Supporting Physical activity & Reducing sedentary behaviour in Arthritis (SuPRA)

Study Protocol and Statistical Analysis Plan

Clinical Trial Registration Number: NCT02585323

1.0 RESEARCH QUESTION & PROJECT OVERVIEW

This project will address the **Research Question**: Can a non-intrusive physical activity tracking tool, combined with a group education session and advice provided by a physiotherapist (PT), increase physical activity in people with knee osteoarthritis (OA)? We focus on knee OA because it is common (affecting 1 in 10)[1;2] and expensive.[3] There is ample evidence that physical activity improves pain, mobility and quality of life.[4-6] Physical inactivity among people with arthritis, however, is a known public health concern.[7] The 2011 Canadian Community Health Survey found less than half of people with arthritis were physically active.[8] Several modifiable risk factors are associated with low physical activity participation, including lack of motivation,[9] doubts about the effectiveness of prescribed exercises,[10] and lack of health professional advice to adjust their physical activity based on disease status.[11]

The proposed project will combine **the best evidence of implementation interventions** and **digital technologies** to develop a FitViz application (FitViz app) to pair with Fitbit® Flex™ (Fitbit, Inc. San Francisco, CA), a popular wireless physical activity tracking device. Our **overarching goal** is to determine whether the Fitbit/FitViz app, plus a brief education session and counselling by a PT, can improve physical activity participation and reduce sedentary behaviour in people with knee OA. To achieve this goal we will carry out three aims:

Aim 1 – To develop the FitViz **application to pair with Fitbit:** Building on our work in arthritis self-management[12-15] and interactive digital design,[16;17] the FitViz app will consist of the Activity Tracker that will monitor and display individuals' physical activity and sedentary time. The privacy-secured information will be automatically saved to provide feedback to patients about their activity level, and can be shared with health professionals for consultations.

Aim 2 – To conduct a pilot study for the Fitbit/FitViz **app intervention:** We will pilot test the Fitbit/FitViz app intervention with OA patients for a 1-month duration.

Aim 3 – To evaluate the efficacy of the Fitbit/FitViz **app intervention in patients with OA:** Based on the best evidence on physical activity implementation and our work in patients' help-seeking experience,[13-15;18] we anticipate that the Fitbit/FitViz intervention will improve physical activity in people with OA. The intervention will be evaluated in a proof-of-concept randomized controlled trial (RCT). We hypothesize that, compared to participants in a control group, those in the intervention group will: 1) increase moderate/vigorous activity as determined by an objective measure, 2) reduce sedentary time during waking hours, 3) improve in OA disease status, and 4) improve in their self-efficacy of OA management.

1.1 Significance and Potential Impact

The *Supporting Physical activity & Reducing sedentary behaviour in Arthritis (SuPRA)* project is significant for three reasons. First, it adapts an existing popular activity tracking device to provide on-demand feedback and health professional support for OA patients. By customizing existing technologies and connecting to a secure user-friendly social network, patients may monitor their progress and share information at a time they prefer, and with people of their choice. Second, our mixed-methods evaluation design will provide insight into new paradigms for supporting an active lifestyle in people with chronic diseases. Finally, we have the integrated expertise in health research, computer science, sociology and biostatistics, which is needed to design and rigorously evaluate this new digital intervention. Our interdisciplinary approach will contribute to solving a long-standing problem of low uptake of digital tools in the health sector due to poor conceptualization and design of the current tools.[19-21]

This project is also timely in answering the call-for-action by the Arthritis Alliance of Canada to **reduce obesity and improve pain management in people with OA**.[3] Physical activity is indeed a key component in maintaining a healthy body weight and managing pain. The literature indicates several effective strategies for improving physical activity in people with chronic conditions[22-25] (see Section 2.1). In reality, however, some strategies[25] can be implemented only in areas where arthritis-trained PTs and occupational therapists

(OTs) are available locally. By developing a FitViz app that is compatible with an automatic physical activity tracker, patients can share their activity information and obtain feedback from health professionals regardless of their place of residence. Hence, the proposed intervention has the potential to broaden the reach of effective strategies to improve physical activity in arthritis patients across the country.

