Postoperative Management for Degenerative Spinal Conditions

Sponsored by: Patient-Centered Outcomes Research Institute (PCORI)

Contract Number: CER-1306-01970

ClinicalTrials.gov: NCT02184143

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Version # 8.0

DATE June 24, 2014

Postoperative Management for Degenerative Spinal Conditions

Protocol

Design Synopsis

Title: Comparative Effectiveness of Postoperative Management for Degenerative Spinal Conditions

Sponsor: PCORI

Type of study: Comparative Effectiveness

Objective: The proposed study will conduct a two-group randomized control trial to compare which of two treatments provided by telephone – a cognitive-behavioral based physical therapy (CBPT) program focusing on self-management strategies or an education program about postoperative recovery - are more effective for improving patient-centered outcomes in older adults recovering from lumbar spine surgery for degenerative conditions.

Specific Aim 1: To determine the most important treatment outcomes to older adults undergoing lumbar spine surgery for degenerative conditions.

Hypothesis 1: The most important outcomes to older adults undergoing lumbar spine surgery will include pain, physical functioning, and general health.

Specific Aim 2: To compare whether a CBPT program or an education program is more effective in reducing disability and pain and improving general health, physical activity, and physical function following lumbar spine surgery for degenerative conditions.

Hypothesis 2: CBPT participants compared to education participants will demonstrate significantly greater improvement in disability (Oswestry Disability Index), pain (Brief Pain Inventory), general health (12-item Short Form) and physical activity (movement accelerometers) at 6 and 12 months following lumbar spine surgery and physical function as measured by standardized performance tests of strength, gait speed, and mobility (5-Chair Stand, Timed Up and Go, 10-Meter Walk) at 12 month follow-up.

Specific Aim 3: To determine how CBPT improves outcomes in patients following lumbar spine surgery for degenerative conditions.

Hypothesis 3*:* Participants reporting decreases in fear of movement and increases in pain self-efficacy will demonstrate improvement in outcomes following the CBPT program at 6 and 12 months following lumbar spine surgery.

Specific Aim 4: To determine which sub-groups of adults are most likely to benefit from CBPT following lumbar spine surgery for degenerative conditions.

Hypothesis 4*:* CBPT participants that are 60 years or older, have a fusion procedure, and report clinically significant depressive symptoms will demonstrate greater improvement in outcomes at 12 months following lumbar spine surgery.

Study design: Multicenter, prospective randomized controlled trial.

Comparators:
Group 1: CBPT
Group 2: Education

Study duration: 4 years (2-month start-up, 4-month qualitative data collection, 24-month accrual, 12-month follow-up, and 6 months analysis and writing). Participants will be followed for 1 year from the time of surgery.

Sample size: 260 eligible patients are planned to be consented; 221 are expected to be retained at 12-month follow-up.

Number of study sites: 2

Inclusion criteria
1) Radiographic evidence of lumbar spinal stenosis secondary to degenerative changes;
2) Surgical treatment of a lumbar degenerative condition (spinal stenosis, spondylosis with or without myelopathy, and degenerative spondylolisthesis) using laminectomy with or without arthrodesis procedures;
3) English speaking due to feasibility of employing study personnel to deliver and assess the study intervention; and
4) Age older than 21 years (younger individuals do not typically have a lumbar degenerative condition)

Exclusion criteria
1) Patients having microsurgical techniques as the primary procedure, such as an isolated laminotomy or microdiscectomy (individuals having these minimally invasive surgical techniques tend to have a less severe case of lumbar degeneration and a shorter recovery time than individuals having arthrodesis or laminectomy without arthrodesis);
2) Patients having surgery for spinal deformity as the primary indication (patients with spinal deformity as the primary spinal disorder tend to have a different recovery trajectory compared to the inclusion population);
3) Patients having surgery secondary to pseudarthrosis, trauma, infection, or tumor;
4) Presence of back and/or lower extremity pain < 3 months indicating no history of chronic pain;
5) History of neurological disorder or disease, resulting in moderate to severe movement dysfunction. Including but not limited to Parkinson's disease, Multiple Sclerosis, Epilepsy, Brain tumors, Huntington's disease, Alzheimer's disease, Muscular Dystrophy, Stroke, Autonomic Nervous System disorders, Traumatic Brain Injury, Cerebral Palsy, and Amyotrophic Lateral Sclerosis;
6) Presence of schizophrenia or other psychotic disorder, including but not limited to Brief Psychotic disorder and Delusional disorder;

7) Patients not able to return to clinic for standard follow-up visits with surgeon due to time and travel limitation;
8) Patients having surgery under a workman's compensation claim; and
9) Unable to provide a stable address and access to a telephone indicating the inability to participate in either the telephone-based CBPT or education program.

Projected outcome measures

Primary: The 10-item Oswestry Disability Index is a standard measure of condition specific disability that assesses the impact of lumbar spinal disorders on daily living, with questions about pain intensity, lifting, sitting, standing, walking, sleeping, hygiene, traveling, social life, and sex life. The MCID has been found to range from 11 to 12.8 points in patients following lumbar spine surgery. The Brief Pain Inventory is an assessment of pain. The minimum clinically important difference (MCID) for pain has been found to range from 1.2 to 2.1 points in patients following lumbar spine surgery. General physical and mental health will be measured with the physical and mental composite scales of the SF-12. The physical component scale (PCS) assesses the four subdomains of physical functioning, role-physical, bodily pain, and general health and the mental component scale (MCS) assesses the 4 subdomains of vitality, social functioning, role-emotional, and mental health. The minimal clinically significant change for the PCS and MCS has been estimated at 10%.

Secondary: Physical activity will be objectively measured using movement accelerometers (Actigraph GT3X+). The 5 Chair Stand Test from the Short Physical Performance Battery from the Established Populations for the Epidemiologic Study of the Elderly studies will be used to assess strength. The 10-Meter Walk and Timed Up and Go tests will also be used to assess self-selected walking speed and functional mobility, respectively.

Intermediary: The 17-item Tampa Scale for Kinesiophobia will be used to measure fear of movement. The MCID for the TSK has been reported to be 4 points in patients with back pain. The 10-item Pain Self-Efficacy Questionnaire will measure the strength and generality of a person's belief in his/her ability to accomplish a range of activities despite pain.

Randomization: To ensure that the number of subjects is about the same in the two arms of the study for each clinical site, the randomization scheme will frequency-match patients in a 1:1 ratio in blocks of assignments stratified by age and type of surgery (i.e., fusion or no fusion). The 4 frequency-matched strata will be as follows: (1) Age 21-59 and fusion; (2) Age 60-90 and fusion; (3) Age 21-59 and no fusion; (4) Age 60-90 and no fusion. Block size will be determined randomly with the patient as the unit of randomization. Randomization will be administered centrally by the Coordinating Center (Vanderbilt) through the REDCap electronic database.

Statistical analysis: All analyses will be both on an "intention-to-treat" and "as treated" basis.

Safety monitoring: A medical monitor will be responsible for monitoring the accumulated interim data as the trial progresses to ensure patient safety, review efficacy, evaluate recruitment, and assess overall data quality.

1. Primary Hypothesis and Principal Objective

The United States has the highest rate of lumbar spine surgery in the world, with rates increasing over 200% in the last decade (1-3). Medicare spends over $1 billion annually on lumbar spine surgery (4). Despite surgical advances, up to 40% of older adults have persistent pain, disability and functional limitations (5-13). We have found that high fear of movement is a risk factor for increased pain and disability and decreased physical health in patients following lumbar spine surgery (14,15). This finding supports previous work in surgical and chronic low back pain populations (16-24). Brief cognitive-behavioral therapy (CBT) and self-management treatments have proven effective for reducing psychosocial risk factors and improving pain and activity outcomes (25-33). However, these treatments are unavailable or insufficiently adapted for postoperative care.

Preliminary evidence through a currently funded R21 project (R21AR062880) has demonstrated the preliminary efficacy of a CBT-based self-management program for pain and disability in a surgical spine population. Thus, we propose in the current application a large, rigorous evaluation of our cognitive-behavioral based physical therapy (CBPT) program with the goal of engaging adults in their own care and improving pain and functional outcomes. We hypothesize that the CBPT intervention focusing on self-management will decrease pain and disability and improve general health, physical activity and physical function in community-dwelling adults undergoing spine surgery, through reductions in fear of movement and increases in pain self-efficacy.

2. Background and Significance

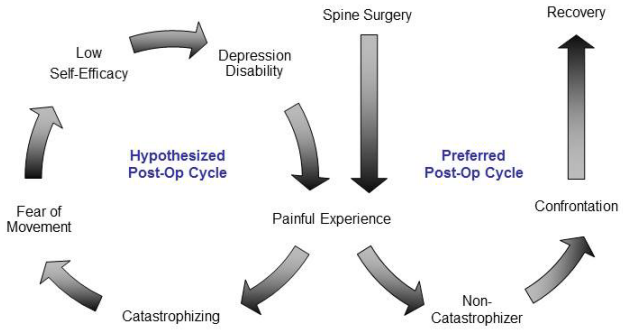
2.1. Importance of the Problem. Degenerative lumbar spinal stenosis is a major public health burden in the United States (U.S.). The prevalence is 45% in individuals greater than 60 years of age (34,35). Lumbar spinal stenosis is a major cause of pain and physical impairment, which results in reduced quality of life (36). This condition is now the most common diagnosis associated with lumbar spine surgery in older adults (36-38). The U.S. has the highest rate of lumbar spine surgery in the world, with rates increasing over 200% since 1990 among adults over age 60 years with degenerative spinal disease (1-3). Medicare spends over $1 billion annually on lumbar spine surgery (4). Despite surgical advances, older adults undergoing lumbar spine surgery have poorer physical and mental health outcomes compared to the general population (39,40). More specifically, up to 40% report persistent pain, functional disability and poor quality of life and 20% to 24% undergo a reoperation (5-13).

