to identify potentially eligible patients.

Characteristics of the Study Population

Target population

Subject Population: African-American patients over the age of 50 with osteoarthritis.

Subjects enrolled by Penn Researchers

189

Subjects enrolled by Collaborating Researchers

125

Accrual

Potential participants will be identified with the assistance of Penn's Office of Human Research using the PICARD system and with the help of a data manager in the PVAMC's CHERP office. We are requesting a waiver of HIPAA in order to identify potentially eligible patients. We plan to recruit 350 patients from Penn Presbyterian Medical Center, the PVAMC and Temple Orthopaedics & Sports Medicine. To achieve this we will recruit approximately 2 patients a week. Presbyterian serves a predominately African American community. For instance, patients who were recently seen at this orthopedic clinic for knee OA are 53% AA. This study site performs approximately 700 primary total knee replacements and sees over 3500 patients with a diagnosis of knee OA each year.

Key inclusion criteria

African-American patient referred to orthopedic doctor at Presby or the PVAMC Age 50 or older Presence of knee OA by American College of Rheumatology as evidenced by: Chronic, frequent knee pain based on the NHANES questions. Moderate to severe knee OA based on WOMAC index score 39. Radiographic evidence of knee OA. We are targeting patients age 50 and over in part because this is the age at which OA is more prevalent, but also it is the lower threshold of the age when orthopaedic surgeons seriously consider joint replacement. Since the prosthesis has 10-20 year life span, orthopaedic surgeons often prefer to postpone knee joint replacement to minimize the need for one or more revisions of the knee replacement. We also include radiographic evidence of OA as an inclusion criterion because surgeons are unlikely to operate on patients without radiographic evidence of disease regardless of the WOMAC score. The WOMAC criterion is critical because it signifies moderate to severe disease that has impacted function and quality of life, key factors in the decision to recommend joint replacement.

Key exclusion criteria

Prior history of any major joint replacement. Terminal Illness (e.g. end stage cancer). Physician-diagnosed inflammatory arthritis (i.e., rheumatoid arthritis, connective tissue disease, ankylosing spondylitis, or other seronegative sypondyloarthroplasty.) Contra-indications to replacement surgery (e.g., lower extremity paralysis as result of stroke). Prosthetic leg, Cognitive impairment (e.g., dementia), No home telephone service.

Vulnerable Populations

Children Form

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other

None of the above populations are included in the research study

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion

none

Subject recruitment

Penn's Office of Human Research and UPHS IT will assist us in identifying potential candidates for this study at Pennsylvania Presbyterian Medical Center using PICARD. A data manager at the PVAMC's Center for Health Equity Research and Promotion office will assist us in identifying potential candidates for this study at the PVAMC. Potential candidates are patients age 50 and over, with knee pain/osteoarthritis (OA). In addition, we will utilize print advertisements to recruit potential candidates at Penn Presbyterian. This advertisement may be published in local print media, or displayed on SEPTA transportation services. Finally we will utilize The Older Adult Research Connection Registry from the Penn Minority Aging Research Center for Community Health. The Older Adult Research Connection Registry is a database of research participants who are 55 and older, and have expressed an interest in being contacted by other researchers at The University of Pennsylvania. Participants recruited through study advertisements or the Older Adult Research Connection Registry will be screened to ensure they are patients within the University of Pennsylvania Health System. We will then check medical charts to look for a knee x-ray showing OA, and the reason for the orthopedic specialist appointment. We are requesting a waiver of HIPAA in order to identify potentially eligible patients. We will then mail letters to these patients to all of these patients requesting permission to contact them about the study via telephone. Patients who have e-mail addresses as part of their EMR will additionally receive this recruitment letter via e-mail. Those who do not opt out will be called by our research staff and assessed for study eligibility after a brief verbal consent process for screening and completion of the baseline telephone interview. Potentially eligible participants will be mailed a consent form to sign and return. If they do not have an x-ray on file with UPHS, we would ask them to mail us the report from a knee x-ray from another health system. After confirmation of radiographic eligibility, eligible patients will then be administered the baseline assessments by telephone. The hospital staff will not have any responsibilities for screening or intervening. All study tasks will be conducted by project-supported staff. In addition, data will be collected by the study staff from medical records and from surveys when we meet/call patients.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?