Our team combines the clinical experience of arthritis health professionals (**Noonan**, **Adam, Aviña, Li**) and expertise in knowledge translation (KT) (**Li, Hoens**), multimedia and visualization (**Gromala**, **Shaw**), communication and entertainment technologies (**Smith**), clinical epidemiology, biostatistics, and outcomes research (**Goldsmith, Aviña**, **Backman**), medical sociology (**Townsend**), and objective physical activity measures (**Feehan**). Of note, Dr Gromala was a first-generation designer at Apple Computer; hence, she has ample expertise in human-computer interaction and user-centred design. Also, she has experience in developing Fitbit-compatible apps through her current work in customizing the device for chronic pain management. We have adopted an Integrated KT approach, wherein knowledge users have been involved as equal partners alongside researchers from the planning stage to project completion. Future implementation of the Fitbit/FitViz app will be facilitated by individuals in leadership roles within our partner organizations. Further, Drs Li, Gromala and Shaw are Network Investigators of Graphics, Animation & New Media (GRAND, a Network of Centres of Excellence [NCE]). Hence, we will benefit from GRAND NCE's guidance about partnering with industry to produce the FitViz app on commercial platforms.

2.0 BACKGROUND – Physical Activity in People with OA: Solid Evidence, Weak Uptake.

Arthritis is the most common cause of severe chronic pain and disability worldwide.[26;27] In Canada, arthritis affects over 4.6 million people and is projected to affect 10 million within a generation.[3] The vast majority of these people will have OA. Analysis by the Arthritis Alliance of Canada estimates one new diagnosis of OA every 60 seconds, resulting in nearly 30% of the employed labour force having difficulties working due to OA.[3] There have been major advances in treatment, but the use of effective interventions has severely lagged. For example, there is evidence that physical activity and weight management can improve pain, mobility and quality of life.[4-6] 2008 guidelines by the OA Research Society International (OARSI) specifically recommend the use of aerobic, muscle strengthening and water-based exercises, as well as weight reduction as the first-line management of knee/hip OA.[28] The Canadian Physical Activity Guidelines recommend at least 150 minutes of moderate-intensity physical activity per week, performed in 10-minute bouts, for maintaining good health.[29]

Physical activity is an essential first-line treatment for people with OA,[28] partly due to its effect in managing weight.[30;31] Furthermore, it reduces risks of metabolic syndromes, such as the level of plasma glucose.[32] The gap between this knowledge and the 'action' of being physically active, however, is astounding. The 2011 Canadian Community Health Survey reported that over 57% of people with arthritis were physically inactive during their leisure time, compared to 46% of those without arthritis.[33] This concurs with a 2013 systematic review that only 13% of people with OA accumulated $\geq$ 150 minutes per week of moderate/vigorous physical activity in bouts of 10 minutes.[34] Another recent study using accelerometers, an objective physical activity measure, found over 90% of people with knee OA did not meet the physical activity guidelines.[7]

The current public health message is that *being physically active is good*, but people with knee OA may be reluctant to perform moderate/vigorous activity due to pain and fatigue.[9;10;35] For these people, maintaining some level of activity is still important. Recent studies indicate that sedentary lifestyle[*] (i.e., too much sitting) is a predictor of poor health outcomes.[36-40] Interestingly, light activities[†], even done below the moderate

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[*] **Sedentary behaviour** = Any waking behaviour with an energy expenditure of < 1.6 metabolic equivalent tasks (METs) or less while in a sitting or reclining posture.

[†] **Light activity** = Activities with an energy expenditure of 1.6-2.9 METS.

intensity level (e.g., daily tasks done while standing or walking slowly), provide health benefits[32;41;42] and decrease cardio-metabolic biomarkers in people with chronic diseases.[32;42] The detrimental health effect of 'sitting too much' is independent of the person's physical activity level. Being an 'active couch potato'[39] (i.e., when someone exercises for an hour a day but sits still for the rest of the time) is bad for one's health. Hence, there is a need for interventions to improve moderate/vigorous physical activity, as well as decrease sedentary behaviours.