The estimated percentage of people over 60 years is expected to increase by 75% over the next 20 to 30 years (41,42). Thus, an increased number of older adults will experience age-associated degenerative conditions and spine surgery rates and Medicare expenditure will continue to rise (43). Innovative and accessible postoperative treatments, such as the proposed study, are needed to address this variability in postoperative outcomes and prevent long-term physical disability and chronicity in older adults after spine surgery. This study will provide data to support the utilization of innovative and accessible rehabilitation interventions that can be used by older adults across a range of painful conditions.

2.2. Cognitive-Behavioral Predictors of Poor Outcomes. Robust evidence indicates that patient demographic and psychosocial characteristics are strongly related to surgical spine outcomes (44). Furthermore, several studies have found that specific cognitive-behavioral factors of fear of movement and avoidance coping are associated with increased pain and disability after surgery for lumbar disc and various spinal disorders (16-20). We have demonstrated that high fear of movement is a risk factor for increased pain and disability and decreased physical function in patients following lumbar spine surgery for degenerative conditions (14,15). Fear of movement refers to an excessive fear of physical activity resulting from a dysfunctional belief that movement will cause harm or reinjury (45). The proposed study translates these recent observations into an interventional study which seeks to determine whether a multimodal rehabilitation intervention, targeting fear of movement and decreased physical activity, is effective for improving recovery in older adults following lumbar spine surgery.

2.3. Fear-Avoidance Model. The conceptual framework for the hypothesized effect of fear of movement on pain, disability, and function after lumbar surgery is based on the fear-avoidance model of Vlaeyen et al. (46). The fear-avoidance model has been successfully tested in adults with chronic low back pain (21-24). This model has also been tested across age groups. Studies suggest that age moderates the relationship between catastrophizing and pain outcomes and that fear of movement may play a stronger mediating role in older compared to younger patients (47-49). Our own work and that of other

Figure 1. Theoretical Model for Lumbar Spine Surgery



investigators have demonstrated this model's applicability to older adults following spinal surgery (19,20,50,51). This adaptation of Vlaeyen's fear-avoidance model has been extended to include the key concept of low self-efficacy, which is related to avoidance of physical activity in community-dwelling older adults (52-55) and poor outcomes in patients with musculoskeletal pain (56-60). This model provides a theoretical rationale, supported by the literature, for identifying and intervening on specific cognitive-behavioral risk factors in older adults following lumbar spine surgery for degenerative conditions.

The model suggests that after an acute insult, such as surgery, pain that is perceived as non-threatening will lead to a return to normal activity and eventually functional recovery. In contrast, pain that is perceived as threatening will promote anxiety and give rise to pain catastrophizing (i.e., tendency to magnify pain sensations) and fear of movement. This fear persists beyond the expected healing time and leads to low self-efficacy and avoidance behaviors and a "disuse" syndrome. Subsequently, depressive symptoms and disability increase avoidance of physical activity and perpetuate the pain process. It is important to note that the conceptual framework does not suggest a direct causal flow among risk factors or that all factors are necessary for persistent disability. Instead, fear of movement or low self-efficacy, when present, can perpetuate the disability cycle, resulting in restrictions in physical function and productive social roles. Evidence on the fear-avoidance model in chronic low back and spine surgery populations support a biopsychosocial approach to postoperative rehabilitation and the need for identification of high risk subgroups based on demographic and cognitive-behavioral factors.

2.4. Cognitive-Behavioral Therapy and Self-Management. Cognitive-behavioral therapy (CBT) interventions have strong empirical support, with documented positive influence on fear of movement, pain catastrophizing, and self-efficacy in chronic pain populations (61-65). Moreover, studies have demonstrated that brief (4 to 6 sessions) and telephone-administered CBT-based programs are effective approaches for reducing pain and improving function in patients with chronic and surgical pain (25-33). CBT programs commonly include relaxation (i.e., deep breathing and progressive muscle relaxation), cognitive restructuring, and behavioral techniques for pain management (66-69). Well-accepted cognitive restructuring strategies involve identifying "automatic negative" thoughts, acquiring positive coping self-statements, and distraction techniques (70-72). Finally, common behavioral techniques consist of pacing, graded activity, and graded exposure in vivo (GEXP) (69,73). GEXP involves gradual increases in activity by systematically challenging beliefs about harmfulness of activities (73). CBT-based self-management programs have also demonstrated improvement in patient outcomes and the adoption of a physically active lifestyle, as well as improvement in fear-avoidance beliefs and self-efficacy, in various populations with chronic conditions (74,75). Patient-oriented self-management programs, consisting of goal-setting, problem-solving strategies, and action-plans, are particularly effective for community-dwelling older adults with chronic conditions (76,77). These evidence-based CBT and self-management strategies provide the basis for the proposed multimodal rehabilitation intervention.

2.5. Physical Therapy after Spine Surgery. Surgeons routinely offer physical therapy to older adults after spine surgery, without high-quality evidence that this postoperative approach reduces barriers to improved outcomes (78). Several randomized trials have found no significant difference between standard physical rehabilitation and either no treatment or an educational booklet (79-81). These results may be due to the inability of physical therapy to address the psychosocial factors, such as fear of movement, often associated with poor surgical spine outcomes. Participation and engagement in

physical activity and exercise is also closely related to self-efficacy in community-dwelling older adults (52-55). The literature suggests that behavioral components should be added to exercise programs in order to provide a multimodal approach to postoperative rehabilitation (82,83). This recommendation is based on the demonstrated effectiveness of combining CBT-based strategies and physical therapy into interdisciplinary rehabilitation programs for patients with chronic low back pain. Randomized controlled trials have found that rehabilitation delivered through a team approach (psychologists and physical therapists) are more effective than usual care in reducing fear of movement, pain and disability (84-87). Studies also suggest that physical therapists can implement the cognitive-behavioral skills necessary to reduce pain and disability (88-93). Overall, the literature recommends multimodal rehabilitation for older adults after spine surgery; however, CBT and self-management treatments are unavailable or insufficiently adapted for postoperative care. There are currently no accessible and effective treatments that clinicians can recommend, and older adults can do, after spine surgery to improve outcomes.

2.6. Multimodal Rehabilitation after Spine Surgery. The current knowledge base of multimodal therapeutic strategies after lumbar spine surgery is limited. To date, only two studies have investigated combining CBT strategies and physical therapy in patients following surgery for lumbar degenerative conditions (94,95). Single-site randomized controlled trials by Christensen et al. (94) and Abbott et al. (95) found significantly lower leg pain with an 8 week group behavioral physical therapy intervention and decreased disability with a 3 session psychomotor therapy program, respectively, at 2 years following lumbar fusion. However, limitations of both studies are that interventions excluded empirically-supported cognitive strategies and were not designed to increase self-efficacy and improve physical activity through self-management. An additional limitation is that interventions were not designed for older adults. Studies by Christensen and Abbott included participants that were less than 65 years of age and had no history of prior spinal surgery or comorbidities, which is not representative of patients undergoing spine surgery for degenerative conditions. The proposed study will fill important knowledge gaps and generate critical information on the effectiveness of a CBT-based self-management approach to postoperative rehabilitation for community-dwelling adults.

2.7. Study Innovation. Our novel CBPT program is a patient-oriented self-management treatment for adults, which is characterized by active participation and personal responsibility (96), and is designed to maximize gains in functional outcomes that are relevant and meaningful to patients. CBT-based self-management programs have demonstrated improvement in patient outcomes and the adoption of a physically active lifestyle in various adult patient populations (97-102). Our study is innovative from a clinic perspective, because rehabilitation in surgical populations has not traditionally focused on self-management. Rather surgeons have focused on infection control and other factors that emphasized the clinician's role.

There is an evidence gap concerning how psychosocial factors and patient characteristics affect postoperative treatment response in adults recovering from surgery. Studies reporting physical therapy and education comparisons have not investigated the mechanisms through which rehabilitation affects long-term outcomes. Furthermore, studies demonstrate limited adjustment for confounding factors (103-108). While little is known about the influence of patient-level factors on outcomes following specific therapies, there is an expansive observational literature documenting that patient characteristics affect long-term outcomes after lumbar spine surgery. The proposed study will be the first to examine potential mediators for improvement in postoperative outcomes as a result of a self-management approach and

whether sub-groups of patients based on age are more likely to benefit from the CBPT intervention. Results will further our understanding of tailored interventions based on age for pain management (49).

The proposed study is innovative in its use of a telephone-delivery model. Qualitative research helped overcome accessibility barriers by adapting the CBPT program for delivery over the telephone (109). Our telephone-delivery model addresses the financial and transportation constraints and mobility issues that typically render clinic-based rehabilitation impractical for an aging population (110-113). We will be able to treat adults from "hard-to-reach" and underserved populations, such as older adults with multiple comorbidities and residents of rural areas. Home-based programs also appear to be superior to highly supervised center based programs in terms of adherence to exercise, especially in the long-term for older adults (50 years or older) (114). As centers of excellence are created in our evolving health care market, patients will travel longer distances to receive specialty care. There will be a critical need for easily accessible programs that support older adults in their home community. The implementation of our CBPT program over the telephone will help patients engage in purposeful, goal directed behaviors at home and at work and participate fully in family and community life. The long-term goal is to empower adults to return to a productive life both inside and outside the home and ultimately improve their quality of life and participation in society. The next step in our work is the current proposal which conducts a large, rigorous evaluation of our CBPT program in a racially/ ethnically diverse patient population, with the goal of engaging adults in their own care and improving pain and functional outcomes. These data will be useful in guiding the development of accessible interventions that can be used across a variety of painful conditions.

