Title:
Informed Decisions and Patient Outcomes: An Interdisciplinary Approach to Chronic Hip Pain.

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2018.02.14	IRB approved amendment to add qualitative interviews
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Research Protocol:

Informed Decisions and Patient Outcomes: An Interdisciplinary Approach to Chronic Hip Pain.

I. Objectives

Only 25% of patients with Non-Arthritic Hip Disease (NAHD) report acceptable outcomes two years after elective surgical treatment.[1] Suboptimal outcomes may be explained in part by current gaps and inconsistencies in approaches to diagnosis and treatment. An in-depth examination of factors that influence patients' treatment decisions and the associated outcomes is needed to inform a more rigorous decision-making process and to optimize NAHD patient outcomes. Physical examinations have been prescribed in the literature proposing evaluation components for young, active patients with hip disease[2] and techniques for the adult hip.[3] Jorgensen et al. also provided an evidence-based treatment algorithm for patients with NAHD that utilizes radiographic findings to support treatment decisions.[4] No interdisciplinary evaluation approaches have yet to be described; decision-making should be a collaborative effort between patients and providers utilizing the best clinical evidence, interdisciplinary approaches, and patient values.

This study aims to understand how interdisciplinary evaluations, as part of a shared decision-making process, can harmonize efforts of multiple providers to optimize patient care by comprehensively addressing impairments contributing to disease or injury. Abnormal movement patterns are common to persons with NAHD both before and after surgical intervention.[5–10] Posture and movement training implemented by physical therapists has demonstrated preliminary effectiveness in reducing pain and improving function in patients with NAHD contemplating surgical intervention.[11] Thus, physical therapists, who provide posture and movement training, can fill a critical gap in an interdisciplinary shared decision-making process involving patients with NAHD. We aim to develop and test an integrated, interdisciplinary shared decision-making process which includes physical therapists, physicians, and patients designed to identify patient impairments and facilitate treatment decisions to optimize outcomes.

Our main hypothesis is that an **interdisciplinary evaluation and subsequent treatment of patients with NAHD will improve patient-reported outcomes and satisfaction through a more informed, comprehensive decision-making process.** The rationale that underlies the proposed research is that this interdisciplinary shared decision-making approach will standardize and better inform decision-making processes to optimize treatment selection and outcomes. To accomplish our objective, the main hypothesis will be tested by the following specific aims:

1. Compare outcome expectations between patients, physicians, and physical therapists prior to treatment for NAHD.
2. Identify the extent to which an interdisciplinary evaluation between a physical therapist and physician influences treatment decisions of persons presenting to a hip arthroscopy clinic for NAHD.
3. Quantify the effect of PMT on patient-reported outcomes and biomechanics in persons with NAHD.
4. Identify the extent to which PMT influences treatment decisions of persons with NAHD.

The overall objective of this project is to yield empirical data that will inform an interdisciplinary shared decision-making model for the treatment of NAHD. This work will directly address the current gap in the clinical care and outcomes of patients with NAHD by informing the treatment decision-making process.

II. Background and Rationale

Outcomes after hip arthroscopy are suboptimal for the majority of individuals with non-arthritic hip disease (NAHD). Hip arthroscopy is a treatment option growing in popularity with a 5-fold increase in surgeries over the past decade.[12] Hip arthroscopy has been shown to improve hip function in carefully selected patients with NAHD[13,14]; however, data from our laboratory[15] and other investigators[1,16] indicate that a majority of patients who undergo hip arthroscopy for chronic hip joint pain do not achieve optimal function.[17] A recently published systematic review and meta-analysis demonstrated that only 25% of patients achieve an optimal state of health an average of 2.5 years post-operatively.[1] A separate cohort of 595 patients who received hip arthroscopy demonstrated approximately a 40% failure rate 2 years post-operatively defined by conversion to total hip arthroplasty, revision, or less than a 10-point improvement on the non-arthritic hip score.[5] Collectively these data show that *getting better* is not the same as *doing well*; this discrepancy represents an opportunity to advance our treatment approach for individuals with NAHD.