2.1   Evidence on Interventions for Improving Physical Activity

Several modifiable risk factors are associated with low physical activity participation in people with arthritis. These include lack of motivation,[9] doubts about the effectiveness of exercise,[10] and lack of health professional advice.[11] These risk factors highlight the need for a multifaceted approach that provides support in terms of knowledge, skill development and timely advice from health professionals, as well as motivational support to stay active. In health promotion, the Theory of Planned Behaviour[43] has been used extensively to predict health-related behaviours (Figure 1).[44] The theory[43] posits that the adoption of a health-related **behaviour** is driven by the person's **intention** and **perceived behavioural control (PBC)**. The latter represents the perceived skills/ability, resources and opportunities to perform the behaviour.[45] Furthermore, the strength of **intention** is determined by **PBC**, **attitudes** toward the behaviour, and **subjective norm** (e.g., the perception of how others view the behaviour and the importance of these views to the person). In a meta-analysis, Hagger et al.[46] reported that intention and PBC accounted for approximately 30% of the variance in physical activity behaviours, whereas attitude and PBC accounted for 40% of the variance in intention. Rhodes et al. found that interventions targeting *affective attitude* (i.e., enjoyment, pleasure) were particularly effective for predicting intention and physical activity behaviours.[47] Examples of affective attitude interventions include using music[22] and interactive video games,[23] as well as an activity-friendly environment (e.g., availability of facility or sidewalks).[24]

Once patients start being active, they need feedback on their progress. A 2010 Cochrane review concluded that 'graded exercise activity', which initially focuses on simple exercises for weaker muscles and less painful areas before gradually increasing to more challenging activities, is effective for improving adherence to physical activity programs in chronic musculoskeletal conditions.[25] Refresher sessions are recommended to improve performance accuracy.[48] Progression of activities can be guided by a PT.[25] These interventions are, however, challenging to implement because only some parts of Canada have access to publicly funded arthritis-trained PTs for ongoing consultation and monitoring (e.g., urban areas in Ontario, Alberta and BC).[49] Given the low physical activity participation, multi-faceted interventions that enable patients to communicate their activity performance, obtain feedback from health professionals and receive motivational support across geographic locations have potential to address the gap in care. The use of online consultation for patients with arthritis has been recently studied in a RCT.[50] All participants had access to an arthritis exercise website. The intervention group also received distant supervision by a PT via emails. The study shows a significantly greater improvement in moderate-level physical activity in the intervention group at six months (38% vs. 22% in the control group) and nine months (35% versus 11%).[50] It did not, however, assess the effect on sedentary time reduction.

3.0   PROGRESS TO DATE

Projects conducted by members of this team have laid the groundwork for developing, testing and disseminating the proposed intervention. For example, to improve physical activity in patients with OA, Nominated Principal Applicant (NPA) **Li** developed a CIHR-funded web-based physical activity coach called *OPEN* (Osteoarthritis Physical Activity and Exercise Network, funding number: KPC-113990; Appendix A). Guided by the Theory of Planned Behaviour, OPEN is an online interactive program that 1) demystifies the myths surrounding arthritis and physical activity, 2) provides details of suggested activities based on individuals' preferences, and 3) coaches patients to set and achieve physical activity goals. A community-based RCT is underway.[51]

Our team also completed a pilot study to determine the primary outcome measure. **Feehan** and **Li** recruited 22 healthy individuals to access the accuracy of two research-based accelerometers measuring physical activity and sedentary behaviour (Actigraph[TM] GT3X: the most commonly used accelerometer for objective physical activity measure,[52;53] and SenseWear[TM] Mini: a newer multi-sensor physical activity monitor that has recently been adopted for research purposes). Although both accelerometers were able to accurately record moderate/vigorous activity, SenseWear performed notably better than Actigraph in differentiating between sedentary and non-sedentary/light physical activities (SenseWear sensitivity = 0.98; specificity = 0.70; positive predictive value = 0.81).[54] Based on these findings, we will use SenseWear as the primary outcome measure for evaluating the Fitbit/FitViz app intervention.