No

The following documents are currently attached to this item:

Subject recruitment (vaapprovedrecruitmentletter.pdf)

Subject recruitment (templerecruitmentletter.pdf)

Subject recruitment (2011-06-15repair-actionad.pdf)

Subject recruitment (actionrecruitmentletter_ver1.0.doc)

Subject compensation*

Will subjects be financially compensated for their participation?

Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

A total of \$50 will be paid to the participant for completing all parts of the study (the screening, baseline, educational intervention, and 12-month follow-up.) The breakdown of payments are as follows: 1) \$30 will be paid to the participant upon completing the educational intervention 2) an additional \$20 will be paid to the participant upon completing the 12 month follow-up questionnaire

over the phone.

Study Procedures

Suicidal Ideation and Behavior

Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?

No

Procedures

Eligible individuals who provide verbal consent to participate in the study will undergo the same screening procedures utilized in our previous and ongoing observational studies of similar patient populations. (Screening form attached.) They will complete a brief screening questionnaire to confirm the presence of chronic, frequent knee pain and rate pain severity and functional limitations. The Arthritis Supplement National Health and Nutrition Examination Survey will be used to identify the presence of chronic, frequent knee pain. This survey assesses the presence of pain in the knee on at least half of the days over the past month, and pain in either knee for more than 6 months. Potential subjects that answer yes to both questions will be categorized as having chronic, frequent knee pain. Individuals that screen positive for chronic, frequent knee pain using the above questions will then proceed to the next phase of screening which uses the WOMAC index. Only individuals with moderate to severe chronic knee pain as defined by WOMAC index will be eligible for enrollment. The WOMAC scale is validated and reliable. We have used this scale for screening patient into our previous studies and works well. A score of greater than 39 is considered severe enough for consideration of surgical referral. Patients who score less than 39 will not be eligible for the study. They will also be asked to self-identify race/ethnicity at that time. We field-tested our screening process in prior studies and it takes 10 minutes to determine if a patient is a potential candidate for the study. To assess for radiographic eligibility, we will view patients existing knee x-ray. We will look at the x-ray report for signs of osteoarthritis. Knee radiograph reports documenting osteophytes with joint space narrowing, bony sclerosis, or possible deformity of bone ends or simply osteoarthritis will be considered radiographic confirmation of OA. Consistent with our original strategy, we will randomize only patients with radiologic evidence of knee OA. (1) age 50 or over; (2) chronic frequent knee pain; and (3) radiographic evidence of OA as defined above. These are the same criteria used in our previous study. Patients will be given a verbal consent prior to screening and baseline interview. If the patient is found to be eligible according to the screening and baseline survey and radiographic confirmation, they will be sent an informed consent to read and sign. We will track recruitment on an ongoing basis by calculating the number of patients approached, number who meet criteria, number who consent to enroll, and number randomized weekly. For those eligible patients who are not enrolled, we will assess and record reasons for non-enrollment. This recruitment strategy will be assessed periodically to make necessary adjustments. Eligible patients will be randomized to either the DA intervention arm or the attention control arm. Once eligibility for randomization has been determined and consent obtained, the study coordinator will be informed. The study coordinator will notify the statistician that a patient is eligible and the data manager will then generated random assignment to one of the two study arms (intervention vs. attention control). The study coordinator will notify the interventionist of the treatment assignment. The randomization schedule will be developed according to standard randomization procedures by the study statistician. Once a patient is randomized, that patient will be included in the intention to treat analysis. Once the patient is randomized, they will be asked to complete the Baseline Survey. This can occur over the phone or in person. (Baseline survey attached.) Subjects randomized to the attention control arm will receive an educational program (an NIH-developed booklet) that summarizes how to live with knee OA but does not specifically mention joint replacement. (Booklet is attached.) This booklet provides information about OA, examples of exercises one could do to improve pain and reduce stiffness, types of non-drug pain relief such as massage, and information about various medications. The interventionist will give the participant the booklet and describe what can be found inside. They are also encouraged to ask their doctor any questions they may have about the information in the booklet or questions they may have about their OA. The purpose of this educational program is to provide a tangible clinical incentive to the control group for participating in this additional component of the study. The intervention and attention control treatments will both be administered in the clinic at the study site. We have given a careful consideration to minimize differences in the treatment experience between the attention control

