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Incorporating Specific Functional Strength Integration Techniques to Improve Functional Performance for Veterans After Total Hip Arthroplasty: Protocol for a Randomized Clinical Trial

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Abstract

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Background.—Total hip arthroplasty (THA) is a common procedure, yet persistent deficits in functional performance exist after surgery. These deficits may be related to movement compensations observed after THA, which negatively affect quality of life and may increase morbidity and health care utilization, including in the veteran population. However, the best rehabilitative approach to remediating movement compensations and physical function deficits has not been determined.

Objective.—The objective is to determine if a functional strength integration intervention (FSI), as part of a post-THA rehabilitation program, improves movement compensation, physical function, muscle strength, and self-reported outcome measures more than a control group (CON) undergoing a standard of care exercise program.

Design.—This is a 2-arm randomized, controlled clinical trial.

Setting.—The Veteran Affairs outpatient physical therapy clinics and academic research laboratory will be the settings.

Participants.—One hundred veterans undergoing THA for hip osteoarthritis will be included in the study.

Interventions.—Participants will be randomized to either the FSI or CON group and participate in visits of physical therapy over 8 weeks. The FSI protocol will include targeted exercise to improve muscular control and stability around the hip and trunk to minimize movement compensation during daily activity combined with progressive resistance exercise. The CON protocol will include patient education, flexibility activity, and low load resistance exercise.

Measurements.—Functional performance, muscle strength and endurance, and self-reported outcomes will be measured at baseline (prior to surgery), midway through intervention (6 weeks after surgery), at the end of intervention (10 weeks after surgery), and 26 weeks after THA.

Limitations.—The inability to blind treating therapists to study arm allocation is a limitation.

Conclusions.—The proposed study aims to determine if targeted FSI can affect movement compensation to improve functional outcomes after THA more than traditional rehabilitation paradigms.

As a result of population aging, total hip arthroplasty (THA) surgeries to treat the pain and disability from hip osteoarthritis (OA) are expected to increase to a projected 500,000 per year by 2030.[1,2] Due to its prevalence, THA is a common orthopedic procedure,[3] yet full recovery of physical function is a considerable challenge after THA because physical function difficulties persist after surgery and individuals' overall physical ability remains lower than their peers without hip OA and THA.[4]

Current evidence suggests that persistent physical function deficits after THA exist and that deficits in physical function occur in several key domains of daily living. Specifically, deficits in hip muscle strength,[5,6] balance and postural control,[7,8] walking,[9,10] and stair climbing[11] are important, long-term problems after THA. In conjunction, physical function after THA is characterized by the presence of movement compensations, which are commonly observed during activities of daily living such as walking and stair climbing. In particular, slow walking speeds observed after THA are related to low internal hip abduction

moments, reflecting abnormal movement control at the hip and pelvis during gait.[10,12–14] Therefore, it may be that deficits in physical function after THA specifically relate to underlying movement compensations.

Movement compensation plays an important role in recovery after THA. In particular, movement compensations serve as important biomarkers of functional decline in a variety of older adult populations,[15,16] because they are associated with increased fall risk,[15,16] poor functional outcomes,[17] and the presence of poor muscle strength and balance. For example, a Trendelenburg compensated gait pattern, often observed after THA, is related to abnormal movement control at the hip and pelvis during gait and to slow gait speed[10,12–14] and may impact quality of life because people after THA report lower SF-36[18] scores than their peers.[18,19] The recovery of physical function may be even more challenging for veterans undergoing THA, because they report severe physical health-related quality of life deficits[20] compared with both veterans and the general population not receiving joint arthroplasty.[21] Veterans with THA also have a higher prevalence of severe limitations in activities of daily living (ADL), more comborbidities, and higher utilization of heath care services than non-military persons receiving joint replacement.[21]

The ideal rehabilitation strategy to manage movement compensation and deficits in physical function after THA has not been established. Combining muscle strength training and movement compensation remediation may improve physical function. This type of rehabilitation, functional strength integration (FSI), would: (1) utilize weight-bearing exercises to improve muscle coordination and joint stabilization,[22] (2) aim to improve sensorimotor control and stability by emphasizing muscle co-activation, and (3) focus on remediating movement compensations by emphasizing muscle recruitment, muscle strength, coordination, and stability.[23] Preliminary data suggest that this type of training may improve mechanics during daily activity,[24] with additional literature suggesting an improvement in functional performance and quality of life in people with hip injury.[25] However, this type of rehabilitation approach has not been studied in veterans after THA.