Further, to assess whether it is feasible for people with joint pain to use the proposed physical activity tracking intervention for an extended period of time, **Feehan** and **Li** completed a second pilot study. Ten patients with rheumatoid arthritis (RA) were recruited to wear a Fitbit Flex for four weeks and a SenseWear Mini in Weeks 1 and 4. All 10 participants complied with the protocol. The ease of use of Fitbit and Sensewear was rated 4.8 and 3.4 (on a 5-point scale), respectively, indicating the feasibility for people with joint pain to wear these devices for an extended period.

4.0   RESEARCH APPROACH

Our research approach is guided by the eight-phase 'Action Cycle' of Graham's *Knowledge-to-Action Process*.[55] In this study, we have modified the Action Cycle to reflect our goal of improving physical activity among patients with knee OA. The eight phases are: 1) identifying the problem; 2) identifying the evidence-based solution; 3) assessing barriers to applying the solution; 4) adapting the solution to the users' context; 5) developing a tool to enhance uptake of the solution; 6) ensuring the tool is user-friendly; 7) evaluating outcomes; and 8) sustaining ongoing use of the solution. We have identified low physical activity level in people with knee OA as the **problem**. Our **solution** is to support patients to be active by developing a new multi-faceted intervention for this population. Phases 1 to 4 are described in the previous sections of this application. The proposed FitViz app development and research plan that follows (Sections 4.1-4.3) will address Phases 5 to 7. In the section that details our KT plan (Section 7.1), we will address Phase 8.

4.1   Aim 1: Development of the Communication & Social Network Application (Months 1-6)

The FitViz app will be developed in the first six months. This new app will be compatible with Fitbit Flex (Figure 2), a wireless physical activity monitoring device which is worn as a wrist band. Fitbit is a compact gross body movement tracking device that tracks and displays steps walked, stairs climbed and gross physical exertion. It can be worn during water-based activities. Fitbit has an open source platform that permits customization of a new and secured application for users with chronic diseases.

We will develop the FitViz app using Ruby on Rails web application development framework[56] and application programming interface (API). Housed on a secure server with password-protected access at the Arthritis Research Centre (ARC) of Canada, the FitViz app will synchronize wirelessly with Fitbit Flex and will display the patients' physical activity level and sedentary time. The information will be automatically saved to provide on-demand feedback to the patient, and can be shared with health professionals. Congratulatory messages will be shown on the FitViz app and e-mailed to individuals when they achieve their weekly goals of moderate/vigorous physical activity and reduced sedentary time.

To display the physical activity information to patients and their health professionals, we will design a personalized visualization of weekly measures of physical activity (i.e., calories burned, steps taken and sedentary time; Appendix B: Sample Screenshot). This visualization is currently available on the Fitbit online platform, and can be modified for the FitViz app to show information relevant to people with OA. The physical activity report will allow patients to share the information with their health professionals. It will also graphically demonstrate the benefits of being active for the individual.

