Official Title: Foot progression angle modification: an exploratory six-week telerehabilitation intervention in people with knee osteoarthritis.

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1 Objectives

The primary objective of this study is to examine the feasibility of conducting a gait modification intervention delivered using primarily a telerehabilitation model (video and/or teleconferencing). Specifically, we will assess 1) adherence and compliance to the program, 2) performance of the gait modification in laboratory and real-world settings, and 3) satisfaction with the program. We will also examine the effectiveness of the program by comparing 4) patient-reported outcome (e.g., pain and physical function) and 5) knee joint moments before and after the program.

2 Background

2.1 Knee OA is a costly public health problem impairing function and quality of life

Globally, knee OA is a leading cause of disability [1] and several epidemiological studies have suggested that knee OA affects approximately 12% of the adult population [2-4]. In Canada, OA accounts for annual direct and indirect costs in excess of $27 Billion, stemming from health care services, treatments, and wage-related productivity losses [5]. Given the ageing population and concomitant increase in OA prevalence [6], the economic costs are also expected to rise. The large proportion of health care spending related to knee OA is allocated to surgical intervention (mainly knee replacement surgery), which only serves a small minority of patients with late-stage disease [7]. Therefore, inexpensive treatments to manage clinical and structural progression of majority of people with early- and mid-stage knee OA are needed.

2.2 A modifiable risk factor of progression: knee joint load

It is well accepted that excessive and/or abnormally distributed tibiofemoral (knee) joint load are key risk factors for the clinical and structural progression of knee OA [8]. While knee joint load is difficult to measure directly, quantitative gait analysis provides the tools to non-invasively estimate knee joint load [9, 10]. Over the last two decades, the knee adduction moment (KAM) has been established as a valid [9, 11] and reliable [12] outcome for estimating knee joint load during walking. The relevance of the KAM to knee OA is well accepted, primarily due to the relationships between elevated KAM magnitudes and worse clinical [13] and structural disease progression outcomes [14-18]. Elevated KAM magnitudes are also related to higher risks of pain during aerobic exercise [19-21], and aerobic exercises like walking are a core component in knee OA rehabilitation guidelines [22]. Therefore, lowering KAM may be a means of reducing the risk of disease progression, while also decreasing pain during activities such as walking.

2.3 Toe-in and toe-out walking to lower KAM and improve knee OA-related symptoms

Several components of walking motion contribute to KAM magnitudes, one of which is the frontal plane ground reaction force lever arm [23], such that decreasing the lever arm can result in lower KAM magnitudes. The lever arm is affected by a number of walking characteristics, including the position of the foot in the horizontal plane during the stance phase [24]. The angle between the foot and the forward direction of walking, in the horizontal plane, is called the foot progression angle (FPA) where external rotation of the foot is “toe-out” while internal rotation is “toe-in”. Previous work has shown increased toe-out typically elicits lower KAM magnitudes later in stance, while increased toe-in elicits lower KAM magnitudes in early stance [25, 26]. Because of this relationship between FPA and knee joint load, and the protective effect of greater natural toe-out angles on structural disease progression [27], the FPA is a biomechanical target for knee OA management.

Many studies to date have investigated the feasibility and biomechanical efficacy of modifying one's FPA, both in healthy and knee OA populations [28]. Modifying FPA can be readily performed within a single practice session and can be guided by a variety of feedback modalities [29]. Through two clinical trials, our research group has demonstrated that increases in toe-out angle, practiced over ten to sixteen weeks, can result in clinically meaningful improvements in pain, physical function, and a reduction in KAM magnitude [30, 31]. Another three clinical trials have shown that increased toe-in angles, practiced over six weeks, can result in reduced knee pain and KAM magnitudes [32-34]. Despite the well understood biomechanical changes associated with FPA modification, and a growing understanding of the clinical response, FPA modification is not yet ready for clinical implementation.

2.4 Delivering gait modifications

Several barriers exist that have limited the widespread implementation of gait modification for managing knee OA. Traditionally, gait modifications are taught using expensive laboratory equipment to provide the needed accurate feedback for instructing the new walking pattern [31-33, 35]. Wearable sensor devices [36, 37] have also shown potential as a mobile solution to the generally inaccessible gait laboratory, but they are not widely available in the clinical setting and still need refinement in their application. Previously, we used a simple mirror placed in front of a treadmill to visually provide feedback to the learner, which was successful in teaching the toe-out gait modification and is more clinically feasible that using motion capture technology [30]. However, this simple mirror strategy still requires in-person appointments and significant practice time, limiting accessibility and long-term feasibility. A solution that is clinically feasible, time efficient, and effective in improving the target outcomes is still needed. Importantly, in a post-COVID world, interventions that can be delivered remotely have gained increased importance.