Thus, the purpose of this investigation is to determine if an FSI rehabilitation program after THA improves functional performance, reduces movement compensation, and improves quality of life outcomes for veterans after THA.

Methods

We are conducting a double blind (outcomes assessors and patients), randomized controlled trial of 100 veterans undergoing THA for hip OA in the Denver, Colorado area. One arm of the trial includes participation in an FSI rehabilitation program in an outpatient setting; the second arm is a control group of standard outpatient physical therapy.

Participants

One hundred veterans aged 50 to 85 years with hip OA scheduled for a unilateral, primary THA will be enrolled, with at least 80 participants expected to complete the study (Fig. 1). Potential participants will meet the following inclusion criteria: (1) no severe contralateral leg OA (ie, < 5/10 pain with stair climbing) or other unstable orthopedic conditions that limit

function, (2) no neurological or pulmonary problems that severely limit function, (3) no uncontrolled hypertension or diabetes, and (4) body mass index ≤ 40 kg/m^2. Potential participants who do not meet the above criteria will be excluded from the study.

Participant Recruitment and Randomization

Veterans will be recruited primarily from the Rocky Mountain Region Veterans Administration Medical Center. On referral to the study, and prior to surgery, eligible participants will visit the Geriatric Research, Education and Clinical Center Human Movement Analysis Lab for informed consent and baseline measurements. Two weeks after surgery, following physician approval, participants will be randomized into 1 of 2 treatment arms: the FSI (experimental) group or CON (control) group, with stratification by surgical approach and sex using random block sizes of 2 and 4. The allocation sequence was generated in an Excel spreadsheet by the study statistician (J.F.) and is stored on a separate server from other study-related documents. Therefore, the study staff who are recruiting, screening, and enrolling patients do not have access to the allocation sequence. Because existing literature suggests differences in recovery may exist between surgical approaches, stratification by anterior or posterolateral surgical approach will eliminate the possibility of confounding of the study outcomes.

Interventions

Following THA surgery, standard inpatient postoperative protocol will be implemented for all participants (Fig. 2). On returning home, participants in both groups will receive a home visit via phone or in person from a study physical therapist to ensure safety, provide ADL advice, and monitor for complications. Randomization and initiation of study treatment will follow a 2-week recovery period to ensure participant safety. Following randomization, both groups will participate in an 8-week (14 visits) outpatient rehabilitation program at 1 of 3 outpatient physical therapy clinics in the Denver metropolitan area. The rehabilitation program for both groups will be delivered by a licensed physical therapist who has attended specific training delivered by the study physical therapist overseeing the clinical program and fidelity of the protocol (D.J.). Both groups will also have a home exercise program. Detailed intervention descriptions, which are provided to treating therapists as part of training, are provided below and in the Supplementary Appendix (available at https://academic.oup.com/ptj).

Functional Strength Integration Treatment Arm

The FSI program will target the integration of strength training and movement retraining to improve functional performance for veterans after THA. The exercise program will address the well-established, long-term impairments of muscle weakness and functional movement compensations after THA.[5,26,27] Specifically, the FSI intervention involves strengthening for the hip musculature similar to previously published protocols,[28,29] combined with techniques emphasizing early initiation of hip muscle recruitment to stabilize the pelvis, thus integrating strength and movement pattern training to improve movement compensation and maximize functional performance. The FSI program includes exercise in 3 domains: pelvic stability training, functional training, and strength training (Table). Activities in the pelvic stability training domain include early surgical-limb weight-bearing activities and core

muscle strengthening exercises designed to progressively increase in difficulty based on participant performance benchmarks and therapist monitoring. Activities in the functional training domain focus on gait and stair climb activity, which progresses to higher level agility training. The strength training domain includes progressive, resistance exercise to remediate strength in the lower extremities in the major muscle groups impacted by THA.[30] The strength training exercises will include use of weighted pulleys and weight-training machines. Therapists will determine an 8-repetition maximum for each muscle group, and weight will be increased by at least 10% every 2 weeks to maximize muscle hypertrophy and strength gains. The novelty of the FSI program lies in the focus on integrating strength and function through progressive functional exercises promoting muscle coordination around the hip, thus optimizing alignment between femur, pelvis, and lumbar segments.[31]