2.8. Study Significance. This novel CBT-based self-management approach to postoperative rehabilitation seeks to redefine the transdisciplinary model of health care and increase access to well-established pain management strategies. Our line of work is part of a current shift in the physical therapy treatment paradigm toward "psychologically informed" rehabilitation and compelling data is needed to support this expanded scope of practice. There is an urgent need for adults to have readily accessible treatments that allow them to take an active role in their care. Our long-term goal is to provide low-cost, evidence-based programs that clinicians can recommend, and adults can do, to improve pain and functional outcomes. Furthermore, the proposed study will examine how cognitive-behavioral factors and age play a role in the efficacy of treatment for pain and disability in community-dwelling adults. Results will further our understanding of tailored interventions based on age for pain management. Our interventional approach is designed to empower adults to return to a productive life both inside and outside the home and ultimately improve their quality of life and participation in society.

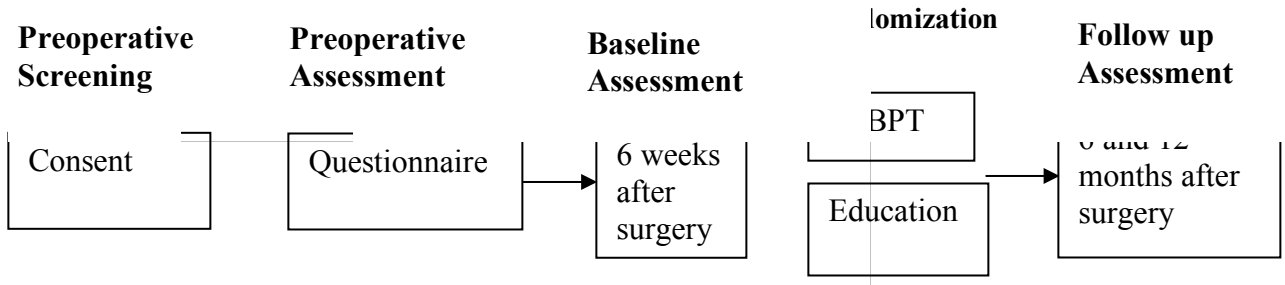
3. Study Design

3.1. Design overview. The CBPT study is a multi-center, prospective randomized controlled trial of CBPT versus education in adults following lumbar spine surgery for degenerative conditions. The primary hypothesis for the study is that the CBPT intervention will decrease pain and disability and improve general health, physical activity, and physical function in this surgical population, through reductions in fear of movement and increases in pain self-efficacy.

Eligible patients will be randomized to one of the 2 treatment groups after undergoing surgical treatment for a lumbar degenerative condition. Patients will be asked to complete a preoperative questionnaire and participate in a postoperative baseline assessment prior to the start of the intervention phase (6 weeks

after surgery). This baseline assessment will occur at a standard postoperative clinic visit. Patients will also be asked to participate in follow-up visits at 6 and 12 months after surgery. The primary outcomes are self-reported pain, disability, and general health. Secondary and tertiary outcomes include physical activity and physical function, respectively. Additionally, use of pain medication, re-hospitalization following initial spine surgery, and surgeries following initial spine surgery will also be ascertained and compared between the two treatment groups at 6 and 12 months after surgery. A schematic of the trial design is presented below in Figure 2.

Figure 2: Trial Design



3.2. Comparators. Patients who meet the eligibility criteria and have signed an informed consent statement will be randomly assigned to one of two groups after surgery and completing the baseline assessment:

Group 1: CBPT
Group 2: Education

Randomization will provide patients a 50/50 opportunity to be in either group. The stratified randomization scheme will assign patients in randomly permuted blocks of assignments stratified by age and type of surgery (i.e., fusion or no fusion). The 4 frequency-matched strata will be as follows: (1) Age 21-59 and fusion; (2) Age 60-90 and fusion; (3) Age 21-59 and no fusion; (4) Age 60-90 and no fusion. This scheme will ensure that the two groups will be balanced by age (to minimize age effects of pain and disability) and by fusion (to minimize effects of differences in injury severity, procedural complexity, and recovery time).

The randomization plan will be prepared and administered centrally by the Coordinating Center (Vanderbilt) but will not require real time interaction with Vanderbilt staff members. Requests for randomizations will be made by the study physical therapist using a secure web-based application. An assignment will be issued only if the database shows that the patient is eligible, the consent statement has been signed, and a baseline assessment completed.

3.2.1. Treatment Group 1. The CBPT program focuses on a patient-oriented self-management approach to reduce pain and disability and improve physical activity and function, through reductions in fear of movement and increases in self-efficacy. Brief CBT programs for pain developed by Woods and Asmundson (84), Williams and McCracken (69), and Turner et al. (115) and a self-management approach developed for older adults by Lorig (101,102,116,117) provide the basis for the CBPT

program. Sessions cover an introduction and rationale for treatment, deep breathing (118), progressive muscle relaxation (119), graded activity plan, goal-setting (120), distraction techniques (29), automatic thoughts (72), coping self-statements (72), pacing techniques (121), and relapse prevention and symptom management plans (122). Each session builds upon the content of the previous session and weekly action plans are personally tailored based on patient goals. The program consists of six weekly telephone sessions with a trained physical therapist. The first session is approximately 60 minutes and the remaining 5 sessions are approximately 30 minutes (see Appendix 9.2. for more detail). Each patient randomized into the CBPT program will receive a binder to follow along with the study therapist.

Potential Adverse Effects. There are no potential adverse effects specific to the cognitive-behavioral and self-management strategies. There may be distress related to discussing mood and beliefs about pain and functional activity.

3.2.2. Treatment Group 2. The education program focuses on postoperative recovery and is based on web-based modules that were developed and tested in Dr. Wegener's NIH-funded project in patients with musculoskeletal injury (R01AR054009). Educational modules were adapted in collaboration with community-dwelling adults who completed preliminary testing of the CBPT program (109). Sessions address benefits of physical therapy, proper biomechanics after surgery, importance of daily exercise, and ways to promote healing. Education on stress reduction, sleep hygiene, energy management, communication with health providers, and preventing future injury are also provided. The education program is matched to the CBPT treatment in terms of session frequency, length and contact with the study therapist. Each patient randomized into the education program will receive a binder to follow along with the study therapist (see Appendix 9.3 for more detail).

Potential Adverse Effects. There are no potential adverse effects specific to the educational treatment. There may be distress related to discussing their surgery and recovery.

3.3. Standardization of Postoperative Treatments across Centers. The clinical course of the patients in both arms of the study will follow the universal protocols for postoperative management of lumbar degenerative conditions at academic medical centers. All patients return for a standard postoperative clinic visit at 6 weeks to assess surgical recovery and usually receive a prescription for physical therapy (2x/week for 6 weeks). Minor variability in practices, such as need for physical therapy referral and duration of physical therapy, as well as type of oral analgesics will be at the discretion of the treating surgeon. This may impart some variation in care across the centers, but will realistically mimic the current state of the art for the best care possible in each of the treatment arms. Relevant details regarding postoperative treatment will be recorded and used in the analysis as necessary to balance comparisons between groups.

3.4. Therapist Training and Certification of Centers. Two study physical therapists at Vanderbilt will be delivering both the CBPT and education treatments. The study therapists will complete a formal training course (sponsored by Vanderbilt) in both the CBPT and educational treatments. Formal training will occur during one 2-day session with the PI of the study (Dr. Archer) and a clinical psychologist (Dr. Wegener) specializing in CBT and self-management techniques. A written competency for both treatments and a skills test for the CBPT program will be completed at the end of training. After passing both tests (scores > 85), both treatments will be implemented with study staff and progression will be

discussed during weekly research meetings. Then, a pre-test of the CBPT and education treatments will occur with 2 patients from each center. All sessions during the pre-test are audiotaped and reviewed by the PI and Dr. Wegener to evaluate adherence to each of the treatment protocols and to specific CBT and self-management competencies. Prior to initiation of the study, completion of the therapist training course, competency and skills tests, practice sessions, and the pre-test will be documented.

4. Patient Selection

4.1. Overview and Clinical Centers. Approximately, 260 community-dwelling adults will be recruited from the centers. The two centers are academic medical centers with large numbers of lumbar degenerative conditions and with a proven track record for prospective study of patients having lumbar spine surgery (5R01HS017990 and R21AR062880). Eligible patients will be identified and recruited at the participating clinical centers subject to the inclusion and exclusion criteria listed below.

The Coordinating Center (Vanderbilt) will develop a master recruitment plan and work with the other center (Johns Hopkins) to customize this master plan. Recruitment goals will be set for each individual center and monitored on an ongoing basis.

4.2. Inclusion criteria. In order to qualify for inclusion in the trial, patients must satisfy the following inclusion criteria:

1) Radiographic evidence of lumbar spinal stenosis secondary to degenerative changes;
2) Surgical treatment of a lumbar degenerative condition (spinal stenosis, spondylosis with or without myelopathy, and degenerative spondylolisthesis) using laminectomy with or without arthrodesis procedures;
3) English speaking due to feasibility of employing study personnel to deliver and assess the study intervention; and
4) Age older than 21 years (younger individuals do not typically have a lumbar degenerative condition).