Persons with NAHD also often present with abnormal movement patterns, which persist after surgery and are associated with worse function. Preliminary data from our lab show patients two years post hip arthroscopy for NAHD with <70% self-reported hip functioning had reduced sagittal plane hip, knee, and ankle excursion during a step-down compared to those with >80% function. Furthermore, persons with NAHD have slower gait speed and cadence,[8] decreased external hip joint moments during gait,[5,6] and reduced joint motion during gait[7,8] and stairs.[10] Persons with NAHD also demonstrate compensatory strategies that impact other joints: during sit to stand transfers, participants demonstrated reduced knee-joint contributions to their total support moment compared to controls and took longer to perform the task.[9]

The decision-making process of patients who choose to undergo hip arthroscopy is currently unknown. The lack of information regarding suboptimal outcomes after hip arthroscopy and lack of evidence regarding non-operative treatment likely contributes to these decisions. Initial investigations demonstrate improved patient-reported hip function, overall health, and pain levels after non-operative treatment of NAHD.[18–20] After 3 months of non-operative treatment, 44% of patients with NAHD reported satisfactory function and did not proceed to surgery.[20] Feasibility data from a subsequent randomized controlled trial evaluating the effect of posture and movement training (PMT) indicated preliminary improvements in patient-reported hip function and hip kinematics.[11] While these studies assessed effectiveness of PMT, they didn't investigate how PMT can influence treatment decisions. We hypothesize that PMT can optimize outcomes and affect treatment decisions.

The proposed trial will fill a critical gap in the literature by examining the process by which patients with NAHD select an intervention following (1) an interdisciplinary evaluation and (2) posture and movement training. The results of our research will allow us to explore contributing factors to the shared decision-making process with patients with NAHD and investigate long-term effects of interdisciplinary evaluation and treatment. ***These outcomes are expected to have an important positive impact on patient health by providing an evaluation and treatment protocol to maximize outcomes for patients with NAHD that may be extended to other similar patient populations.***

III. Procedures

A. Sample

Sample Size and Power Calculation:
The main goal of this study is to evaluate changes in self-reported performance, biomechanics, and treatment decisions after interdisciplinary care. With a sample size of 96 persons randomized to receive an interdisciplinary evaluation, we estimate we will have 76 participants randomized to receive posture and movement training (Figure 1). Our primary endpoint is improvement of the Hip Outcome Score.[21,22] With a sample size of 30 participants per group, we will have at least 80% power to detect an effect size of 0.75 between the two groups at a significance level of 0.05 based on a two-sample t-test. We have a 15-month recruitment period planned to ensure full recruitment. These data will be used to generate accurate sample size calculations for a larger randomized controlled trial which will consider longer follow-ups.

Eligibility, Recruitment, and Retention:
Eligible participants will be recruited from patients who present to the Hip Preservation Clinic at OSUWMC for an appointment with an orthopaedic physician. All new patients will be approached by research personnel for the informed consent process. Patients who elect to participate will then complete baseline surveys followed by their scheduled appointment with the orthopaedic physician. The physician will confirm or deny NAHD diagnosis[26] and inclusion/exclusion criteria (Table 1) from his or her evaluation. Participants who have a confirmed diagnosis of NAHD and meet all inclusion and exclusion criteria will proceed with the study; participants who do not meet inclusion/exclusion criteria will be withdrawn from the study; baseline surveys will be maintained (with permission from the participant) for additional analyses to investigate expected treatment of patients presenting to the Hip Preservation Clinic.

