Return to Physical Activity at 24 to 48 Months Status Post Total Knee Replacement: A Needs Assessment Study

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Return to Physical Activity at 24 to 48 Months Status Post Total Knee Replacement: A Needs Assessment Study (TKPANA)

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The primary aim of this investigation was to determine the physical functioning and physical activity levels of patients 2 to 4 years status-post total knee replacement. Subjects were recruited from a pool of 248 subjects who were recent study participants in an RCT at the University of Pittsburgh's Physical Therapy Clinical and Translational Research Center (PT-CTRC). Consenting subjects completed two self-report physical functioning questionnaires including the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Short Form 36 (SF-36). They also completed performance based physical function outcomes measures including Single-Leg Stance, Repeated Chair Stand Test, Stair Climb Test (STTotal-11), 4 Meter Walk, 40 Meter Walk and 6-minute Walk Test (6MWT). Subjects then completed an interview with questions developed from the Health Belief Model. Physical activity was measured via the SenseWear Armband (SWA) for seven consecutive days during "waking hours."

The results of the needs assessment were mixed. Physical functioning declined for six of seven performance based tests, with four of the tests showing a statistically significant decline in status. The stair climb test was the only physical functioning test in which subjects show an improvement, which was statistically insignificant.

Physical activity compliance for the group was higher than previous studies and higher than physical activity compliance for the general population when compared to Healthy People 2020 Midcourse Review. Despite this rather impressive result, two thirds of the group did not

meet physical activity guidelines and the lower quartile averaged only 3 mins of moderate physical activity per day. This was the result from a cohort of subjects which had a 21% higher compliance with PA guidelines than the full group of study participants from the benchmark study at the 6 month follow-up. Results also suggested that physical functioning and physical activity are not correlated statistically, with the exception of a weak correlation between physical activity and the 6 minute walk test and WOMAC scores. The clinical relevance of this study is that it justifies an extended late stage (9 to 12 month) intervention to promote physical activity following total knee replacement.

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Preface

This research was partially funded through a Patient-Centered Outcome Research Institute (PCORI) Award (CER-1310-06994). The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The views in this article are solely the responsibility of the authors and do not necessarily represent the views of the PCORI, its Board of Governors, or Methodology Committee.

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1.0 Statement of Problem of Practice

1.1 Overview of Physical Activity Guidelines

The Physical Activity Guidelines Advisory Committee (PAGAC) issued a 650 page summary report that ultimately resulted in the release of the 2008 Physical Activity Guidelines for Americans. To achieve substantial health benefits, the committee advocated for weekly physical activity in the range of 500 to 1000 MET-minutes. MET-minutes however are not public health friendly units of measure for physical activity. This was then translated to 150 to 300 minutes of moderate intensity physical activity per week. While this may seem daunting to an individual who has been largely sedentary, it translates to 30 minutes of moderate intensity physical activity five times per week. For those that cannot, or will not, tolerate 30 consecutive minutes of moderate intensity PA, it has been further clarified that the PA can be distributed into three bouts of ten minutes per day while maintaining largely the same health benefits. Physical activity guideline recommendations are nearly identical across the globe. This includes the Canadian Physical Activity Guidelines, the European Physical Activity Guidelines, the Australian physical activity guidelines and those from the World Health Organization.

Despite the known benefits of compliance with physical activity guidelines, including a positive impact on modifiable risk factors of chronic disease, otherwise referred to in the literature as non-communicable disease, physical activity compliance is dismal across age groups, gender, ethnicity and disability status. The persistent and unchanging epidemic of health complications associated with a sedentary lifestyle constitute a national public health crisis. Heart disease alone

accounts for 1 in 4 deaths annually (CDC 2015). The Million Hearts website, published by the department of Health and Human Services (HHS), reports that when you broaden the scope of inquiry to include heart disease and stroke it encompasses 1 in 3 deaths annually. This accounts for 1 in 6 health care dollars spent and $316.6 billion in health care costs and lost productivity.

1.2 Overview of Physical Activity Compliance

According to the Healthy People 2020 Midcourse Review (2016), only 21.3% of American adults meet the minimum PA recommendations of 150 minutes of moderate intensity aerobic physical activity per week. There is an ongoing national health epidemic of chronic disease rooted in non-compliance with PA guidelines. Generally, PA tends to decline even further in end-stage osteoarthritis due to pain, swelling and immobility. Arthritis and associated physical inactivity can result from, or result in, obesity and uncontrolled modifiable risk factors of chronic disease. Total joint replacement (TJR) can allow patients to resume PA levels previously compromised by pain, swelling and associated symptoms of arthritis. However, research has repeatedly shown that PA levels remain unchanged or decrease even further following TJR. There has even been a call to implement a Physical Activity Vital Sign (PAVS) in addition to the traditional vital signs of heart rate, blood pressure, respiration, body temperature and more recently, pain (Sallis et al. 2016).

One constraint associated with the traditional care model in TJR is that access to patients / clients is limited due to them typically being discharged from care with essentially no intervention from health care providers between six and twelve months, with a one year follow-up with the surgeon prior to being fully released. Another constraint would be the lack of funds to cover

interventions within these non-traditional time frames. In traditional reimbursement scenarios, patients would have likely exhausted their benefits through payments caps and bundling. Fee for service would be an option, but would eliminate many, if not most, candidates from middle and lower socioeconomic status. The struggle to find a finding source for what has traditionally been classified as a preventative measure is not a new challenge.

The primary aim of this investigation will be to establish whether or not patients status-post total knee replacement are compliant with physical activity as per the Physical Activity Guidelines for Americans and to establish through quantitative and qualitative measures, whether a need exists for a continuum of care beyond traditional sub-acute care. This may require a fundamental shift in the perception of the role of physical therapists, and other health care practitioners, through the continuum of care across the lifespan. It may help to eliminate the concept of "discharge" of a patient from our collective vocabulary. It should be framed as a transition within a continuum of care versus a discontinuation of services. This shift may require a creative re-allocation of resources or budgeting for longitudinal interventions within a bundled care environment. Communication would need to be consistent across disciplines emphasizing the importance of the interdisciplinary team in helping patients to maintain their independence and quality of life.

While the problem area identifies physical activity compliance within the healthy adult population, my problem of practice deals with a specific sub-population of adults: historically poor physical activity compliance of individuals who are post-total joint replacement. This population is unique in that they had a problem, specifically end-stage osteoarthritis, which significantly impacted their functional mobility through pain, compromised gait and generally declining functional status. Total joint replacement surgery relieves the pain, restores mobility and

functional independence. However, 94 to 98% of patients never fully utilize the restored capacity due to maintaining pre-operative sedentary behavior (Harding et al. 2014). The goal of this inquiry is to maximize compliance with physical activity guidelines post total joint replacement to allow patients to regain and maintain their independence and quality of life across the lifespan.

2.0 Literature Review

2.1 Self-Report Physical Activity and Physical Functioning Questionnaires

Assessing PA levels via Self-Reported Physical Activity Questionnaires (SRPAQ) is challenging within the general adult population due to issues with recall and over reporting of activity levels (Silsbury 2015). These challenges are compounded due to lack of validation and reliability testing within populations suffering from chronic disease including osteoarthritis and subsequent TJR. However, they are commonly utilized within the general population due to being the most practical and economical outcome measures. Silsbury (2015) states that the gold standards for assessing PA are accelerometers and Doubly Labelled Water (DLW). DLW utilizes isotopes of hydrogen and oxygen in water given to subjects, which can then be used to determine metabolism through an equation of water and CO2 metabolized during activity. Cost is the limiting factor in use of DLW as it costs $1500 per participant, which precludes it's use by most investigators.

Pros associated with the use of SRPAQ's within the general population are that they are inexpensive, easy to administer and widely accepted as the most universal physical activity measure in clinical settings. However, universal drawbacks associated with the use of SRPAQ's include reliability, validity, variable burden, poor recall and overestimation of activity. Addressing SRPAQ's in assessing PA post total knee arthroplasty, Bolszak et al. (2014) adds poor recall and reporting bias to the list of cons. In fact, they go as far as to say that "no physical activity questionnaire has proven to be valid and reproducible in this population."

Naal et al. (2009) evaluated the validity of several SRPAQ's including the University of California, Los Angeles (UCLA) scale, the Tegner score and the Activity Rating Scale (ARS) as compared to the International Physical Activity Questionnaire (IPAQ). While they initially endorse the UCLA as exhibiting excellent reliability and as being the most appropriate SRPAQ of the three assessed for use with total joint patients, they go on to acknowledge the weakness of the UCLA is that it does not assess frequency, intensity and duration of PA. This is a key distinction, as it significantly compromises the usefulness of the results of the UCLA as it relates to whether an individual actually meets or exceeds current PA guidelines or not.

Similarly, Silsbury et al. (2015) published a systematic review of ten SRPAQ's in healthy adult populations. These included the four versions of the IPAQ, Recent Physical Activity Questionnaire (RPAQ), PA Assessment Tool (PAAT), Six-point Scale, Human Activity Profile (HAP), Single-item measure and the G-S 1 week recall. While still advocating for measuring energy expenditure via the gold standards of accelerometers or DLW, they identified the IPAQ short form 'past 7 days' (IPAQ-S7S) as the most appropriate SRPAQ for clinical and research use due to world-wide use, excellent test-retest reliability and moderate validity with accelerometers and DLW. The shortcoming of the IPAQ-S7S, which the authors fail to mention is that it only assesses frequency and duration of PA. Due to the IPAQ-S7S's inability to discriminate intensity, there is no way to confirm level of health benefit being provided. There could be a substantial health benefit, some health benefit or no health benefit at all. Without a measure for intensity, there is no way to know. These conclusions corroborate the prior systematic review findings of van Poppel et al. (2010) where they examined 23 SRPAQ's and concluded that the IPAQ was the most widely validated and most often utilized PA measure. However, in the end, they concluded that no decision could be made regarding the best PA questionnaire.

A short-coming of many of the SRPAQ's discussed above is that they do not have the sensitivity to discriminate between light and moderate activity. Several studies, including Wagenmakers et al. (2008), have shown that patients following total joint replacement tend to spend more minutes of PA in light versus moderate or vigorous activity. Therefore, an effective SRPAQ needs to be able to discriminate between light and moderate levels of physical activity. A second possible short-coming of SRPAQ's identified by Altschuler el al. (2009) was that respondents frequently misinterpreted intensity as emotional or psychological versus physical intensity.

Unfortunately, the net result of the studies discussed above examining the appropriateness, reliability and validity of SRPAQ's is that there is no consensus for use of a universally adopted SRPAQ in the TJR population. Each have their own drawbacks in accurately measuring PA frequency, intensity and duration. Kennedy et al (2008), quoting Ethgen et al (2004), stated that the Medical Outcomes Study 36-item Short Form Health Survey Questionnaire (SF-36) and the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) are most frequently cited in the total joint replacement literature. The collective findings of this portion of the literature review are what likely informed Piva et al's (2017) protocol including the SF-36 and WOMAC in conjunction with accelerometer data.

2.2 Accelerometers

Accelerometers have emerged as the measure of choice for research applications where the size of the population is reasonable for their implementation. Accelerometers are more accurate than SRPAQs, while being significantly less expensive and less of a burden to patients than the

"gold standard" of DLW. They have the capacity to accurately capture PA while also discriminating between light, moderate and vigorous activity. There was, however, significant variation in how they were utilized in the literature. Challenges existed related to balancing patient burden and accuracy of estimates of PA. Twenty-four-hour wear time would capture all relevant PA data, but in the process, would maximize patient burden and potentially affect compliance. To lessen patient burden and maximize compliance, the alternative is to decrease wear time. In order to minimize inaccuracies, a consensus needed to be reached as to the optimal wear time for minimal patient burden and optimized accuracy of the estimates of PA throughout the day. The second challenge that needed addressed was to identify the appropriate time frame for sufficient recovery post TJR to accurately capture estimates of return to PA.

Guidelines also need to be established and standardized for use of accelerometry in measuring PA compliance. From a purely practical standpoint, the units of measure of the tool being used needs to correlate to the established PA guidelines, which for establishing health-enhancing benefits of PA is measured currently in minutes per week. This is a drawback of many of the SRPAQ's surveyed. It is, however, an additional benefit of using accelerometers for data collection. Therefore, Naal et al. (2010) concluded that accelerometers are the most appropriate objective measure of PA in the TJR population.

2.3 Accelerometer Wear Time

Investigators also need to establish a consensus for how long accelerometers need to be worn per day to accurately estimate PA. As was mentioned previously, wearing sensors 24 hours per day would be an undue burden on participants and may compromise compliance. Two studies

(Bolszak et al. 2014 and Harding et al. 2014) chose 10 hours per day for accelerometer wear time. While decreasing participant burden, the 10-hour wear time also unnecessarily compromised results. In fact Herman et al. (2014) found that 10-hour wear time could lead to 42% less data collected versus 14-hour wear time. Wear time of 14 hours is also referred to in the literature as "waking hours." While not mentioned specifically in any study, this could be attributed in part to compliance only during work hours, which could primarily be sedentary. Active hours following work would potentially not be accounted for with this scenario. Herman et al. (2014) advocates for 14-hour wear time for this improved accuracy of estimating total PA. Further supporting the 14-hour wear time was data from Almeida et al. (2016) which indicated that a 14-hour wear time only had a 0% to 5% variance versus a 24-hour wear time. It can then be concluded that adopting a 14-hour wear time or wear time during waking hours for collection of accelerometer data would minimize patient burden and optimize the accuracy of collected PA data.

2.4 Timing of Intervention

A second guideline that needs to be established is when to gather data, and ultimately, when to target interventions to improve outcomes. The timeframe must allow for sufficient healing to occur post-TJA, while at the same time not allowing the patient to unnecessarily settle into a sedentary pattern. While several studies (Arnold et al. 2016; Harding et al. 2014 & Vissers et al. 2012) have assessed return to PA 3 to 6 months post-TJA, ultimately, they all concluded that 6 months was insufficient time for post-operative improvements in range of motion, strength and functional mobility to be translated into PA. Despite patients reporting decreased complaints of pain, decreased reliance upon assistive devices, and improved functional mobility, investigators

felt as though patients were unlikely to be adequately healed at 6 months to begin advocating for progression toward meeting PA guidelines. They reported missing patient's peak physical functioning potential and acknowledged that best results may occur at 1 year post-operatively.

Kennedy et al. (2008) asserts that improvements plateau by six months following TKR and by one year postoperatively patients are considered to be beyond the recovery phase of the operation. This author agrees when only considering physical function testing utilized in this study. However, this traditional standard of care has not shown to translate to compliance with PA guidelines at recommended levels post-operatively. The collection of these recommendations for further study is what informed this author's hypothesis that 9 to 12 months post-operatively could be an ideal time to target patient compliance with PA guidelines with extended late stage intervention.