For over two decades telecommunication technologies have been explored as a means to deliver rehabilitation at a distance, which we will refer to as telerehabilitation [38]. These technologies can be used to complement face-to-face consultation and rehabilitation, or as the sole delivery method. In recent years, strong evidence has arisen demonstrating the effectiveness of telerehabilitation for treating musculoskeletal conditions, including knee OA [39]. In 2015, a non-inferiority trial found that telerehabilitation after total knee replacement surgery resulted in similar improvements in pain and physical function to traditional face-to-face physical therapy [40]. Patients and physical therapists alike found satisfaction in using this telerehabilitation approach [41]. Telerehabilitation has also shown promise for physical activity counseling [42] and exercise rehabilitation [43] of people living with knee OA. Again, patients and physical therapists expressed satisfaction with the rehabilitation and believe it was effective [44, 45]. This body of work demonstrates the feasibility and efficacy of telerehabilitation, particularly in populations with knee OA. Given this, there is a strong potential for using a telerehabilitation model to deliver gait modification to those living with knee OA.

Previous in-person gait modifications for knee OA have used a specific kinematic or kinetic variable target that the learner must "aim" at. For example, our previous studies used 10° and 15° increases to toe-out as the target, which we guided using visual feedback [30, 31]. While we had success with this strategy, there are two important limitations. First, a standard target may not be

appropriate for some, limiting the efficacy of the treatment or creating frustration and eventual discontinuation. Second, it requires substantial practice using feedback to become proficient, which typically requires equipment and guided practice sessions. A more flexible approach would be to allow participants to self-select the modification they will perform, for example, they could select the *amount* of FPA increase. The primary advantage is a significantly reduced need for structured practice and feedback, lessening the burden on the clinician and patient. The disadvantage is that the patient may not self-select a large enough change in FPA to elicit a biomechanical response. Without the need for specific targeted practice, this self-directed strategy could help to facilitate the delivery of gait modification via a telerehabilitation model.

2.5 Monitoring performance and adherence

To date, most gait modifications for knee OA have focused on knee loading and clinical outcome measures, spending little time examining the actual performance of the modification itself (i.e. how accurately the individual executes the gait modification). When performance has been measured, it has typically been done in laboratory settings, before and after a modification intervention, and always in reference to a specific target [30, 31, 46]. It is likely these performances in laboratory settings are subject to the Hawthorne effect, and do not necessarily reflect performance outside the laboratory. Unfortunately, the performance of the modification during daily walking activities (outside the laboratory environment) is currently unknown, which constitutes an important gap in our knowledge. As performing the modification during daily walking is arguably more important than doing so in the laboratory setting it is vital that we quantify performance in these settings.

Given the potential of toe-in and toe-out walking modifications to benefit those with knee OA, it is important to address the limitations in our current knowledge before wider implementation can be expected. Our proposed study will be a pilot clinical trial focusing on self-directed FPA modification using a blended delivery (1 introductory session in person with the remainder via telecommunication). Performance and adherence to the gait modification will be monitored using a novel wearable sensor system co-designed by our research group and colleagues from Shanghai Jiao Tong University, Shanghai, China. This study will be the first knee-OA specific gait modification program delivered via telerehabilitation and will provide the first examination of performance and adherence to the program during daily walking activities.

3 Hypotheses

3.1 Primary hypothesis:

H1: We expect participants will adhere to the program by attending an average of 70% of the scheduled video or telephone appointments. Participants will report increasing compliance with the program week over week.

H2: Performance of the gait modification will improve over the six-week program. During real-world walking and the laboratory-measured gait assessment at follow-up. participants will exhibit increased FPA magnitude (more toe-in or toe-out) and decreased variability compared to baseline FPA.

H3: Participants will report feeling satisfied with the gait modification program.

H4: Significant improvements in pain and physical function will be reported between the Immediate Group and Delayed Group at week 6 of the study (Follow up for the Immediate

Group and the secondary baseline for the Delayed Group). We also expect to see significant within-group improvements in pain and physical function in the Delayed Group when comparing their change from baseline to secondary baseline (control) with their change from secondary baseline to follow up (intervention).

H5: Significant decreases in the knee adduction moment late stance peak and impulse will be exhibited between the Immediate Group and Delayed Group at week 6 of the study (Follow up for the Immediate Group and the secondary baseline for the Delayed Group). We also expect to see significant within-group decreases of the knee adduction moments in the Delayed Group when comparing their change from baseline to secondary baseline (control) with their change from secondary baseline to follow up (intervention). Knee flexion moment peak and impulse will not significantly increase for these same comparisons.