4.2   Aim 2: Pilot Testing (Months 7-9)

To ensure user-friendliness of the FitViz app with the intervention, we will recruit 10 patients with OA to participate in pilot testing. The sample size is based on published usability studies on web-based interactive tools for patients with arthritis,[58-62] including two studies led by investigators in this team.[58;62] These studies identified all major usability issues with a sample between 9 and 15 patients. For the pilot testing phase, participants are eligible if they 1) have a physician confirmed diagnosis of knee OA, or are 50 years or older and have felt pain/discomfort in or around the knee during the previous year that last year more than 28 separate or consecutive days, 2) have no previous diagnosis of RA, psoriatic arthritis, ankylosing spondylitis, polymyalgia rheumatica, connective tissue diseases, fibromyalgia or gout, 3) have no history of using disease-modifying anti-rheumatic drugs or gout medications, 4)have no prior knee arthroplasty and not on the waiting list for total knee or hip replacement surgery, 5) have not had surgery in the back, hip, knee, foot, or ankle joints in the past 12 months, 6) have no history of acute injury to the knee in the past six months, 7) have an email address and daily access to computer with internet connection, 8) are able to attend a 1.5-2 hour group session at Arthritis Research Canada, Mary Pack Arthritis Centre, or a Fraser Health Facility, and 9) are able to attend a 1-hour phone interview. We will exclude people who 1)have previously used any physical activity wearables, 2) have received a steroid injection in a knee in the last 6 months, 3) have received a hyaluronate injection in a knee in the last 6 months, 4) use medication that may impair activity tolerance (e.g., beta blockers), and 5) are at risk when exercising, as identified by the Physical Activity Readiness Questionnaire (PAR-Q).[69] Participant will be recruited from community physiotherapy clinics in BC within Fraser Health, community health centres within the metropolitan areas of Delta, Surrey, Burnaby, New Westminster, Langley, Coquitlam, Maple Ridge, Chilliwack, Mission, and Abbotsford, on social networking websites (Facebook, Twitter, Kajiji, Craigslist), and the Arthritis Research Canada website. Participants will also be recruited from Arthritis Consumer Experts' (ACE) JointHealth e-blast, ARC Arthritis Patient Advisory Board, and consumer collaborators' group newsletters, websites, and social media (e.g. CARP, The Arthritis Society).

Pilot Study Procedure: Interested individuals will be screened for eligibility and consented. After completing the baseline measurements, participants will be asked to wear the study team's Fitbit Flex for 4 days prior to starting the intervention. Following this, they will attend a 1.5-2 hour education session at which they will receive standardized education from a physiotherapist from Fraser Health. Research staff will be present to set up participants' Fitbit and FitViz app. Physical activity information captured from the 4 days of wearing the Fitbit Flex will be used by the physiotherapist to set participant's goals. Participants will use the Fitbit/FitViz app for 1 month for the intervention. Information about their physical activity and sedentary behaviours will be captured by the Fitbit and synchronized with the FitViz app's Activity Tracker function. The app will display personalized activity summaries, which will be shared with the study PT over 2 bi-weekly phone calls for the 1-month duration.

Outcomes Measures: The primary outcomes measure will be time spent in moderate/vigorous physical activity, and we will also record the time spent in sedentary behaviours. Secondary outcomes measures will be measured with the Knee Injury & OA Outcome Score (KOOS),[77;78] Partners in Health Scale, and Theory of Planned Behaviour questionnaire. Participants will wear a SenseWear Mini accelerometer for 7 days at baseline and at the end of the Month 1, and complete the questionnaires at the same time-points. Demographic variables and comorbid conditions will also be collected at baseline. Further details about the SenseWear, KOOS, and Partners in Health Scale can be found in Section 4.3.

At the end of Month 1, participants and the physiotherapists will also be asked to complete the System Usability Scale[65;66] to assess the overall usability of the app (0-100, higher = more user-friendly; a mean score of $\geq$ 87.5 is considered an excellent tool[65;66]). A PhD trainee will conduct an interview with each participant and PT to further examine the user experience.

4.3   Aim 3 – Evaluate the efficacy of the Fitbit/FitViz app intervention (Months 10-24)

This evaluation will employ a **mixed-methods design**. Results of the proof-of-concept study will be enriched by in-depth interviews, which will provide information on how individuals use the Fitbit/FitViz app to manage their physical activity in the context of their daily life. Combined, the quantitative and qualitative data will provide a rich source for designing the future implementation strategy.