4.3. Exclusion criteria. Patients who satisfy any of the following exclusion criteria will be ineligible for enrollment in the trial:

1) Patients having microsurgical techniques as the primary procedure, such as an isolated laminotomy or microdiscectomy (individuals having these minimally invasive surgical techniques tend to have a less severe case of lumbar degeneration and a shorter recovery time than individuals having arthrodesis or laminectomy without arthrodesis);
2) Patients having surgery for spinal deformity as the primary indication (patients with spinal deformity as the primary spinal disorder tend to have a different recovery trajectory compared to the inclusion population);
3) Patients having surgery secondary to pseudarthrosis, trauma, infection, or tumor;
4) Presence of back and/or lower extremity pain < 3 months indicating no history of sub-acute or chronic pain;
5) History of neurological disorder or disease, resulting in moderate to severe movement dysfunction. Including but not limited to Parkinson's disease, Multiple Sclerosis, Epilepsy, Brain tumors,

Huntington's disease, Alzheimer's disease, Muscular Dystrophy, Stroke, Autonomic Nervous System disorders, Traumatic Brain Injury, Cerebral Palsy, and Amyotrophic Lateral Sclerosis;
6) Presence of schizophrenia or other psychotic disorder, including but not limited to Brief Psychotic disorder and Delusional disorder;
7) Patients not able to return to clinic for standard follow-up visits with surgeon due to time and travel limitation;
8) Patients having surgery under a workman's compensation claim; and
9) Unable to provide a stable address and access to a telephone indicating the inability to participate in either the telephone-based CBPT or education program.

5. Trial Protocol

5.1. Overview. The patient-related activities of the CBPT trial can be divided into the following phases:

- Phase 1: Qualitative data collection (Vanderbilt site only)
- Phase 2: Screening for eligibility;
- Phase 3: Consent and enrollment into trial prior to surgery;
- Phase 4: Baseline data collection (6 weeks after surgery);
- Phase 5: Randomization and Treatment;
- Phase 6: Post-treatment follow-up phase (6 and 12 months after surgery);

The visit and data collection schedule described below is summarized in Appendix 9.4.

5.2. Phase 1: Qualitative Data Collection (Vanderbilt only)

5.2.1. Patient Interviews. Twenty interviews will be conducted at Vanderbilt to identify patient-centered outcomes for the randomized controlled trial. However, data collection will occur until redundancy or saturation is reached (i.e., no additional information is obtained from the last informants). Interview participants will be recruited through a stratified purposeful sampling approach from a current cohort of 80 adults who have been enrolled into a NIH-funded pilot trial comparing the CBPT and education programs. This purposeful sample will be stratified by responders (i.e, reduction in disability of 12.8 points or greater as measured by the Oswestry Disability Index) or non-responders (i.e., reduction < 12.8 points) at 12 months following surgery. Research personnel will contact eligible individuals by mail and then phone to determine interest in participation and verbal and written consent will be obtained.

5.2.2. Focus Groups. After the interviews, focus groups will be conducted to: 1) identify any outcomes that might have been missed by the interviews; 2) review existing measurement scales used to capture all identified outcomes; 3) generate discussion on how measurement scales might be improved to better capture patients' actual experiences with these outcomes over time and across contexts (e.g., work, family, recreation); and 4) to review models of patient surgical outcomes developed from the interviews. Four focus groups are planned, with 6 to 8 participants in each. Groups will be comprised of patients that were not involved in the interview process and recruitment will occur through the stratified purposeful sampling approach described above. 2 hours will be allotted for each group. Groups will be led by Dr. Schlundt (co-investigator) and an experienced moderator from the Qualitative Research Core

at Vanderbilt University. Focus group participants will be asked to read and sign informed consent forms at the start of the session. Groups will include a spontaneous reporting of symptoms and health concerns and how patients managed symptoms. Then codes and categories (i.e., outcomes) will be presented that were identified through the interviews. Measures will also be presented that reflect these outcomes to answer the research question – *" Do outcome measures commonly used in surgical spine trials adequately reflect what is most important to patients?"*

5.2.3. Pilot Testing and Cognitive Interviews. The final outcome measures/items will be piloted via mail or email with 25 patients who have participated in the interviews or focus groups. Ten additional patients will be recruited for in-person cognitive interviews (i.e., talk out loud as they complete the measurement tool). The cognitive interviews will assess the following for the outcome scales/items: 1) comprehension; 2) process by which the respondent retrieves relevant information from memory; 3) decision process to answer each item; and 4) response process.

5.3. Phase 2: Screening for Eligibility. Patients will be screened for eligibility in each center by the local research coordinator in close coordination with the surgeon co-investigators. Screening through the medical record will occur prior to surgery and a scheduled preoperative clinic visit. Additional screening will occur either during the preoperative clinic visit or after by the study coordinator through a list of screening questions. All potentially eligible patients will be entered into REDCap, a study number assigned, and eligibility criteria confirmed. The Coordinating Center (Vanderbilt) will be available to adjudicate eligibility.

5.4. Phase 3: Consent and Enrollment. Eligibility will be confirmed with the treating surgeon and through a list of screening questions for the patient. Patients will then be approached for their consent to participate in the randomized controlled trial following their preoperative clinic visit. The study coordinator will perform the consent process using a scripted dialogue and materials developed for the CBPT study. A power point presentation will also be made available for use by the research team to describe the study and what it means to participate in the study.

Once consented into the randomized trial, patients will complete a preoperative questionnaire. This assessment will gather data on patient demographic and injury characteristics, medical and social history, expectations of surgery, fear of movement, pain self-efficacy, affect, depressive symptoms, and preoperative levels of pain, disability, and general physical and mental health. Patients will also be asked to complete a battery of physical performance tests to assess strength, mobility, and gait speed.

5.5. Phase 4: Baseline Data Collection. The date of surgery is the 0 time for reckoning baseline visit and all follow-up visits (i.e., all follow-up visits are scheduled at specific times measured from the date of surgery). The surgery scheduler will schedule both the surgery and a standard 6-week postoperative clinic visit for the patient. The Research Coordinator at each site will contact patients to schedule a baseline study visit prior to their standard 6-week postoperative clinic visit with the surgeon. Patients at this study visit will complete questions on work status, medication, physical therapy, expectations, and satisfaction and a battery of questionnaires to measure fear of movement, pain self-efficacy, depressive symptoms, general physical and mental health, and pain and disability outcomes. Physical function will be assessed through performance-based tests that include the Chair Stand test, 10-Meter Walk test, and

Timed Up and Go. Patients will be provided with an accelerometer to wear for 7 days following the study visit.

Study personnel conducting the baseline assessment will be unaware of the patient treatment condition. All data from the baseline self-reported assessment will be entered directly into the REDCap Data Entry System by the patient. Data from the performance based tests will be recorded on case report forms by study personnel and then transferred to the REDCap Data Entry System. Details as to the information collected during the baseline assessment is included as Appendix 9.4.

5.5.1. Accelerometer Data. Each accelerometer will be initialized at the Coordinating Center (Vanderbilt) to record three-dimensional accelerations raw signal at 40 Hz. However, detailed instructions on how to wear and care for the accelerometer will be provided by the Study Coordinator at each local site during the baseline visit. Patients will be asked to wear the accelerometer secured at the right hip with a waist belt for seven consecutive days excluding night rest (sleep). All patients will also be given a stamped, self-addressed envelope to return the accelerometer to the Coordinating Center (Vanderbilt) after wearing for seven days. Research personnel at Vanderbilt will download the data using ActiLife v6.4 software. If wear interval data are not available for at least 4 days (with each day being at least 10 hours), the Research Coordinator at the Coordinating Center (Vanderbilt) will contact the patient by phone and ask them to wear the accelerometer for another 7 days. The accelerometer will then be mailed from the coordinating center (Vanderbilt) to the patient along with a self-addressed stamped envelope to return after wearing for seven days.

5.6. Phase 5: Randomization and Treatment. Once the patient has been consented, undergone surgery for a lumbar degenerative condition, and completed the baseline assessment, the Research Coordinator at each site will update the REDCap Data Management System and the patient will be randomized electronically. To ensure that the number of subjects is about the same in the two arms of the study for each clinical site, the randomization scheme will assign patients in a 1:1 ratio in randomly permuted blocks of assignments stratified by age and type of surgery (i.e.; fusion or no fusion). Block size will be determined randomly with the patient as the unit of randomization.

The randomization plan will be prepared by the study's biostatistician and administered centrally by the Coordinating Center (Vanderbilt), but will not require real time interaction with Vanderbilt staff members. Requests for randomization will be made by the study therapist using a secure web-based application. An assignment will be issued only if the database shows that the patient is eligible, the consent statement has been signed, and a baseline postoperative assessment completed. Enrollment will be documented in the patient's chart according to center protocol.

5.6.1. Treatment. Once patients have completed the baseline assessment with the Research Coordinator and received the movement accelerometer, the study physical therapist will call the patient to schedule the first treatment session. Patients will complete 6 sessions over the phone. Sessions will be scheduled on a weekly basis.

5.7. Phase 6: Post-treatment Follow-up Phase (6 and 12 months after surgery). The randomization computer program will generate a personalized appointment schedule for the patient; this schedule will

indicate the ideal date for each follow-up visit, as well as the time window around the ideal date during which the follow-up visit may be done.

