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Retraining the automatic reaction to physical activity and sedentary stimuli in adults 60 years of age or older: A cognitive bias modification protocol

ABSTRACT

Background: To counteract the pandemic of physical inactivity, current interventions mainly rely on reflective processes that focus on increasing the motivation to be physically active. Yet, while these interventions successfully increase intention, their effect on actual behavior is weak. Recent findings suggest that this inability to turn the intention into action is explained by negative automatic reactions to stimuli associated with physical activity. These automatic reactions could be particularly strong in older adults, who are more likely to associate physical activity with fear, pain, or discomfort. **Objective:** The aim of this program is to test the effect of an intervention that targets the automatic processes underlying physical inactivity in older adults. Training older adults to inhibit the automatic attraction toward sedentary stimuli is hypothesized to increase physical activity, thereby contributing to improving physical functioning and quality of life. **Methods:** To test these hypotheses, older adults will be enrolled in a controlled double-blinded study with a 1, 3, 6, and 12-month follow-up. Participants will be randomized (1:1 ratio) to receive a 12-session cognitive-bias modification training for 3-week based on a go/no-go task in an experimental or a control condition (placebo). The primary outcome will be the number of steps per week. Secondary outcomes include automatic approach-avoidance tendencies, explicit affective attitudes toward physical activity, physical function, and quality of life. **Discussion:** The study is expected to inform public-health policies and improve interventions aiming to counteract the pandemic of physical inactivity.

KEYWORDS: Attentional Bias, Aging, Exercise, Sedentary Behavior

Background

Over the past two decades, society has encouraged people to be more physically active [1-3]. As a result, most individuals are now aware of the positive effects of regular physical activity and have the intention to exercise [4]. Yet, this intention is not sufficient, as exercise plans are often not executed [5]. Despite gradually scaling up actions that promote physical activity over the years, people are becoming less active. From 2010 to 2016, the number of inactive adults has increased by 5% worldwide, currently affecting more than 1 in 4 adults (1.4 billion people) [6]. This gap between intention and action is a challenge that health professionals need to address in order to counteract the pandemic of physical inactivity [7, 8].

Physical activity is one of the top contributors to health, reducing rates of cardiovascular disease [9], cancer [10], hypertension [11], diabetes [12], obesity [13], and depression [14]. This wide spectrum of benefits is particularly important for older adults, who often suffer structural and functional deterioration in several physiological systems. Physical activity can reduce and delay the impact of this age-related deterioration in health [15] and functional independence. However, in the Americas, more than 60% of older adults are physically inactive [16]. Current interventions to enhance physical activity in older adults rely mainly on reflective processes by providing rational information about the health benefits of a physically active lifestyle [17]. From this perspective, changing conscious goals should lead to substantial behavioral change [18]. Yet, meta-analyses indicate that these interventions are more effective in changing intentions than actual behavior [19]. Thus, new interventions targeting alternative processes (e.g., automatic processes) are needed.

The engagement in physical activity is governed not only by reflective processes, but also by automatic affective reactions acting outside conscious awareness [20]. For example, in active individuals, stimuli associated with physical activity attract attention [21, 22], trigger positive affective reactions [23, 24], and activate approach tendencies [25]. These automatic reactions are thought to facilitate the translation of intention into action. From this perspective, physical inactivity is the result of an imbalance between strong negative automatic reactions to stimuli associated with physical activity and a relatively weaker intention to be physically active. This imbalance between reflective and automatic processes can be particularly pronounced in older adults, who are more likely to spontaneously associate physical activity with fear, pain, or discomfort felt during physical exercise. Therefore, older adults could be particularly responsive to and benefit the most from an intervention targeting the automatic reactions to physical activity and sedentary stimuli.

Interventions targeting automatic reactions to health-related stimuli have already proven to be successful in changing behavior [26-32]. For example, interventions have been used to retrain the automatic reaction to alcohol [27]. Using a joystick, patients were repeatedly asked to avoid pictures on a screen that

were related to alcohol and to approach pictures unrelated to alcohol. Results showed that adding to a regular treatment an intervention targeting cognitive bias reduced the relapse rates one year after treatment discharge by 9% to 13% [27-29]. These interventions have also proven to be useful in impacting smoking [30], social anxiety [31], and eating behavior [32]. Based on these encouraging results, the current project proposes to test the effect of a cognitive-bias intervention on another health behavior: physical activity.