CON Arm

There is no standard of care for rehabilitation following THA.[32] Observed practice patterns from previous investigations[30] and discussion with area clinicians indicate that patients do not routinely receive rehabilitation services beyond their 2- to 3-day hospital stay. To control for volume of rehabilitation in the FSI group, participants in the CON group will attend outpatient physical therapy for 14 visits over 8 weeks. The CON group program was designed as a reasonable alternative approach to rehabilitation after THA seen in clinical practice. This pragmatic approach to the study design allows for a comparison of 2 types of rehabilitation programs and still allows a determination of benefit of the FSI program in clinical practice.[33] In addition, this pragmatic design was important to address the ethical concerns regarding withholding physical therapist services from 1 group, or creating placebo or sham treatment, and to overcome the resource limitations of a 3-arm trial design. Specifically, the CON program includes education, functional ADL training, and therapeutic exercise domains that are progressed according to a time-based protocol consisting of 3 phases. However, the activities in the exercise domain will be limited to low-load exercise such as isometric muscle exercise, ROM, and flexibility activities and will not include progressive strength training exercise or specific movement retraining, exclusive to the FSI group.

Fidelity Oversight

There will be 2 therapists to treat study participants (1 FSI and 1 CON) at each physical therapy clinic. Each therapist will be unfamiliar with the specifics of the other treatment arm. All therapists will receive on-site training from the study team to be trained in each treatment protocol. Training sessions will be repeated annually to ensure protocol adherence. A manual will be provided to each clinic with protocol details for each group, including clinic and home exercise details and documentation forms. Therapists will be instructed not to share intervention details or manuals with other therapists. The study team will also conduct on-site observations once during each participant’s treatment duration to ensure protocol adherence. The study team will also oversee therapists via chart review to monitor for protocol adherence and will be available to discuss complications and participant continuation. New therapists will undergo the same procedures for initial training/ monitoring if necessary.

Primary Outcome

Baseline testing will occur within 2 weeks prior to THA and outcomes will be assessed 3 times postoperatively. Postoperative testing will occur midway through the intervention ($POST_1$, 6 weeks postop), end of the intervention ($POST_2$, 10 weeks postop), and 26 weeks after THA ($POST_3$). The $POST_2$ assessment will serve as the primary endpoint.

The primary study outcome is the 6-minute walk test (6MWT), which was chosen because it captures performance over a period of time that best mimics community ambulation with activities of daily living. Further, 6MWT outcomes are important long-term functional limitations identified for people living with THA.[34] The test will be performed on a 30.5-m walkway, and the total distance covered will be measured. The 6MWT is reliable and valid in the post-THA population and can detect small changes in function after THA.[35]

Secondary Outcomes

Performance-based measures.—Additional performance-based physical function measures include the 4-meter walk test, the Functional Gait Assessment, 30-second sit to stand test, and record of physical activity. The 4-meter walk test will be used to generate gait speed values, which have been associated with morbidity and mortality in older adults.[36] The Functional Gait Assessment is a 10-item objective outcome measure designed to measure dynamic balance. It has been validated in older, community-dwelling adult populations.[37] The 30-second sit to stand test is an important physical performance measure related to lower extremity strength[38] and fall risk.[39] Physical activity will be recorded as average free-living daily step count with ActiGraph (Pensacola, FL, USA) activity monitors worn around the waist. Data will be collected over 10 days following each outcomes assessment.

Self-reported outcomes.—Participants will complete the Veterans RAND 12 Item Health Survey, the Western Ontario and McMaster Universities Osteoarthritis Index, the Patient Activation Measure tool, and motivation scale and will track adverse events such as falls, injuries, pain, and medication use. The Veterans RAND 12 Item Health Survey is a reliable, self-report survey for assessing health-related quality of life for veterans. The Western Ontario and McMaster Universities Osteoarthritis Index assesses the impact of OA on pain, stiffness, and disability[40] and is a valid, reliable, and responsive instrument often used in clinical trials.[40] The Patient Activation Measure tool measures activation and engagement in patients' own health care and is measured on 4 levels, with level 1 as the lowest level of activation.[41] Higher levels of activation are related to lower levels of hospital admittance and health care utilization.[42]