Patients will have follow-up visits at 6 and 12 months after surgery. Each visit will have an interval of time surrounding the ideal date for the visit during which the visit may be done and the data included in the trial database. The ideal date for a visit is the exact anniversary from surgery. Visit windows (+/- 2 weeks for all visits) will be constructed to be contiguous, so that at any point in time, some visit window is open, subject to a check on the minimum separation required between consecutive visits. Patients at the study follow-up visits will complete the same questions and battery of questionnaires as the baseline assessment and wear an accelerometer for 7 days. Patients will also be asked questions on intervening events such as re-hospitalization and surgery. At the 12-month follow-up, patients will return for an on-site visit and complete the performance-based tests.

Study personnel conducting the follow-up assessment will be unaware of the patient treatment condition. All data from the follow-up self-reported assessment will be entered directly into the REDCap Data Entry System by the patient or on case-report forms. Data from the performance based tests will be recorded on case report forms by study personnel and then transferred to the REDCap Data Entry System. The types of specific data to be collected at each of the follow-up visits are included as Appendix 9.4.

5.7.1. Accelerometer Data. See section 5.5.1 for procedures with regard to accelerometers.

5.8. Outcomes. All outcomes will be assessed using widely used, standardized measures. They are described below.

5.8.1. Primary Outcomes. The Brief Pain Inventory (BPI) (123) will assess pain intensity. The 4-item pain intensity subscale assesses current, worst, least, and average pain. The subscale uses a numerical rating scale with 0 representing 'no pain or does not interfere' and 10 representing 'pain as bad as you can imagine or completely interferes.' Scores greater than or equal to 5 indicate moderate to severe pain intensity and interference. The BPI has proven both reliable (Cronbach's alpha > 0.80) and valid (highly correlated with well-validated generic measures of pain and general health and condition specific disability) in both surgical patients and patients with chronic low back pain (124-126). The minimum clinically important difference (MCID) for pain has been found to range from 1.2 to 2.1 points in patients following lumbar spine surgery (127). The 10-item Oswestry Disability Index (ODI) (128) is a standard measure of condition specific disability that assesses the impact of lumbar spinal disorders on daily living, with questions about pain intensity, lifting, sitting, standing, walking, sleeping, hygiene, traveling, social life, and sex life. Ratings for each item are from 0 (high functioning) to 5 (low functioning). Total scores are divided by the total possible score and multiplied by 100 to create a percentage of disability. The ODI has demonstrated strong test-retest reliability (Pearson's r > 0.80) and validity, and good internal consistency (Cronbach's alpha > 0.70) in both surgical spine patients and patients with chronic low back pain (129-130). The MCID has been found to range from 8.2 to 12.8 points in patients following lumbar spine surgery (127,131). General physical and mental health will be measured with the physical and mental composite scales of the SF-12 (132). The physical component scale (PCS) assesses the four subdomains of physical functioning, role-physical, bodily pain, and general health and the mental component scale (MCS) assesses the 4 subdomains of vitality, social

functioning, role-emotional, and mental health. Total subscale scores range from 0 to 100, with 100 indicating the highest level of health. The PCS and MCS of the SF-12 have demonstrated responsiveness, good test–retest reliability, good internal consistency, and validity with correlations greater than 0.90 with the SF-36 in generalized and various patient populations (132-134). The minimal clinically significant change for the PCS and MCS has been estimated at 10% (134).

5.8.2. Secondary Outcome. Physical activity will be measured objectively using a commercially available movement accelerometer (ActiGraph GT3X+), a small triaxial accelerometer (46 mm × 33 mm × 15 mm) that weighs approximately 19 grams (135). The water resistant device assesses acceleration in three individual orthogonal planes using a vertical axis, horizontal axis and a perpendicular axis. Accelerometers are used in physical activity monitoring because of their small size, low cost, convenience, the ability to record data for several days (136), and ability to assess multiple dimensions of physical activity (e.g., total activity, time spent in different levels of intensity and predicted energy expenditure) (137-139). Accelerometers have proven valid with moderate correlations with the criterion method of doubly labeled water for total and active energy expenditure in young and older adults (140,141). For the purpose of this study, the monitor will be initialized to record three-dimensional accelerations raw signal at 40 Hz. Physical activity will be assessed using total volume of physical activity, expressed as the mean counts per minute over the duration of accelerometer monitoring. In addition, percentage of time spent in commonly used domains of physical activity intensity (sedentary, light, moderate, and vigorous) will be considered.

Chair Stand test from the Short Physical Performance Battery (SPPB) from the Established Populations for the Epidemiologic Study of the Elderly studies will be used to assess strength (142). The Chair Stand test has demonstrated good to excellent test-retest reliability, good internal consistency (Cronbach's alpha > 0.70), and predictive validity in analyses showing risk for mortality and disability (143,144). The 10-Meter Walk (146) test will measure self-selected walking speed. Ambulatory support devices may include canes, crutches, or walkers and will be recorded. The time it takes for subjects to complete the task is measured with a stop watch and recorded as meters per second (m/sec). Excellent inter-rater and intra-rater reliability (ICC > .90) and good test-retest reliability for self-paced timed walking speed tests using a stopwatch have been reported (146). Validity for walking speed tests has been determined by significant correlations with self-report measures of function and mortality in older adults (146,147). The MCID for the 10-meter walk test at a comfortable pace has been estimated to be 0.16 meter/second and a meaningful change in older adults has been documented at 0.10 meter/second (148). The Timed Up and Go (TUG) test will be used to assess functional mobility (149). Time less than 10 seconds indicates functional independence and more than 30 seconds demonstrates functional dependence. The TUG has been shown to have excellent test-retest reliability (149,150) and be a valid and responsive performance measure in older individuals (151). The MCID for the TUG has been reported as a reduction in time ranging from 1.2 to 2.3 seconds in older adults with pain (152).

5.8.3. Intermediary Outcomes. The Tampa Scale for Kinesiophobia (TSK) (153) will be used to measure fear of movement. Participants are asked to rate each item on a 4-point Likert scale with scoring alternatives ranging from 'strongly disagree' to 'strongly agree.' The MCID for the TSK has been reported to be 4 points in patients with back pain (154). The TSK has been found to have good internal consistency (Cronbach's alpha > 0.70) and test-retest reliability (Pearson's r > 0.70) in surgical patients and patients with various musculoskeletal conditions (155,156). The 10-item Pain Self-Efficacy Questionnaire (PSEQ) (157) will measures the strength and generality of a person's belief in his/her

ability to accomplish a range of activities despite pain. Participants rate how confident they are on a 7-point scale from 'not at all confident' to 'completely confident.' Scores range from 0 to 60, with a score greater than 40 indicating high pain self-efficacy (158). The PSEQ has been found to have excellent internal consistency (Cronbach's alpha > 0.90), good test-retest reliability (Pearson's r > 0.70), and construct validity through correlations with depression, anxiety, coping strategies, pain ratings, and work-related tasks in patients with chronic pain (158).

5.9 Other Outcomes. At each clinic and study visit, the treating surgeon and/or research personnel will record the type and frequency of pain medication use. Data on number of re-hospitalizations (including length of stay) and number and type of surgeries (e.g., revision spine surgery) following initial spine surgery will also be collected from medical and billing records at each site and through patient self-report.

5.10. Safety Issues. Safety issues can be divided into (i) safety concerns related to the therapeutic interventions and (ii) concerns related to patient privacy.

5.10.1. Safety Concerns Related to the Therapeutic Treatments. There are no potential adverse effects specific to the participation in cognitive and behavioral therapy and self-management interventions. There is the potential for physical discomfort (increased pain and reduced activity level) and falls due to participating in the physical performance tests. There may also be distress related to answering questions and discussing mood and pain beliefs.

5.10.2. Safety Issues Related to Patient Privacy. It is the investigator's responsibility to conduct the protocol under the current version of Declaration of Helsinki, Good Clinical Practice, and rules of local IRBs. The investigators must ensure that the patient's anonymity be maintained in their data submission to the coordinating center (Vanderbilt). Patients will only be identified by an identification code and not by their name, SSN, or hospital medical record number. Study Site Investigators will maintain a separate confidential enrollment log which matches identifying codes with the patients' names and addresses (i.e., available only to local clinic staff). All study material will be maintained in strict confidence.

5.11. Retention. The study participants will receive an honorarium in recognition of their time and effort. Twenty patients will be compensated $25 for participating in an interview and 32 patients will receive $50 for completing a focus group session and $100 (max) for travel reimbursement to Vanderbilt. 10 patients will be compensated $25 for participating in a cognitive interview and $100 (max) for travel reimbursement to Vanderbilt. For the trial, a $25 payment will be given for completing the baseline assessments at a standard postoperative clinic visit (6 weeks following surgery) and a $25 payment for each follow-up assessment (6 and12 month time points). A $50 payment will be given for each complete accelerometer assessment (i.e., 4 days of data). For the 12-month on-site visit, participants will be reimbursed $100 (max) for travel reimbursement. Treatment group participants will also be compensated $50 for the 6-session program to reimburse for phone expenses. We will also keep participants engaged through distribution of follow-up reminder letters and phone calls.

5.12. Management of Concomitant Conditions. Concomitant conditions will be managed with the standards of care at the local treatment facility and should not be affected by study participation.

5.13. Adverse Event Reporting. The CBPT trial will monitor and report adverse events to ensure patient safety. Definitions and procedures for reporting adverse events are designed to satisfy 45 CFR Part 46, Subpart A; the "Common Rule", shared by 17 Departments and Agencies as well as 21 CFR 312, the FDA regulation for adverse events. The Common Rule requires written procedures and policies for ensuring reporting of "unanticipated problems" involving risks to participants to IRBs, appropriate institutional officials, and the Department or Agency Head.