4 Methods and Approaches

4.1 Study design

This delayed-control, randomized exploratory clinical trial will be a 6-week gait modification intervention, delivered using a telerehabilitation model to older adults with knee OA. Participants will be randomized to either the Immediate Group, where they will begin the 6-week intervention after completing the baseline assessment, or the Delayed Group, who will wait 6 weeks before completing a new baseline (called a Secondary Baseline) before beginning the intervention. The intervention will consist of instructing the participants to increase their toe-in or toe-out angle during walking "as much as is comfortable". Data will be collected both in laboratory settings (screening, baseline, follow up, and retention) as well as real-world environments (sensorized shoe and self-reported outcomes). Practice of the gait modification, after the initial introduction, will be delivered via videoconference (or telephone if necessary). The study will assess both the feasibility and effectiveness of gait modification delivered using a telerehabilitation model. A flow diagram of the study is included in Appendix A.

4.2 Participants

A total of 30 participants with symptomatic and radiographically confirmed knee OA that is predominantly affecting the medial knee compartment will be recruited from the community to participate in this study. Participants will be randomized to either the immediate or delayed group (see Section 4.3.3 Randomization & Study Groups).

4.2.1 Inclusion and Exclusion Criteria

All eligible participants will: 1) be 50 years of age or greater, 2) exhibit signs of tibiofemoral OA (a score of ≥2 on the Kellgren and Lawrence (KL) grading scale [47]) predominantly in the medial compartment, 3) self-reported knee pain ≥ 3 / 10 on a numerical rating scale of pain (NRS; 0 = "no pain" and 10 = "worst pain imaginable") during most days of the previous month, 4) are comfortable walking intermittently for 30 minutes, and 5) fit into the available sizes of sensorized shoes (sizes spanning US women's 5 to men's 13).

Exclusion criteria include: 1) any knee surgery or intraarticular injections within the past 6 months, 2) a history of joint replacement surgery or high tibial osteotomy, 3) current or recent (within 6 weeks) corticosteroid injections, 4) use of a gait aid, 5) currently on a wait list for joint

replacement surgery or high tibial osteotomy, 6) any inflammatory arthritic condition, and 7) any other conditions that may affect normal gait or participation in an aerobic exercise program. Additionally, potential participants will undergo an initial gait screening similar to a recent study [48] (details are outlined below – section 4.3.1-A), with the goal of identifying participants who are capable of reducing their KAM magnitude when FPA is modified. This gait screen will examine changes in knee load while walking with increased toe-in and toe-out, compared to natural FPA. Those who cannot elicit a reduction in KAM impulse ≥ 2% when FPA is changed by 10° in either direction will be excluded from the study as they would be considered non-responders.

4.2.2 Sample Size Calculation

This study is primary focused on investigating the feasibility of delivering the gait modification using a telerehabilitation model and using wearable sensors to monitor performance. Past feasibility or pilot studies using gait modification for knee OA have included 10-20 participants [31, 32]. Indeed, it is also a feasible recruitment goal that our research group has achieved in previous pilot testing with this population [31]. The primary statistical test will compare the between-group difference in FPA at follow up using an analysis of covariance. With a large effect size expected (f = 1.0), power of 80%, alpha of 5%, and two groups with three covariates (two stratification variables and baseline FPA) we require a minimum of 14 participants. Given we are also interested in our secondary analyses, and to account for dropout, we will be recruiting a total of 15 participants per group for a total of 30.

4.3 Procedures

4.3.1 Recruitment and screening

Potential volunteers will be recruited via print and social media, and via our database of previous participants who have indicated interest in participating in future studies. Furthermore, participants who will be enrolled in a related study [H19-02323], and who are interested in participating in this study, will also be evaluated for eligibility. Interested volunteers will complete an online screening form followed by a telephone screen by the study coordinator (Ms. Krowchuk) to assess inclusion and exclusion criteria. Those deemed preliminarily eligible will be sent the consent form for review and any remaining questions will be answered by the study coordinator. The participant will then be invited to attend a gait screening appointment at the Motion Analysis and Biofeedback Laboratory in UBC Hospital. Informed consent will be obtained prior to any data collection at the screening session.

4.3.1 A) Gait Screening Appointment – Data Collection:

The assessment will consist of a thorough explanation of the study requirements, time commitments, and a biomechanical gait screen. The gait screen will be performed using motion capture to measure self-selected FPA and joint moments during walking on an instrumented treadmill. Fifty-four retroreflective markers will be placed on the skin over boney landmarks and 7-high speed cameras (sample rate = 200 Hz) will track the positions of these markers in three dimensions. Additionally, two force platforms within the treadmill (sample rate = 2000 Hz) will measure ground reaction forces during walking. The participants will walk for a total of 8-10 minutes consisting of natural FPA, toe-out and toe-in FPA walking. The specific amount of change in FPA is not relevant, so long as a range of FPA magnitudes are recorded over the collected walking trials. These data will be used to determine whether the participant is a

responder to FPA modification, and which direction (toe-in or toe-out) elicits the greatest response.