arm and the DA intervention arm. Patients in both arms undergo identical screening procedures and baseline assessments. Patients randomized to the attention control arm will then receive the attention control educational booklet, instead of the DA intervention. Patients randomized to the DA Intervention will watch a Knee OA Decision Aid (DA) developed by the Foundation for Informed Medical Decision Making and then receive a brief counseling session called "AskMe3." The DA is a video that provides viewers with information about OA, treatment choices such as lifestyle changes, non-drug treatments, medication, injections, complementary therapies, and surgery, as well as the pros and cons of each type of treatment. The AskMe3 is a communication skill-building intervention, which instructs patients to ask 3 questions to the doctor: 1) What is my main problem? 2) What do I need to do? 3) Why is it important for me to do this?. Interactions and assessments with the attention control arm and the DA intervention arm from this point forward will be identical. At 6 months post-intervention, all of the patient's medical charts will be reviewed for evidence of knee joint replacement surgery. At 12 months post-intervention, all patients in both arms will undergo a survey over the phone and an assessment of the primary study outcome; receipt of joint replacement.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception

Does your project use deception?

No

Analysis Plan

The analyses plan will focus on the impact of the DA intervention on study outcomes using the original treatment assignment as randomized for each participant regardless of compliance (intent-to-treat). Statistical methods will control for the study site and the clustering of patients within providers. We propose enrolling and randomizing 350 participants to DA intervention or control. Analyses will be done using SAS version 9.1.3. We will first compare the distribution of baseline prognostic factors between participants the DA and control groups to assess the effectiveness of the randomized allocation. Continuous variables will be graphed using histograms to determine symmetry of their distributions and identify any potential outliers. Variables with fairly symmetric distributions will be summarized using means and standard deviations. Those with highly skewed distributions will be described using medians and interquartile ranges. In addition, some may be categorized to facilitate their use in further analyses. Categorical data will be summarized using frequencies and percentages. Any baseline prognostic factors that are meaningfully imbalanced between the two groups will be controlled for in secondary analyses testing the intervention effects. The research team will make extensive efforts to collect complete information on each subject enrolled in the study. Participants will be randomized before they arrive for their appointment with the orthopaedic surgeon. The primary type of dropout may occur before randomization if the participant does not complete the baseline survey. This type of dropout will not affect our study results because the participants will not have been randomized. Once they arrive for the visit, they will receive the intervention or control just before their appointment with the surgeon. Missing data for the 6 month referral outcome should be minimal (1%) due to the nature of the data collection via chart abstraction. Missing data are most likely to occur for the 12 month knee replacement outcome which will be assessed via telephone interview with the participant and verification by medical chart review. Our experience indicates that up to 10-20% of subjects who initially enroll may be lost to follow-up; because 12 month knee replacement is a secondary exploratory outcome, we have not adjusted our sample size for this attrition. The analyses will be intent-to-treat in that, to the extent possible, all randomized patients will be included in the analyses regardless of receipt of the appropriate intervention or loss to follow-up. Patients who are lost to follow-up may be missing key outcomes or measures that may prevent inclusion in some analyses. Furthermore, in our analysis we will compare the characteristics of participants who are lost to follow-up with those who complete the study as well as if there are differences by treatment arm. Primary specific aim: To examine the effect of the DA intervention on the likelihood of receiving a recommendation for knee joint replacement when clinically indicated. Secondary aim: To examine the effect of the DA/MI intervention on the rate of knee replacement receipt within 12 months. Recommendation of knee joint replacement 6 months after intervention will be assessed for all patients by chart abstraction. Receipt of knee joint replacement will be assessed for all patients 12 months post-intervention initially through telephone survey and then validated by medical record review. These outcomes are dichotomous (present or not present). We will first calculate the unadjusted percentages of

each by DA and control groups. We will then use logistic regression to analyze each outcome controlling for the clustering within provider using GEE. Results will be presented using frequencies, percentages, odds ratios, and adjusted 95% confidence intervals.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?