5.13.1. Definitions. We will use the following definitions in identifying adverse events.

- **Adverse event**. An adverse event is any untoward medical occurrence that may present itself during treatment or administration with clinical procedure and which may or may not have a causal relationship with the treatment. Adverse events include any unanticipated problems involving risks to participants, or breaches of protocol which might entail risk to participants. The term "unanticipated problem" includes both new risks and increased rates of anticipated problems.

- **Serious adverse event**. A serious adverse event (SAE) is an adverse event occurring at any time during the study that results in death, inpatient hospitalization or prolongation of existing hospitalization, or a persistent or significant disability/incapacity. Other events may also be considered an SAE if, based on medical judgment, the event jeopardized the patient to the point of requiring medical or surgical intervention to prevent the occurrence of any of the conditions for an SAE listed above.

- **Unexpected adverse event**. An unexpected adverse event is any adverse event with specificity or severity that is not consistent with the risk information in the study protocol.

- **Associated with the use of the treatment** means that there is a reasonable possibility that the adverse experience may have been caused by the treatment.

5.13.2. Monitoring and Reporting Adverse Events. Adverse events will be recorded on study data forms whether or not they are thought to be associated with the study or with one of the study treatments. Adverse events may be discovered during regularly scheduled visits or through unscheduled patient contacts between visits. Adverse events will be monitored both as secondary outcomes of the study (i.e., falls during the physical function tests) as well as adverse events that are not outcomes per se of the study.

At the first study team meeting, investigators will review definition of all outcomes, adverse events and serious adverse events and revisions to the protocol will be made as appropriate. Summary data on adverse events (together with study outcomes) will be monitored by the medical monitor at semiannual meetings or more frequently, as needed. These summaries will include analyses comparing rates of adverse events by blinded treatment group, by clinic, or in other subgroups requested by the medical monitor. Where applicable, signs and symptoms associated with the adverse event will be graded as to severity by the clinical site staff as mild, moderate, or severe using the Common Terminology Criteria for Adverse Events.

After each review, the medical monitor will issue a written summary of its review of the study data, including adverse events, for transmission to the IRBs at each of the study centers. Analyses or listings of adverse events will not be provided to the IRBs; however, adverse events involving unanticipated problems involving risks to participants, or breaches of protocol which might entail risk to participants must be reported to local IRBs as soon as possible after they are discovered. Each participating center is responsible for ensuring that all local IRB requirements for reporting adverse events are met.

5.13.3. Reporting Serious Adverse Events. Serious adverse events (SAE) must be reported upon discovery at the clinical center. This will involve completing an SAE CRF describing the severity and details of the event. The SAE form, together with a memo summarizing the circumstances of the event and the current status of the patient, must be faxed to the coordinating center (Vanderbilt) within one working day of the discovery of the SAE. Also, within one day, the clinical center must notify the coordinating center (Vanderbilt) of the SAE by telephone or confirmed e-mail. The coordinating center (Vanderbilt) will transmit the SAE form to the medical monitor. If the SAE occurs at the coordinating center (Vanderbilt), the coordinating center will transmit the SAE form and memo to the other study center. The medical monitor will review each SAE report and provide comments to the PCORI project officer within one week of receipt of the report.

6. Statistical Design and Analysis

6.1. Study Aims and Hypotheses

Specific Aim 1: To determine the most important treatment outcomes to older adults undergoing lumbar spine surgery for degenerative conditions.

> ***Hypothesis 1:*** The most important outcomes to older adults undergoing lumbar spine surgery will include pain, physical functioning, and general health.

Specific Aim 2: To compare whether a CBPT program or an education program are more effective in reducing disability and pain and improving general health, physical activity, and physical function following lumbar spine surgery for degenerative conditions.

> ***Hypothesis 2:*** CBPT participants compared to education participants will demonstrate significantly greater improvement in disability (Oswestry Disability Index), pain (Brief Pain Inventory), general health (12-item Short Form) and physical activity (movement accelerometers) at 6 and 12 months following lumbar spine surgery and physical function as measured by standardized performance tests of strength, gait speed, and mobility (Chair Stand, 10-Meter Walk, Timed Up and Go) at 12 month follow-up.

Specific Aim 3: To determine how the CBPT treatment improves outcomes in patients following lumbar spine surgery for degenerative conditions.

> ***Hypothesis 3****:* Participants reporting decreases in fear-of movement and increases in pain self-efficacy will demonstrate improvement in outcomes following the CBPT program at 6 and 12 months following lumbar spine surgery.

Specific Aim 4: To determine which sub-groups of adults are most likely to benefit from the CBPT program following lumbar spine surgery for degenerative conditions.

Hypothesis 4*:* CBPT participants that are 60 years or older, have a fusion procedure, and report clinically significant depressive symptoms preoperatively will demonstrate greater improvement in outcomes at 6 and 12 months following lumbar spine surgery.

6.2. Outcome Measures. The outcomes are defined above in Section 5.9. They are summarized below:

Primary Outcome Measure:

- Self-reported disability (Oswestry Disability Index)
- Self-reported pain (Brief Pain Inventory)
- Self-reported general health (SF-12)

Secondary Outcome Measure:

- Physical Activity (Movement accelerometer: total daily amount of physical activity)
- Physical Function (Chair Stand, 10-Meter Walk, Timed Up and Go)

Other Outcomes:

- Use of pain medication
- Re-hospitalization following initial spine surgery (number and length of stay)
- Surgeries following initial spine surgery (number and type)

6.3. Statistical analysis

6.3.1. Specific Aim 1. ***Patient Interviews.*** All patient interviews will be audio-recorded and transcribed by the Qualitative Research Core using a commercial transcription service (www.rev.com). Qualitative analysis will occur in three interrelated phases: 1) individual quotes will be isolated in the interview transcripts; 2) a hierarchical coding system will be developed to organize the quotations in relationship to the study questions and to capture the full range and depth of participant response; and 3) the structure, frequency, and interrelationships of the coded quotes will be used to develop an integrative model of how patients understand and value the outcomes of surgery. We will use a coding system from our preliminary focus groups with neurosurgical back pain patients as the starting point for this work. The analysis will begin by looking at simple frequencies of codes and proceed towards a theoretical framework. The process will include both inductive analysis (theory to fact) and deductive analysis (fact to theory). The resulting framework will be communicated using diagrammatic models supported by a narrative text. The text will incorporate direct quotations from patients to illustrate and communicate important constructs and relationships. Management of transcripts, quotations, and codes will be done using a local instance of open source qualitative data analysis software (http://cat.ucsur.pitt.edu/ default.aspx). The resulting models and narratives will be reviewed by investigators and stakeholders and revised based on their feedback.

Focus Groups. All focus groups will be audio-recorded and transcribed and qualitative analysis of the focus groups will concentrate on generating items that can be used to measure outcomes. The interviews will have identified the major categories of symptoms/outcomes that patient's value and the

focus groups will allow us to better understand how these outcomes vary over time and as a function of context. Quotes will be used to generate a pool of measurement items, and an inductive/deductive approach similar to that employed for the interviews will be used to group the items into categories. Further analysis will be used to eliminate redundancies and improve item wording until an item pool has been generated. The generated list of items will be reviewed by the investigators and stakeholders by making adjustments to categories, placement of items within categories, and specific wording of items. If qualitative data identify additional patient-reported outcomes that were not projected, the investigators will make every effort to identify previously validated and reliable "off-the-shelf" scales to assess these domains.

Pilot Testing and Cognitive Interviews. Pilot testing will be used to empirically reduce the number of items, eliminate items will little or no variance, and check on the internal consistency of item categories. In addition, this will provide a very preliminary check on construct validity. Items that lack face validity or are not well-understood will be changed or removed. Finally, if respondent burden is too great in the opinion of the pilot patients, the survey will be appropriately shortened, while not compromising our ability to achieve our specific aims. The cognitive interviews will be recorded and transcribed and used to further refine the outcome tool. We expect some items will be dropped and others reworded for greater clarity. Our goal is to create a tool kit that is short enough so that it will not create an undue burden on patients, yet detailed enough to capture a more nuanced view of outcomes as we understand them from the qualitative work. We will also assess reading level of items and edit accordingly to ensure they are accessible to older adults with lower levels of education. The final patient-centered outcomes and measures will be reviewed by the investigators and stakeholders prior to implementation during Phase 2 of the study.

6.3.2. Specific Aim 2. The data will be explored numerically and graphically. Group means and corresponding confidence intervals will be calculated for baseline variables, to confirm balance between groups. The characteristics of the patients who are lost to follow-up will be compared to those who complete the follow-up assessments. For each outcome variable, we will fit a multivariable regression model, with site as a covariate. We will explore possible non-linear (quadratic, cubic) effects of the treatment over time. We plan on adjusting for the baseline measurement of the outcome variable, age, type of surgery, site, and depressive symptoms. A random slope over time may be included to allow a separate slope to be estimated for each patient. The primary analysis will be intent-to-treat; missing observations due to drop-out and other reasons not related to the treatments will be handled with multiple imputation methodology. Our use of Bayesian estimation procedures will allow us to easily impute missing data within our models. In most cases, this will allow us to use data with some missing values, and avoid the information loss that is inherent in complete case analysis. Where it is unlikely that values are missing at random, we will include an imputation sub-model that uses available covariates to account for plausible patterns of non-random missingness. Though it is not possible to demonstrate that data are missing at random, including as many predictor variables in the imputation model as possible generally increases the chances that the missing at random assumption (conditional on the covariate values) is reasonable (159). To quantify the effect of the number of sessions completed by study participants on outcomes of interest (i.e., dose-response), we intend to explicitly model the response following session *j* for subject *i* in the following linear model: $y_{ij} - y_{i0} = \alpha_0 + \alpha_1 I[\text{session} = j] + \epsilon_i$ where the function *I* is an indicator for *j* sessions completed, and *yij - yi0* is the change in response after session *j* from baseline (session 0). This model can be generalized to account for a non-linear response to dose.