2.5 Patient Expectations following TJR

A study by Jones et al. (2012) examining the difference between actual and expected activity following TKR was enlightening. It has been established that compliance with physical activity guidelines in the general population is approximately 20%. Patients status-post TKR exhibit even lower compliance levels with PA recommendations across their sub-population. Despite this data, patients undergoing TKR have very high, and likely unrealistic expectations, for activity post-surgery. In this study, they calculated that meeting PA guidelines of walking 150 minutes at 4 mph equates to walking 10 miles per week. Patients over estimated their expected post-surgical activity at the 1 year follow-up by 12.5 MET-hours per week or 14 miles per week. That translates to over-estimating their activity by 140% of PA Guidelines for Americans. This

calls into question how realistic their pre-surgical goals were, as well as their understanding of the PA guidelines.

To be able to effectively address PA as a modifiable health risk factor, these inaccurate perceptions and expectations need to be addressed proactively (Jones et al. 2012). Education both pre-operatively, post-operatively as well as at the 6 and 12-month follow-up appointment needs to provide guidance toward establishing goals that are Specific, Measurable, Achievable, Realistic and Time-based (SMART). Arnold, Walters and Ferrar (2016) state that, in and of themselves, surgery and associated reductions in pain are insufficient in facilitating return to PA post total joint implantation. There needs to be a facilitated change in behavior. Physical therapists are well positioned, but underutilized, to serve in this role as facilitator within the healthcare community. Due to a variety of factors, including restrictions imposed by insurance providers, fee for service intervention and the traditional post-operative medical model, the true benefits of TJR are never fully realized.

2.6 Theoretical Framework

The theoretical approach that this author would advocate for rooting this intervention plan in would be the Health Belief Model. The key constructs of the Health Belief Model are Perceived Susceptibility, Perceived Severity, Perceived Benefits and Perceived Barriers as well as extension constructs of Cues to Action and Self-Efficacy. Perceived Susceptibility is the belief that an individual may acquire a disease or enter a harmful state as a result of a behavior. Intervention strategies include highlighting negative consequences and personalizing outcomes to establish an accurate perception of risk. Perceived Severity is the belief in the seriousness or extent of harm

from acquiring a disease or entering a harmful state as a result of a behavior. Similar to Perceived Susceptibility, intervention strategies include highlighting negative consequences, but also recommends establishing a realistic perception of consequences. Perceived Benefits is the belief in the advantages of reducing the risk for acquiring a disease or entering a harmful state as a result of enacting a health behavior. Intervention strategies include specifying the health behavior and reinforcing the potential benefits of compliance. Perceived Barriers is the belief regarding the difficulty or actual and imagined costs of adopting a new behavior. Intervention strategies include establishing problem solving and decision making strategies that emphasize minimal costs and correcting misperceptions. Individuals must believe that the benefits outweigh the risks. The first extension construct, Cues to Action, is the collection of internal and external prompts that result in the adoption of a new health behavior. Intervention strategies include use of external prompts as a reminder system to encourage ongoing compliance with the health behavior. The second extension construct, Self-Efficacy, was first described by Bandura (1977) as the individual's confidence to acquire a new health behavior. Intervention strategies include modeling, incremental goal setting and attributing setbacks to external versus individual failure (Orji et al. 2012). Important considerations are that progress may not be linear, but potentially cyclical. Re-evaluation of benefits, barriers, cues to action and self-efficacy may be required to progress from adoption to long-term implementation of the modified health behavior. This emphasizes the importance ongoing assessment of progress toward mutually agreed upon and appropriate SMART outcome goals.

2.7 Traditional Post-TJR Care Plan

Due to a variety of reasons, prevention and wellness initiatives have not traditionally been formally addressed as a matter of course during physical therapy interventions. While the groundwork could be set for resuming PA at recommended levels during "prehab", pre-operative and post-operative interventions, research has repeatedly shown that the optimal time frame to resume PA is one year post-operatively. This is well beyond the time frame patients are discharged from physical therapy in traditional care settings. This traditional course of 1 to 2-day hospitalization, 2 to 3 weeks of home care or rehabilitation and 2 to 3 months of outpatient care needs to be re-imagined. If a peak of physical functioning is in fact achieved at 1 year, there needs to be a process in place to address PA compliance 9 to 12 months post-operatively. This is a time frame within traditional recovery models post-TJR where individuals have no contact with health care professionals. They have likely been discharged from physical therapy for up to 6 months and have not had an appointment with their surgeon for 3 months. While intervention at this point in recovery is non-traditional within the context of the current medical model, it is reasonable, justifiable and necessary nonetheless. Remembering that participation in PA at recommended levels manages co-morbidities associated with chronic disease and sedentary behavior amplifies these same risk factors, the compliance level relevant to PA following TJR can no longer be ignored as a contributor to the public health crisis associated with inactivity.

2.8 Public Policy Framework

This concept of integrating prevention, wellness and innovative research is not unprecedented in health care strategies of the American Physical Therapy Association (APTA) or the National Institutes of Health (NIH). The APTA publication "Transforming Health Care: The public policy priorities of the American Physical Therapy Association 2017 – 2018" outlines six important issues facing the Physical Therapy profession currently. Three of those initiatives can be directly or indirectly impacted by addressing physical activity compliance following TJR. They include the following: addressing public health epidemics facing Americans, maximizing potential for success through new models of care implemented by non-physician providers and advancing research and clinical innovation. The NIH's "Research Plan on Rehabilitation: Moving the Field Forward" (2016) aligns itself with very similar objectives. It cites Peacock et al. (2015) who asserted that health disparities are more likely to be experienced by individuals with disabilities. This highlights the need for clinical and translational research emphasizing lifestyle and wellness interventions to minimize these health disparities through innovative care delivery models at lifespan transitions. This approach would maximize functional outcomes while minimizing the impact of modifiable health behaviors. Specifically, within translational science, the NIH advocates for interventions that are adaptable to individual variability, environment and lifestyle. The type of intervention advocated for by the NIH is tailor made for implementation of the Health Belief Model.

Wagenmakers et al. (2008) encouraged patients to be more active during the post-operative rehabilitation phase. He emphasizes that this is beneficial from an individual perspective due to the correlation between PA and independence as well as from a societal perspective due to the positive impact of PA on an individual's general health. Unfortunately, the body of research over

the past decade indicates that we are failing to increase PA post-operatively. Both Harding et al. (2014) and Kersten et al. (2012) advocate for further research emphasizing strategies and interventions to improve PA and generally encourage a physically active lifestyle following TJR. Kersten et al. (2012) suggests a focus on long terms interventions encouraging a physically active lifestyle post-TJR. While they do not define "long term" interventions, the body of literature would indicate that the gap needs filled between 9 and 12 months post-operatively when patients have little to no contact with medical professionals in the context of traditional post-TJR care. Harding et al. (2014) draw the same conclusion regarding post-operative PA, but framed it through a different lens. They conclude that surgery alone is not likely to facilitate a return to PA at health enhancing levels. A challenge is issued for health care professionals to develop effective strategies to translate improved capacity following TJR to improved outcomes. This would also require challenging the "status quo" of current post-operative treatment protocols. More recently, there was a call by Arnold et al. (2016) to optimize PA intervention design and even calls to implement tele-rehabilitation for the enhancement of aftercare programs (Eichler et al., 2017). This strategy may represent a valuable adjunct intervention to a newly designed protocol or stand-alone follow-up strategy for those who may be geographically isolated.

2.9 Physical Activity Compliance Post-Total Joint Replacement

Informed by the collective body of relevant research, an unacceptably low number of patients are compliant with recommended levels PA as per the guidelines following TJR. This compromises the health and quality of life of patients due to co-morbidities associated with chronic disease. PA is a modifiable risk factor has a health-enhancing benefit that can positively impact

those co-morbidities. Generally, interventions have focused on a time frame when pain, gait dysfunction and immobility were addressed by surgery, but insufficient time had passed for patients to then translate that into compliance with PA as per guideline recommendations.

2.10 Intervention Framework

A study recently published by Piva et al. (2019), entitled Effectiveness of Later-Stage Exercise Programs versus Usual Medical Care on Physical Function and Activity After Total Knee Replacement - A Randomized Control Trial (KTX) became the benchmark framework for this follow-up needs assessment. The primary outcome of the KTX study was self-reported physical functioning assessed via the Western Ontario and McMaster Universities Osteoarthritis Index – Physical Function (WOMAC-PF). The secondary outcome was physical functioning assessed by a battery of performance-based tests. The primary outcome of the WOMAC-PF score did not show the benefit of later-stage exercise in physical therapy clinical settings or community settings. The secondary outcome of performance-based functioning did, however, seem to suggest greater functional improvements were experienced by the physical therapy clinical arm group.

The suggestion was made that a better model might be a 2-stage approach, where individualized physical therapy would be followed by a community based long term exercise group to maximize long-term benefits. This aligns with the recommendations from an earlier study investigating the association of physical functioning and physical activity in women with rheumatoid arthritis which suggested longitudinal studies to determine if improved physical functioning will increase physical activity (Piva, SR. Almeida, GJ. and Wasko, MC., 2010).

Harding et al. (2014) established that total joint replacement surgery alone is unlikely to facilitate a return to PA. Fransen et al. (2017) took it one step further and concluded that a community-based 8-week group exercise program in addition to a standard post-operative protocol did not significantly alter outcomes or PA levels. This author would advocate for a combination of the approaches utilized in these three studies, but with modifications to each informed by the body of literature reviewed above. The later-stage exercise program established by Piva et al. (2019) appears promising for physical functioning outcomes. When considering PA as a primary outcome, an extended late stage intervention implemented at 9 to 12 months post-operatively may facilitate compliance with PA as per guideline recommendations. The addition of a community based component and accountability partners with a common long term goal, such as a 1 mile walk or community bike ride, may further enhance participation levels.

3.0 Methods

3.1 Inquiry Questions

The inquiry questions of the needs assessment are as follows:

1. What is the level of physical activity among individuals 24 to 48-months post- total knee replacement?"

2. What is the level of physical functioning among individuals 24 to 48-months post- total knee replacement?"

3. What are the physical activity and physical functioning needs of individuals 24 to 48-months post- total knee replacement?"

3.2 Setting

The setting for TKPANA was the Physical Therapy Clinical and Translational Research Center (PT-CTRC) at the University of Pittsburgh.

3.3 Participants

A recruitment pool of 248 participants was identified from the KTX study at the University of Pittsburgh's PT-CTRC, which investigated intensive late stage individualized exercise program versus community group-based exercise program following TKR. Following screening for

exclusion criteria, recruitment letters were sent to a pool of 167 subjects. Study participants were from western Pennsylvania, primarily from the urban and suburban regions surrounding Pittsburgh, PA. For the benchmark study, most participants were identified by their knee surgeon. Eighteen knee surgeons from 7 offices located around Allegheny County informed their patients about the study through letters and through face-to-face office encounters. Alternative recruitment methods included public media and research registries used to boost recruitment.

The recruitment group consisted of subjects from the parent study who were 24 to 48 months post-operative at the time of data collection for the needs assessment. Inclusion criteria for the KTX study were 60 years or older, 2 to 4 months status post primary unilateral TKR, had medical clearance from the knee surgeon to participate in the study and were English speakers. Exclusion criteria for the KTX study were contraindications to exercise, neuromuscular disorders of the lower extremities, inability to independently walk 50 meters, regular participation in supervised exercise, terminal illness, intent to undergo another TKR or unavailability during the study period.

Additional exclusionary criteria for consideration for this needs assessment included not having a complete data set from the KTX study at baseline, 3 months and 6 months post-operatively as well as subsequent ipsilateral or contralateral orthopedic surgical intervention. Recruitment letters were sent out 50 at a time to the 167 KTX subjects and then second batch of 50 letters were sent until the target recruitment total of 19 to 22 subjects was reached to establish statistical significance. Enrollment was on a first come, first serve basis.

3.4 Design

The study design was a needs assessment to understand the level of physical activity and physical functioning of individuals 24 to 48-months post- total knee replacement including supports and barriers of physical activity and physical functioning.

3.5 Instrumentation

Measures include self-reported physical functioning, performance based physical function, physical activity measures via accelerometer and qualitative assessment of supports and barriers for physical functioning and physical activity.

3.5.1 Self-reported physical functioning questionnaires:

3.5.1.1 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The WOMAC is a 24 item self-report health questionnaire for patients with hip and / or knee osteoarthritis including 3 sub-scales for pain (5 items), stiffness (2 items) and physical functioning (17 items). Time to administer is approximately 12 minutes along with an estimated 5 to 10 minutes to score. High scores on the WOMAC indicate greater symptoms and a decline in physical functioning while lower scores indicate less symptoms and improved physical functioning. (See Appendix E for the WOMAC questionnaire).

3.5.1.2 Short Form – 36 (SF-36)

The SF-36 is a 36 item self-report health questionnaire assessing quality of life measures. These quality of life measures include eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. Scores range from 0 to 100 where higher scores indicate a more favorable health state. (See Appendix F for the SF-36)

3.5.2 Performance based physical function outcomes measures include the following:

3.5.2.1 Single-Leg Balance (SLB)

Standard balance tests have somewhat limited usefulness as physical function outcomes measures due to originally being intended to discriminate between poor and acceptable balance in elderly individuals versus being utilized to discriminate between good and excellent balance in higher functioning populations. Clinically, SLB is a pass / fail only test. Despite these drawbacks, the single-leg stance was found to be somewhat reliable and able to discriminate reasonably between functional levels (Curb et al. 2006). For the purposes of this inquiry, SLB was evaluated as the average of three trials with a 60 second maximum cut time. (See Appendix H for Single – Leg Stance protocol and norms)

3.5.2.2 Repeated Chair Stand

Subjects are seated and asked to stand to a full upright position five times followed by returning to a seated position without assistance while being timed. Curb et al. (2006)

has demonstrated reliability of .80 for five chair stands along with good discrimination. (See Appendix I for Chair → Stand protocol and data)

3.5.2.3 Stair Climb Test (STTotal-11)

Individuals are timed (in seconds) via an 11-step stair ascent / descent test (STTotal-11) with rail on preferred side. Almeida et al. (2010) showed that the STTotal-11 has good inter-rater reliability as well as validity in the TKA population. (See Appendix J for Stair Climb protocol and data)

3.5.2.4 4 Meter Walk Test (self-selected pace)

Participants self-selected gait speed is measured in meters / second over a 4 meter pathway. A gait speed of less than 1 meter / second indicates the need for intervention to reduce the risk of falls. Dependent upon resources, gait speed can be measured with cones 4 meters apart along with a stopwatch or with auto triggering infrared beams. (See Appendix K for Gait Speed protocol and data)

3.5.2.5 40 Meter Walk Test (fast paced)

This is a test of short distance walking activity. It's described as a fast-paced walking test that is timed over 4x10m (33ft) for a total 40m (132ft). This is a direct measure of the ability to walk quickly over short distances. (See Appendix L for 40 Meter Walk Test protocol and data)

3.5.2.6 6-Minute Walk Test (6MWT)

The 6MWT was designed to assess chronic respiratory disease and heart failure patient's tolerance to exercise. Testing is self-paced and participants may rest as needed. It has been utilized in diverse populations including those status post hip and knee arthroplasty. Positive correlations have been established between the 6MWT and peak VO2 as well as the SF-36. (See Appendix M for 6MWT protocol and data)

3.5.3 Physical Activity Monitoring via SenseWear Armband (SWA)

Physical activity was measured via accelerometer, the SWA, in minutes per day as is the standard outlined in Physical Activity Guidelines for Americans. The wear time of 10 hours per day, versus 14 hours per day or "waking hours", has shown to capture 42% less data and a significantly less accurate picture of overall physical activity compliance (Herrmann et al. 2014) while only having 0% to 5% variation from 24 hour wear time (Almeida et al. 2016). Expectations regarding SWA wear time were communicated as "waking hours" with the anticipation that wear time would be maximized and that 14 hours per day could be achieved by all subjects. To balance patient burden with the accuracy of PA data, the minimum wear time was established as 12 hours per day.