The above approach for screening can determine which modification is more optimal, resulting in improved biomechanical outcomes [35, 49]. However, this method of gait analysis is not feasible in clinical settings. Therefore, we will collect a series of measurements related to knee joint loading (specifically the KAM) that are clinically-available with the goal of examining their ability to predict whether a participant will reduce their KAM magnitudes more using toe-in or toe-out modification. These measures will include body mass (kg), frontal plane tibial angle (degrees), and walking speed (m/s), which will be collected using a standard bathroom scale, gravity inclinometer, and timing gates, respectively [50]. These measures alone predicted 67% of the variance in overall peak KAM (body mass = 41% alone) [50], which is often the early stance peak. In addition, FPA will be measured using both a categorical and continuous method. While wearing wet socks, participants will walk over a 3m long piece of medical exam table paper taped to the floor. First, FPA will be visually categorized as neutral, small toe-in/out, large toe-in/out by Ms. Krowchuk. Then, the foot imprint made by the wet socks will also be measured to extract the angle between the long axis of the foot imprint and the walking direction. These data will be compared with the quantitative gait screening assessment outlined above to A) predict KAM magnitudes and B) predict the direction of FPA change that would result in the largest reduction in KAM magnitudes. This examination is exploratory, with the goal of informing future clinical trials in settings without access to motion capture.

4.3.1 B) Gait Screening Appointment – Data Analysis

Immediately after data collection, the walking data will be processed in commercially available software (Visual 3D) and joint moments will be calculated using inverse dynamics. The KAM impulse (KAMi: area under the total KAM – time curve) and the FPA during 20%-80% of stance will be extracted. The reduction in KAMi for a given change in FPA will be linearly regressed and if a 2% reduction in KAMi is not achieved with a minimum of 10° of FPA change, the participant will be excluded. This cutoff value is based on our previous clinical trial which found average KAM reductions of 2% are possible with approximately 10° of toe-out. Additionally, a recent study used this same cutoff to screen participants for a KAM modifying treatment (lateral wedge insoles) in people with knee OA [48]. If a 2% reduction is achieved, the direction of FPA (either toe in or toe out) that elicits the largest reduction in KAMi for a given FPA change will be selected as the FPA modification to be used in the intervention to follow. These methods of screening for response to FPA change and personalizing the direction of FPA change were shown to improve biomechanical outcomes relative to a non-personalized approach [35, 49]. The results of the screening (whether the participant is eligible or not) will be communicated to the prospective participant with 24 hours. In total, this gait screening appointment will last 1.5 hours.

After completing the screening appointment, the participants will be provided a pair of sensorized shoes (see section 4.3.2), charger, instructional booklet, and a walking diary to take home for a minimum of seven days. The instructional booklet outlines details of how to care for and use the sensorized shoes while at home and in the community. Notably, the participant will be instructed to turn the sensor on prior to beginning their walk, and off again after completing a walk. This will result in a single data file per walking bout. The wireless charging unit will be included to allow for charging the sensorized shoes as needed, much like a smart phone. An

online or printed self-report diary will be provided to track daily walking volume, walking times on each day, daily knee pain using an NRS (e.g. overall pain, pain during walking), non-walking exercise activities, and any adverse events related to their knees or walking. Additionally, an 11-point numerical rating scale will be used to report weekly confidence in how accurately the FPA modification was performed (0 = "no confidence at all/unable to perform" and 10 = "completely confident") and difficulty in performing the modification (0 = "not difficulty" and 10 = "most difficult/unable to perform") for all diary weeks after week one. A minimum of ten-minutes of daily walking will be requested to ensure enough data for the analysis.

C) X-ray Assessment

Those meeting all criteria and who have passed the screening appointment will be referred to a local medical imaging clinic, either Greig Associates, Downtown Radiology, or UBC Hospital Radiology. Imaging will consist of a standing, semi-flexed postero-anterior radiograph of both knees. Osteoarthritic severity will be determined by the consensus of two independent assessors using the Kellgren and Lawrence (KL) grading scale [47]. The x-ray assessment will last 30 minutes.