Primary aim

The overall primary objective of this project is to investigate the effectiveness of an intervention targeting automatic reactions to physical activity and sedentary stimuli in older adults.

Secondary aim

The secondary objective is to test the effects of the intervention on reflective and automatic processes underlying physical activity, physical functioning, and quality of life.

Methods

Study design and settings

Our study follows a placebo (sham-controlled), double-blinded design with a 12-month follow-up (Figure 1).

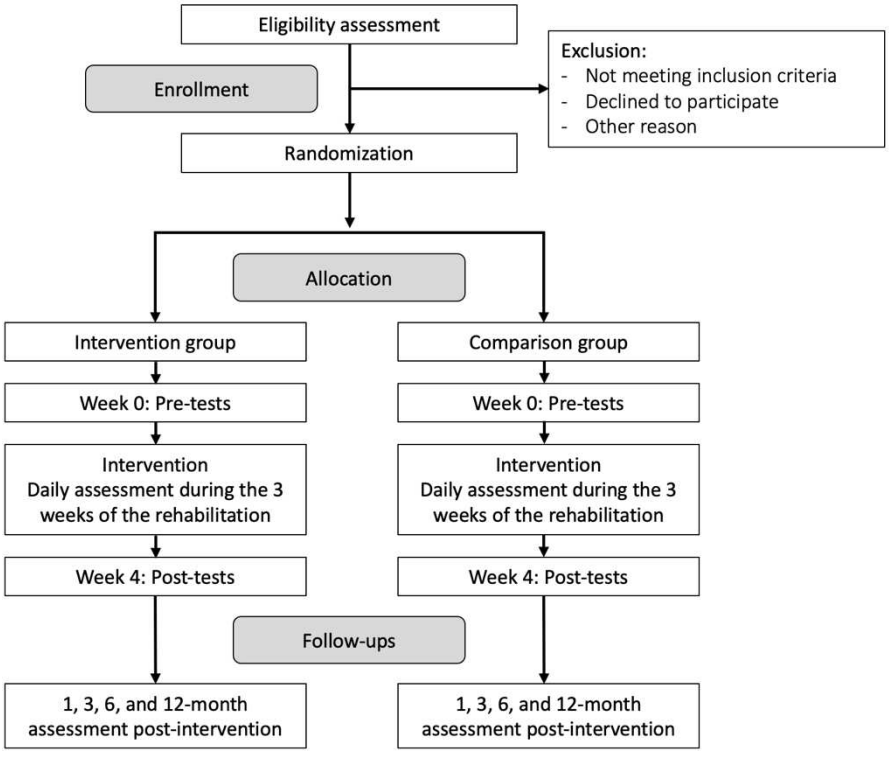

Figure 1. Study design

Participants

Older adults aged 60 years and older will be enrolled in the study.

Recruitment

Recruitment will occur by placing posters in a: strategic areas, such as public areas where permissible and b: posting on social media (Facebook, Twitter). Interested seniors will be asked to contact the researcher directly. Once the interested person initiates the contact leaving a phone message or sending an e-mail, we will follow up on them and will invite them to attend in an in-person meeting aiming to increase their intention to be physically active based on the "Ask-Assess-Advise" approach and to inform them about the study. Participants will receive a copy of the consent form prior to the first meeting so that they know from the onset what the study entails. Interested participants will be given an opportunity to ask any question over the phone or in the meeting before written informed consent is obtained. Consent will be only obtained once the participant has fully understood what the study entails and accept to take part in the study. If they decide to participate, they can withdraw from the research at any time and/or refuse to answer any questions, without suffering any negative consequences.

Eligibility

To participate in this study, volunteers must be 60 or over 60 years old and able to understand instructions in English. We will not include people who a: present diagnosed psychiatric disorders or neurological pathologies (cardiovascular accidents, Parkinson's or Alzheimer's disease, dementia), b: unable to carry out the training program, or unable to understand the protocol, c: having motor deficit preventing physical activity without external help, d: having physical health status preventing physical activity and, e: alcohol or substance dependence.

Sample size

Based on a meta-analysis reporting the effect size of interventions using the go/no-go task ($g = .39$) [32, 33], a desired statistical power of .9, and an alpha of .05 [34], a sample size calculation indicated that a minimum of 108 patients per condition is needed.