The proof-of-concept study will employ a stepped wedge RCT design, whereby the intervention will be sequentially rolled out to participants over a number of time periods.[67;68] This design is particularly suitable when the proposed intervention is likely to do more good than harm, because it allows all participants to receive the intervention by the end of the study.[68] The order in which individuals receive the intervention is, however, determined at random. The strength of the stepped wedge design is that it can properly address the efficacy question, while avoiding the dilemma of withholding the intervention to some participants, as in a parallel group design. In the proposed study, individuals are <u>eligible</u> if they 1) have a physician confirmed diagnosis of knee OA, or are 50 years or older and have felt pain/discomfort in or around the knee during the previous year that last year more than 28 separate or consecutive days, 2) have no previous diagnosis of RA, psoriatic arthritis, ankylosing spondylitis, polymyalgia rheumatica, connective tissue diseases, fibromyalgia or gout, 3) have no history of using disease-modifying anti-rheumatic drugs or gout medications, 4) have no prior knee arthroplasty and not on the waiting list for total knee or hip replacement surgery, 5) have not had surgery in the back, hip, knee, foot, or ankle joints in the past 12 months, 6) have no history of acute injury to the knee in the past six months, 7) have an email address and access to internet on a daily basis, and 8) are able to attend a 1.5 hour group education session. We will exclude people who 1)have previously used any physical activity wearables, 2) have received a steroid injection in a knee in the last 6 months, 3) have received a hyaluronate injection in a knee in the last 6 months, 4) use medication that may impair activity tolerance (e.g., beta blockers), and 5) face a level of risk by exercising as identified by the Physical Activity Readiness Questionnaire (PAR-Q).[69]

Participants will be recruited from community physiotherapy clinics in BC within Fraser Health. Community health centres within the metropolitan areas of Delta, Surrey, Burnaby, New Westminster, Langley, Coquitlam, Maple Ridge, Chilliwack, Mission, and Abbotsford, on social networking websites (Facebook, Twitter, Kajiji, Craigslist), and the Arthritis Research Canada website. Participants will also be recruited from Arthritis Consumer Experts' (ACE) JointHealth e-blast, ARC Arthritis Patient Advisory Board, consumer collaborators' group newsletters, websites, and social media (e.g. CARP, The Arthritis Society), and VCHRI weekly e-update which is distributed to staff, researchers, faculty, and affiliates of VCHRI. To ensure the research is completed in the timely manner, the RCT recruitment will begin during usability testing. Eligible and consenting individuals will be re-consented when the RCT enrolment is ready.

<u>Study Procedure (Figure 3)</u>: Interested individuals will contact the research assistant who will screen for eligibility and obtain informed consent. After completing the baseline measures, they will be randomly assigned to the Immediate Intervention Group or the Delayed Intervention Group (i.e. control) in 1:1 allocation ratio. Randomization will be performed using computer-generated random numbers in variable block sizes, which are necessary to ensure adequate allocation concealment.

The <u>Immediate Intervention Group</u> will attend a 1.5-hour group education session (3-6 participants), where they will receive standardized education by a PT from Fraser Health Authority or Vancouver Coastal Health. The session will address physical activity and the detrimental effect of sedentary behaviour in people with OA. Ways to increase enjoyment while exercising will be highlighted, such as exercising outdoors and with music. Research staff will be present to set up participants' Fitbit and FitViz app. At the end of the session, the PT will help participants set activity goals and provide personalized activity options.

In Months 1-2, participants will use the Fitbit/FitViz app. Information about their physical activity and sedentary behaviours will be captured by the Fitbit and wirelessly synchronized with the FitViz app's

Activity Tracker function. The app will display personalized activity summaries, which will be shared with the study PT. The PT will review the progress with participants via four biweekly phone calls and progressively modify their activities. Participants may also contact the PT via email at any time if they have questions. In Months 3-9, participants will continue using the Fitbit/FitViz app and have access to the PT via email, but no biweekly phone calls. The Delayed Intervention Group will receive the full intervention three months later. Both groups will receive a monthly study newsletter during the 9-month period.