3.5.4 Health Belief Model (HBM) Questionnaire (Modified for PA from Champion's HBM)

Question:	Probe:
1. What are the consequences of your current level of physical activity?	**A. What are some consequences of adopting a sedentary lifestyle?** **B. Are you able to <u>maintain</u> your current health status?** **C. Are you able to <u>improve</u> your current health status**
2. Specifically, are there any potential negative impacts (consequences) of inactivity (physical activity and physical functioning) on your life, as well as on the lives of other important people in your life? (partner, children, parents, peers, colleagues)	**A. How likely are you to suffer from a chronic disease as a result of adopting a sedentary lifestyle?** **B. How serious are the consequences? 0 to 10?** **C. What is the severity of their impact? 0 to 10?**
3. What are the benefits of physical activity for you?	**A. Do you have any modifiable health risk factors currently? Explain.** **B. What would you like to continue doing?** **C. What would you like to eventually be able to do?**
4. What are the barriers to physical activity for you?	**A. What would be the "cost" of being physically active for 30 minutes per day?** **B. Do the benefits of being physically active outweigh the risks / costs?**
5. How can you increase your self-awareness and support your need to be physically active?	**A. What external cues might you utilize to encourage yourself to be physically active at recommended levels?** **B. Can you identify an "accountability partner" for mutual encouragement?**
6. How confident are you on a scale of 0 to 100 that you can be more physically active?	**A. How can you increase your physical activity?**

3.6 Data collection

Data will be stored on a single computer in possession of the Principle Investigator. Both the computer and file will be password protected with unique passwords. Personal identifying information will be stored in a separate password protected file.

Table 3.1. TKPANA Timeline

Study Introduction	10 Minutes
Signing of Informed Consent	5 Minutes
WOMAC (Electronic)	10 Minutes
Stair Climb Test	5 Minutes
Sit to Stand (x 5 repetitions)	5 Minutes
Single Leg Stance	5 Minutes
6 Minute Walk Test	10 Minutes
Gait Speed	5 Minutes
Distribution of SenseWear Armband (SWA)	10 Minutes
Health Belief Model Questionnaire	15 Minutes
Rest Time (as needed)	10 Minutes
Total Session #1 Time:	**90 Minutes**
Total Session #2 Time – Collection of SWA	**15 Minutes**

3.7 Data analysis

Descriptive statistics and baseline characteristics for the group were reported. Data analysis was conducted for self-reported physical functioning, performance based physical functioning and physical activity including a comparison between the 6-month follow-up data for those with a 24 to 48 month follow-up as compared to those without a 24 to 48 month follow-up. An analysis was also conducted with 6-month data as compared to newly collected 24 to 48-month post-op data within the needs assessment group.

Physical functioning and physical activity underwent statistical analysis for mean, median, quartile ranges, minimum and maximum values. These data were graphically represented by box plots. They were also analyzed for change from 6 months to 24 months via the Wilcoxon signed rank test (a non-parametric equivalent of the paired t test). Correlation coefficients for change in self-report and performance based physical functioning at 6 months and 2 to 4 years were analyzed via Spearman's Rho.

The Health Belief Model Questionnaires were transcribed and analyzed for trends and themes across the constructs including Perceived Susceptibility, Perceived Severity, Perceived Benefits and Perceived Barriers as well as extension constructs of Cues to Action and Self-Efficacy as they relate to physical activity compliance following total knee replacement.

4.0 Results / Outcomes

4.1 Descriptive and Baseline Characteristics

The study's participants consisted of twenty-two subjects of which sixteen were female and six were male. Twenty subjects identified as White and two identified as Black. The TKPANA study had a higher percentage of females (12%) and white participants (8%) as compared to the KTX study. Eight subjects had a high school diploma and fourteen subjects reported some college education (Table 4.1). The participant's ages ranged from 62 years old to 81 years old with a mean age of 69.5 years old. BMI and number of co-morbidities were comparable across KTX and TKPANA participants (Table 4.2). The subjects averaged 3.38 years from surgery to TKPANA follow-up assessment (Figure 4.1).

Table 4.1. TKPANA Descriptive Statistics

	Has 2 year FU		No 2 year FU	
	N	Col %	N	Col %
Gender				
Male	6	27.3	89	39.4
Female	16	72.7	137	60.6
Race				
White	20	90.9	186	82.3
Black	2	9.1	39	17.7
American Indian or Alaskan Native	0	0	1	.004
School				
Missing	0	0.0	1	0.4
High School	8	36.4	69	30.5
Some College	14	63.6	156	69.0

Table 4.2. TKPANA Baseline Characteristics

Group	N	Label	Minimum	Median	Quartile Range	Mean	Std Dev	Maximum
Has 2 year FU	**22**	**Age**	62.00	68.00	6.00	69.50	5.11	81.00
		BMI	19.27	27.59	4.54	28.42	6.32	44.32
		Number of Comorbidities	1.00	4.00	2.00	4.32	2.10	10.00
No 2 year FU	**226**	**Age**	60.00	69.00	9.00	69.87	6.71	87.00
		BMI	18.83	30.91	7.55	31.35	5.53	52.41
		Number of Comorbidities	1.00	4.00	2.00	4.38	1.83	11.00

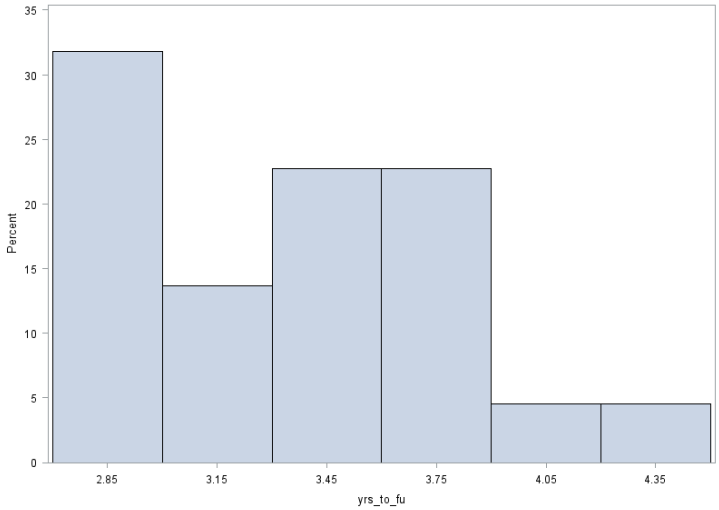

Figure 4.1. Histogram – Time in years from surgery to 2-year assessment

4.2 Physical Activity Results

Physical activity results for the 22 TKPANA participants, via the SenseWear Armband data, showed that the median number of minutes spent in moderate to vigorous PA per day for the group was 17 minutes per day at the 24 to 48 month follow-up. The data set for the group was positively skewed with a mean of 31.82 minutes, due in large part to an outlier who averaged 200 minutes (3 hours and 20 minutes) of moderate to vigorous PA per day (Figure 4.2). The US PA Guidelines of 30 minutes 5 times or more per week were met by 7 of 22 subjects (31.8%). When analyzed by the metric of 150 min / week, 10 of 22 subjects met the guidelines. At the same time, the 7 least active subjects within the group averaged of less than two minutes of moderate to vigorous PA per day. In fact, the mode, representing the data on moderate to vigorous PA was 0.00 minutes per day. At the 6-month follow-up of the KTX study (9 months post-operatively),

31.8% of the TKPANA subjects met the PA Guidelines. As a comparison, 26.2% of KTX subjects who did not participate in TKPANA met the PA Guidelines (Table 4.4).

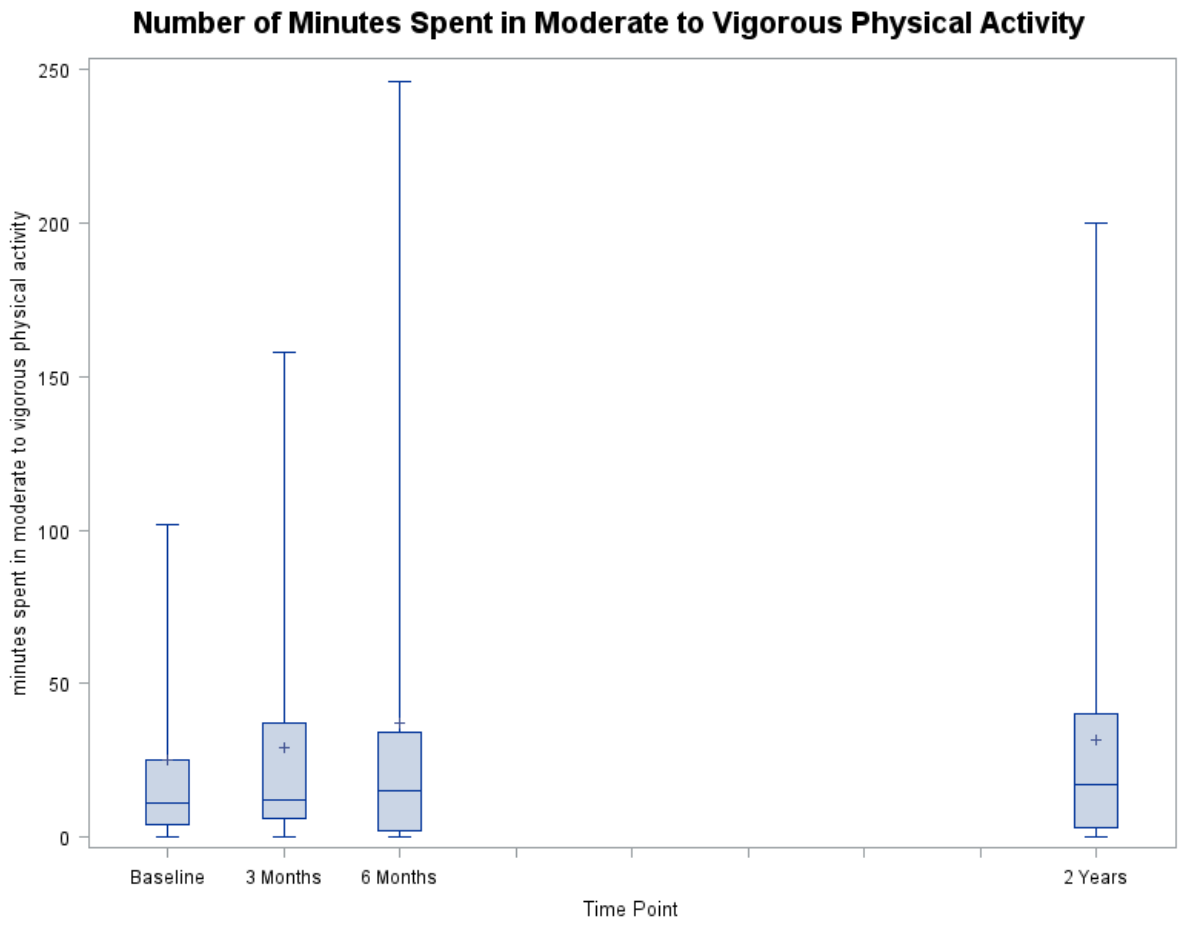

Figure 4.2. Minutes spent in moderate to vigorous physical activity

The box plot for Figure 4.2 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

Table 4.3. Comparison of Number of Minutes Spent in Moderate to Vigorous Physical Activity at 6 month and 2 year follow-up

Analysis Variable: minutes spent in moderate to vigorous physical activity							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
6 Months	**22**	0.00	2.00	15.00	37.00	34.00	246.00
2 Years	**22**	0.00	3.00	17.00	31.82	40.00	200.00

Table 4.4. Number of Participants Meeting Guidelines of 150 minutes / week of Moderate to Vigorous PA

Has 2 Year Follow-up (TKPANA)				
	Baseline	**3 Months**	**6 Months**	**2 Years**
No	14 63.64%	14 66.67%	15 68.18%	12 54.55%
Yes	8 36.36%	7 33.33%	7 31.82%	10 45.45%
Total	22	21	22	22

Table 4.4 (continued)

No 2 Year Follow-up (KTX)				
	Baseline	**3 Months**	**6 Months**	**2 Years**
No	151 69.91%	128 66.32%	135 73.77%	*** ***
Yes	65 30.09%	65 33.68%	48 26.23%	*** ***
Total	216	193	183	***

4.3 Physical Functioning Results

Analysis of performance based physical functioning, was analyzed via the Wilcoxon signed rank test as a change from 6 month follow-up (9 months post-operative) to 2 – 4 year follow-up (Table 4.5). The Single leg balance (surgical leg) (Figure 4.3), Repeated Chair Stand, 4-meter walk (self-selected pace) (Figure 4.5), 40-meter walk (fast paced) (Figure 4.6) and 6-minute walk test (endurance test) (Figure 4.7) all demonstrated a decline in performance as compared to the KTX 6-month follow-up appointment (9 months post-operative). Results were statistically insignificant ($p > .05$) for Single leg balance (surgical leg) and Repeated Chair Stand. Single leg balance (non-surgical leg) exhibited a statistically significant change of -2.59 seconds ($p = .01$). The Stair Climb test was the only performance based physical functioning test that improved from the 6-month follow-up to the 24 to 48-month assessment of the TKPANA study. However, the improvement was neither statistically significant ($p=.07$) (Figure 4.4) nor clinically relevant. All

gait speed tests demonstrated statistically significant decline from 6 months to 2 years including the 4-meter walk test ($p<0.0001$), 40-meter walk test ($p=0.004$) and 6-minute walk ($p=0.01$)(Table 4.5). Calculations for gait speed in the 4-meter walk test across the 22 with 2 year follow-up resulted in a mean of 1.11 meters per seconds, a median of 1.09 meters per second and a standard deviation of .22.

As it relates to changes in performance based physical functioning in Table 4.5, a positive change for minutes spent in PA, SLB, 6MWT and a negative change for repeated chair stands, stair climb, 4 meter walk test and 40 meter walk test indicate an improvement in status. Conversely, a negative change for minutes spent in PA, SLB, 6MWT and a positive change for repeated chair stands, stair climb, 4 meter walk test and 40 meter walk test indicate a decline in status. On the WOMAC, a negative change indicates an improvement in status, while a positive change indicates a decline in status as it relates to pain, stiffness and functional limitations. On the SF-36 a score of 0 is equivalent to maximum disability and a score of 100 is equivalent to no disability. Therefore a negative change indicates a decline in status, while a positive change indicates an improvement in status.