Accelerometer Analysis. Raw data form the accelerometer will be pre-processed using ActiLife v6.4 software, and integrated into 60-second and 10-second epochs for assessing wear/non-wear intervals and time spent in various physical activity intensities, respectively. Non-wear will be defined as at least 60-minute intervals of "zero" activity counts with 2-min incidental wear intervals allowed. Wear intervals lasting less than 30 minutes will be classified as non-wearing. Total daily wear time will be calculated by subtracting non-wear time from 24 hours. Primary analyses will use total volume of physical activity, expressed as the mean counts per minute over the duration of accelerometer monitoring. Secondary analyses will use percentage of time spent in commonly used domains of physical activity intensity (sedentary, light, moderate, and vigorous).

6.3.3. Specific Aim 3. Separate regression models will be used to explore associations between changes in fear of movement and pain self-efficacy and changes in pain, disability, general health, and physical activity from baseline to 6 and 12 months after surgery for the entire sample. We will construct a mediation model that estimates the effect of the mediation by changes in fear of movement and in pain self-efficacy on outcomes as the result of surgery. This comprises 3 sub-models that relate (1) the treatment to health outcomes directly, (2) the treatment to fear of movement and pain self-efficacy and (3) both the treatment and fear of movement and pain self-efficacy to health outcomes simultaneously. This will demonstrate any mediation effect, if present, by seeing how the relationship between treatment and outcomes changes when the potential mediators are added or removed.

6.3.4. Specific Aim 4. Regression models will be used to explore the interaction between patient characteristics and treatment for each outcome in the entire sample. Important sub-groups will be identified based on the strength of association between the response to treatment (change in outcomes) and each covariate included in the model (i.e., patient age, type of surgery, depressive symptoms). To illustrate, consider the simplified model with just one covariate:

$y_i^{(1)} - y_i^{(0)} = \mu + \beta_1 I(treat_i) + \beta_2 x_i + \beta_3 x_i I(treat_i) + \epsilon_i$ where *xi* is some covariate of interest from the list above. β1, β2 and β3 are parameters for the treatment, covariate and treatment-by-covariate interaction, respectively. Sub-groups that show a stronger response to treatment will have relatively large, negative interaction parameter values, indicating that they would reduce the outcome score beyond treatment in the absence of the covariate.

6.4. Missing data. Missing data are a serious concern that complicates the interpretation of the study results. We will address this issue from both a trial conduct and analysis perspective. Regarding trial conduct, we will

1. Limit participant burden and inconvenience in data collection
2. Provide compensation for participation and completion in the study
3. Select high quality investigators
4. Provide pre-study training of investigators as well as on-study reinforcement
5. Monitor and report missing data rates during the trial
6. Emphasize the importance of full participation in the trial during the consent process
7. Collect information on the reasons for missing data
8. Actively engage participants in the study and educate them about the importance of their engagement

9. Collect surrogate information on participants who miss clinic visits
10. Hold regular CBPT meetings to discuss strategies for enrollment and engagement of participation
11. Set targets for acceptable rates of missing data

While these efforts will help to minimize missing data, we recognize that missing data are inevitable.

Our use of Bayesian estimation procedures will allow us to easily impute missing data within our models. In most cases, this will allow us to use data with some missing values, and avoid the information loss that is inherent in complete case analysis. Where it is unlikely that values are missing at random, we will include an imputation sub-model that uses available covariates to account for plausible patterns of non-random missingness. Though it is not possible to demonstrate that data are missing at random, including as many predictor variables in the imputation model as possible generally increases the chances that the missing at random assumption (conditional on the covariate values) is reasonable.

6.5. Justification of Sample Size in the Randomized Trial. We estimated power for the study, based on a target of 110 patients per arm with complete follow-up data at 12 months. Power was estimated by generating simulated data, then using the simulated data to try to estimate the original model parameters. We are interested in determining whether the model can estimate the effects of the treatment with adequate precision. We used a simplified model of treatment effect, a fixed effect model that describes the difference between measurements at the baseline $y^{(0)}$ and after treatment $y^{(1)}$:

$$y_i^{(1)} - y_i^{(0)} = \mu + \beta I(treat_i) + \epsilon_i$$

where $\epsilon_i \sim N(0,\sigma^2)$ is the residual for individual i, and I is the indicator function, here evaluating to 1 if the individual is in the treatment group and 0 otherwise. Thus, β describes the effect of the treatment, and μ the expected change in the absence of treatment. For Aim 4, power was measured with respect to the ability to distinguish a non-zero effect of the subgroup-treatment interaction effect (β3).

We generated 200 simulated datasets by resampling available pilot data from a currently funded R21 project (1R21AR062880-01). Control subjects were resampled from control individuals in the pilot data, and treatment subjects were also resampled from control individuals, but with the target effect size added to the sampled values. Power was estimated by fitting Bayesian models to each of the simulated datasets for each response variable and recording the proportion of calculated 95% credible intervals (BCI) for β that excluded zero.

6.6. Interim analysis. A medical monitor is responsible for monitoring the accumulated interim data as the trial progresses to ensure patient safety and to review efficacy. During the first year of the study, involvement of the monitor will occur prior to randomizing the first patient. A conference call will be conducted to review study procedures and the monitoring of adverse events to ensure that a comprehensive safety monitoring plan is in place

After the trial commences, the medical monitor will review data or other issues twice a year. The monitor may request more frequent meetings if necessary. He may also request additional safety reports on a more frequent basis. For example, all serious adverse events (SAE) are reported to the medical monitor for consideration and recommendations as they occur. The medical monitor will review semi-annual reports by masked treatment groups of the primary and secondary outcomes as well as all adverse events that are not identified as outcomes per se.

The medical monitor also reviews the overall progress of the trial in terms of recruitment and data quality and makes a formal recommendation to the Primary Investigator at the end of each scheduled meeting as to whether the trial should continue unmodified, continue with protocol modifications, or be stopped.

7. Human Subjects Issues

7.1. Overview. The study protocol, questionnaires, consent forms, and brochures will be submitted to each participating center's IRB. Sites that recruit patients will submit their recruitment materials to their IRB prior to use. A site may not initiate any patient contact about the CBPT trial until the site has IRB approval for the trial. All study personnel must complete training in the Protection of Human Subjects. The proposed study anticipates recruiting a significant proportion of racial/ethnic minorities (African-Americans, Asian-Americans and Hispanics) as well as non-Hispanic white subjects.

7.2. Institutional Review board (IRB) Approval. A site may not initiate patient activities in the CBPT trial until the site has IRB approval for the trial. Consent forms must have IRB approval. Sites must provide the coordinating center (Vanderbilt) with a copy of the initial IRB approval notice and subsequent renewals as well as copies of the IRB approved consent statements.

7.3. Human Subjects Involvement, Characteristics, and Design. The proposed study includes community-dwelling adults who are having surgical treatment of a lumbar degenerative condition (spinal stenosis, spondylosis with or without myelopathy, and degenerative spondylolisthesis) using laminectomy with or without arthrodesis (i.e., fusion) procedures. Eligible and consenting participants will return for a 6 week postoperative clinic baseline visit. At this postoperative visit, all participants will complete a baseline assessment and will then be randomized to one of the 2 study groups (CBPT vs. education). Based on preliminary data, the study population will be on average 59 years of age, 59% female, and 84% White. All human subjects training and assessment will require approval from the Vanderbilt and Johns Hopkins Institutional Review Board (IRB), and all human subjects' involvement will utilize informed consent documentation.

7.4. Sources of Materials. All materials will be collected and recorded for research purposes. The socio-demographic, clinical, and outcomes information collected during this investigation will be obtained from multiple sources, including subjects directly, medical records, and hospital databases. These data will be entered directly into REDCap (a secure, web-based application) when possible or recorded on case report forms and then transferred to REDCap when necessary (e.g., performance-based physical function test results). All data will be secured by password-only access for the purpose of confidentiality. The surgery and clinic notes will also be used to collect data. Outcomes data will be derived from questionnaires completed both in the clinic and at home and activity monitors, and through interactions between the patient and research personnel during physical performance tests. Study personnel collecting the outcome data will be unaware of the patient treatment condition.

7.5. Potential Risks. The risk to human subjects of participation in this study is minimal due to the nature of this behavioral treatment. The possibility exists that a subject may experience a degree of emotional discomfort related to learning about and managing elevated fear of movement beliefs and

depressive symptoms and completing questions on depressive symptoms and general physical and mental health. We will anticipate and respond by providing subjects with information about their questionnaire results and discuss with them any issues or concerns raised by the testing. Research personnel and study physical therapists will have a list of referral sources available for individuals who request or are in need of further counseling or support. In addition, research staff will review assessment forms immediately upon completion and if an individual reports severe depression, suicidal ideation or other medical/ psychological problem requiring attention the staff will contact the referring surgeon and arrange for appropriate referral. Physical risks encountered during participation in this study may occur during the performance-based tests, such as an increase in pain symptoms, a decrease in short-term activity level, or a fall. However, research personnel will closely monitor patients during these tests and stop testing if an excessive increase in symptoms or problems with balance is noted. There is a small risk of breach of confidentiality, but the data for this study will be secured in a password protected database. Access to this database will be limited to the investigators and study staff. Data will be deidentified for data analysis and interpretation.