Ethics and dissemination

This research will be performed in accordance with the Declaration of Helsinki. The study was approved by the University of Ottawa (Canada) Research Ethics Boards (H-09-22-8453). Potential participants will be informed of study details, including procedures, risks and benefits, confidentiality, and the voluntary nature of participation, before signing the consent form. Data will be kept on the uOttawa OneDrive, with access limited to team members. This system is protected by multi-factor authentication, meets Personal Health Information Protection Act requirements, and is serviced by the uOttawa

cybersecurity team. To guarantee that the research output is fully accessible to the public, the manuscripts will be published as preprints (e.g., SportRxiv) and data, material, and scripts will be made publicly and freely available on open repositories (e.g., Zenodo). Results will be published in relevant scientific journals and be disseminated in international conferences.

Intervention

Cognitive-bias modification task

The intervention of the proposed project is based on a go/no-go task in which older adults need to quickly decide whether or not they should react to a stimulus [40]. The task has been adapted to train inhibitory processes counteracting the automatic attraction to sedentary stimuli and to promote the automatic approach to stimuli related to physical activity. Specifically, a rectangle containing an image, or a word will be presented on a screen.

Intervention group

In the intervention group, older adults will be instructed to restrain their actions when the rectangle is tilted to the right and to react by pressing a key on the keyboard when the rectangle is tilted to the left, irrespective of the content of the rectangle (because the training is meant to be implicit). In order to train inhibitory processes counteracting the automatic attraction to sedentary behavior, 90% of the rectangles tilted to the right (counterbalanced across participants) will contain a picture or a word related to sedentary behavior (Figure 2). To foster the automatic attraction toward physical activity, 90% of the rectangles tilted to the left will contain a picture or a word related to physical activity.

Control group

In the comparison group, instructions will be identical, but the percentage of physical activity and sedentary stimuli will be equal in each tilt condition (i.e., 50% sedentary stimuli and 50% physical activity stimuli in both right- and left-tilted rectangles) (Figure 2).

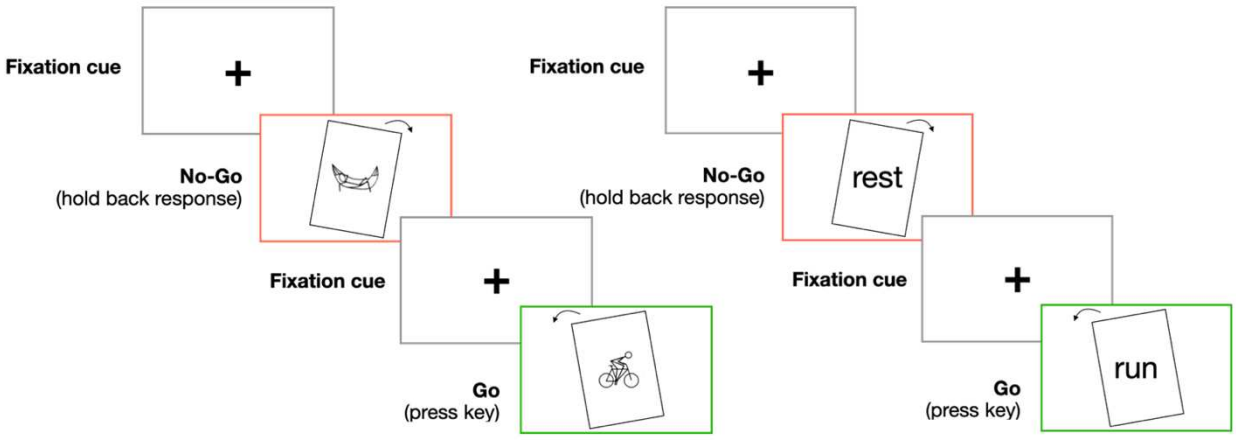

Figure 2. Go/No-go task based on images (left panel) and words (right panel).

Experimental protocol

Participants will be invited to attend a meeting aiming to increase their intention to be physically active based on the "Ask-Assess-Advise" approach [17] and to inform them about the study. Those who accept to participate will receive a physical activity tracker (GT9X-BT) [41]. Participants will be trained for 3 weeks (4 sessions/week) in the go/no-go task (Figure 3). Each training session will consist of 2 blocks of 400 trials for a total of 30 min. To assess the effect of the intervention, primary and secondary outcomes will be collected for one week, the week before the first session, the week following the last session of the intervention, as well as 1, 3, 6, and 12 months post intervention.