Follow-up assessments will be performed at the end of Months 3, 6 and 9. To better understand the reasons people do or do not adopt and maintain recommended levels of physical activity, all participants will be interviewed for one hour by phone after the intervention by a PhD medical sociology trainee. Interviews will focus on 1) goals set, strategies used, barriers/facilitators to being physically active, 2) their experience with the intervention, 3) the nature of activities they engage in, and 4) their experience of being a research participant. These data will enrich the RCT data, and inform the design of the future implementation strategy.

Outcome Measures: Our **primary outcome measure** will be time spent in moderate/vigorous physical activity. In addition, we will record the time spent in sedentary behaviours. Participants will wear a SenseWear Mini accelerometer for 7 days at baseline, and Months 3, 6 and 9. SenseWear is a multi-sensor monitor that is worn on the upper arm over the triceps. It integrates tri-axial accelerometer data, physiological sensor data and personal demographic information to provide estimates of steps, energy expenditure and METs. Almeida et al.[70] determined that a minimum of 4 days of wear is required to reliably assess energy expenditure from different levels of physical activity in people with RA (intraclass correlation coefficient - ICC > .80). Tierney et al.[71] showed in 2013 that SenseWear was a valid tool for estimating energy expenditure during activities of daily living in this population (ICC = 0.72). Further, a strong relationship was found between SenseWear and indirect calorimetry measures of energy expenditure for activities of daily living (Pearson's r = 0.85).[71] SenseWear can be worn 24 hours a day. Hence, it can capture a full picture of physical activity and sleep pattern, as well as the off-body time throughout the day.[72;73]

An important feature of the SenseWear Mini is its ability to differentiate between sedentary and non-sedentary/light physical activities,[54] making it an ideal instrument to assess both active and sedentary behaviours. We will calculate the **average daily moderate/vigorous activity accumulated in bouts per day**. A bout is defined as 10 or more consecutive minutes at the level of $\geq$ 3 METs (i.e., the lower bound of moderate/vigorous activity), with allowance for interruption of up to two minutes below the threshold.[74] For sedentary behaviours, we will calculate the average daily time spent with an energy expenditure of < 1.6 METs, occurring in bouts of 20 minutes or more during waking hours.[40;42;75;76]

Secondary outcomes will be measured with 1) the **Knee Injury & OA Outcome Score (KOOS)**,[77;78] 2) the **Partners in Health Scale, 3) Theory of Planned Behaviour, 4) The Patient Health Questionnaire-9 (PHQ-9)**, and 5) **The Self-Reported Habit Index (SRHI)**.[79] The KOOS consists of five subscales: knee pain, stiffness, daily activity, sports/recreation, and quality of life. It was originally developed for people recovering from injuries such as anterior cruciate ligament and meniscus injury, and has been validated in people with OA.[77;78] KOOS includes all the items of WOMAC in its original format,[80] and has a normalized aggregate score varying from 0 (worst outcome) to 100 (best outcome). The Partners in Health Scale is a 12-item measure designed to assess self-efficacy, knowledge of health conditions and treatment, and self-management behaviours such as adopting a healthy lifestyle (Cronbach's α=0.82).[79] In addition, motivation for physical activity will be measured with Rhodes's 7-point Likert-type Theory of Planned Behaviour questionnaire.[81-83] It consists of 16 items measuring all components of the theory. Previous studies using this measure have shown good predictive validity and internal consistency in adult populations.[81-83] The PHQ-9 consists of nine questions (rated from 0 to 3) that correspond to nine diagnostic criteria for major depressive disorder. A total score of greater than 11 indicates a major depressive disorder.[98] A difference of at least 5 points indicates clinical change over time.[99] The SRHI is a 12-item scale, rated on a 7-point Likert scale, that measures characteristics of habitual behavior (reliability

minimum α=0.81). We will ask participants to rate their strength of habit for three specific activity-related behaviors: sitting during leisure time at home, sitting during usual occupational activities, and walking outside for 10 minutes. A higher score indicates a stronger habit or behavior that is done frequently, automatically, and done without thinking about it.[100,101]. Demographic variables and comorbid conditions will also be collected at baseline. We will also track the FitViz app usage statistics (frequency & duration of use) and adverse events (falls, cardiovascular and musculoskeletal events)[84] during the evaluation periods.