4.3.2 Sensorized shoe details

The sensor module is embedded in the shoe (Figure 1) and consists of a 3-axis accelerometer (signal range: ±4g), gyroscope (±500°/s), and magnetometer (±1200μT) which samples data at 100 Hz. A previously published custom sensor fusion algorithm [51], programmed into a microcontroller, calculates the FPA in real time and stores it on a microSD card for later extraction. FPA is calculated based on five calculations: 1) orientation estimation of the sensor, 2) gait event identification (heel strike and toe off), 3) trajectory estimation of the foot, 4) heading vector estimation, and 5) foot vector estimation [51]. Orientation was determined by integrating angular velocity and was then corrected based on accelerometer and magnetometer data. A zero-velocity detection algorithm determined heel strike and toe-off gait events. The foot and heading vector were computed based on orientation and trajectory estimation, and the FPA was calculated as the angular difference between the two vectors projected onto the horizontal plane. The magnetometer was pre-calibrated to determine an accurate magnetic north [52]. The sensorized shoe design and algorithm has been validated during treadmill [53] and over-ground walking [54] with excellent validity and reliability (absolute error = 1.7º and intraclass correlation coefficients > 0.9).

4.3.3 Randomization and Study Groups

Participants will be randomly allocated to either an Immediate Group or a Delayed Group after completing the baseline collection. The Immediate Group will be introduced to the gait modification and sent home with the sensorized shoes to begin the intervention as described below. The Delayed Group will schedule their

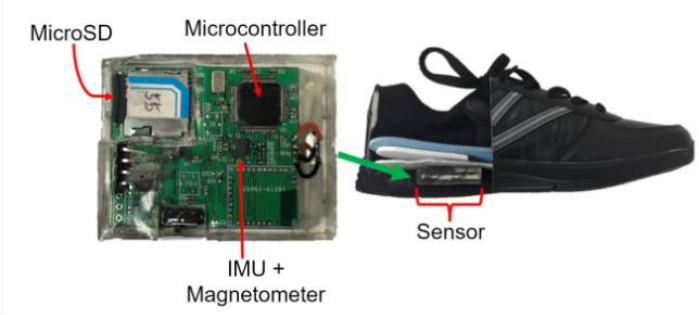


Figure 1. Sensor module construction and placement within the shoe. IMU, inertial measurement unit (accelerometer and gyroscope).

secondary baseline for 6 weeks in the future and receive no intervention for that time period. After the 6 weeks of no intervention, the Delayed Group participants will return to the lab to receive their secondary baseline assessment and begin the intervention thereafter. We will use a variable block size stratified (KL grade and sex) randomization sequence with allocations sealed in envelopes, kept by Ms. Krowchuk, and revealed after the baseline data collection is complete.

4.3.4 Data Collection

An identical baseline, secondary baseline, follow-up , and retention gait assessment (Table 1) will be conducted at the Motion Analysis and Biofeedback Laboratory in UBC Hospital. In a delayed-control study design the Delayed Group undergoes both a control condition and an intervention condition. For the Delayed Group, the control condition is assessed as the change from the baseline to the secondary baseline assessments, while the intervention is assessed as the change from the secondary baseline to the follow-up assessments. The Immediate group does not need the secondary baseline as they will only be undergoing the intervention condition, which is assessed as the change from the baseline to the follow-up assessment.

These assessments will consist of questionnaires, a timed stair climb, and over-ground gait analysis. These sessions will be conducted by Ms. Krowchuk and Mr. Charlton. These assessments will last 1.5 hours each.

Table 1. Timepoints for each data collection broken down by group. Each of the data collection appointments consists of questionnaires, a timed stair climb, and the gait analysis as described below.

	Week 0	**Week 6**	**Week 10**	**Week 12**	**Week 16**
Delayed Group	Baseline	Secondary Baseline		Follow up	Retention
Immediate Group	Baseline	Follow up	Retention		

<u>4.3.4 A) Questionnaires & the Timed Stair Climb:</u>

Baseline & Secondary Baseline Questionnaires:

Q1: 11-point numerical rating scale (NRS) depicting average knee pain over the previous week where 0 = “no pain”, 10 = “worst pain imaginable”

Q2: Knee Injury and Osteoarthritis Outcome Score (KOOS) [55]

Q3 Pain Catastrophizing Scale [56]

Q4: Arthritis Self-Efficacy Scale [57]

Q5: Expected global rating of change in pain and physical function using a 15 point Likert scale where -7 = “a very great deal worse” and +7 = “a very great deal better” [58]. This will be administered at the baseline for the Immediate Group and the secondary baseline for the Delayed Group.

Follow-up Questionnaires:

Q1: 11-point numerical rating scale (NRS) depicting average knee pain over the previous week where 0 = “no pain”, 10 = “worst pain imaginable”

Q2: Knee Injury and Osteoarthritis Outcome Score (KOOS) [55]

Q3: Perceived global rating of change in pain and physical function using a 15-point Likert

scale where -7 = “a very great deal worse” and +7 = “a very great deal better” [58].