Table 1. Inclusion / Exclusion Criteria

Inclusion Criteria
• Over 18 years old • NAHD diagnosis
Exclusion Criteria
• Osteoporosis or rheumatoid arthritis • Systemic health condition • Legal representative required for treatment decisions • Spine, hip, knee, or ankle surgery or major injury** • Pregnancy[23] • Total hip arthroplasty candidate (Tönnis grade $\geq$ 2)[24] • Periacetabular osteotomy candidate (LCEA<20*, ACEA<18*, acetabular index >10)[25]
** participants with current spine or lower extremity injury will be excluded from all aspects of the study; participants with history of spine or lower extremity injury will be evaluated by the physician to determine their appropriateness for evaluation (and treatment) by a physical therapist

Demographic data will be collected on potential participants who refuse participation. Reason for refusal will also be collected. This data is important to collect to understand what patients are not interested in an interdisciplinary evaluation and/or treatment. Identifying to what patients and in what situations this protocol is applicable can inform application of this protocol to clinical practice. After reviewing the consent document for the trial, those who deny participation will be asked if their demographic information (age, gender, insurance) along with their reason of refusal can be recorded. A verbal script will be provided for this interaction. Information will only be recorded for those who verbally agree to have their demographics and refusal reason recorded. No identifiable information will be maintained on these participants.

B. Research Design

To accomplish the aims of this project, a randomized controlled trial will be conducted with two randomizations (Figure 1).