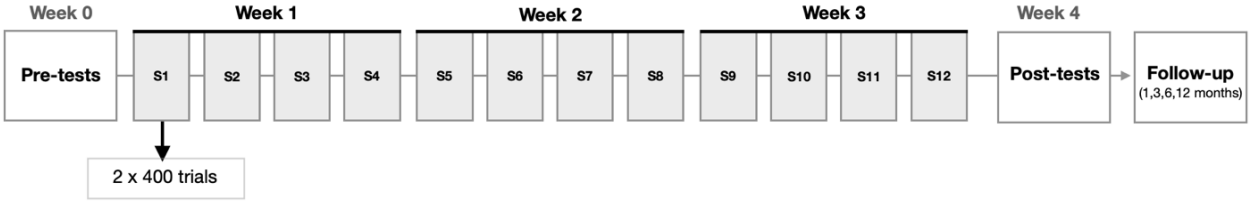

Figure 3. Protocol timeline.

Allocation and blinding

Participants and research assistant will be blinded to the groups' allocation. The participant blinding success will be appraised by asking them to guess in what group there were at the trial termination. Besides, the research assistant blinding success will be appraised via detecting the group allocation (Experimental vs. Control) by research assistant at the end of data collection phase. The randomization will be generated on a computer and an independent coworker will carry out the randomization. The participant's identification number will be used to determine the sequence of randomization. Participants will be randomized in a 1:1 ratio between the intervention and active control condition.

Outcomes

Participants will first respond to questions related to their age, sex (male, female), weight, and height.

Primary outcome

The project focuses on device-based measures of physical activity and sedentary behaviors. Specifically, the primary outcomes collected using a physical-activity tracker will be the number of steps. Participants will be given the tracker and will be trained on how to wear the device (ie, over the right hip, affixed to an elastic belt, preferably worn under their waistbands). Currently, the waist based Actigraph is the most used device to objectively measure physical activity. Participants will be instructed to used it all

day long for 7 days and not to used it during shower or when they sleep at night. If the participant uses the tracker less than for 4 days in a row for at least 7 hours per day, they will not be included in the study. The number of steps measured in the week pre- and post-intervention, as well as 1, 3, 6, and 12 months after the intervention will be used as the primary outcome.

Secondary Outcomes

The secondary outcomes will allow the examination of indirect health effects related to an increase in physical activity and a decrease in sedentary behavior.

1. Reflective and automatic processes underlying physical activity

(a) *Explicit Affective Attitude Toward Physical Activity:* Explicit attitudes toward physical activity will be calculated as the mean of two items (Cronbach's alpha = 0.92) based on two bipolar semantic differential adjectives on a 7-point scale (unpleasant-pleasant; unenjoyable-enjoyable). The statement begins with "For me, to participate in regular physical activity is …" [42].

(b) *Approach-avoidance task:* A contextual approach-avoidance task will be used to measure automatic approach and avoidance tendencies toward physical activity and sedentary behaviors [36]. Participants will be asked to move a manikin on the screen "toward" (approach condition) and "away" (avoidance condition) from images depicting physical activity and sedentary behaviors by pressing keys on a keyboard. Each trial will be started with a black fixation cross presented randomly for 250–750 ms in the center of the screen with a white background. Then, the manikin will be appeared in the upper or lower half of the screen. Concurrently, a stimulus depicting "movement and active lifestyle" (i.e., physical activity) or "rest and sedentary lifestyle" (i.e., sedentary behavior) will be presented in the center of the screen. Participants quickly must move the human figure "toward" a stimulus (approach) depicting physical activity and "away" from a stimulus (avoidance) depicting sedentary behaviors, or vice versa. After seeing the manikin in its new position for 500 ms, the screen will be cleared. In case of an incorrect response, error feedback (i.e., a cross) will be appeared at the center of the screen.