Q4: Satisfaction with the gait modification program and the telerehabilitation sessions using a 7-point Likert scale where -3 = “extremely unsatisfied” and +3 = “extremely satisfied”.

Q5: Convenience of telerehabilitation sessions on an 11-point NRS where 0 = “extremely inconvenient” and 10 = “extremely convenient”.

Q6 Difficulty of performing the gait modification during daily walking on an 11-point NRS where 0 = no difficulty/easy and 10 = most difficulty imaginable/unable.

Retention Questionnaires:

Q1: 11-point numerical rating scale (NRS) depicting average knee pain over the previous week where 0 = “no pain”, 10 = “worst pain imaginable”

Q2: Knee Injury and Osteoarthritis Outcome Score (KOOS) [55]

Q3: Perceived global rating of change in pain and physical function using a 15-point Likert scale where -7 = “a very great deal worse” and +7 = “a very great deal better” [58].

Q4: Difficulty of performing the gait modification during daily walking on an 11-point NRS where 0 = no difficulty/easy and 10 = most difficulty imaginable/unable.

At the baselines, medical history, anthropometrics (height, body mass etc.), age, and symptom duration will also be recorded by the assessor. At each assessment, a timed stair climb will be conducted as an objective measure of physical function. This will take place in a stairwell adjacent to the laboratory. The time taken to climb 12 steps (1 flight) will be recorded using a hand-held stop watch with the instruction to “climb as quickly, but safely as possible” [59]. Two repetitions of this test will be performed, and the fasted time will be used.

4.3.4 B) Gait Analysis:

A gait assessment will be performed at the baselines and follow up using identical procedures. A total of 54 reflective markers (45 lower limb, 9 upper limb) will be affixed to the skin bilaterally over key anatomical landmarks as is standard in our laboratory [26]. Fourteen high-speed cameras (sample rate = 120 Hz) will track the positions of these markers and two floor-embedded force platforms (sample rate = 1200 Hz) will measure ground reaction forces. Five passes along the 10m instrumented walkway will be performed shod, wearing the sensorized shoes for standardization. Walking speed at the baseline assessment will be measured using two timing gates placed at a known distance along the walkway. At follow-up, participants will first complete five walking passes at a self-selected speed and then be constrained to walk within ±5% of their baseline walking speed, due to the impact of walking speed on joint moments. After walking in the motion capture system, a lap of the hallways around our laboratory space will be performed while wearing the sensorized shoes (approximately 3 minutes total). This will provide a controlled measurement of FPA from the sensorized shoe for comparison with FPA measured during daily at-home walking. After the baseline appointment, the randomization will be revealed, and the participant will either be allocated to the Immediate Group or the Delayed Group. The Immediate Group will undergo the intervention condition (see section 4.3.5). Conversely, the Delayed Group will undergo the control condition first (see section 4.3.6), and then return for a secondary baseline, after which they would enter the intervention condition (see section 4.3.5).

4.3.5 Intervention Condition: Gait modification

The intervention will be delivered via telecommunication technology, except for an introduction

to gait modification at the baseline appointment. Five telerehabilitation sessions will be conducted over the six weeks between baseline and follow-up appointments. These sessions will be conducted via a password protected official UBC Zoom videoconference application (Zoom Video Communication, Inc., USA) when possible, and a telephone when not. The study trainer will provide a meeting link and password ahead of the scheduled appointment via email. A review of the participants' practice, perceived confidence in performing the gait modification, difficulty in performing the gait modification, daily pain levels over the day and during walking, and adverse events will be recorded by the study trainer. If possible, the participant will "demonstrate" their gait modification on video. No audio or video recordings will be kept, only notes taken by the study trainer during the session. The sessions will last between 15 and 30 minutes. Outside of these sessions, participants will be expected to practice their gait modification in as much of their walking activity as possible. Practice performance will be monitored by the sensorized shoe.

The direction of the gait modification (toe-out or toe-in) will be dictated by the gait screen (section 4.3.1-A), while the magnitude of the increase to FPA will be self-selected, with the goal of increasing "as much as is comfortable". At baseline, the participant will be shown what their natural FPA looks like and what an increase FPA might look like, while being encouraged to use that as a reference when they are unsure if they have increased enough. The telerehabilitation appointments will serve to guide the participants in performing their modification. To assist participants with adherence and self-efficacy we will use, behaviour change techniques derived from physical activity and exercise interventions for knee OA during the telerehabilitation appointments [60]. These will include: 1) a discussion of the benefits related to performing the gait modification in their daily walking, 2) co-development of realistic goals for practicing the gait modification, 3) identification of potential barriers to practice and possible solutions, and 4) encouragement to self-monitor and use the diary to track progress. These techniques will be revisited at each telerehabilitation session with the study trainer to promote accountability, review successes and failures, and collaborate on adjusting goals or finding solutions to barriers.