Muscle performance measures.—Isometric hip abductor and extensor muscle, and knee extensor and flexor muscle strength will be assessed utilizing hand-held dynamometry. Isometric hip abduction strength testing will be performed in side-lying at 0 degrees of flexion/extension and 0 degrees of hip abduction,[30] hip extensor strength testing will be performed in prone, and knee extensor and flexor strength will be assessed in a seated position with the hips and knees at 90 degrees of flexion. Testing will include warm-up repetitions followed by 3 separate maximal voluntary isometric contractions while receiving

visual and verbal feedback. Additionally, participants will complete hip abductor endurance testing using a static single-limb balance test, conceptualized from the Trendelenburg test proposed by Hardcastle[43] and measurement of pelvis angle by Youdas et al[44] and Asayma et al.[45] This modified Trendelenburg test[43] assesses control of the pelvis during timed, single limb stance and indicates the ability of the lateral hip muscles to maintain pelvic control during closed-chain, functional tasks and therefore serves as a measure of hip abductor muscle endurance.[43]

Biomechanical analysis.—Lower extremity biomechanical measures will be used to quantify movement patterns during level walking and stepping up/down in the Geriatric Research, Education and Clinical Center Human Movement Analysis Lab. Surgical limb peak internal hip abduction moments will be calculated with 3-D instrumented motion analysis. To do this, lower extremity joint kinematics will be quantified from retro-reflective markers tracked via an 8-camera, high-speed motion capture system (Vicon Motion Systems, Oxford, United Kingdom) at 100 Hz. Lower extremity joint kinetics will be derived from ground reaction force data recorded from 2 force platforms (2000 Hz) embedded in the floor that are synchronized with the cameras (Bertec, Columbus, OH, USA). Continuous internal hip abduction moments will be calculated during functional task performance using a standard inverse dynamics approach integrating kinematic and kinetic data using Visual 3D software (C-Motion, Germantown, MD, USA). All joint moments will be normalized to participant body mass and height.

Sample Size

Statistical power was estimated using variability estimates from Heiberg et al (2015), where the change in 6MWT distance was assessed for 60 participants following THA.[46] The observed SD at 3 months post-surgery for the sample was 81.3. Based on this, a 2-sample, 2-sided *t* test at the 5% level with 80 participants (40 per group) would have 90% power to detect a clinically meaningful difference of at least 59.7 m.[47] We will recruit 100 participants (50/group) to allow for a 20% loss to follow-up.

Statistical Analyses

Preliminary descriptive and graphical analyses (eg, boxplots, scatterplots, and profile plots over time) will be used for data checking and visualization. All analyses will be performed in SAS v9.4 or higher and all data will be stored in REDCap.

Primary analysis.—The primary analysis will be an intent-to-treat comparison between groups of the change in 6MWT distance from baseline to $POST_2$ (end of intervention). Statistical inference regarding the difference between treatment groups will be based on the estimated coefficient for a group indicator variable in an analysis of covariance model with the change from baseline at $POST_2$ for the 6MWT distance being the response variable. Additional covariates will include the surgical approach stratification variable and the baseline value of the 6MWT distance to improve the precision of the estimate. The conclusion about differences between treatment groups will be determined by this single statistical test to protect against an elevated risk of false positive conclusions.

Secondary analyses.—Differences between groups in the secondary outcomes for physical function, muscle strength and endurance, and peak internal hip abduction moment from baseline to $POST_2$ will also be analyzed as described above. All outcomes will be analyzed at $POST_3$ to evaluate the long-term impact and sustainability of the FSI training.

Discussion

Potential Impact and Significance

Resolving movement compensation to improve physical function requires specific training. Targeted FSI: (1) utilizes weight-bearing exercises to improve muscle coordination and joint stabilization,[22] (2) aims to improve sensorimotor control and stability by emphasizing muscle co-activation, and (3) focuses on remediating movement compensations by emphasizing muscle recruitment and movement quality.[23] This approach offers a unique combination of activities as part of a rehabilitation program designed to improve movement quality and physical function.

No consensus currently exists for managing individuals after THA, although emerging literature supports the benefits of physical therapist intervention. In a systematic review of rehabilitation strategies following THA, DiMonaco and Castiglioni concluded that rehabilitation can improve muscle strength and functional performance outcomes following THA.[32] However, variable approaches to types of exercise, timing of rehabilitation initiation, and exercise intensity led to a lack of agreement on the optimal rehabilitation prescription following THA. A second review article by Minns-Lowe et al also identified benefits of rehabilitation after THA but emphasized that study quality and intervention improvements are needed.[48] Additional studies have provided evidence that progressive, high-intensity strength training early after THA may be safe and effective for improving strength and physical function.[28,29,49–51] However, studies have not emphasized FSI as a central component of a rehabilitation program to address movement compensations that affect functional performance. The successful implementation of the proposed FSI program will explore whether the FSI intervention can remediate functional performance deficits after THA.