Table 4.5. Performance Based Physical Functioning Comparison

Compare 6 months to 2 years for the 22 with 2 year follow up

Values in table are change from 6 months to two years (2 year value - 6 month value)

p-values coming from the Wilcoxon signed rank test (a non-parametric equivalent of the paired t-test)

	Median	IQR	minimum	maximum	p-value
Minutes spent in moderate to vigorous physical activity	0.00	18.00	-139.00	79.00	0.75
SLB surgical leg (seconds)	0.00	4.38	-31.76	17.13	0.77
SLB non-surgical leg (seconds)	-2.59	9.07	-31.47	16.73	0.01
Repeated Chair Stands (seconds)	-0.16	2.89	-3.73	4.67	0.89
Stair Climb	-0.91	1.92	-7.65	9.31	0.07
Time to walk 4 meters	0.56	1.02	-0.44	1.95	<0.0001
Time to walk 40 meters	1.50	2.24	-3.99	9.93	0.004
6-minute walk test	-35.89	63.70	-91.66	58.96	0.01
WOMAC Physical function	0.50	6.00	-16.00	11.00	0.86
SF-36 Physical function t-score	-2.50	12.00	-16.00	20.00	0.14

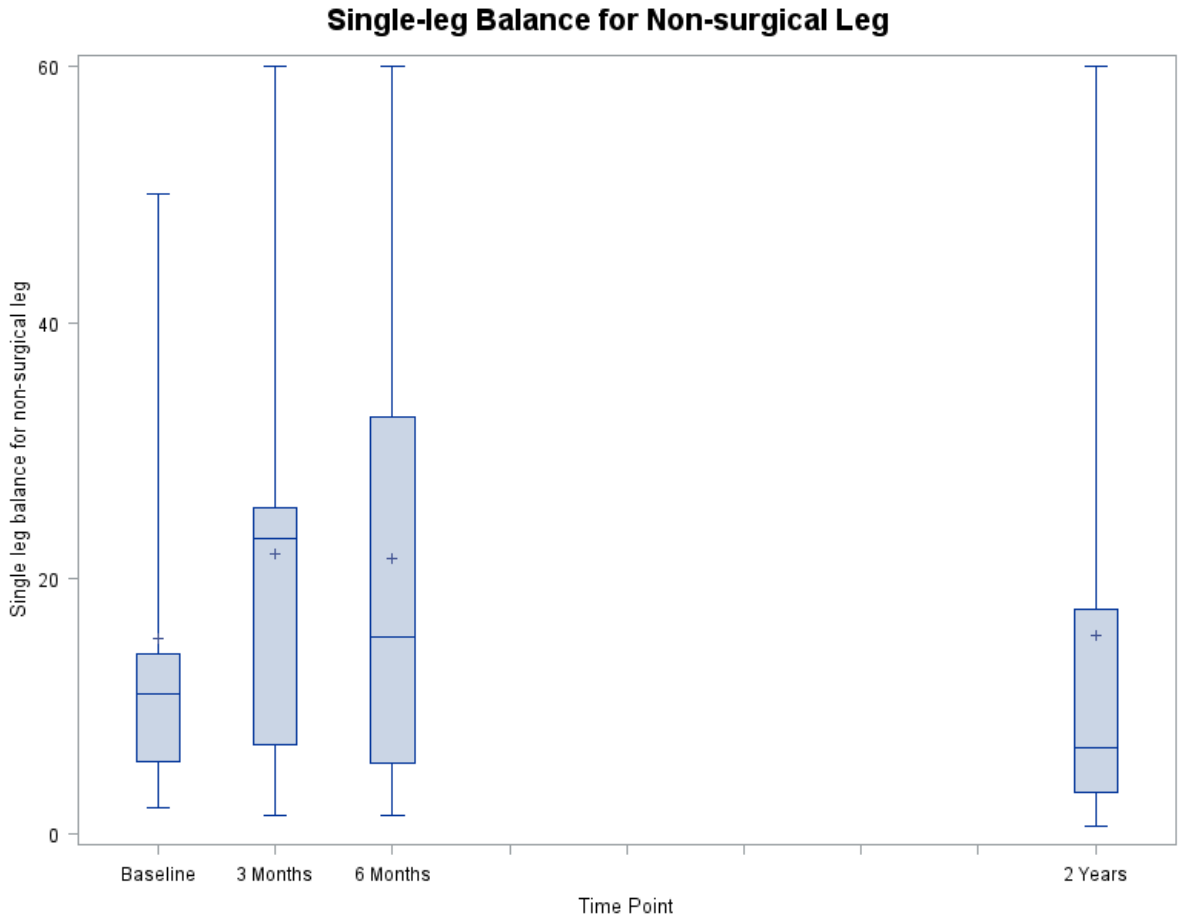

Figure 4.3. Single Leg Balance Non-Surgical Leg

The box plot for Figure 4.3 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

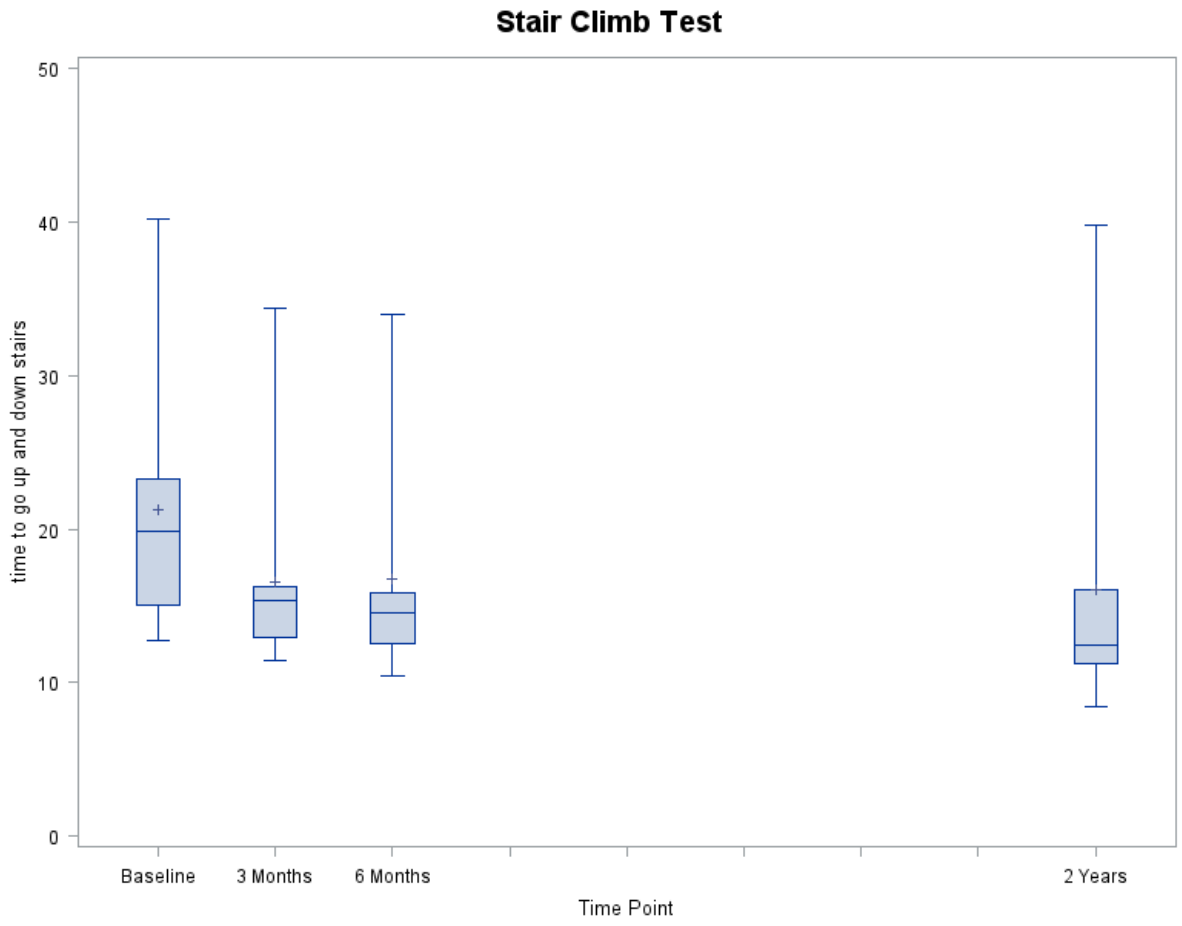

Figure 4.4. Stair Climb Test

The box plot for Figure 4.4 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

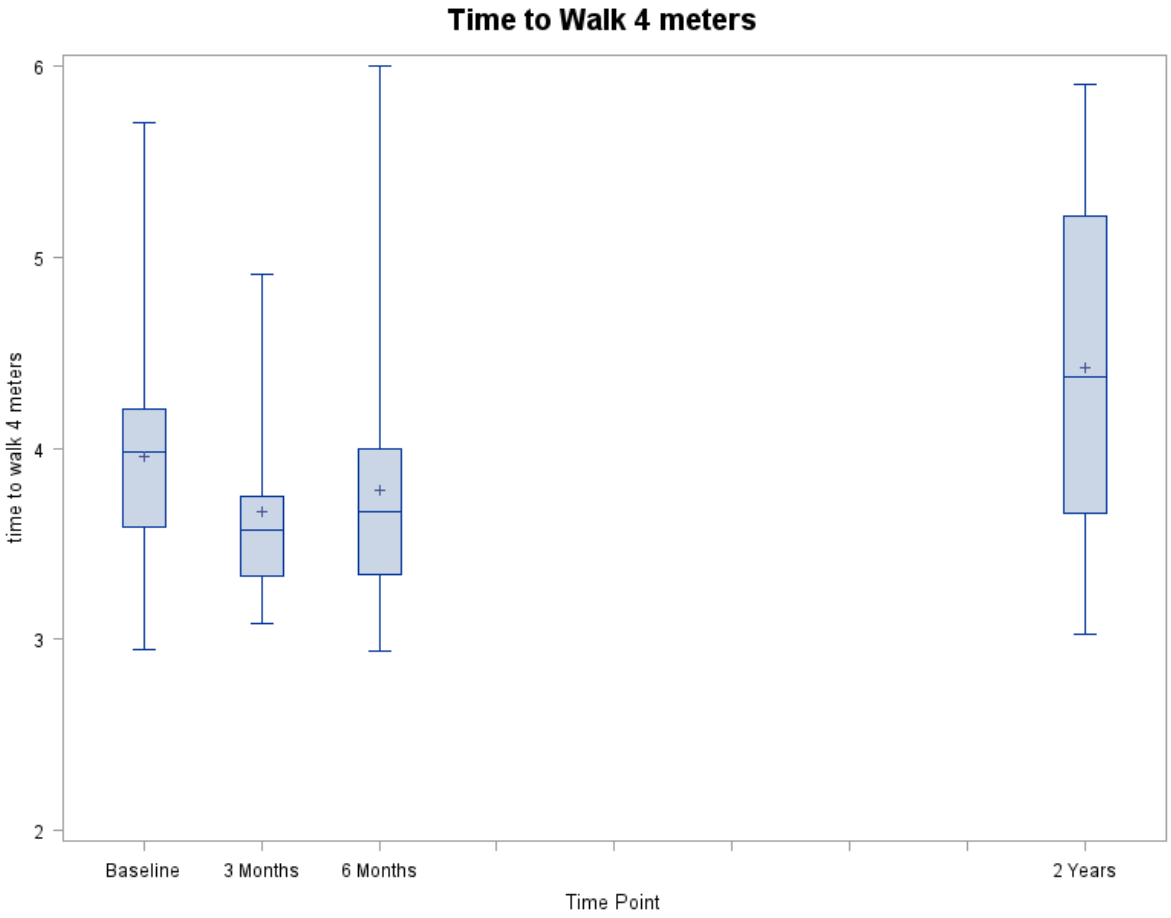

Figure 4.5. 4 Meter Walk Test (self-selected pace)

The box plot for Figure 4.5 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

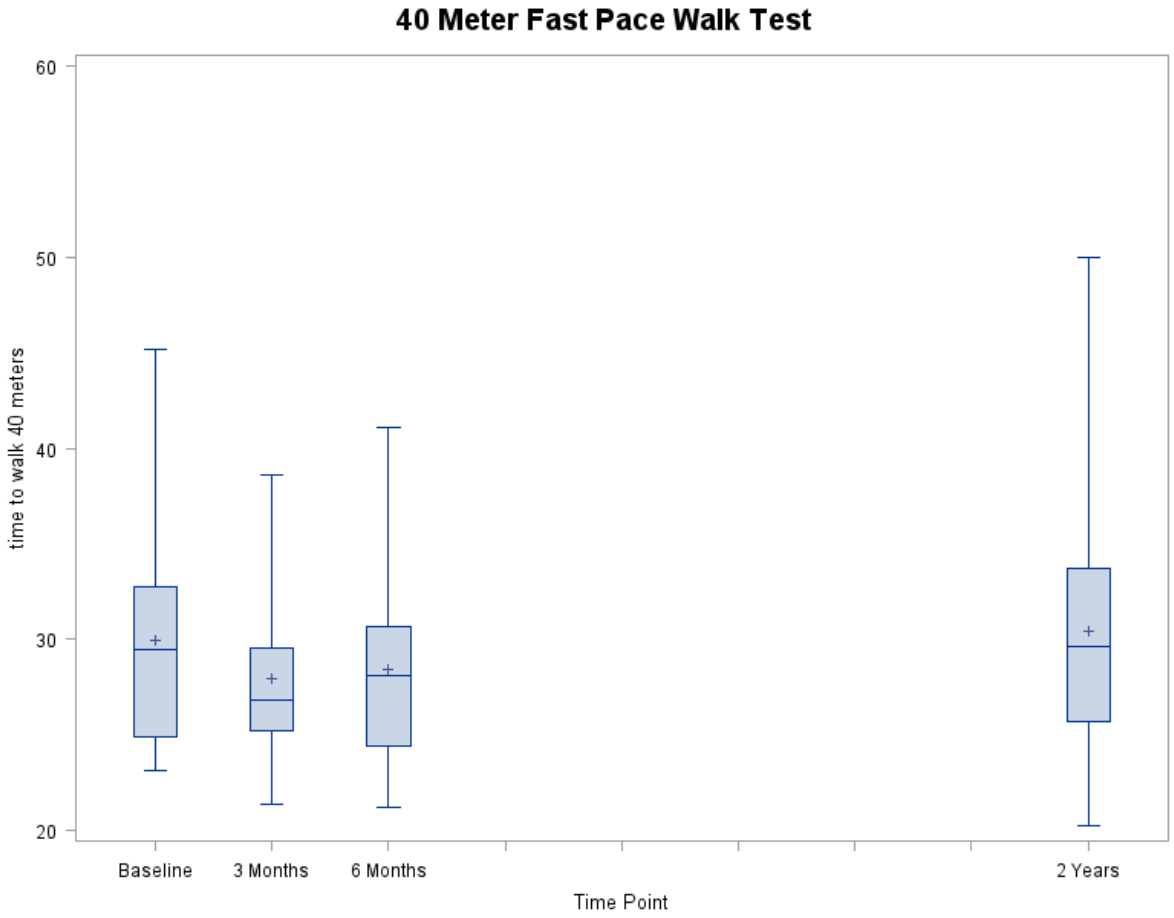

Figure 4.6. 40 Meter Walk Test (fast paced)