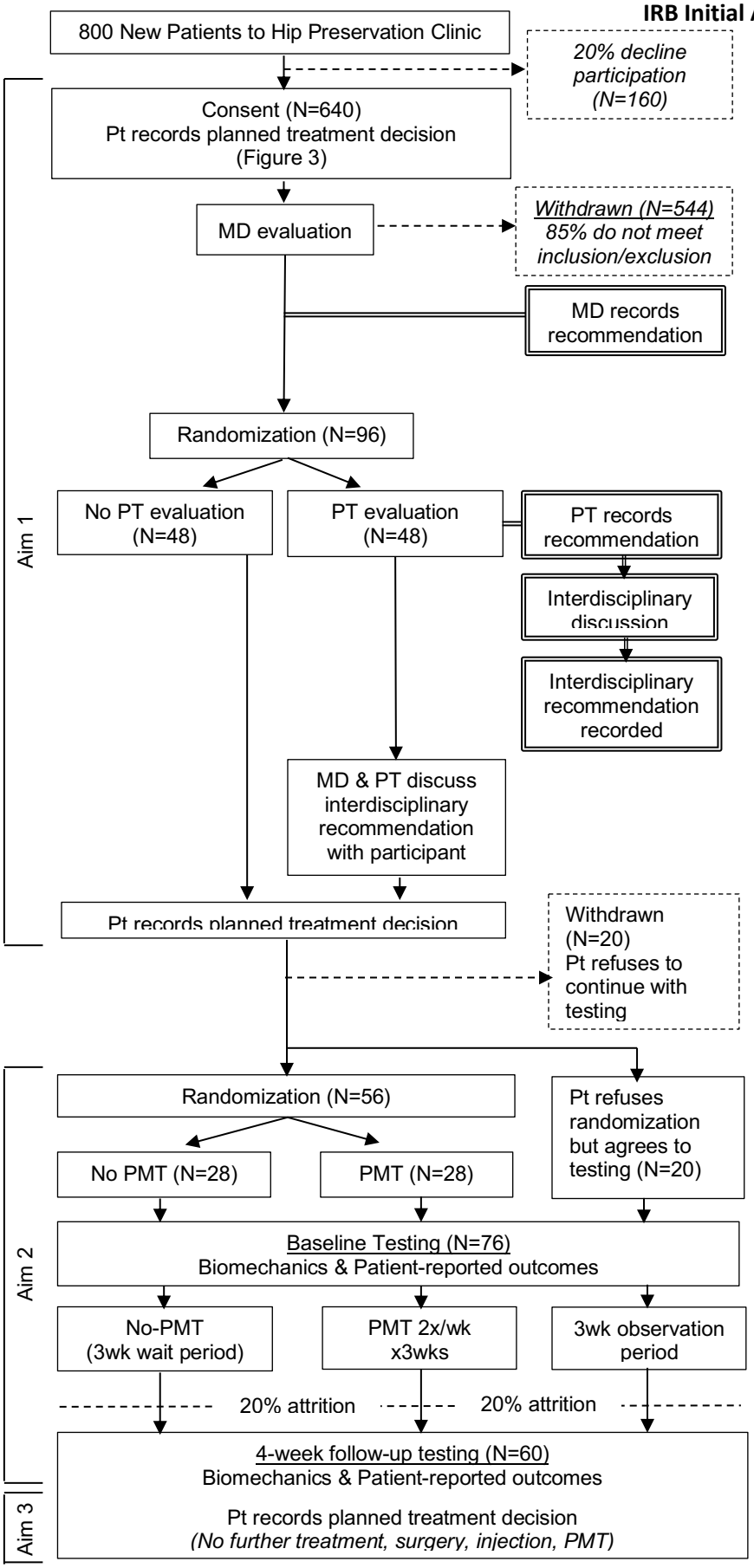

Figure 1. Participant Recruitment and Retention
Pt= participant; MD = physician; PT= physical therapist

All potential participants are presenting to the Hip Preservation Clinic for an evaluation from an orthopaedic physician; after the informed consent process, patients who elect to enroll will proceed with that evaluation. The physician's evaluation will be standardized to include the components listed in Table 2; however, additional standard-care tests may be added at the physician's professional discretion. After inclusion and exclusion criteria are confirmed by the physician, participants will be randomized to receive an additional same-day evaluation by a physical therapist.

Physician-determined clinical diagnosis will be recorded from the electronic health record.

Table 2. Orthopaedic Physician Evaluation Components

Subjective	Mobility	Movement	Radiology
•Pain history •Treatment history •Past medical and family history	•Hip range of motion •Pain provocation tests for hip	•Walking gait	•XR alpha angles •XR center edge angles
XR = x-ray (radiograph)			

A board-certified physical therapist will conduct a same-day evaluation of the participant in the Hip Preservation Clinic lasting approximately 10 minutes. The physical therapist will have access to the participant's subjective information provided during his or her evaluation with the physician. The evaluation will be standardized to include the components listed in Table 3; however, additional standard-care tests may be added at the physical therapist's professional discretion.

Table 3. Physical Therapy Evaluation Components

Posture		Movement	
•Standing alignment •Seated alignment	•	•Walking gait •Sit-to-stand •Single leg squat •Single leg balance	•

The physical therapist and physician will develop a plan of care based on both of their recommendations for participants who were randomized to receive the interdisciplinary evaluation. Both clinicians will then discuss the interdisciplinary recommendation with the patient.

All participants will record their planned treatment decision, confidence in that decision, and outcome expectations before and after their appointment.

All participants will then be randomized to receive or not receive posture and movement training (PMT). Participants who refuse to be randomized will be asked if they'd like to participate in the laboratory testing, but proceed with their intervention of choice during the 3-week observation period. Participants who deny testing will be withdrawn from the study. Participants in the PMT group will receive PMT twice weekly for three weeks. Participants in the no-PMT group will undergo a 3-week wait period. This time period is aligned with current clinical processes for surgical or injection intervention and does not disrupt clinical equipoise. All participants will complete testing before and after the 3-week intervention period. Furthermore, all participants will complete 3- and 6-month post-intervention follow-ups. Testing procedures are detailed in the next section.

C. Outcome Measures

Research personnel obtaining informed consent, randomizing participants, and administering surveys will be located in the clinic during the trial. Personnel will conduct field notes (stored in REDCap) regarding study physician and physical therapist actions including, but not limited to, times when entering and leaving the evaluation room, time discussing with each other, and questions for research staff.

