Improving Resilience and Longevity for Workers Through Exercise
Protocol

The Canadian workforce is aging. The most prevalent age group is 50-54 years and most of these Canadians will aim to continue working over the next 10 years [1]. However, the impact of arthritis on aging Canadians compromises their ability to continue working [2]. By 2031, over 2 million Canadians aged 45 to 64 years will have arthritis. Among those with arthritis, one of three is expected to be out of work [3]. This unemployment rate is worse than for any other chronic health condition [3].

We aim to boost the ability of older adults with the most common arthritis, osteoarthritis (OA), to engage in the workforce for as long as they desire. Osteoarthritis targets older adults and currently affects 4.4 million Canadians, a number expected to grow to 10 million in the next two decades [4]. The disease causes degeneration of all joint tissues, most commonly in the knee and hip [5]. Further, OA affects the Canadian labour force: 30% of those with OA will experience difficulty at work [4]. Pain and immobility caused by OA result in frequent absences from work and, ultimately, lost productivity [6].

Identifying strategies to promote productivity among older workers with knee and hip OA will be of great public health significance in the coming decades. However, we face two challenges. First, obesity among sedentary workers is a risk for worsening knee and hip OA. A five unit increase in body mass index is associated with a 35% increased risk of developing OA [7]. Second, large occupational loads on the knee and hip worsen OA. Pooled data from 66 studies (n=526,343) revealed that, compared to workers who stand, those required to frequently squat, kneel, and carry have over a 60% increased risk of worsening chronic pain [8]. Therefore to promote productivity, we must address obesity while minimizing exposure to large loads. Unfortunately, few studies have investigated strategies to improve productivity among aging workers with OA [9]. A systematic review showed that exercise has the most promise in achieving this goal because it reduces pain and sick time, and improves mental health [9]. By comparison, ergonomic interventions (e.g., mechanical patient lifts, ergonomic work-stations), and education yield a minimal effect on pain, sick time, or longevity in the workplace [9]. Not surprisingly, there is a call for studies examining exercise for the aging worker with knee and hip OA [9].

RESEARCH PURPOSE AND SCOPE

The purpose of this study is to examine the impact of an OA-specific aerobic and strengthening exercise program, delivered within the workplace, on mobility, pain, physical capacity, and resilience among workers with knee or hip OA as well as those with no joint pain. We hypothesize that exercise designed for OA, delivered at work, will improve all of these outcomes.

METHODOLOGY

Participants

Participants will be women and men employed in administrative roles at Ford Motor Company in Oakville. All eligible participants will be welcome to participate.

Inclusion and Exclusion Criteria: We will recruit 40 participants from Ford. Inclusion criteria include part- or full-time employment in an administrative role at Ford. Men and women will be welcome. The exclusion criteria include a self-reported history of patellofemoral symptoms because the exercise program delivered to the intervention group places large loads on this joint. Participants with a previous osteoporotic fragility fracture will be excluded. Those with osteoporosis but no fragility fracture will be eligible. Exclusion criteria include active non-arthritic joint disease (e.g., gout); conditions that might be exacerbated (e.g., unstable angina); neurological conditions such as a stroke; leg trauma within 3 months; and cancer. Participants will be screened for the American College of

Rheumatology (ACR) criteria for clinical knee or hip OA. However, participants not meeting this criterion will still be eligible to participate.

Recruitment & Sample Size: Participants will be recruited through the research coordinator at McMaster. Administrative personnel at Ford who are not in a supervisory role (i.e., Fitness Centre Manager) will disseminate recruitment posters and an email/verbal script. Both will request that interested employees directly contact the research coordinator. These materials will explicitly state that the decision to participate, or not participate, will not be shared with Ford administration.

Our primary outcome is change in self-reported mobility on the Lower Extremity Functional Scale (LEFS). Self-reported mobility is critically important from the patient's perspective [13] and is likely to see the largest effect of exercise [14]. The minimal clinically important difference (MCID) of the LEFS is 5 points [15, 16]. Rehabilitation produces changes of ≥10 LEFS points, with an effect size of 0.5[17]. Given a Type I error=0.05 on change, n=27 will yield 81% power.

Randomization: An independent research assistant will conduct randomization and concealed allocation. Participants will be randomized to receive either the exercise intervention, or no intervention. After baseline, the independent research assistant will provide each participant with one sequentially numbered, sealed, opaque envelope that identifies the intervention they will receive.

Interventions

Exercise Program: A 12-week exercise intervention will be offered in the workplace. Ford employees will complete their exercise program at Ford in the on-site exercise facility. 20 of the 40 participants will be randomized to the exercise intervention.