At-home walking between the baseline and follow-up data collection appointments will be monitored using the sensorized shoes. Participants will be asked to wear the shoes during as much of their daily outdoor walking activity as possible but to record at least 10 minutes per day (or 70 minutes per week). The sensor will be turned "on" immediately before beginning, and "off" immediately after completing a walk. One hour of charging will be needed every 2-3 days to maintain battery power. Apart from these two actions, the participant will not interact with the sensor in any other way. We will also provide instructions along with the shoes to remind participants how the sensor fits in the shoe and to troubleshoot any issues that may arise.

While the sensorized shoes have the storage capacity to record the amount of data that could be collected over the six weeks, there is the possibility of an incident leading to data loss. To mitigate potential data loss, the study trainer will schedule a meeting with the participant at a mutually agreed upon location during weeks 2 and 4. During this meeting the study trainer will download data from the sensor; no discussion of the intervention or the participants' progress will be discussed.

4.3.6 Control Condition: Wait period

Participants allocated to the Delayed Group at the baseline assessment will be sent home to

undergo a 6-week waiting period. During these 6 weeks they will be asked to maintain their current level of activity. No data will be collected during this time. After the 6-week waiting period, the Delayed Group will return for a secondary baseline (identical to the original baseline). This will constitute the pre-post data collection for the control condition. They will then enter the intervention condition as described above in section 4.3.5.

4.3.7 Data processing and analysis

Marker-based motion capture data (as collected during the baseline and follow-up assessments) will be processed using commercially available software using standard techniques our research group has used in previous studies [26, 30, 61, 62]. Sensorized shoe data captured during the baseline and follow-up gait assessment and at-home or community walking will be processed using custom MATLAB scripts.

4.4 Outcome Measures

4.4.1 Primary Outcome Measures

The primary outcomes of this study are those related to feasibility.

A) Modification Performance
    a. Change in FPA between baseline and the primary end point (6-week follow up). Measured via in-lab motion capture and the sensorized shoe during hallway walking.
    b. The change in FPA during at-home walking, comparing the mean baseline at-home walking FPA with each walking bout (represented by a single data file on the sensor module) recorded during the intervention period. Measures of FPA variability will be calculated (variance, standard deviation, interquartile range) in addition to the proportion of steps taken with ≥7° of increase relative to their baseline FPA. Our previous results suggested 7º of change is required to elicit a statistically significant reduction in KAM magnitude [30, 31].

B) Adherence
    a. The total number of telerehabilitation sessions attended over the intervention period. Acceptable adherence is attending all 5 sessions.

C) Compliance
    a. Self-reported confidence in performing the gait modification during at-home walking. Measured via the weekly diary on an NRS scale (0 = no confidence at all, 10 = complete confidence). Acceptable confidence ratings by week 6 are ≥7/10.
    b. Self-reported walking time using the sensorized shoe during at-home walking. Measured via the weekly diary. Acceptable walking time is an average of 70 minutes per week based on our instructions to walk a minimum of 10 minutes per day.

D) Difficulty
    a. Self-reported difficulty in performing the gait modification on an NRS scale (0 = no difficulty and 10 = most difficulty imaginable). Acceptable difficulty by week 6 is ≤4/10.

E) Satisfaction
    a. Satisfaction with the gait modification program and the telerehabilitation sessions on a 7-point Likert scale where -3 = “extremely unsatisfied” and +3 = “extremely satisfied”. Scores of +2 or +3 will be considered “satisfied” and acceptable.