Evaluation Day	Baseline	4-week	3-month	6-month
-Demographics -Diagnosis -History of treatment (past PT programs, injection & medication history, past provider types) -Decision Conflict & Regret Scales -Planned treatment -Patient-reported function (HOS & iHOT-33) -Exit survey *-Provider recommendations recorded in EHR and REDCap*	-Patient-reported function (HOS, iHOT-33 & PROMIS) -Movement biomechanics -Anthropometrics -Hip strength	-Patient-reported function (HOS & iHOT-33) -Movement biomechanics -Anthropometrics -Hip strength -Decision Conflict & Regret Scales -Planned treatment	-Patient-reported function (HOS, iHOT-33, & PROMIS) -Movement biomechanics -Anthropometrics -Hip strength -Decision Conflict & Regret Scales -Planned or completed treatment	-Patient-reported function (HOS, iHOT-33, & PROMIS) -Movement biomechanics -Anthropometrics -Hip strength -Decision Conflict & Regret Scales -Planned or completed treatment
PT = physical therapy; HOS = Hip Outcome Score; iHOT-33 = 33 item International Hip Outcome Tool; EHR = electronic health record; PROMIS = PROMIS Physical Function Scale				

All participants will record their planned treatment decision before their evaluation with the physician, after completing all evaluation(s), and after the 3-week intervention period. These data will be stored and managed in Research Electronic Database Capture (REDCap™).[27]

Which treatment(s) would you select at this point?
Injection
Surgery
Physical therapy (including posture/movement training)
Other: _____
None

How confident are you that an injection would improve your symptoms?

Not confident at all	Somewhat confident	Moderately confident	Very confident

How confident are you that surgery would improve your symptoms?

Not confident at all	Somewhat confident	Moderately confident	Very confident

How confident are you that physical therapy would improve your symptoms?

Not confident at all	Somewhat confident	Moderately confident	Very confident

How confident are you that no treatment would improve your symptoms?

Not confident at all	Somewhat confident	Moderately confident	Very confident

How confident are you that _____ would improve your symptoms?

Not confident at all	Somewhat confident	Moderately confident	Very confident

Figure 2. Treatment Decision Recording Form

All participants will complete the Decision Conflict and anticipated Regret scales before their evaluation with the physician, after their evaluation(s), and after the 3-week intervention period.[28,29] These data will be stored and managed in Research Electronic Database Capture (REDCap™).[27]

All participants will be e-mailed an exit survey using REDCap to collect feedback from participants regarding the mechanics of the study and their thoughts on the evaluation(s).

All participants will complete a survey collecting demographic information, treatment history, and patient-reported functioning after their evaluation(s). Treatment history and patient-reported functioning will be recorded for all participants after the 3-week intervention period and at the 3-

and 6-month follow-ups. The patient-reported functioning questions will include the Hip Outcome Score Activities of Daily Living (HOS),[21,22] the 33-item International Hip Outcome Tool (iHOT-33),[30] and the PROMIS Physical Function scale. These data will be stored and managed in Research Electronic Database Capture (REDCap™).[27]

All participants will complete biomechanical and clinical testing in the Motion Analysis and Performance Laboratory at the Jameson Crane Sports Medicine Institute before and after the 3-week intervention period and at the 3- and 6-month follow-ups.

The 3-dimensional (3D) biomechanical testing uses surface mounted retroreflective markers and an 12-camera motion analysis system (Motion Analysis, Santa Rosa, CA) (240 Hz) to collect trunk and lower extremity joint motion (kinematics) during three (3) tasks: walking gait, sit-to-stand, and a forward tap-down. Kinetic data will be captured simultaneously and synced using 4 force platforms (Bertec, Worthington, OH) embedded in the floor to capture ground reaction forces (1200 Hz) from each limb during bilateral tasks.[31,32] Markers will be secured with double-sided tape to the anatomical landmarks and broad surfaces of the lower extremities, pelvis, trunk, neck, arms, and hands in order to define segment position and track their motion relative to the proximal segment. Standing calibrations will be performed to create subject-specific models to determine segment pose and ankle and knee joint centers. Hip joint center trials will be used to calculate hip joint centers.[33]