The box plot for Figure 4.6 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

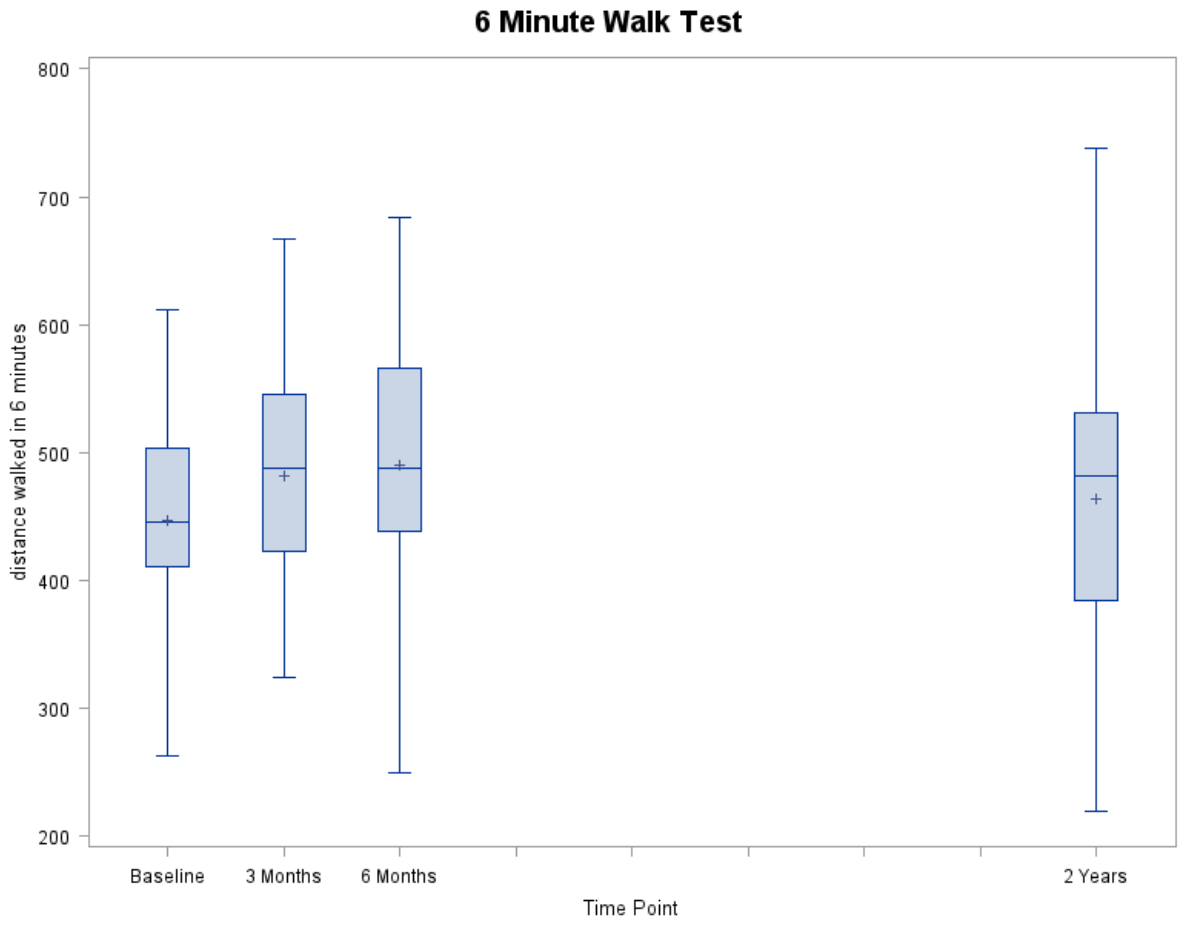

Figure 4.7. 6 Minute Walk Test (6MWT)

The box plot for Figure 4.7 shows a five figure data set summary for the 22 with 2 – 4 year follow-up where the lowest data point represents the minimum, the lower portion of the box represents the lower quartile range, the horizontal divider in the box represents the median, the "+" sign represents the mean, the upper portion of the box represents the upper quartile range and the highest data point represents the maximum.

Correlation Coefficients via Spearman's Rho and Scatterplots indicate no statistically significant correlation between physical activity and any of the performance based physical functioning tests, self-report physical functioning instruments or time from surgery to TKPANA follow-up**,** with the exception of a negligible to weak correlation for PA as compared to 6MWT and WOMAC.

Table 4.6. Correlation Coefficients

Compare the change in physical function (from 6 months to 2 years) with the change in physical activity (change time spend in moderate/vigorous pa from 6 months to 2 years) and with the time from surgery to the two-year assessment.

	Spearman's Rho	p-value
SLB surgical leg	-0.13	0.56
SLB non-surgical leg	0.05	0.84
Repeated Chair Stands	-0.08	0.74
Stair Climb	-0.14	0.52
Time to Walk 4 meters	0.14	0.55
Time to Walk 40 meters	-0.13	0.57
6-minute Walk Test	**0.20**	**0.36**
WOMAC Physical Function	**-0.23**	**0.24**
SF-36 Physical Function t-score	0.18	0.42
Time from Surgery to 2 yr Follow-up	-0.15	0.50

4.4 Health Belief Model Questionnaire

The Health Belief Model (HBM) Questionnaire sought to identify motivating factors for compliance or barriers contributing to non-compliance with PA as per the guidelines. Participants meeting the PA guidelines reported factors influencing PA compliance including physical well-being, less stiffness, improved strength, improved emotional outlook, intrinsic motivation, prioritizing an active lifestyle and enjoyment of the chosen activity. One participant summed it up nicely for the more active subjects stating, "Here is my outlook, I haven't gotten to the point where I'm ready to give up tennis and racquetball to take up chess and bridge." Others reported overcoming barriers stating, "Recovery isn't the hard part. The knee replacement didn't hold me back. Everything else did." One subject reported the benefits of PA compliance as an equation of "1/3 (chosen activity), 1/3 exercise and 1/3 socialization." Another participant stated "Half the battle is finding something you enjoy." A benefit of PA compliance reported by a participant was that "you can work through issues" and "cleanse your mind."

Participants not meeting the PA guidelines identified needs surrounding self-efficacy, overcoming fears, navigating changing community resources, accountability partners and finding motivation to start. One participant stated "the less you move, the less you want to move." They actually quoted Newton's Laws of Motion to emphasize their point. Another stated "I wish I was as healthy as I was 10 years ago." One subject utilized their own informal medical inventory to compare their health and function to family, friends and others in the community. Barriers to participation often centered around time issues, weather complications, fear of falling or injury and self-efficacy with previously unchallenging activities.

5.0 Discussion

The hypothesis for Inquiry Question #1 was that the physical activity of TKPANA subjects 24 months post-operatively will be significantly less than PA compliance in the general population (21.3%). There were mixed results with regard to hypothesis #1 as it relates to PA compliance. Seven of twenty-two subjects (31.8%) meeting PA guideline recommendations is unexpected given the low PA compliance findings from previous studies. On the other hand, the mode for moderate to vigorous activity for the group was 0.0 minutes per day. The lower quartile participated in an average of 3 minutes per day of moderate to vigorous activity. These are the data associated with a group that overall was skewed to the upper quartile of PA compliance on the normal distribution curve when compared with the KTX group.

The 2nd edition of the Physical Activity Guidelines for Americans recommends 150 to 300 minutes of moderate to vigorous PA per week for substantial health benefits. While seven of twenty-two TKPANA subjects met the minimum recommendation, five of twenty-two (22.7%) met the upper limit of those recommendations. The guidelines report seeing additional benefits beyond 300 minutes of moderate to vigorous PA per week. This needs assessment brought to light the need for physical therapists to establish PA goals and to individualize them using the framework of Specific, Measurable, Achievable, Realistic and Time-based (SMART) goals.

Despite the 2nd edition of the PA Guidelines for Americans being released, the fact remains that most of the study participants could not accurately describe the recommendations contained within the PA guidelines. When questioned, one subject was able to accurately describe the definition of compliance with the PA guidelines for Americans. Three of the participants were, however, vaguely familiar with the concept of 120 - 150 minutes of moderate to vigorous PA per

week when questioned further. The subjects that participated in this needs assessment had total knee replacements, participated in post-surgical rehabilitation and subsequently participated in both the KTX study and the TKPANA study. While PA compliance education was not a stated objective for either study, sixteen participants could not offer any answer in an attempt to articulate the current PA guidelines. Four participants associated PA compliance with 10,000 steps a day, as that is the metric utilized by consumer based wearable activity trackers such as those from Fitbit, Garmin and iWatch. Despite that fact, while participating in a study with a primary emphasis on PA, only one of twenty-two subjects met the consumer-centric benchmark of 10,000 steps per day.

The hypothesis for Inquiry Question #2 was that the performance based physical functioning of TKPANA subjects will be significantly improved at 24 months post-operatively as compared to the 6 month follow-up (9 months post-operative). Hypothesis #2 was not supported as all but one of the performance based physical functioning tests showed a decline in performance from 6 months to 2 years. Four of the tests, SLB (non-surgical leg), 4-meter walk (self-selected pace), 40-meter walk (fast paced) and 6 minute walk (endurance test), showed a statistically significant decline in performance ($P < \text{or} = .01$). One test, the Stair Climb Test, showed a statistically insignificant improvement in performance. One possible explanation for this improvement would be that it was the only performance-based physical functioning test that participants were likely to regularly encounter in daily life. Climbing stairs is a component of functional mobility encountered on a daily basis by most individuals, as compared to tests such as single leg balance, repeated stands and fast-paced walking.

In addition to having statistically significant changes from 6 months to 2 years for the 4-meter walk test, there were concerning potential clinical implications when raw times were converted to meters per second. Norms for the 4-meter walk test establish a threshold of 1 meter

per second, with gait speeds slower the 1 meter per second threshold indicate an increased fall risk for household ambulators. Thirteen of the twenty-two participants (59.1%) displayed self-selected gait speeds slower than the 1 meter per second threshold. A second clinical fall risk indicator is the 30 second threshold for SLB. SLB (non-surgical leg) for participants in this investigation showed that fifteen of twenty-two subjects (68.2%) did not achieve the age corrected threshold norm of fourteen seconds. The combination of these functional tests suggest an increased fall risk for more than 2/3rds of this sub-population.

The hypothesis for inquiry question #3 was that the Health Belief Model Questionnaire would help to identify the physical activity and physical functioning needs of individuals 24 to 48-months post- total knee replacement. The first and most obvious concern revealed by the HBM Questionnaire was the lack of understanding of the PA guideline recommendations. If an individual cannot describe the PA guidelines, they are unlikely to be able to be able to gauge their progress toward meeting them. While many patients do not perceive it as such, PA is a modifiable health risk factor. Patient education needs to emphasize the analogy that exercise is medicine. Patients need to understand that decreasing "doses" of PA result in an increasing probability of experiencing complications associated with modifiable risk factors of chronic disease. The converse is also true. Patients need to associate increasing "doses" of PA with minimizing the possibility of experiencing complications associated with modifiable risk factors of chronic disease while at the same time maximizing function, independence, quality of life and active lifespan.

Good perspective and insight was gleaned from individuals who may have overcome barriers to meet or exceed the PA guideline recommendations. Common themes surrounded simply overcoming inertia to begin activities even if they were considered to be enjoyable. It was also difficult to ignore the importance placed upon the social and emotional benefit attributed to

PA compliance described by several of the participants. These were obviously in addition to the physical effects and health benefits described.

Individuals who were not yet meeting PA guideline recommendations echoed consistent themes of difficulty finding motivation to start, lack of accountability partners, overcoming fears and lack of self-efficacy. A strategically implemented later stage intervention, would be ideal in addressing these barriers when physical functioning is optimized and there is a teachable moment to guide individuals toward compliance with PA guidelines.

5.1 Limitations

Limitations of this study include being under-powered due to small sample size and being a pilot study with a positively skewed sampling of the entire population of KTX relating to PA and a higher proportion of white females as compared to the benchmark study.

5.2 Implications for Further Inquiry

I propose a three pronged inquiry agenda moving forward. The first line of inquiry will explore the efficacy of an extended late stage intervention facilitating return to PA at 9 to 12 months following TKR. This aligns with the findings of this needs assessment as well as the review of literature. In fact, a suggestion for further inquiry from the KTX study proposed a 2 stage approach to later stage exercise delivery. The first stage would address persistent functional limitations with a second phase incorporating long term group exercise in a community setting.

The culmination of this long term group exercise could facilitate a transition to compliance with PA per the guidelines. An extended late stage intervention also aligns with APTA's Vision Statement to address "The complex needs of society, such as those resulting from a sedentary lifestyle," as well as the NIH goals and funding priorities outlined in their Plan for Rehabilitation. The importance of this extended late stage intervention is highlighted by 54.55% of the study participants not meeting PA guideline recommendations, the decline in functional status at 24 to 48 months status post TKR and the co-morbidities associated with modifiable risk factors of chronic disease linked to the adoption of a sedentary lifestyle.

The second line of inquiry will explore the factors contributing to a decline in physical functioning status following TKR. This was an unexpected finding of this needs assessment study. Factors that may need to be considered include natural age progression, the role of maintenance programs on long-term recovery or the effects of co-morbidities on independence, quality of life and active lifespan. Two of the three factors are directly impacted by the substantial health benefits associated with PA compliance at recommended levels.

The third line of inquiry will specifically examine changes in physical functioning as it relates to elevated fall risk. Crossover factors shared with the physical functioning inquiry may need to be considered when investigating fall risk. Natural age progression, the role of maintenance programs and the effects of co-morbidities can all impact balance and fall risk. The presumed secondary benefits of undergoing TKR, following pain relief and improved functional mobility, should be scrutinized if in fact those benefits are never realized or not maintained for a period of even two to four years post-operatively.

5.3 Implications for Practice

A demonstrated need exists to advocate for physical activity across the continuum of care. It is integrally aligned to the APTA's Vision Statement. There are both newly forming and established advocacy opportunities at the national level. Despite the calls outlined in the APTA's Vision Statement, health and wellness is only currently becoming an emerging consideration on both the national and state level. At the national level, in January of 2018, the APTA formed the Council on Prevention, Health Promotion and Wellness. Another national health promotion and wellness initiative operates within the Geriatrics Special Interest Group (SIG).

According to the APTA website, Louisiana is the only state to have a wellness SIG. The APTA asserts that physical therapy services to promote health, wellness and fitness are considered within the scope of practice for physical therapy regardless of a particular state's practice act verbiage. In fact, only 21 states have health promotion and wellness specific terminology in their practice acts. Pennsylvania specifically is not included in that list of states with health promotion and wellness specified in their practice act. Efforts by this author to explore establishing a health and wellness SIG in PA met with enthusiasm, but also the unforeseen resistance due to unendorsed CEU content. There is a disconnect between the APTA's vision statement and the availability of endorsed CEU's for wellness content to inform and implement evidence-based best practices.