There are potential limitations to this study. In particular, the multi-modal design of the FSI program may leave questions as to which part of the intervention is directly related to functional improvement. However, it is important that the FSI group includes a strength remediation component to ensure patients' ability to participate in the movement retraining aspect of the protocol. Because movement compensations and physical function deficits persist after THA, it may be that current postoperative management and rehabilitation strategies are not adequately returning patients to optimal physical functioning. Remediating movement compensation and physical function relies on both adequate strength and specific movement retraining. Additionally, the pragmatic study design in the choice of control group may not allow for us to determine the absolute efficacy of the FSI program. However, this design does allow us to assess the benefit of FSI in clinical practice compared with alternative rehabilitation practices and may help clinicians decide between the 2 exercise programs when treating their own patients.[33] Because few evidence-based recommendations exist to guide exercise prescription after THA, this study will add significant knowledge

regarding postoperative rehabilitation guidelines and has high potential to change clinical practice for veterans undergoing THA.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Ethics Approval

This study has received ethics approval from the Colorado Multiple Institutional Review Board (COMIRB 16–0956) and approval from the Veterans Administration Research and Development Committee.

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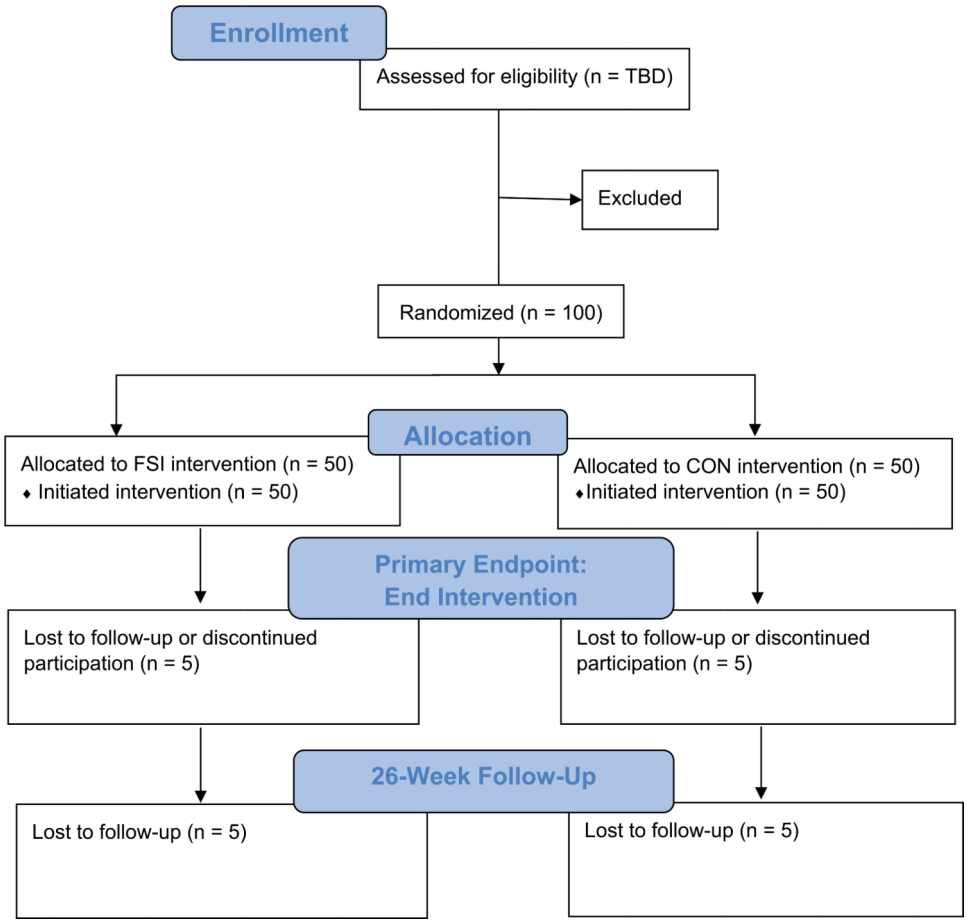

Figure 1.