Power Calculation: Our collaboration with PABC, Fraser Health, and patient groups will allow the study to recruit 60 eligible participants within 6 months. For a proof-of-concept study, it is reasonable to expect moderately large difference between groups after the physical activity intervention. In one of our pilot studies involving 27 patients with RA, Feehan et al. found an average of 71.8 minutes (SD=96.2) of activities at 3 METs bouted at 10-minute intervals (unpublished data). Assuming an attrition rate of approximately 15%, we anticipate 50 of the 60 participants will complete the study. With a sample size of 50 and α-level of 0.05, we will have 96.3% power to detect a between-group difference of at least 10 minutes, or 13.9% in the primary outcome measure after the intervention (Appendix C).

Data Management: Prior to use, the SenseWear unit will be configured using the participant's handedness, smoking status, age, sex, height and weight and set to collect data in one-minute intervals. All data will be downloaded and processed using the SenseWear Professional™ software (Version 8.1), and stored at the secured server at ARC, which backs up the data every 24 hours. The processed data will then be exported for further processing and data analysis using a customized data analysis protocol developed by Feehan using MATLAB® software. Self-reported outcome measures will be administered using the online survey system hosted by ARC. This is a fully encrypted, secure website with 128-bit SSL encryption, which is also used by many major banks. To minimize human error, skip logics for questions and the available range for each variable will be programmed in the online questionnaire. Databases will be created in the Microsoft Excel format, which can be easily converted into SAS, SPSS, and other statistical packages for statistical analysis. We will use multiple imputations to investigate the impact of missing data in the study, although every effort will be used to minimize the amount of missing data.

Data Analysis: Because the aim of a proof-of-concept study is to demonstrate evidence of efficacy, an intention-to-treat analysis will be performed. The main analysis will include the bouted mean moderate/vigorous activity minutes (primary outcome measure), bouted mean sedentary minutes, the KOOS and the Partners in Health Scale. For the main comparison, we will use analysis of covariance (ANCOVA) to compare between the Immediate Intervention Group and Delayed Intervention Group at 3 months, using the baseline measure as a covariate. In addition, ANCOVA will be used to assess the difference between the Intervention Group at 3 months and the Control Group at 6 months, with the baseline measure as a covariate. We anticipate that the two groups should be similar if the delay of 3 months in the Delayed Intervention Group does not influence the effect of the intervention. We will also use repeated measure ANOVA to assess the within group differences over the four assessment periods. No adjustment will be made for multiple comparisons because Type II error is a greater concern than Type I error in proof-of-concept studies.[85;86] Descriptive analysis will be used to summarize participant characteristics and comorbid conditions.

The literature suggests that physical activity and chronic disease self-management experiences are different for men and women.[87;88] Although this project is not powered to examine the effect in outcomes for men and women separately, exploratory analysis will be done to assess trends in each group. The results will provide information for a sample size calculation in future studies of online physical activity interventions.

We will also examine the mechanism of the intervention on physical activity participation by conducting mediation analysis using the bootstrapped sampling distribution model by Preacher & Hayes.[89;90] Changes in Theory of Planned Behaviour variables over the intervention period (i.e., between baseline and 3 months) will be examined as potential mediators on physical activity behaviour after the 3-month intervention.

For the qualitative interviews, we will conduct an iterative content analysis, whereby codes will be identified and revised as interviews are analyzed. Initial open coding (i.e., assigning conceptual labels to the content) will be followed by clustering the labels into thematic categories. Quotes representative of the thematic categories will be identified to illustrate participants' perspectives on physical activity, nature of activities, and their experiences as research participants. These data will inform the interpretation of statistical analyses and the design of future studies, for example, ways for health professionals to provide feedback about physical activity to patients with OA or propose activities to facilitate health behaviour change.

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