No

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**
- x **Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.**
- x **Wherever feasible, identifiers will be removed from study-related information.**
A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
- x **A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)**
- x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**
- x **Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.**

Subject Confidentiality

This study utilizes several methods to protect patient privacy. First and foremost the collection of sensitive information about subjects is limited to the amount necessary to achieve the specific aims of the research, so that no unneeded sensitive information is being collected. Second, all hard copies of patient data (i.e. informed consents) are kept in locked drawers which reside in locked rooms. Only approved research staff, meaning staff that has obtained certificates in good clinical practice and that have signed confidentiality agreements, have access to these files. Third, all digital patient data is kept on password protected computers on University protected servers at Penn the PVAMC and Temple Hospital. Patient data is stored on encrypted local hard drives that are password protected. Only approved staff are granted access to digital files. Furthermore, identifiers will be removed from study-related information. Finally, all research staff is educated in the rules of patient confidentiality and protection. No research staff would ever share any information with outside persons. At the conclusion of the study all study data from the PVAMC and Temple Hospital will be deidentified and then transferred to Penn via CD media for study analysis.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?

No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The

privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

This study utilizes several methods to protect patient privacy. First and foremost the collection of sensitive information about subjects is limited to the amount necessary to achieve the specific aims of the research, so that no unneeded sensitive information is being collected. Second, all hard copies of patient data (informed consents) are kept in locked drawers which reside in locked office rooms. Only approved research staff have access to these files. Patient data is stored on encrypted local hard drives that are password protected. No one can gain access to an individual tracking database table unless explicitly granted a user ID, password, and specific access. Third, research procedures (i.e. administering the survey) are conducted with the patients privacy in mind; we always give our research subjects the choice of where they would like to conduct the research (i.e. private room). Finally, all research staff is educated in the rules of patient privacy and protection. No research staff would ever share any information with outside persons.

Data Disclosure

Will the data be disclosed to anyone who is not listed under Personnel?

No

Data Protection*

- Name**
- Street address, city, county, precinct, zip code, and equivalent geocodes**
 - All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- Telephone and fax number**
- Electronic mail addresses**
 - Social security numbers**
 - Medical record numbers**
 - Health plan ID numbers**
 - Account numbers**
 - Certificate/license numbers**
 - Vehicle identifiers and serial numbers, including license plate numbers**
 - Device identifiers/serial numbers**
 - Web addresses (URLs)**
 - Internet IP addresses**
 - Biometric identifiers, incl. finger and voice prints**
 - Full face photographic images and any comparable images**
 - Any other unique identifying number, characteristic, or code**
- None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?

No

Tissue Specimens Obtained as Part of Research*

Are Tissue Specimens being obtained for research?

No

Tissue Specimens - Collected during regular care*

Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?

No

Tissue Specimens - otherwise discarded*

Would specimens otherwise be discarded?

No

Tissue Specimens - publicly available*

Will tissue specimens be publicly available?

No

Tissue Specimens - Collected as part of research protocol*

Will tissue specimens be collected as part of the research protocol?

No

Tissue Specimens - Banking of blood, tissue etc. for future use*

Does research involve banking of blood, tissue, etc. for future use?

No

Genetic testing

If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."