Physical therapists routinely set physical functioning goals and incorporate patient goals as a component of the assessment process. Physical activity may even be discussed during the implementation of the plan of care. However, PA goals are not routinely established or monitored in the post-operative phase. The priority is regaining range of motion, strength and physical functioning. It is important that the PA guidelines have been established. Yet, in practice, questions still remain. How do you interpret PA guideline compliance? Is it strictly 150 minutes

per week? Technically, the simple answer is yes. However, most healthcare providers would likely agree that a 2 ½ hour walk once per week while being completely sedentary for the remainder of the week would meet the definition of compliance but not the intent of the guidelines.

The results of this needs assessment suggest that physical functioning and physical activity are not correlated statistically, with the exception of a negligible to weak correlation for PA as compared to 6MWT and WOMAC. Due to this lack of correlation, return to physical activity would be optimized with the proposed individualized extended late stage intervention. Timing of this intervention would be paramount importance. Individuals post-total knee replacement are ideal candidates for this targeted intervention. The process for undergoing this type of surgical intervention typically involves conservative management and pre-habilitation, total joint classes, surgical intervention, hospital based intervention and some combination of interventions at a rehabilitation center, home care and / or outpatient treatment. This timeline would allow for patient selected PA goals to be set pre-operatively and assessed throughout the course of care.

A differentiated approach will meet individuals where they are along the continuum of compliance with PA guidelines. Sedentary individuals need to be guided toward establishing a goal of moving more and sitting less, as is advocated in the guidelines themselves. Minimally active individuals need to be guided toward establishing achievable and realistic goals progressing toward compliance with meeting the lower recommendation for substantial health benefits of 150 minutes per week. Moderately active individuals meeting the lower recommendation should be guided toward establishing achievable and realistic goals progressing toward the upper recommendation of 300 minutes per week. Lastly, an evidence based extended late stage intervention aligned to patient generated pre-operative goals will target resumption of physical activity progressing toward meeting PA guidelines.

Appendix A IRB Approval

University of Pittsburgh
Institutional Review Board

Human Research Protection Office
3500 Fifth Avenue, Suite 106
Pittsburgh, PA 15213
Tel (412) 383-1480
www.hrpo@pitt.edu

APPROVAL OF SUBMISSION (Expedited)

IRB:	STUDY19010125
PI:	Douglas White, PT
Title:	Physical Activity 24 to 48 Months Status Post Total Knee Replacement - A Needs Assessment Study
Funding:	None
Date:	March 4, 2019

On 3/4/2019, the Institutional Review Board reviewed and approved the above referenced application through the administrative review process. The study may begin as outlined in the University of Pittsburgh approved application and documents.

Approval Documentation

Review type:	Initial Study
Risk Level:	No greater than minimal risk
Approval Date:	3/4/2019
Expiration Date:	

Expedited Category:	(5) Data, documents, records, or specimens, (4) Noninvasive procedures, (7)(b) Social science methods
Determinations:	
Approved Documents:	• WOMAC_Osteoarthritis.pdf • PA Post TKR - HBM Interview.docx • PA Post TKR - Recruitment Letter.pdf • PA Post TKR - Informed Consent_Version_2-15-19.pdf • PA Post TKR - Phone Script_Version_2-15-19.pdf

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at http://www.hrpo.pitt.edu/.

Research being conducted in an UPMC facility cannot begin until fiscal approval is received from the UPMC Office of Sponsored Programs and Research Support (OSPARS). Contact OSPARS@upmc.edu with questions.

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Emily Bird.

Please take a moment to complete our Satisfaction Survey as we appreciate your feedback.

University of Pittsburgh
Institutional Review Board

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3500 Fifth Avenue, Suite 106
Pittsburgh, PA 15213
Tel (412) 383-1480
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MODIFICATION APPROVAL

IRB:	MOD19010125-002
PI:	Douglas White
Title:	Physical Activity 24 to 48 Months Status Post Total Knee Replacement - A Needs Assessment Study
Date:	March 19, 2019

On 3/19/2019, the Institutional Review Board reviewed and approved the above referenced Modification through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

The proposed modifications are well justified and appropriate and do not alter the risk to benefit considerations of the study. The requirements under CFR 46.111 continue to be met.

Approval Documentation

Approval Date:	3/19/2019
Expiration Date:	

Determinations:	
Approved Documents:	• PA Post TKR - Informed Consent_Final.pdf • PA Post TKR - Phone Script_Version_2-15-19.pdf • PA Post TKR - Recruitment Letter.pdf • PA Post TKR - HBM Interview.docx • WOMAC_Osteoarthritis.pdf

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at http://www.hrpo.pitt.edu/.

Research being conducted in an UPMC facility cannot begin until fiscal approval is received from the UPMC Office of Sponsored Programs and Research Support (OSPARS). Contact OSPARS@upmc.edu with questions.

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Emily Bird at eak20@pitt.edu.

Please take a moment to complete our Satisfaction Survey as we appreciate your feedback.

Appendix B Recruitment Letter

University of Pittsburgh

School of Education
&
School of Health and Rehabilitation Sciences

Douglas J. White, PT
Bridgeside Point 1
100 Technology Drive, Suite 470
Pittsburgh, PA 15219
Phone: 724 255-1301
Email: DJW89@pitt.edu

To our Patients that have participated in our total knee replacement and exercise study in the past 24 to 48 months:

We are writing to inform you about a research study that is currently being conducted in collaboration with Department of Physical Therapy and School of Education at the University of Pittsburgh. The purpose of this study is to determine the level of physical activity in people 24 to 48 months after a total knee replacement (TKR).

Criteria for this study include:

- Have participated in the KTX Study at the PT - CTRC
- Be able to walk short distances without a cane or walker;
- Have not had a TKR on the other knee;
- Have no other disease that affect the lower limbs;
- Have no acute illness or uncontrolled cardiovascular disease.

Participation in this study requires you to attend a testing session of approximately 1 hour and a 15 minute follow-up supervised by experienced physical therapists. All the activities related to this research study will be performed in Bridgeside Point 1 (the same location as the previous study) in a building with easy access and their own free parking lot.

There is no cost to participate! In addition, you will be paid $30 for participation in the first session of this research study. You will be paid an additional $10 once the activity monitor is returned at the follow-up session, for a total of $40 for completion of the study.

If you would like further information concerning this study, you can contact ***Douglas White, PT at 724 255-1301.*** We hope that you will consider participating in the study.

Sincerely,

Sara R. Piva PhD, OCS, FAAOMPT
Associate Professor of Physical Therapy
School of Health and Rehabilitation Sciences

Douglas J. White, PT
EdD Candidate in Health and Physical Activity
School of Education

Appendix C Phone Script

Telephone Screening	
Study name: PANA Date (mm/dd/yyyy) _____	Initials of completer: _____

Eligible □ Yes □ No

Surgical release obtained	□ Yes □ No
Needs PCP / Other medical release	□ Yes □ No
Release obtained	□ Yes □ No

(Greetings and Introductions).

Thanks for your interest in our research study. My name is Douglas White and I am the Principle Investigator of the study. The objective of this study is to determine the level of physical functioning and level physical activity subjects participate in 2 to 4 years after total knee replacement.

In order to determine if you are eligible to participate in the study, we would like to ask you some questions. It is possible that some of the questions may make you feel uncomfortable. You don't have to answer any of those questions if you don't want to. We can always complete the questionnaire in person if it makes you uncomfortable. However, by not answering all the questions, you may be considered ineligible for the study. There is a rare possibility (less than 1% or 1 in 100 people) that confidentiality of this phone conversation could be breached, however, to

the best of our ability this information will be kept confidential. If based on the information gathered by the phone you seem eligible for the study, we will schedule an in-person appointment to further confirm your eligibility. If you are not eligible, all information obtained during this phone conversation will be immediately destroyed.

Does this sound like something you would be interested in? Yes No

Can I have your verbal consent to ask you these questions? Yes No Time of permission:____:____ AM / PM

When was your total knee replacement surgery?	□ Yes	□ No	Yes if between 24 to 48 months
Have you had other surgery since your total knee replacement?	□ Yes	□ No	
Do you need a cane, walker or crutches to walk 150'?	□ Yes	□ No	
Have you had two or more falls in the past year?	□ Yes	□ No	
THE NEXT QUESTIONS ARE USED TO DETERMINE IF EXERCISE IS SAFE FOR YOU			
Have you ever been diagnosed with heart disease (heart attack, heart surgery, angina 'chest pain')? *Even if no, ask follow-up questions:* *1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?* *2. Do you feel unreasonably out of breath?* *3. Do you experience dizziness, fainting, or blackouts?* *4. Do you feel pain in your chest when you do physical activity?* *5. In the past month, have you had chest pain when you were not doing physical activity?*	□ Yes *□ Yes* *□ Yes* *□ Yes* *□ Yes* *□ Yes*	□ No *□ No* *□ No* *□ No* *□ No* *□ No*	If Yes, what is it? _____ Is it under control? □ Yes □ No * Any yes indicate need to have a medical clearance from cardiologist (obtain phone #) Inform research coordinator

Review ACSM contraindications for exercise questionnaire (Pg. 4) • Yes to absolute contraindication • Yes to relative contraindication	□ Yes	□ No	If yes subject to absolute contraindication is excluded If yes to relative contraindication subject will require medical clearance
Do you have a history of high blood pressure?	□ Yes	□ No	Is it under control? □ Yes □ No If no, inform res. coordinator
Have you been diagnosed with a neurologic condition such as Parkinson's disease, stroke, transient ischemic attack?	□ Yes	□ No	If Yes, does it affect your ability to walk? □ Yes □ No Inform research coordinator
Have you been diagnosed with a muscular disease such as muscular dystrophy?	□ Yes	□ No	
Do you have a severe visual impairment?	□ Yes	□ No	
Have you been sick lately (e.g. infection, flu, pneumonia, hospitalization)?	□ Yes	□ No	If Yes, specify-when? _____ Is it better? □ Yes □ No Inform research coordinator
THIS IS NOT AN EXCLUSION CRITERION Do you have diabetes? If yes query if well controlled: *1. Is your blood sugar often above what doctor recommended?* *2. Do you feel shaky, confused, or dizzy when you exercise?*	□ Yes □ Yes □ Yes	□ No □ No □ No	* Yes to 1 or 2 indicate need to have a medical clearance from PCP or endocrinologist (obtain phone #). Inform research coordinator.
THIS IS NOT AN EXCLUSION CRITERION Do you have asthma or other lung disease? If yes, ask:	□ Yes	□ No	If yes, specify?

Has your doctor ever said that you should not do physical activity because of your lung disease? Do you use an inhaler? Is it needed for exercise?			Inform research coordinator.
THIS IS NOT AN EXCLUSION CRITERION Do you have any chronic infectious disease (e.g. mononucleosis, hepatitis, AIDS)	□ Yes	□ No	If yes, specify? Inform research coordinator.
Have you been diagnosed with any terminal illness?	□ Yes	□ No	
THIS IS NOT AN EXCLUSION CRITERION Do you take prescription drugs? *If yes, what are they for?*	□ Yes	□ No	*Inform research coordinator.* ** Remind patient to bring the list of medication IF eligible.*
Do you know of any other reason why you should not do physical activity?	□ Yes	□ No	Specify. Inform research coordinator.

Dark shade: absolute exclusion criteria

Light shade: relative criteria

Thank you for answering these questions!

Based on your answers:

a. ____ you are not eligible to participate in this study.

b. ____ you seem to be eligible to participate in this study and we can schedule an in-person visit

---

If a, (*In case subject NOT <u>eligible</u> provide him/her with the following information)*

Unfortunately, based you on answers it seems that you're not eligible to participate in this study. All information obtained during this phone conversation will be immediately destroyed. Thank you for your interest and time.

If b, ask "Would you like to participate in this study?" ☐ Yes ☐ No

(If ELIGIBLE subject refuses to participate in study ask the following question)

Miss/Mr…….. Can you please indicate the reason why you would not like to participate in this study?

(If ELIGIBLE subject agrees to participate in the study ask the following question)

When would be a good time to schedule your medical evaluation?

Mon Tue Wed Thu Fri

What is your mailing address?

Address:

City: State:

ZIP: ☐☐☐☐☐-☐☐☐

What is your phone number?

Home:

Work:

Cell:

What is your e-mail address?

E-mail:

What is the best way to reach you?

☐ Email ☐ Home ☐ Work ☐ Cell

Miss/Mr……. You will receive an envelope with the Informed Consent document and a letter confirming this appointment. The Informed Consent document explains details about the study. Please read this document before your appointment. This letter will include instructions on what to wear and what to bring for your appointment. The envelope will also contain the driving directions and instructions on where to park when you arrive for your appointment. Additionally, we will call you a couple of days after your appointment. If you have any question or not receive the envelope in a week, please call us. Do you have our phone number (probably in the study flyer they received)? Provide if not.

Signature of interviewer: _____

Contraindications for Exercise Questionnaire

Performance tests and aerobic and muscle strengthening exercise will be performed in this study. According to the American College of Sports Medicine, it is recommended that individuals with certain medical conditions not perform physical activity.

Have you at any time been diagnosed with the following conditions:

1 A recent significant change in the resting ECG suggesting significant ischemia,	☐	☐
2 Unstable angina	☐	☐
3 Uncontrolled cardiac dysrhythmias causing symptoms or hemodynamic	☐	☐
4 Symptomatic severe aortic stenosis	☐	☐
5 Uncontrolled symptomatic heart failure	☐	☐
6 Acute pulmonary embolus or pulmonary infarction	☐	☐
7 Acute myocarditis or pericarditis	☐	☐
8 Suspected or known dissecting aneurysm	☐	☐
9 Left main coronary stenosis	☐	☐
10 Moderate stenotic heart disease	☐	☐
11 Electrolyte abnormalities (e.g. hypokalemia, hypomagnesemia)	☐	☐
12 Tachydysrhythmia or bradydysrhythmia	☐	☐
13 Hypertrophic cardiomyopathy and other forms of outflow tract obstruction	☐	☐
15 High-degree atrioventricular block	☐	☐
16 Ventricular aneurysm	☐	☐

References

Modified from Gibbons RJ, Balady GJ, Bricker J et al. ACC/AHA 2002 guideline update for exercise testing: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Exercise Testing) [Internet]. 2002. Cited 2007 June 15]. Available from www.acc.org/clinical/guidlines/exercise/dirlndex.htm

Thompson, Walter R. Gordon Neil F. Prescatello, Linda S. ACSM's Guidelines for

Exercise Testing and Prescription Tenth Edition. Lippincott Williams and Wilkins,

Baltimore 2017. Pg. 54 Source: ACSM's Guidelines for exercise testing and prescription, 10th edition (2017)

Appendix D Informed Consent

University of Pittsburgh

School of Education
&
School of Health and Rehabilitation Sciences

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **PHYSICAL ACTIVITY AT 24 TO 48 MONTHS STATUS POST TOTAL KNEE REPLACEMENT: A NEEDS ASSESSMENT STUDY**

PRINCIPAL INVESTIGATOR:
Douglas J. White, PT
Bridgeside Point 1
100 Technology Drive, Suite 470
Pittsburgh, PA 15219
Phone: (412) 383-6735
Email: DJW89@pitt.edu

CO-INVESTIGATORS:
Carl Fertman PhD, MBA, MCHES
Associate Professor
School of Education
Department of Health and Physical Activity

Fredric Goss, PhD, FACSM
Associate Professor
School of Education
Department of Health and Physical Activity

Sara R. Piva, PT, PhD
Associate Professor
School of Health and Rehabilitation Sciences
Department of Physical Therapy

Why is this research being done? There is not enough information to tell us how physically active patients are at later stage post Total Knee Replacement (TKR). This research study will provide such information by assessing physical activity and physical functioning 24 to 48 months after surgery. The study will assess physical activity and physical functioning in three ways. 1) Self-report questionnaire along with a brief interview 2) Physical functioning testing 3) Physical activity monitoring

Who is being asked to take part in this research study? You are being asked to participate in this study because you have had a unilateral TKR 24 to 48 months ago. In total, we will invite at least 24 people to participate in this research study.