Proposed CONSORT diagram. CON = control group; FSI = functional strength integration; TBD = to be decided.

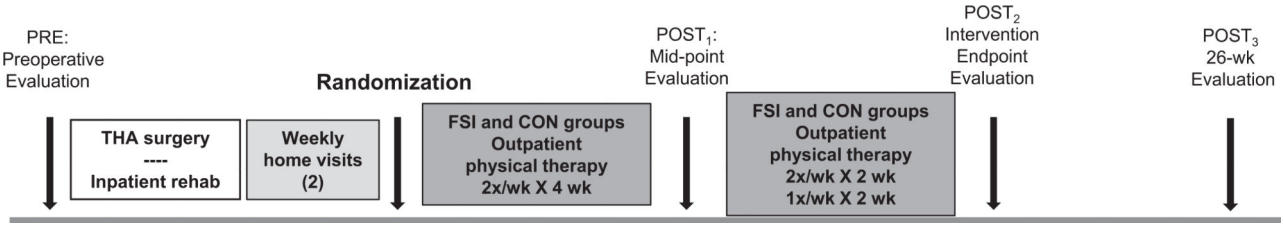

Figure 2.

Study protocol timeline. CON = control group; FSI = functional strength integration; THA = total hip arthroplasty.

Table 1.

Summary of Exercise Details and Progression for FSI and CON Programs[a]

Phase	FSI Program[b]	CON Group Program[c]
Phase 0	Following inpatient stay, home visits provided by study physical therapist 1 ×/week to ensure safe transition home after THA	
Phase I	PST: Standing, weight shifting, and supported single-leg balance; isometric abdominal training supine; see progression criteria below[b] FT: Gait training, review postop precautions; see progression criteria below[b] ST: Lower extremity progressive resistance exercise (2 sets × 8 reps at 8RM); see progression criteria below[b]	Weeks 1–2 PED: Review postsurgical precautions, ADL advice FT: Gait training with AD TE: Muscle setting exercise for hip and knee (continue from inpatient therapy), P/AAROM for all hip motions
Phase II	PST: Foam surface weight shifting, unsupported single-leg balance, standing pelvic lift; resisted abdominal stabilization training (supine)[b] FT: Gait training with no AD, sit-stand activity, small step-up forward and lateral; ST: Progress lower extremity resistive exercise by at least 10% (2 sets × 8 reps)[b]	Weeks 3–5 PED: Continue education on postsurgical precautions, AD utilization and ADL advice FT: Gait training with AD TE: AA/AROM for all hip motions, low load supine resistive exercise; flexibility activity for spine and lower extremity
Phase III	PST: Foam surface single-leg balance and pelvic lift, balance board, progress to BOSU balance trainer (BOSU, Ashland, OH) for all activity; supine bridging, upper abdominal curl, hundreds (Pilates), side lying series (Pilates)[b] FT: Moderate → high step ups forward, lateral, down. Agility training, wall squats[b] ST: Progress lower extremity progressive resistive exercise by at least 10% (2 sets × 8 reps)[b]	Weeks 6–8 PED: AD progression, ADL advice on safe activity resumption FT: Gait training with/without AD as indicated TE: AROM all hip motions, supine resistive exercise, stretching, and flexibility activity for spine and lower extremity

[a]Additional detail is provided in the Supplementary Appendix (available at https://academic.oup.com/ptj). AAROM = active assisted range of motion; AD = assistive device; ADL = activities of daily living; AROM = active range of motion; CON = control group; FSI = functional strength integration; FT = functional training; P/AAROM = passive/active assistive range of motion; PED = patienteducation; PST = pelvic stability training; RM = repetition maximum; ST = strength training; TE = therapeutic exercise; THA = total hip arthroplasty.

[b]FSI group activities in each domain will besupervised closelywith verbal, visual, and tactile cues to promote optimal posture and movementquality. Progression of activities in the PST and FT domains will be based on therapist assessment of movement quality, specifically the absence form fatigue, and the ability to maintain a level pelvis with hip muscle activation during the task. Therapists will progress strengthening exercises when participants are able to demonstrate proper form during the prescribed 8 repetitions (eg, 80% of 1RM). Therapists will be encouraged to motivate participants to work at a high level of difficulty and progress toward Phase III as quickly as possible.

[c]CON group activities are progressed based on the post-operative timeline indicated above (by phase and week).