7.6. Recruitment and Informed Consent. Prototype consent will be prepared for the CBPT trial. Individual sites may add material but may not delete material thought to be necessary for informed consent. Clinical sites may reformat and reword information to conform to their local requirements. Before approaching patients for enrollment prior to surgery, discussions will be conducted with patients' surgeons to obtain permission. The surgeon and clinical staff will be fully informed of the nature of the study and any risks and benefits. The research coordinator will approach the patient after the preoperative clinic visit or a preoperative education class. The coordinator will meet with the patient, as well as family members, and will describe the proposed study protocol using a scripted dialogue and materials developed for the CBPT study. It will be emphasized to all study participants and family members that the data collected will be for research purposes and that refusal to participate in the investigation will have no effect on the patient's routine treatment. The person obtaining consent will inform the patient that there is no obligation to participate in the study, and will provide her name and phone number where she can be reached if they have further questions or wish to withdraw from the study at any time. The person obtaining the consent will also provide the patient with a written copy of the consent forms and provide ample time for the patient and family to have questions answered prior to enrollment. Copies of the signed consent forms will be given to the patient, and this fact will be documented in the patient's record.

7.7. Protections Against Risk. Under the auspices of the participating center's Institutional Review Board, all participants will be protected by the project's staff strict adherence to study protocols governing participant safety, data privacy, informed consent, withdrawal from the study without prejudice, and immediate reporting directly to the site PI and the IRB of any adverse events involving the participants. Data obtained with subject identifiers will be kept in locked file cabinets to ensure confidentiality, and all paper file contents will be shredded before disposal. All subjects will be assigned a unique study number for use in the REDcap database and all electronic data will be kept in password-protected computer files to ensure confidentiality. Participants will continue to have access to their usual sources of medical care throughout the study. These measures will provide a very high level of protection against risk to the participants.

Time and patient inconvenience have been considered in the study design. We have worked over the past year to construct a streamlined testing battery to minimize respondent burden by selecting the least time-intensive and cumbersome measures available given our study aims and scientific standards and by adapting our battery in accordance with patient feedback and tolerability (e.g., eliminating or replacing measures proven to be cumbersome). Patients will also be reimbursed for their time and travel according to standard rates used in other studies. Although potential risk is minimal in the context of this study, we have carefully powered the study to include only the number of patients needed to adequately address our Aims, further minimizing unnecessary inconvenience and risk.

7.8. Potential Benefits of the Proposed Research to Human Subjects and Others. All participants will gain additional assistance in managing their pain and disability and we anticipate that patients in the CBPT group will report greater improvements in pain, disability, and function related to learning cognitive-behavioral and self-management strategies. There may also be a potential benefit derived from being enrolled in an investigation and having additional patient assessments. Such additional assessments may detect unrecognized clinical and health issues, which could be of benefit to patients' outcomes. Finally, participants may derive a great deal of personal comfort in knowing that their psychological distress and negative pain-related beliefs are part of the surgical recovery process. Thus, a potential benefit may be a reduction in stress and anxiety over recovery. The potential for direct patient benefit outweighs any minimal risk of harm to the participants.

7.9. Importance of the Knowledge to be Gained. The proposed study is intended to provide new knowledge about the processes and outcomes of a novel approach to providing health care to a surgical population. Such knowledge is important because the population of surgical spine patients is growing rapidly, the current treatment regimen appears insufficient based on outcome variability, and there are few other promising therapeutics alternatives for dealing with postoperative recovery. There is also a very real possibility of advancing our knowledge of the utility and efficacy of cognitive-behavioral based physical therapy treatment and of telephone delivery of rehabilitation for persons at-risk for poor surgical outcomes as it relates to clinical outcomes with resultant improvements in persistent pain and disability, and daily functioning. The potential importance of this knowledge outweighs the minimal risk of harm to the participants.

7.10. Patient Confidentiality. All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentiality. All paper, records will be kept in locked file cabinets. All electronic records of study data will be identified by coded number. Clinical information will not be released without written permission of the patient, except as necessary for monitoring by the IRB, PCORI, or medical monitor. Consent procedures and forms, and the communication, transmission and storage of patient data will comply with individual site IRB and PCORI requirements for compliance with The Health Insurance Portability and Accountability Act (HIPPA).

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9. Appendices

9.1. Participating Centers

Vanderbilt University Medical Center (Coordinating Center)
Johns Hopkins Medical Center

9.2. Summary of the CBPT Intervention by Session

Topics	***Major Content and Activities***
All Sessions include: Graded Exposure in Vivo; Goal-Setting; Problem-Solving	Each session builds upon the content of the previous session. Format includes: 1) review of previous session personally-tailored activity and walking goals and skills homework, 2) problem-solving barriers to completing goals, 3) introduction of new content through discussion and worksheets, and 4) review of homework assignment to be completed before next session.
Session 1: **Goal Setting** Introduction; Establish a Graded Activity Plan and Fear Hierarchy; Deep Breathing	Review purpose of the program, conduct semi-structured patient interview, explore gate control theory of pain, complete a graded activity plan and fear hierarchy, set activity goals based on hierarchy, explore walking history and set walking goals, introduce deep breathing as pain management strategy.
Session 2: **Your Mind and Recovery** Distraction Techniques; Progressive Muscle Relaxation	Check graded activity practice and activity goals, set new activity goals, review walking goals and set new goals, problem-solve barriers to completing goals, introduce distraction as pain management strategy and complete worksheet, introduce progressive muscle relaxation CD.
Session 3: **Balance your Thinking** Identify Negative Thoughts; Positive Self-Statements	Review activity and walking progress and set new goals, problem-solve barriers to completing goals, introduce event-thoughts-feeling-action handout, identify negative thoughts that effect activity using worksheet, practice replacing negative thoughts with positive self-talk and complete worksheet.
Session 4: **Rest and Activity** Activity Types; Pacing; Benefits of Program	Review activity and walking progress and set new goals, problem-solve barriers to completing goals, review activity types handouts, explore pacing strategies for pain management and complete worksheet, identify benefits of program so far and complete worksheet.
Session 5: **Managing Setbacks** Relapse Prevention Plan	Review activity and walking progress and set new goals, problem-solve barriers to completing goals, review relapse cycle handout, complete managing setbacks worksheet.
Session 6: **Staying Healthy** Pain Management Plan; Wrap-up	Review activity and walking progress, problem-solve barriers to completing goals, complete pain management plan worksheet, identify benefits of program so far and complete worksheet, reinforce importance of regular exercise and follow-up visits with surgeon and other health care providers.

9.3. Summary of the Education Intervention by Session

Topics	*Major Content and Activities*
Session 1: **Physical Therapy**	Review purpose of the program, conduct semi-structured patient interview, describe physical therapy, introduce benefits of physical therapy, describe different physical therapy techniques, and introduce different exercise programs.
Session 2: **Promote Back Healing I**	Discuss importance of proper posture and transitions, describe proper sleeping positions, and introduce ways to promote healing.
Session 3: **Promote Back Healing II**	Discuss importance of proper body mechanics, describe proper lifting techniques, and describe proper ergonomics at home and at work.
Session 4: **Home Exercise**	Describe the importance of a home exercise program (HEP), discuss the goals of a HEP, introduce the components of a HEP, and discuss the benefits of a HEP.
Session 5: **Prevent Future Injury**	Discuss ways to prevent re-injury, describe mechanisms of low back strain, introduce ways to manage a low back strain.
Session 6: **Staying Healthy**	Describe ways to stay healthy, discuss specific benefits of exercise and not smoking, and discuss ways to reduce stress, improve sleep, eat healthier, and conserve energy.

9.4. Data Collection Schedule

Assessment/Procedure	Pre-op	Baseline	6 month	12 month
Patient Consent	X			
Patient Characteristics				
Age, Gender, Race/Ethnicity	X			
Marital Status	X			
Educational Level	X			
Insurance Status	X			
Height/Weight	X			
Smoking Status	X	X	X	X
Working status	X	X	X	X
Medical History/Co-morbidities				
Pain Duration	X			
Prior Spinal Surgery	X			
Co-morbidities	X	X	X	X
Current medications	X	X	X	X
Intervening Events		X	X	X
Surgical Characteristics				
Type (fusion/no fusion)	X			
Spinal levels	X			
Revision (yes/no)	X			
Psychosocial Characteristics				
Fear of Movement (TSK)	X	X	X	X
Pain Self-Efficacy (PSEQ)	X	X	X	X
Depressive Symptoms (PHQ-9)	X	X	X	X
Expectations of Recovery	X			
Satisfaction		X	X	X
Primary and Secondary Outcomes				
Pain (BPI)	X	X	X	X
Disability (ODI)	X	X	X	X
General Health (SF-12)	X	X	X	X
Chair Stand	X	X		X
10 Meter Walk	X	X		X
Functional Mobility (TUG)	X	X		X
Physical Activity Counts (Accelerometer)		X	X	X
Health Services Utilization				
Physical Therapy Services	X	X	X	X
Narcotic Use	X	X	X	X
Re-hospitalization		X	X	X
Additional Surgery		X	X	X