A 12-week supervised exercise program designed for OA knees and hips will emphasize strengthening leg muscles with minimal loads. Each exercise program will be 30 minutes and offered at 7:00am (Mon, Tues, Wed, Thurs, Fri). These timeslots will enable participants to exercise at the start of their workday. Participants will be asked to attend 3 or more supervised exercise sessions weekly [18]. Strengthening will focus on "body weight" strategies that we have used previously, such as squats and lunges. A certified yoga instructor will offer exercise modifications and education about anatomy, OA, and proper lower limb alignment. Over 12 weeks, the exercises will be progressed. These exercises yield nominal loads while increasing leg strength [19]. Our previous randomized controlled trial of this intervention (n=31), delivered within the community, yielded improvements in pain, mobility and self-reported physical function without adverse events.

Control Program: 20 of the 40 participants will be randomized to the control group. These participants will be asked to refrain from changing any interventions or activity existing at baseline over the 12-week intervention period. Afterwards, these participants will be offered the same exercise program free of charge.

Outcome Measures

Outcome measures will be collected at baseline and immediately after the 12-week exercise program.
Primary Outcome: The primary outcome is the change between baseline and follow-up on the LEFS [16, 20, 21]. The LEFS consists of 20 items on an adjectival scale that assess difficulty during mobility tasks ranging from transfers to running. This range avoids ceiling and floor effects. It is reliable and valid in OA and has superior sensitivity to change compared to similar measures [17, 21, 22].

Secondary Outcomes

- *Pain:*
    - The Intermittent and Constant Osteoarthritis Pain (ICOAP) self-report questionnaire consists of two subscales: constant and intermittent pain [23]. Data from the ICOAP demonstrate excellent test-retest reliability, internal consistency, and criterion validity in knee and hip OA [24]. The ICOAP shows responsiveness following physiotherapy [25].
    - As well, we will collect the Knee/Hip injury and Osteoarthritis Outcome Score (K/HOOS) [26]. The K/HOOS is a patient-administered, 42 item questionnaire. Study participants are asked to answer questions on a 5-point Likert scale, which takes approximately 10 minutes to complete. The K/HOOS consists of 5 subscales: pain, other symptoms, activities of daily living (ADL), function in sport and recreation and knee-related quality of life (QOL). The questionnaire results in a normalized score out of 100 for each subscale, where 100 indicates no symptoms and 0 indicates extreme symptoms. The questionnaire relies on subject's recall from the previous week [26].
    - Participants will also complete the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire. This 30-item questionnaire addresses upper extremity physical function and symptoms [27.]

- *Physical Capacity:*
    - The strength (peak torque) developed during extension and flexion of the hip and knee during maximum voluntary isometric contractions (MVICs) will be measured using a hand-held dynamometer. The peak value for each of knee and hip extension and flexion will be extracted. The reliability scores for these data are excellent [28].
    - Peak grip strength will also be captured using a hand-held dynamometer because grip strength is related to disability, morbidity and mortality [29].
    - In addition, participants will be asked to complete a treadmill walking submaximal fitness test. Maximal oxygen uptake (VO_2max) is the best measure of cardiovascular fitness and is a good indicator of health status [30]. This test requires exposure to no more than 85% of maximum heart rate. It is ideal for assessing fitness of people not accustomed to maximal intensity exercise and has produced valid, reliable data in older women [31].

- *Mobility*: The mobility performance measures selected reflect the core set of mobility measures recommended by the Osteoarthritis Research Symposium International (OARSI) [32].
    - Six-Minute Walk Test (6MWT) - The 6MWT is used to quantify walking ability. The 6MWT is an inexpensive clinical tool that involves recording the distance that participants cover while walking indoors at their own pace for 6 minutes. Participants are free to stop or use a mobility aid to complete the walking task, making this measure clinically useful. The 6MWT measurement will be recorded indoors in a well-lit, tiled rectangular hallway. The score recorded is the total distance traveled in 6 minutes. Instructions for the 6MWT will correspond with the published protocol [33]. The 6MWT yields highly reliable (intraclass correlation coefficient=.96) and valid data [34].
    - Stair Climbing - Participants will be asked to ascend and descend a 9-step staircase as quickly as possible, without compromising their safety. The hand rail can be used as needed. The participants will be asked to start at the base of the stairs at a distance from the first step of their choosing. The participants will be instructed not to run or jog, and not to skip any steps. Time to ascend and descend will be recorded separately, to the nearest 10^{th} of a second, using a stopwatch. Participants will be asked to repeat this procedure two times, where scores from only the ascent and descent on the second attempt are recorded.

Data from our laboratory demonstrate excellent test-retest reliability of the stair ascent and descent tasks among 29 adults (ICC=0.881, 0.843 respectively).

- 30-Second Chair Stand Test - The 30 second chair stand task quantifies the number of sit-to-stand movements that can be completed within 30 seconds, starting from a seated position in an armless chair of a standard height (45 cm). After an opportunity to practice the task, participants will be asked to perform this task at a comfortable pace. Knee extensor strength is a strong predictor of performance on repeated chair stand tests [35]. In addition, lower extremity muscle power was predicted from performance of the 30 second chair stand in 14 older adults [36].