What procedures will be performed for research purposes? Research personnel will explain this study including the risks and benefits. You will sign a consent form before any research activities take place. After signing this consent form, you will receive a screening examination which is described in detail in the next section. We will tell you after the screening examination if you are eligible to participate in the study. If you agree to participate, you will complete the self-report physical functioning questionnaire, participate in a brief interview, perform physical function testing and be issued a physical activity tracker to be worn for 1 week.

SCREENING PROCEDURES: Procedures to determine if you are eligible to take part in a research study are called "screening procedures". You will be asked questions to determine if exercise is safe for you. These will be confirmed via a check of vital signs prior to participation in the physical examination.

Questionnaires: You will be asked to complete a couple of questionnaires that will ask questions about how your knees affect your ability to perform various physical activities and participate in physical activity. We expect it will take about 30 minutes for you to complete these questionnaires.

PHYSICAL FUNCTIONING QUESTIONNAIRE – Western Ontario and McMaster Universities Osteoarthritis Index

BRIEF INTERVIEW – To determine your thoughts on benefits of physical activity as well as barriers to participation in physical activity.

PHYSICAL EXAMINATION - You will be examined by a tester who will assess the movements of your knees and your ability to move around. We will time you while you walk on a straight course, go up and down stairs, stand from a chair 5 times with your arms crossed over your chest, stand over one foot. We will measure how much your knees bend, how far you walk during 6 minutes. The therapist will also take blood pressure measurements, height and weight. At the end of the physical exam, you will be instructed how to wear a portable activity monitor on the back of your left arm. The activity monitor is no bigger than a cell phone and weighs no more than 3 oz. You will be asked to wear the device for 7 consecutive days to monitor your daily activities. We expect this entire physical examination process will take about 1 to 1.5 hours to complete.

MONITORING / FOLLOW-UP PROCEDURES: Procedures performed to evaluate the effectiveness and safety of the experimental procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring and follow-up procedures include wearing the physical activity monitoring device for 7 consecutive days. We will make arrangements to collect the activity monitor the week following the first session. You will not be charged for participation in the study; we will pay all of the costs. Your total time commitment to this study will be approximately 1 week.

What are the possible risks, side effects, and discomforts of this research study? Risks associated with Interviews and Questionnaires: Completing the questionnaires may cause you to feel uncomfortable when answering questions of a personal nature. To minimize this risk, you may choose not to answer any of the questions regardless of your reason.

Risks associated with physical examination: The risks associated with the physical examination procedures may include temporary muscle soreness or tripping and falling during testing and/or exercises. During testing and training, risks of tripping and falling will be minimized by providing direct stand-by supervision by the research staff. In addition, the exclusion criteria used in this study provides that individuals who are prone to falling, or have a neurodegenerative disorder will not be participating in the study. Because you will participate in a test of walking performance, there is a rare risk that you may experience chest pain, dizziness, shortness of breath, heart attack, or stroke. There will be a research assistant accompanying you during this walking test, who is trained in emergency procedures.

Breach of confidentiality: It is possible that an incidental breach of confidentiality occurs about your participation in the study. To minimize the risks we will label all data collection forms with assigned study ID number and the link between that ID number and your identity will be securely stored. The link and all research data will be kept in password-protected databases, behind a University firewall. The signed consent document and any other paper-based research document will be secured in locked cabinets and in separate locations.

Risks of wearing the SenseWear device: Wearing the SenseWear device may cause skin irritation. If you report skin irritation you may remove the armband for specific amounts of time as needed. Most irritations are associated with the velcro strap contacting the skin. To reduce irritation you can move the straps upwards/downwards in the arm or put a small piece of cotton fabric between the velcro strap and skin.

What are the possible benefits from taking part in this research study? The primary potential benefit that subjects may experience from taking part in this research is an objective measure of current physical activity compliance as well as identification of barriers and strategies to overcome those barriers.

What treatments or procedures are available if I decide not to take part in this research study? There are no alternative treatment or procedure if you decide not to take part in this research study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study? You will be promptly notified if any new information develops during the conduct of this research study that may cause you to change your mind about continuing to participate.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study? Neither you nor your insurance provider will be charged for the costs of any procedures performed as part of this research study. All testing procedures and experimental treatments related to the study will be funded by the study grant.

Will I be paid if I take part in this research study? You will be paid $30 for participation in the first session of this research study. You will be paid an additional $10 once the activity monitor is returned at the follow-up session, for a total of $40 for completion of the study. In addition, any parking fees related to your participation in this study will be paid for by the study.

Who will pay if I am injured as a result of taking part in this study? University of Pittsburgh researchers and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study? To ensure that the confidentiality of any information obtained about you from this research study is maintained, records associated with your participation in this study will be indicated by a case number. Information linking these case numbers with subject identity will be accessible only to the investigators and their research team and will be stored in a locked file. You will not be identified by name in any publication of results unless you sign a separate form giving your permission (release).

Will this research study involve the use or disclosure of my identifiable medical information? This research study will not involve the recording/disclosure of identifiable medical information.

Who will have access to identifiable information related to my participation in this research study? In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. The physical therapists performing baseline examinations at the PT-CTRC will have access to personal identifiable information.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study? The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 7 years after final reporting or publication of a project.

May I have access to research results in medical records? Subjects will have restricted access to medical information generated as a result of research participation.

Is my participation in this research study voluntary? Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study? You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Before agreeing to participate in this study, or at any time during your study participation, you may discuss your care with another physical therapist or physician who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician or physical therapist.

If I agree to participate in this research study, can I be removed from the study without my consent? The investigators may withdraw your participation if you are unable to complete all of the testing procedures or exercise sessions related to this study. Any identifiable research or medical information recorded for, or resulting from your participation in this research study prior to the date that you are withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

****

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

_____

Social Security Number

(for Vincent Payment)

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

Appendix E WOMAC

Western Ontario and McMaster Universities Osteoarthritis Index

Your Full Name: _____ **Today's Date:**
_____/_____/_____

Month Day Year

WOMAC OSTEOARTHRITIS INDEX

1. **The following questions concern the amount of pain you are currently experiencing in your knees. For each situation, please enter the amount of pain you have experienced in the past 48 hours.**

		None	mild	moderate	severe	extreme
A. Walking on a flat surface	A.	☐	☐	☐	☐	☐
B. Going up or down stairs	B.	☐	☐	☐	☐	☐
C. At night while in bed	C.	☐	☐	☐	☐	☐
D. Sitting or lying	D.	☐	☐	☐	☐	☐
E. Standing upright	E.	☐	☐	☐	☐	☐

2. **Please describe the level of pain you have experienced in the past 48 hours for each one of your knees.**

		None	mild	moderate	severe	extreme
A. Right knee	A.	☐	☐	☐	☐	☐
B. Left knee	B.	☐	☐	☐	☐	☐

3. **How severe is your stiffness after first awakening in the morning?**

None	mild	moderate	severe	extreme
☐	☐	☐	☐	☐

4. **How severe is your stiffness after sitting, lying, or resting later in the day?**

None	mild	moderate	severe	extreme
☐	☐	☐	☐	☐

5. **The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours, in your knees.**

What degree of difficulty do you have with:

		None	mild	moderate	severe	extreme
A. Descending (going down) stairs	A.	☐	☐	☐	☐	☐
B. Ascending (going up) stairs	B.	☐	☐	☐	☐	☐
C. Rising from sitting	C.	☐	☐	☐	☐	☐
D. Standing	D.	☐	☐	☐	☐	☐
E. Bending to floor	E.	☐	☐	☐	☐	☐
F. Walking on a flat surface	F.	☐	☐	☐	☐	☐
G. Getting in/out of car	G.	☐	☐	☐	☐	☐
H. Going shopping	H.	☐	☐	☐	☐	☐
I. Putting on socks/stockings	I.	☐	☐	☐	☐	☐
J. Rising from bed	J.	☐	☐	☐	☐	☐
K. Taking off socks/stockings	K.	☐	☐	☐	☐	☐
L. Lying in bed	L.	☐	☐	☐	☐	☐
M. Getting in/out of bath	M.	☐	☐	☐	☐	☐
N. Sitting	N.	☐	☐	☐	☐	☐
O. Getting on/off toile	O.	☐	☐	☐	☐	☐
P. Heavy domestic duties (mowing the lawn, lifting heavy grocery bags)	P.	☐	☐	☐	☐	☐
Q. Light domestic duties (such as tidying a room, dusting, cooking)	Q.	☐	☐	☐	☐	☐

Appendix F Short Form 36

RAND HEALTH

RAND > RAND Health > Surveys > RAND Medical Outcomes Study > 36-Item Short Form Survey (SF-36) >

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- 1 - Excellent
- 2 - Very good
- 3 - Good
- 4 - Fair
- 5 - Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same
- 4 - Somewhat worse now than one year ago
- 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing **several** flights of stairs	1	2	3
7. Climbing **one** flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking **more than a mile**	1	2	3
10. Walking **several blocks**	1	2	3
11. Walking **one block**	1	2	3
12. Bathing or dressing yourself	1	2	3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
14. **Accomplished less** than you would like	○ 1	○ 2
15. Were limited in the **kind** of work or other activities	○ 1	○ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
18. **Accomplished less** than you would like	○ 1	○ 2
19. Didn't do work or other activities as **carefully** as usual	○ 1	○ 2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ○ 1 - Not at all
- ○ 2 - Slightly
- ○ 3 - Moderately
- ○ 4 - Quite a bit
- ○ 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	○ 1	○ 2	○ 3	○ 4	○ 5
34. I am as healthy as anybody I know	○ 1	○ 2	○ 3	○ 4	○ 5
35. I expect my health to get worse	○ 1	○ 2	○ 3	○ 4	○ 5
36. My health is excellent	○ 1	○ 2	○ 3	○ 4	○ 5

Appendix G TKPANA Clinical Examination Form

TKPANA – Clinical Examination Form

Subject Number: TKPANA_ _____

Blood pressure: _____/_____

Height (cm): _____ Weight (kg): _____ BMI (kg/m²): _____

__NON-SURGICAL KNEE: __ SURGICAL KNEE

Passive knee flexion: _____^{0} Passive knee flexion: _____^{0}

Passive knee extension: _____^{0} Passive knee extension: _____^{0}

*Flexion Contracture= Negative value

*Hyperextension= Positive value

Does the patient have a knee extension lag (≥ 5° difference between passive and active knee extension)?

☐ Yes ☐ No

SINGLE-LEG BALANCE TEST:

	Trial 1	Trial 2	Trial 3
__Non-surgical side:	_____	_____	_____
__Surgical side:	_____	_____	_____

REPEATED CHAIR STAND TEST:

Safe to stand without help: ☐ Yes ☐ No

Time to complete five stands: _____ seconds

Test completed: ☐ Yes ☐ No

Number of sit to stands completed in 30 seconds ___

STAIR CLIMB TEST:

Time to go up: _____ seconds

Time to go down: _____ seconds

Total time: _____ seconds

Side of hand rail used: ☐ Right ☐ Left

TIME TO WALK 4-METERS:

_____ seconds

40 METER (4x10m) FAST PACED WALK TEST

Time of one trial: _____

Speed (in m/s): _____

Use of assistive device: ☐ Yes ☐ No

6 MINUTE WALK TEST:

Distance walked _____ meters

Use of assistive device: ☐ Yes ☐ No

Appendix H Single Leg Balance Test

Specific instructions for the clinical examination follow:

- Participants are asked to stand on one foot for 60 seconds. The other foot is raised so that the raised foot is near but not touching the ankle of their stance limb.
- The participant may use the arms, bend the knee, or move the body to maintain balance.
- The tester uses a stopwatch to measure the amount of time the participant is able to stand on one limb. Time commences when the participant raises the foot off the floor. Time ends when the participant either: (1) uses the raised foot to stabilize body (e.g., touches the floor or hooks raised foot on stance leg), (2) moves the weight-bearing foot to maintain his balance (ie, rotated foot on the ground), (3) a maximum of 60 seconds elapses. Three trials are performed in each side and recorded.

Tester Script:

Now I will show you the test. (Demonstrate) I want you to try to stand on one foot with the other foot raised near, but not touching the ankle, for about 60 seconds. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. We will do it three times.

Stand next to the participant to help him/her into the position. Supply just enough support to the participant's arm to prevent loss of balance. When the participant has raised his/her foot, ask "Are you ready?" Then let go and begin timing as you say, "Ready, begin." Stop

the stopwatch and say "Stop" after 60 sec. or when the participant steps out of position or grabs your arm or steady surface.

Scoring for TKPANA

The recorded score is the average of the three trials with a 60 second maximum cut time.

Clinical Interpretation

Patient to stand on one foot with eyes open

Less than 30 seconds would indicate risk for falls

30 or > seconds is baseline normal for healthy adults

Appendix I Repeated Chair Stand Test

Specific instructions for the clinical examination follow:

This test represents the time it takes for an individual to stand from a chair 5 times with arms crossed over the chest. The tester starts to time when participant starts to stand the first time and stops when participant reaches a full upright position on the 5th chair stand. The tester ensures the participant comes to a full stand and full sit position during the test. A practice trial is done to check whether the participant is able to stand up and to check understanding of the test.

For safety, the chair is placed against the wall and the tester stands close to the side of the chair. Participant starts sitting in a chair towards its anterior border (the anterior border of the chair touches the middle of the posterior thigh of the participant).

Tester Script:

"The next test measures the strength in your legs. Do you think it would be safe for you to try to stand up from a chair without using your arms?" (Demonstrate and explain the procedure.) ***"First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest."*** If it is unsafe to attempt the chair stand or the participant cannot rise without using arms this is the end of the test. Record the test as not attempted.