2. Physical Functioning

(a) *Usual Level of Moderate-to-Vigorous Physical Activity:* The usual level of physical activity will be derived from the short form of the International Physical Activity Questionnaire (IPAQ-SF). The IPAQ-SF is a self-administered questionnaire that identifies the frequency and duration of moderate and vigorous physical activity, as well as sedentary time during the past 7 days to estimate usual practice of physical activity and sedentary behavior [46]. The usual level of moderate-to-vigorous physical activity (MVPA) in minutes per week will be used as a control variable in the analyses.

(b) *6-Minute Walk Test:* The 6-minute walk test (6MWT) has been adopted as the most widely used functional test of exercise capacity given its ease of administration and its ability to reflect function during daily activities. Additionally, the 6-minute walking distance is widely used for measurement of treatment response in clinical practice and clinical trials. The test is conducted by having the participant walk as far as possible on a flat indoor course for a period of 6 minutes. Standardized encouragement will be provided at each minute. Total distance walked in 6 minutes will be documented. The major outcome is the distance walked during the 6 minutes. The major advantages of the 6MWT are that the test requires minimal technical resources and involves a familiar daily activity [44].

(c) *Hand grip strength:* Hand grip strength will be assessed with a dynamometer. Participants will perform the test using their reported dominant hand in a seated position. Two tests would be performed by each participant and the higher value will be recorded as hand grip strength [45].

3. Quality of Life

(a) *World Health Organization Quality of Life (BREF):* The scale assesses quality of life over four domains: Physical Health (seven items), Psychological Health (six items), Social Relationships (three items), and Environmental Health (eight items). Scores for each domain can range from zero to 100, with higher scores indicating better QoL [46].

Data collection and management

All information will be gathered by research assistant. All identifying information from the study data will be eliminated by using a code so that the identity will not be directly associated with the data the participant provided. Each participant will be given a unique confidential identification code upon they accept to take part in the study. All data including coded information will be kept in OneDrive account of principal investigator which is protected by a two-factor authentication. The confidentiality of the information collected will be guaranteed by using this unique confidential code for data storage and analyses. Storage will be maintained for 10 years after the end of the study.

Data analyses

Primary analysis

Statistical analyses will be performed according to the intention-to-treat principle and abide by the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A sequential analysis will be conducted with an interim analysis after 50% of the data is collected and the other analyses after all data is collected [47]. Based on the Pocock boundary, the threshold for significant p-values will be .0294 [48]. If the effect is significant at the interim analysis, thereby indicating that the data provide support for the

hypothesis, data collection will be terminated. Mean, SD, median and range values will be used to summarize the continuous data. The primary outcome (number of steps per week) will be analyzed using multiple linear regressions. Particularly, we will test whether the participants' physical activity level (number of steps) the week after intervention termination will be higher in the intervention group relative to the control group, after adjustment for covariates (i.e., age, sex). Furthermore, we will test whether participants' automatic approach tendencies towards physical activity will be higher and participants' automatic approach tendencies towards sedentary behaviours will be lower in the intervention group compared to the control group.

Secondary Analysis

The continuous outcomes will be analyzed using linear mixed-effects models, which account for the nested structure of the data (i.e., multiple observations within a single participant), thereby providing accurate parameter estimates with acceptable type-I error rates [49]. To examine the effect of the intervention on the evolution of physical activity and sedentary behavior, models will include interaction terms between group (intervention group vs. comparison group) and number of days within or after (follow-up) the intervention. We will treat the continuous secondary outcomes in the similar way to the primary outcome. R software will be exploited for all analyses.

Data Monitoring

The principal investigator will instruct all project team members to ensure that the study will be carried out according to the protocol. Research assistants will need to understand the protocol before starting the data collection. The ethics committee may visit the research sites for quality assurance. No serious adverse event resulting from the intervention is expected; however, all potential adverse events will be documented.

Discussion

Most individuals are aware of the benefits to health of regular physical activity and have good intentions to exercise. Yet, 1.4 billion people worldwide are inactive, which suggests that turning intention into action can be challenging. Recent findings show that the intention-action gap could be explained by negative automatic reactions to stimuli associated with physical activity. This gap is particularly concerning in older adults, who are more likely to spontaneously associate physical activity with fear, pain, or discomfort. Current interventions targeting physical activity largely focus on providing rational information to alter individuals' conscious goals. However, these strategies have been shown to be insufficient to change a behavior and urge that automatic reactions towards physical activity-related stimuli would be involved in the physical activity regulation. Therefore, to promote physical activity, the current project proposes to train older adults to suppress their automatic attraction toward sedentary stimuli and to respond positively to

physical-activity stimuli. The intervention is expected to reduce physical inactivity during the intervention and at follow-up, thereby improving physical functioning. More broadly, the output of this program has the potential to develop an evidence-based, large-scale, low-cost intervention that would complement current reflective approaches in older adults to improve their quality of life. Finally, the results will inform public health policies aiming to counteract a global health problem: The pandemic of physical inactivity.