- *Resilience:* To reflect the ability to adapt to stress and adversity, we selected measures of resilience, work ability, and depression.
  - The Resilience Scale (RS) is a 25-item questionnaire that captures information about personal competence and acceptance of life and self [38]. This questionnaire produces data that are reliable and show good concurrent validity [38].
  - The Work Ability Index (WAI) is a widely-used self-report questionnaire that consists of seven dimensions including current work ability relative to life-time best, work ability related to job demands, number of current physician-diagnosed health conditions, estimated work impairment due to the conditions, sick leave over the past year, own prognosis, and mental resources [39]. The WAI produces reliable data [39].
  - Depressive symptoms will be assessed with the Center for Epidemiologic Studies–Depression (CES-D) Scale, a 20-item scale with emphasis on affect (mood, guilt, worthlessness, helplessness, appetite) [40]. Data from the CES-D are valid and reliable in adult and arthritic populations [40-42].
  - Self-efficacy will be measured using the Arthritis Self-Efficacy Scale (ASES). The ASES measures arthritis-specific beliefs regarding perception of performance on certain tasks to cope with the disease [43]. The ASES produces both reliable and valid data in knee OA [44].

Statistical Analyses: Descriptive statistics will be calculated. A repeated measures analysis of variance will be used to compare the impact of the exercise program on change scores for each outcome measure between the exercise and control groups. Independent analyses will be performed for participants that demonstrated clinical criteria for hip and knee OA.

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Letter of Information and Consent

Improving Resilience and Longevity for Workers Through Exercise

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Introduction

You are invited to participate in a study that will compare 12 weeks of specialized exercise designed for arthritic knees and hips versus no exercise on your resilience in the workplace, mobility, fitness, strength, physical function and pain.

Before agreeing to participate, it is important that you read and understand the proposed study procedures. The information provided describes the purpose, procedures, benefits,

discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In deciding whether you wish to participate, you should understand enough about the risks and benefits to be able to make an informed decision. This is part of the informed consent process. Make sure all of your questions have been answered to your satisfaction before signing this document.

Background and Purpose

By 2031, over 2 million Canadians aged 45 to 64 years will have arthritis. Among those with arthritis, one of three is expected to be out of work. This unemployment rate is worse than for any other chronic health condition. Osteoarthritis, the most common type of arthritis in Canada, affects one in ten Canadians. This condition is associated with pain, problems with mobility, and additional health complications including – but not limited to – chronic inactivity, heart disease, diabetes, and depression. Keeping individuals with knee osteoarthritis physically active is critically important.

Exercise is effective at reducing pain while improving physical function. However we do not know if exercise can boost resilience in the workplace, to allow people with osteoarthritis to work as long as they desire. Previous research shows that exercise holds the most promise for helping people enjoy their work because it reduces sick time, reduces pain, and improves productivity. However, little work has examined the effect of exercise for people with arthritis in the workplace. **The purpose of the study is to investigate whether leg strengthening exercises improve resilience in the workplace, mobility, fitness, strength, physical function and pain in comparison to no exercise in those with knee and/or hip osteoarthritis. A secondary purpose is to evaluate whether exercise improves each of these clinical outcomes among workers with no joint pain.**

Men and women administrative employees at Ford Oakville are welcome to participate in this study. 40 participants will be recruited to in this study. We cannot include anyone who has the following:

- Medical restrictions to physical activity
- Fractures from osteoporosis
- Other forms of arthritis (e.g. psoriatic, rheumatoid)
- Active non-arthritic disease (e.g. gout, patellofemoral symptoms)
- Current use of intra-articular injections or knee/hip surgery
- History of stroke or heart disease
- Use of walking aids such as a cane
- Inability to safely climb 2 flights of stairs
- Leg injury in the last 3 months
- Ankle problems
- Radiation (e.g. cancer treatment)
- Pregnancy

Procedure

If you meet the above criteria and are interested in participating, we welcome you to join our study! You will be asked to provide us with your phone number or email address so that we can contact you to answer any questions that may arise and to book an initial appointment. Also, we will ask you to provide us with the name and contact information for your family physician, and permission to contact your family physician if a health concern arises during your participation in the study.

As a participant in this study, you will be randomly assigned to one of two study arms (exercise program, or no exercise program). Those assigned to the exercise program will be asked to attend supervised exercise classes **at least 3 times weekly, for 12 weeks**. The exercise classes will be offered in the exercise facility at the Ford Oakville Plant. Class times are Monday, Tuesday, Wednesday, Thursday and Friday from 7-8am. You may also attend any other exercise class instructed and approved by the Fitness Centre Manager, should those time slots better fit your schedule. Those assigned to the no exercise program will be asked to maintain their existing activity level for the 12-week period. Unfortunately, we cannot let you choose which study arm you will participate in. However, if you are randomized to the no exercise program, you will be eligible to receive the same exercise program upon completing the second, follow-up data collection.