Not applicable

Consent

1. Consent Process

Overview

A waiver of HIPAA in order to identify potentially eligible patients is requested. A waiver to obtain signed informed consent has been requested for completion of the screening and baseline interview in addition to the review of patients medical record to screen further for eligibility. This waiver will only be applicable to Penn Presbyterian patients. A waiver to obtain signed informed consent was approved by the PVAMC IRB for completion of the screening, however the baseline and intervention cannot be conducted until the PVAMC patient receives and signs the written informed consent and HIPAA authorization. Patients will be informed of staff contact information, that their participation is completely voluntary, that they may withdraw at any time and that the verbal consent applies only to the screening and baseline interview and review of medical record for Penn Presby patients and applies only to the screening and medical review for PVAMC patients. Following completion of the verbal consent, screening (and baseline interview for Penn Presby patients only) and review of patients medical record, research staff will complete written informed consent which contains further details about the study with patients. They will be given the opportunity to read the informed consent, ask questions, and return it signed at their convenience. They will also be encouraged to call with any questions. We will also remind them that this study is completely voluntary and that they would not lose any benefits by choosing not to participate.

Children and Adolescents

Not Applicable

Adult Subjects Not Competent to Give Consent

All adult subjects will be competent to give consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*

Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk***Impact on Subject Rights and Welfare*****Waiver Essential to Research*****Additional Information to Subjects****Written Statement of Research***

Yes

If no written statement will be provided, please provide justification

The following documents are currently attached to this item:

Written Statement of Research (2011-06-29actionverbalconsent.pdf)

Written Statement of Research (2011-06-17actionverbalconsent.pdf)

Written Statement of Research (vaapprovedscreeningscript1.pdf)

Written Statement of Research (2011-06-23actionverbalconsent.pdf)

Risk / Benefit**Potential Study Risks**

There is minimal risk in this study. The primary risk of participation is loss of confidentiality. The investigators have considerable experience in handling confidential patient information and minimizing the risk of loss of confidentiality. All patient information will be de-identified whenever possible and kept in password protected and or locked files.

Potential Study Benefits

Each participant may benefit directly by gaining knowledge about treatment options that are available for patients with knee pain. Both the control arm and the intervention arm offer information about treatment options that are currently available for people with knee pain.

Alternatives to Participation (optional)**Data and Safety Monitoring**

A data and safety monitoring plan will be implemented to ensure that there are no changes in the risk/benefit ratio during the study and that confidentiality of research data is maintained. Investigators and study personnel will meet at least monthly to discuss issues like study progress, modifications, documentation, recruitment, retention, data analysis and confidentiality and to address any issues or concerns at the time. The CRCU database administrator will be responsible for preventing unauthorized access to the trial database. The CRCU database server and study databases have never been compromised as a result of extremely rigorous and secure network firewall technologies. The secure servers are located in a specially designed, highly secured UPENN facility with dedicated uninterrupted power supply and strictly limited access. In addition if a subject decides to withdraw from study participation, the research data collected from that subject will be rendered anonymous. Depending on what data was collected from the patient, his/her data may or may not be used in analysis. A data safety monitoring plan will be implemented at the PVAMC to ensure that there are no changes in the risk/benefit ration during the study and that confidentiality of research data is maintained. The PI and study personnel will meet regularly to discuss any issues like study progress, modifications, documentation, recruitment, retention, data analysis and confidentiality and to address any issues or concerns at the time. The database administrator will be responsible for preventing unauthorized access to the trial database. All information will be stored on PVAMC computers with secure servers in a PVAMC facility. All PVAMC patient information will be storied in protected files on a PVAMC secure network. Study data will be stored on the CHERP's Network Attached Storage (NAS) server (with a single 3Ghz Intel Xeon Processor, Microsoft Windows Server 2003 Enterprise Edition operating system, 1Gb RAM,