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25/10/2022

Consent Form

Please read this consent document carefully before you decide to participate in this study.

Retraining the automatic reaction to physical activity & sedentary stimuli in adults 60 years of age or older

Name and contact information of the researchers:

- Principal Investigator: Matthieu P. Boisgontier, University of Ottawa & Bruyère Research Institute

Telephone: (613) 562-5408. Email: matthieu.boisgontier@uottawa.ca

- Co-Investigator: Ata Farajzadeh, University of Ottawa & Bruyère Research Institute

Telephone: (343) 987-0216. Email: afara098@uottawa.ca

Project funder: This project is funded by the Banting Research Foundation.

Invitation to participate: I am invited to participate in the above-mentioned research study conducted for academic purposes by Professor Matthieu Boisgontier and Ata Farajzadeh. This project is being conducted independently from the organizations and agencies from which participants may be recruited.

Purpose of the study: The purpose of the study is to investigate the effectiveness of an intervention targeting automatic reaction to physical activity and sedentary stimuli in adults 60 years of age or older.

Participation: My participation in this study will include the following:

1) On the first meeting of the study (30 minutes), I will be provided an accelerometer to count the number of steps I make each day. I will be asked to wear this accelerometer at my waist for 7 days and at least 7 hours per day.

2) After one week, I will return the accelerometer, respond to questionnaires focusing on physical activity level and quality of life, and perform a reaction-time task (1 hour). Then, I will be trained for 3 weeks, 4 times per week for 30 minutes on a computerized reaction-time task. The training task consists of sitting in front of a computer and react to images by pressing some keys on the keyboard. At the end of the training, I will be asked to wear the accelerometer for one week (at least 7 hours per day) and response to the questionnaires at the end of that week (1-hour).
3) To assess the effect of the intervention in the long term, I will be invited to respond to the same questionnaire and perform a reaction-time task in a single session occurring 1, 3, 6, and 12 months after the intervention (1 hour).

Risks: My participation in this study will not cause me any risk or discomfort other than those of everyday life.

Benefits: My participation in this study will provide new information contributing to the development of intervention aiming to help older adults adopting a more active and healthier lifestyle. In addition, this new information will contribute to better understand the factors that facilitate and inhibit the engagement in physical activity as well as the effectiveness of a computer-based intervention.

Confidentiality and privacy: My anonymity will be guaranteed by a unique confidential identification code provided by the research team. All data, including coded information, will be kept in password-protected files on a secure computer. My responses to the questionnaires will remain strictly confidential. I understand that the anonymized results of this study may be published in scientific journals and may be presented at academic conference or meeting.

Conservation of data: Anonymous data will be stored indefinitely on the uOttawa OneDrive with access limited to the team members. This system is protected by multi-factor authentication, meets Personal Health Information Protection Act requirements, and is serviced by the uOttawa cybersecurity team.

Voluntary participation: I am under no obligation to participate in this study. If I choose to participate, I can withdraw from the study at any time and/or refuse to answer any questions without suffering any negative consequences. If I choose to withdraw, all data gathered until the time of withdrawal will be removed from the dataset and not used in the study.

Agreement: I have read the above description of the study and I voluntarily agree to participate.

Ethical conduct: If I have any questions related to the study, I may contact the research team (Matthieu Boisgontier and Ata Farajzadeh). If I have any questions regarding the ethical conduct of the study, I may contact the Office of Research Ethics and Integrity via email (ethics@uottawa.ca) or telephone (613-562-5387). To get additional information about my rights as a research participant in the study, I can email Dr. Matthieu Boisgontier (matthieu.boisgontier@uottawa.ca).

Acceptance: By providing my name below and signing the current document, I agree to participate in this scientific study.

A copy of this consent form has been provided to the participant.

Name of participant: **Date:** **Signature:**

Name of researcher: **Date:** **Signature:**