3D Motion Analysis Testing:
1. **Walking gait:** at the participant's self-selected speed (±5% within and between sessions)
2. **Sit-to-stand:** from a standard chair height[34]
3. **Forward tap-down:** 5-repetition step-down task from a 8-inch step[35]

Study personnel will provide verbal instruction and demonstration of each task and participants will perform 2-5 repetitions to familiarize themselves with the tasks. Five trials of walking gait and sit-to-stand will be collected and post-processed. Two trials on each leg will be collected and post-processed for the unilateral forward stepdown. Joint kinematics and external joint moments at the trunk, pelvis, hip, knee, and ankle will be derived using Euler angle calculations and inverse dynamics.[36]

Clinical testing includes recording body mass index with height and weight measurements, and hip strength. Hip strength will be recorded by a licensed clinician or qualified study personnel using dynamometry. Participants will perform hip strength testing in a variety of positions to capture hip extension, flexion, abduction, and rotation strength. Participants will perform at least 2 maximal voluntary isometric contractions on each leg.

<u>Data Storage</u>: All data will stored securely in locked cabinets and on secure data servers. Use of these data is restricted to the specific aims of the study and approved study personnel.

<u>Qualitative Interviews:</u> Qualitative interviews of 4 participants in each group (standard vs. interdisciplinary) for the evaluation will be conducted after completion of the evaluation. Qualitative interviews of 2 participants in each group (PMT vs no-PMT) for the treatment will be conducted at baseline and 4-week follow-up testing. Qualitative interviews of the 2 study surgeons will occur before subject recruitment and after closing of subject recruitment. Qualitative interviews of the study physical therapists participating in the interdisciplinary evaluation will occur before their participation in subject recruitment and after closing of subject recruitment. Qualitative interviews of two study physical therapists participating in the treatment

protocol will occur before subject recruitment and after closing of subject recruitment. All qualitative interviews will be audio recorded for data analysis. Recordings will be labeled based on who completed the interview (participant, surgeon, physical therapist), what intervention the questions regarded (evaluation vs. treatment), and when the interview was conducted (before vs. after intervention).

D. Data Analysis

Aim 1: Intraclass correlation coefficients will be calculated to assess percent agreement between participants and providers for confidence in the selected treatment improving patient outcomes ($P \leq 0.05$).

Aim 2: Chi-square analyses will be used to assess for differences in treatment decisions between the group who receives the interdisciplinary evaluation and the group that does not ($P \leq 0.05$).

Aim 3: Two-way analyses of variance (ANOVAs) will be used to assess for group (no-PMT versus PMT) by time interactions in both 1) moments about the hip during walking, sit-to-stand, and a forward tap-down and 2) patient-reported hip function (iHOT-33, HOS, PROMIS)($P \leq 0.05$). Gait speed, sex, body mass index, duration of symptoms, or age may be used as covariates.

Aim 4: Chi-square analyses will be used to assess for differences in treatment decisions between groups (no-PMT, PMT-improved, PMT-not improved) after the 3-week intervention time period ($P \leq 0.05$).

Data transformation will be used if data do not meet parametric assumptions. Standard data quality and data monitoring procedures will be used to minimize the data missing problem for the study. Potential missing data problems will also be addressed thorough sensitivity analysis. While mixed model analysis using all data can address missing data problems assuming data are missing at random, we will also conduct analyses using the complete data set to further confirm the hypothesis test/estimation is robust with similar conclusions.

De-identified data will be shared with collaborators at Washington University in St. Louis for data analysis, results reporting, and manuscript preparation. Data will be shared via institution-based emails. External collaborators will not receive identifiable data, will not have access to identifiers (or the code key used to link identifiers with coded data set), and will not attempt to re-identify participants.

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