4.4.2 Secondary Outcome Measures

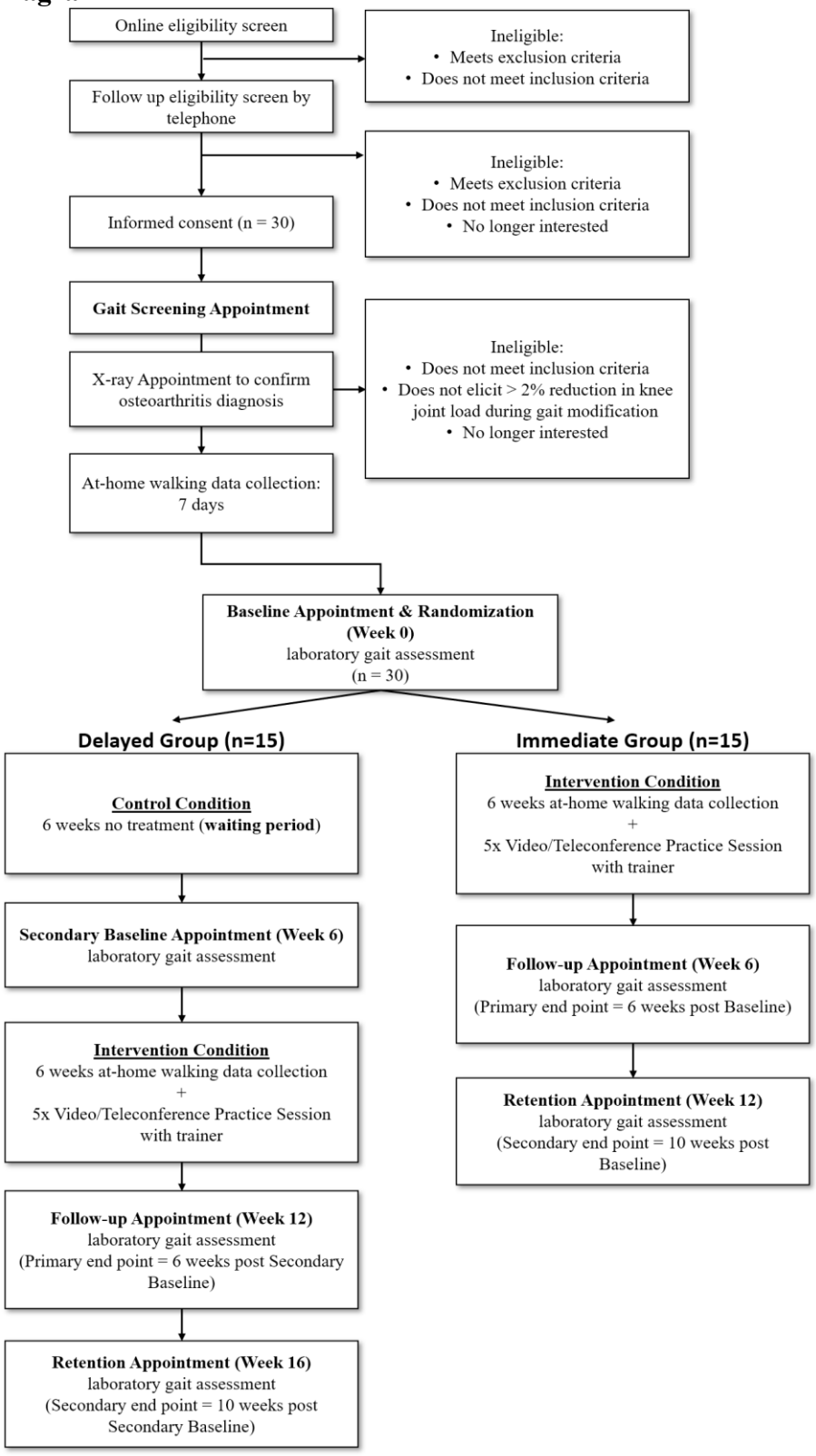
The secondary outcomes are related to the efficacy of the intervention and include the changes in knee OA related symptoms and joint moments, measured during the baselines, follow up, and retention appointments.

F) Knee-OA related symptoms
    a. Pain will be assessed in several ways: 1) the change in score from baseline to follow up and retention of an 11-point NRS where 0 = “no pain at all” and 10 = “worst pain imaginable”, 2) change in weekly average knee pain on an 11-point NRS where 0 = “no pain at all” and 10 = “worst pain imaginable”, 3) the global rating of change score for knee pain on a 15-point Likert scale where -7 = “a very great deal worse” and +7 = “a very great deal better” [58]. The change from baseline to follow-up, and baseline to retention in the KOOS questionnaire subscales will also be assessed to quantify the multifaceted impact knee OA has on the individual [55]. The primary pain outcome will be the WOMAC pain subscale.

G) Joint moments
    a. The KAM is both a valid [11] and reliable [12] estimate of knee joint load, and has important relationships with knee OA-related pain [19-21] and disease progression [14-18, 63]. We will examine KAM impulse and peaks (early and late stance) at baseline, follow up and retention. The knee flexion moment contributes to *in vivo* knee joint forces [10], is related to clinical progression [13] and pain [21], and in some cases may increase with changes in FPA [25]. For this reason, we will also examine the knee flexion moment peak and impulse at baseline, follow up, and retention. The KAM impulse is the primary joint moment outcome.

5 Appendix A

Study Flow Diagram



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