If participant is able to stand, continue: ***"Now that you attempted once, please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch."*** When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing. Count out loud as the participant arises each time, up to five times. Stop the stopwatch when he/she has straightened up completely for the fifth time. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking "*Can you continue?*" If participant says *"Yes,"* continue timing. If participant says *"No,"* stop the test. Additionally, stop the test if:

- Participant becomes tired or short of breath during repeated chair stands or at your discretion, if concerned for participant's safety
- Participant uses his/her arms
- After 1 minute, if participant has not completed rises.

Interpretation

Patient to perform as many as possible in 30 seconds

Normal	8 or more in 30 seconds
Risk of falls with	< 8 in 30 seconds

Appendix J Stair Climb Test

Specific instructions for the clinical examination follow:

This is a test of ascending stairs. It records the time in seconds it takes to ascend a flight of stairs (12 steps, standard height of 17 cm).

- Equipment: timer/stop watch and flight of stairs. Steps heights should be standard (between 16-20cm), and the location of the stairs should have adequate lighting and free from traffic and external distractions.

  Tester: if safety is a concern the test should not be done. The tester can guard behind/below the participant going up the stairs or stay in the starting platform. A practice trial with tester guarding is recommended before testing to assess for safety.
- The use of a handrail is mandatory. The use of walking aid is permitted.
- Scoring: timing starts in the signal to begin and terminates when the participant finishes ascending the steps (time is recorded). The participant can stop and rest during the test if needed but the time keeps on going.

Tester script: ***"For this test, do the best you can by going as fast as you can but don't push yourself to a point of overexertion or beyond what you think is safe for you."***

1. ***Start with both feet on the bottom landing.***
2. ***On start, go to the top of the stairs as fast but as safe as you can.***
3. ***Use the rail.***
4. ***Get ready and START."***

Interpretation

12 steps (measured in seconds) –

Healthy Individual–	8 to 10 seconds
6 months post- TJR –	11 to 15 seconds
12 months post – TJR –	11 – 15 secs

Appendix K 4-Meter Walk: Self-Selected Gait Speed Test

Specific instructions for the clinical examination follow:

This self-selected gait speed test assesses participant's ability to walk 4 meters or 13 feet. The walking course should be set up prior to the assessment visits and the area should be free from clutter and unobstructed and should include at least an extra meter on each end. The tester will mark the start and finish lines on the floor using the masking tape and a construction meter tape to measure the correct distance.

1. The tester will **ask the participant whether they feel safe walking a short distance with or without walking device for the test.** If they don't, do not perform the gait speed test. A walking device can be used during the walk.
2. Participants are **instructed to walk at their usual or normal walking speed (i.e., as they would normally walk to run errands)** and past the finish line ~1 meter after the finish line. The tester will begin timing when the participant begins to move (not when they say **"Ready, begin").** The tester will stop timing when the first foot crosses the masking tape finish line. The tester will record the time when the participant's first foot crosses the 4 meter line. It is imperative that the participant's foot cross the line and not lands on the line as it does not end the test.
3. The tester will write the time on their data sheet and then instruct the participant that they will perform the test again. The participant will walk back to the starting masking tape and repeat the steps for the gait speed test to obtain the second time. Record the fastest time. If unable to repeat the test record the first time and end the gait speed test. If unable to complete the first test mark as not completed.
4. The tester will not walk beside the participant during the gait speed test, as this may set a pace for the participant, but rather slightly behind and to the side and outside of the participant's visual field. For those that normally use a walking device, it is recommended that close attention be paid to these individuals during the test to prevent falling.
5. If the tester has issues with the stopwatch, repeat the test.

Appendix L 40-Meter Walk Test : Fast Paced Gait Speed Test

Specific instructions for the clinical examination follow:

This is a test of short distance walking activity. It's described as a fast-paced walking test that is timed over 4x10m (33ft) for a total 40m (132ft). This is a direct measure of the ability to walk quickly over short distances.

Equipment: timer/stop watch, 10m (33ft) marked walkway with space to turn safely around at each end, 2 cones placed approximately 2 meters beyond each end of the 10m walkway.

The tester marks out a 10m (33ft) walkway with bright coloured tape at each end. Place a cone approximately 2 meters before the start mark and 2 meters beyond the finish mark of the 10m walkway for turning (ensure there is enough space to turn safely around each end, i.e. 2-3m each end).

Subject should be wearing comfortable walking footwear (e.g. tennis shoes/cross trainers).

Tester: if safety is of concern, the tester should follow slightly behind and off to one side to the subject but not as to pace or impede them. If safety is not a concern, the tester should follow well to the side so as they can view crossing at the 10m walkway at both ends.

A practice trial of 1-2 turns is recommended before testing to check understanding.

Procedure: subjects are asked to **walk as quickly but as safely as possible, without running, along a 10m (33ft) walkway and then turn around a cone return then repeat**

again for a total distance of 40m (132ft) (3 turns). Regular walking aid is allowed and recorded.

Verbal Instructions: ***"For this test, do the best you can by going as fast as you can, without running, but don't push yourself to a point of overexertion or beyond what you think is safe for you.***

1. ***Start with both feet on the start line.***
2. ***On start, walk as quickly but as safely as possible, without running.***
3. ***Walk up to the end cone, turn around and walk back to the starting cone behind you, turn again and back to the end cone, then turn once more and return back to the start cone again so that you walk the 10m walkway 4 times in total.***
4. ***Get ready and START."***

Scoring: timing starts on the signal to start at the start line and terminates once the subject crosses back over the start line after completing the 40m (4x10m). When the subject crosses the 10m mark, timing is paused whilst the subject turns around the cone and then is resumed once they cross the 10m mark again. The same is repeated for the following turns and is stopped once the subject crosses the start line for the final time. Time of one trial is recorded to the nearest 100^{th} of a second. Time of one test trial is recorded and expressed as speed m/s by dividing distance (40m) by time (s).

Appendix M 6-Minute Walk Test (6MWT)

Specific instructions for the clinical examination follow:

It is described as a test of aerobic capacity over long distances, and the maximal distance covered in a 6-minute period is recorded.

Equipment: flat walking area such as a hallway or open space, preferably >20m in length, with distance interval markings every 3-5 meters. Cones or bright colour tape to mark boundaries of course or turn points. Timer/stop watch, chair (s) for resting if required e.g. at each end of a walkway or placed around course.

Ensure the walkway is free from traffic.

Subject should be wearing comfortable walking footwear (e.g. tennis shoes/cross trainers).

Tester: if safety is of concern, the tester should follow behind and to one side of subject but not as to pace or impede them. If safety is of no concern, the tester should remain close enough to observe the subject for any distress during testing.

Practice test not normally required in the clinical setting, and if performed as part of existing research protocols then at least 1 hour rest should be allowed before the second test and the greatest distance is then recorded.

Procedure: the aim of this test is to walk as quickly as possible for 6 minutes to cover as much ground as possible. Rest periods are allowed but included in the time (i.e. time is not stopped for resting). Encouragement (e.g. “keep going you are doing really well”) is given at minute interval, and the same course should be used for re-testing within site.

Verbal Instructions: ***"For this test, do the best you can by going as fast as you can, but don't push yourself to a point of overexertion or beyond what you think is safe for you.***

1. ***Start with both feet on the start line.***
2. ***On start, walk as quickly but as safely as possible around the course (outer portion of the track).***
3. ***Continue the course to cover as much ground as possible over 6 minutes.***
4. ***Walk continuously if possible, but do not be concerned if you need to slow down or stop to rest. The goal is to feel at the end of the test that no more ground could have been covered in the 6 minutes.***
5. ***You can sit down to rest if you require.***
6. ***Get ready and START."***

Scoring: the test starts on the signal to start and terminates at 6 minutes. The distance walked over the 6 minutes is recorded in meters. If walking aid is used it is recorded.

<u>Interpretation</u>

Patient to walk on a hard, level surface for 6 minutes with distance measured in meters

400 to 700 meters is the baseline for healthy adults.

< 320 meters would indicate a risk for falls

A change of 54 meters from baseline has been shown to be clinically significant

Appendix N Health Belief Model Questionnaire

Instrumentation:

Qualitative questioning based upon Champion's Health Belief Model Questionnaire

(Modified for PA)

How would you categorize your current level of physical activity?

Sedentary Light Activity Moderately Activity Vigorously Activity

Are you familiar with the current recommendations for physical activity published in Physical Activity Guidelines for Americans?

Question 1:

What are some of the ways your current level of physical activity might positively or negatively affect your health?

Probes:

A. Are you aware of some of the ways your health might be affected by adopting a sedentary lifestyle?

B. Are you able to maintain your current health status?

C. Are you able to improve your current health status?

Question 2:

Specifically, are there any potential negative health outcomes resulting from physical inactivity on your life, or on the lives of other important people in your life? (partner, children, parents, peers, colleagues)

Probes:

A. How likely are you to suffer from a chronic disease because of adopting a sedentary lifestyle?

0 1 2 3 4 5 6 7 8 9 10

B. How serious would the consequences be from the results of that chronic disease?

0 1 2 3 4 5 6 7 8 9 10

C. How severely would those consequences impact your current lifestyle?

0 1 2 3 4 5 6 7 8 9 10

Question 3:

What are the benefits of physical activity for you?

Probes:

A. Do you have any modifiable health risk factors currently? Explain.

B. What would you like to continue doing?

C. What would you like to eventually be able to do?

Question 4:

What are the barriers to physical activity for you?

Probes

A. What would be the "cost", for you, of being physically active for 30 minutes per day?

B. Do the benefits of being physically active outweigh the risks / costs?

Question 5:

How might you increase your self-awareness of your physical activity levels, or what supports might help you become more physically active?

Probes:

A. What external cues or prompts might remind and encourage you to be physically active at recommended levels?

B. Can you identify an “accountability partner” for mutual encouragement?

Question 6:

6. How confident are you on a scale of 0 to 100 that you can be more physically active?

0 10 20 30 40 50 60 70 80 90 100

Probe:

A. Given the discussion we just had, what are some things that you think might be helpful in increasing your current level of physical activity?

Appendix O Wearing Your SenseWear Armband

Wearing Your SenseWear™ Armband

Wear the SenseWear Armband **on the back of your upper LEFT ARM** (the triceps) with the "BODYMEDIA logo" towards the shoulder and the sensors touching the skin.

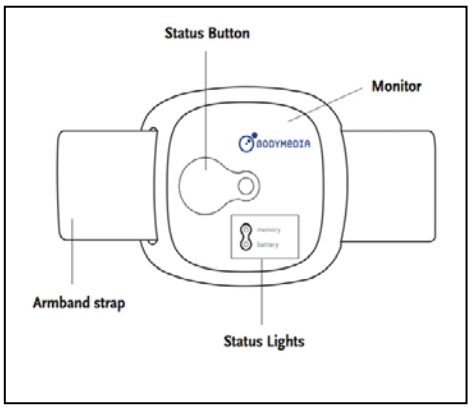
The strap should be tightened to a comfortable fit. Ensure that the **sensors maintain continuous contact with your skin** and that the Armband does not slide off your arm. *Do not over tighten.*

The Armband will **turn on** and begin collecting data **within 10 minutes**. Activation is indicated by a **series of audio tones**. Please note that **there is no power button** on the Armband.

If you do not hear the sounds, **you can check** if your Armband is ready to collect data by pressing the **Armband's Status Button**. If the Armband beeps, it is working correctly. The Status lights will also indicate whether the Armband is ready to collect data:

- If the Status Light is showing **flashing amber**, less than 24h of battery life or memory remain.

- If the Status Light is quickly **flashing red**, the Armband is not able to collect data.



IN ANY OF THE CASES, PLEASE CONTACT THE RESEARCH TEAM.

If activation of the armband takes more than 10 minutes:

a. Try to readjust the position of your armband, or
b. Try putting on lotion or rubbing your arm with an alcohol swab on the area of your arm where the armband rests to help with the conduction. Please make sure that your skin is completely dry.

Please remove the monitor from your arm when bathing, showering, or performing any water activity **(monitor is NOT waterproof)**.

If you have any question regarding the use of the armband or mailing back the device, please contact Doug at 724-255-1301.

Appendix P Activity Monitor Daily Log

Name: _____

ACTIVITY MONITOR DAILY LOG

Start Date: ____/ ____/ ____ End Date: ____/ ____/ ____

Wear the activity monitor during 8 days.
Put the monitor in the back of your right arm when you wake-up, and take it off when you go to sleep at night.
Complete this log on a daily basis to document when you did not wear the activity monitor.

Day 1: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 2: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 3: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 4: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 5: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 6: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 7: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Day 8: ☐ Sun ☐ Mon ☐Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat	☐ Monitor removed for shower ☐ Monitor removed for sleep ☐ Other reasons not to wear the monitor: _____ For how long the monitor was not worn: _____ hs ____ min
Please mail back the activity monitor to the research team after the 8th day. **If you have any questions, please contact Doug White at (724) 255-1301.**	

Appendix Q Performance Based Physical Functioning Data

Data of SLB non-surgical leg (Figure 4.3)

Analysis Variable : Single leg balance for non-surgical leg							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
Baseline	**22**	2.06	5.70	10.95	15.31	14.13	50.10
3 Months	**22**	1.45	6.95	23.07	21.92	25.46	60.00
6 Months	**22**	1.47	5.49	15.36	21.51	32.60	60.00
2 Years	**22**	0.64	3.29	6.72	15.53	17.63	60.00

Data of Stair Test (Figure 4.4)

Analysis Variable : time to go up and down stairs							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
Baseline	**22**	12.77	15.07	19.84	21.27	23.25	40.20
3 Months	**22**	11.41	12.94	15.34	16.55	16.21	34.41
6 Months	**22**	10.39	12.51	14.56	16.78	15.84	34.02
2 Years	**22**	8.41	11.22	12.40	16.02	16.09	39.81

Data of 4 Meter Walk Test (self-selected pace) (Figure 4.5)

Analysis Variable : time to walk 4 meters							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
Baseline	**22**	2.95	3.59	3.98	3.96	4.21	5.71
3 Months	**22**	3.08	3.33	3.57	3.67	3.75	4.91
6 Months	**22**	2.94	3.34	3.67	3.78	4.00	6.00
2 Years	**22**	3.03	3.66	4.38	4.42	5.22	5.91

Data of 40 Meter Walk Test (fast-paced) (Figure 4.6)

Analysis Variable : time to walk 40 meters							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
Baseline	**22**	23.17	24.92	29.49	29.99	32.75	45.17
3 Months	**22**	21.36	25.26	26.82	27.94	29.55	38.63
6 Months	**22**	21.20	24.42	28.12	28.42	30.66	41.09
2 Years	**22**	20.25	25.69	29.64	30.43	33.69	50.03

Data of 6 Minute Walk Test (Figure 4.7)

Analysis Variable : distance walked in 6 minutes							
Time Point	**N Obs**	**Minimum**	**Lower Quartile**	**Median**	**Mean**	**Upper Quartile**	**Maximum**
Baseline	**22**	262.92	410.86	445.38	447.28	503.44	612.10
3 Months	**22**	324.16	423.12	488.28	482.22	545.24	666.86
6 Months	**22**	248.92	438.86	487.39	490.61	566.50	683.94
2 Years	**22**	219.80	384.28	481.24	464.01	531.50	738.09

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