and 2.7TB Internal RAID) which is also password protected. Administrative and technical measures are in place to restrict access to the study data. These servers reside in the PVAMC IT server room (room #A001). Additionally, these servers are networked within the VA firewall to provide the same level of data security as other VA patient care information systems. Our research assistant, Sr. Coordinator, and Interventionist will go through PVAMC training and authorization. All information will be stored securely and only shared with trained study team members. In addition, if a subject decides to withdraw from study participation, the research data collected from the subject will be rendered anonymous. Depending on what data was collected from the patient, his/her data may or may not be used in analysis. A data safety monitoring plan will be implemented at Temple Orthopaedics & Sports Medicine to ensure that there are no changes in the risk/benefit ration during the study and that confidentiality of research data is maintained. The PI and study personnel will meet regularly to discuss any issues like study progress, modifications, documentation, recruitment, retention, data analysis and confidentiality and to address any issues or concerns at the time. The database administrator will be responsible for preventing unauthorized access to the trial database. All information will be stored on Temple Orthopaedics & Sports Medicine computers with secure servers in a Temple Orthopaedics & Sports Medicine facility. All Temple Orthopaedics & Sports Medicine patient information will be stored in protected files on a Temple Orthopaedics & Sports Medicine secure network. Our research assistant, Sr. Coordinator, and Interventionist will go through Temple Orthopaedics & Sports Medicine training and authorization. All information will be stored securely and only shared with trained study team members. In addition, if a subject decides to withdraw from study participation, the research data collected from the subject will be rendered anonymous. Depending on what data was collected from the patient, his/her data may or may not be used in analysis. At the conclusion of the study all study data from the PVAMC and Temple Hospital will be deidentified and then transferred to Penn via CD media for study analysis.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment

There is minimal risk in this study and direct benefit to the patient. The primary risk of participation is loss of confidentiality. The investigators have considerable experience in handling confidential patient information and minimizing the risk of loss of confidentiality. All patient information will be de-identified and kept in password protected and or locked files. On the other hand, each participant may benefit directly by gaining knowledge about treatment options that are available for patients with knee pain. Both the control arm and the intervention arm offer information about treatment options that are currently available for people with knee pain.

General Attachments

The following documents are currently attached to this item:

Cover Letter (action_pre-review_edits30sep2010.doc)

HIPAA Authorization or Waiver (2011-06-23actionverbalconsent.pdf)

Additional forms (heatergcptrainingreport.pdf)

HIPAA Authorization or Waiver (vahipaaconsentapproved.pdf)

HIPAA Authorization or Waiver (vawaiverofindividualauthorizationandapproval.pdf)

Informed consent form (actionvainformedconsentapproved.pdf)

Informed consent form (2011-09-15trackedchangesactionconsentform.pdf)

Questionnaires (action6mochartreview2012-03-20trackedchanges.docx)

Questionnaires (action6mochartreview2012-03-20clean.docx)

Additional forms (christinanashcertifications4.pdf)

Additional forms (2013-02-11templeirbinitialapproval.pdf)

Additional forms (templeapplication-protocol.pdf)

Informed consent form (templeinformedconsent.pdf)
Additional forms (templehipaawaiver.pdf)
Additional forms (cititraining_cbroberts.pdf)
Cover Letter (2015-06-16research_staff_amendment_memo_action.docx)
Additional forms (citicompletionreport_basiscourse_bermudez.pdf)
Additional forms (citicompletionreport_conductresearch_bermudez.pdf)
Additional forms (cititraining_drichardson.pdf)
Additional forms (cititraining_emedvedeva.pdf)
Additional forms (2011-06-16stephaniekeysciti.pdf)
Additional forms (2014-02-18actione-mailrecruitmenttext.doc)
HIPAA Authorization or Waiver (2011-06-29actionverbalconsent.pdf)
Additional forms (heathercititrainingreport.pdf)
Questionnaires (actionscreening.pdf)
Additional forms (ibrahimgcp2009-2010.pdf)
Questionnaires (actionverbalscreeningconsentscript.doc)
Recruitment materials (consent_cover_letter.doc)
Additional forms (actioncontrolarmbooklet1.14.091.pdf)
Questionnaires (actionbaselinever2.0.pdf)
Informed consent form (actionic18feb2011clean.doc)
Informed consent form (2011-09-15cleanactionconsentform.pdf)
HIPAA Authorization or Waiver (2011-06-17actionverbalconsent.pdf)
Recruitment materials (2011-06-15repair-actionad.pdf)
Cover Letter (reconsentver4.0_cover_letter.doc)
Grant Application (ro1grantapplication.doc)
Questionnaires (action12monthfollowup.pdf)
Additional forms (acollier_citi.pdf)
Recruitment materials (actionrecruitmentletter_ver1.0.doc)