We will ask you to attend 2 visits (one before and one after the 12 week intervention period), also in the exercise facility at Ford Oakville. These visits will take approximately 2 hours each to complete.

Measurements at the Start of the Study

1. Complete this form
2. Body size measurements
3. Resting heart rate and blood pressure
4. Mobility performance measurements
    a. 6-minute walk
    b. Stair climb
    c. 30-second chair stand
5. Treadmill walking fitness test
6. Strength assessment of muscles of the knee, hip and hand
7. Questionnaires

This visit will take approximately 2 hours to complete.

Study Arms:

Exercise Program

- 12-weeks of exercise. Each class is 1 hour.
- Weekly attendance at 3 of 4 available time slots offered each week.
- Classes will be offered on-site in the exercise facility at the Ford Oakville Plant

- Classes include a warm-up, series of exercises with a focus on lower extremity strength, balance and flexibility, cool down
- All exercise sessions will be supervised by a Certified Yoga Instructor. All equipment are available for your use. The facility also has bathroom/change room facilities including showers.

No Exercise Program

- We ask that you refrain from changing your physical activity over 12 weeks
- We ask that you maintain any strategies you use to manage with your knee and/or hip pain over 12 weeks.
- Upon completing the second, follow-up data collection, you will be eligible to receive the same exercise program as the exercise group.

Measurements at the End of the Study

1. Body size measurements
2. Resting heart rate and blood pressure
3. Mobility performance measurements
    a. 6-minute walk
    b. Stair climb
    c. 30-second chair stand
4. Treadmill walking fitness test
5. Strength assessment of muscles of the knee, hip and hand
6. Questionnaires

This visit will take approximately 2 hours to complete.

You must complete these measurements at the end of the study to be eligible to receive the $50 stipend.

Total time commitment if you choose to participate in the study

Activity	Time per session	Number of sessions	Total time
Measurement visit	2 h	2	4 h
Classes	1 h	36	36 h
Total:			**40 hours**

Risks & Benefits

There are risks associated with exercise in this study, including the following: fatigue, soreness, heart complications in those with poor heart health, increased risk of fracture especially in those with osteoporosis, and worsening of knee pain in those with patellofemoral syndrome. With regards to the potential muscle soreness, we will teach you gentle stretches and how to use an ice pack to reduce the soreness. If you experience any serious discomfort following an exercise session or laboratory visit, please contact Dr. Monica Maly at (519) 888-4567 x 37916.

You may gain the physical and mental benefits associated exercise. Your participation will help improve our understanding of how exercise, a non-invasive treatment option, affects osteoarthritis of the knee or hip and whether exercise can improve your resilience at work.

Confidentiality

All information obtained during the study will be held in strict confidence. You will be identified in the study by a code only. No names or identifying information will be used in any publication or presentation to Ford, or otherwise. No information identifying you will be available outside the investigation. However, summary information about the group changes as a result of the study will be shared with Ford to give the company the information necessary to consider implementing a similar program in the future. The information we collect will be secured in a locked filing cabinet in the MacMobilize Laboratory at McMaster University to which only the researchers will have direct access. This research space is also locked. Following completion of the study, the information we collect will be destroyed. Representatives of the McMaster University Health Sciences Research Board may require access to your study-related records or may follow up with you to monitor the conduct of the research.

Participation

Your participation in this study is voluntary. If you decide to participate, you can decide to stop at any time, even after signing the consent form or part-way through the study. If you drop out of the study, your data will only be used with your explicit consent. You can withdraw from the study at any time, for any reason, without any negative consequences. You will receive a $50 stipend upon completion of the study. There will be rewards for best attendance during the 12 weeks. Your decision to participate, or not, will not be communicated to Ford.

Questions

If you have any general questions, please call the MacMobilize Research Laboratory at (905) 525-9140 x 20748. If you have any questions about your rights as a research participant or the conduct of the study, you may contact Dr. Monica Maly, the principal investigator at (519) 888-4567 x 37916. This letter is yours to keep for future reference.

This study has been reviewed by Hamilton Integrated Research Ethics Board (HIREB). If you have questions regarding your rights as a research participant, you may contact the office of HIREB chair at 905-521-2100 ext. 42013.

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Consent

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction. I will receive a signed copy of this form.

_____	_____	_____
Participant Name (please print)	Participant Signature	Date

I confirm that I have explained the nature and purpose of this study to the participant named above. I have answered all questions.

_____	_____	_____
Person Obtaining Consent	Signature	Date

_____	_____	_____
Principal Investigator	Signature	Date