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Management of multiple sclerosis symptoms through reductions in sedentary behaviour: protocol for a feasibility study

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ABSTRACT

Introduction People with multiple sclerosis (MS) are less physically active, and more sedentary than their peers despite evidence that activity helps to manage MS-related symptoms. Traditional approaches to increasing physical activity, such as exercise programmes, can be challenging for people with MS, especially those with walking disability. Focusing on decreasing prolonged sitting, and increasing light-intensity activities may be more feasible and result in more sustainable behaviour change in persons with MS. This paper describes the rationale and development of a sedentary behaviour intervention targeting persons with MS.

Methods and analysis The feasibility and preliminary efficacy of a sedentary behaviour intervention will be tested using a prepost intervention design in 40 adults with MS. The 22-week programme includes a 15-week intervention and a 7-week follow-up. The intervention itself is divided into two stages: Sit-Less and Move-More. The Sit-Less stage is designed to encourage participants to break up prolonged sitting bouts, while the Move-More stage promotes increasing steps per day, in addition to interrupting sitting. The intervention is delivered through individual coaching sessions between an interventionist and a participant, and an accompanying newsletter based on social cognitive theory. A Fitbit is used to monitor activity throughout the programme. Process, resource and management metrics will be recorded (eg, retention, time required for communication during the trial). Sedentary and physical activities and MS-related symptoms are measured before and after the intervention and again during follow-up. Experiences with the programme are explored through an online survey and one-on-one interviews.

Ethics and dissemination The Health Research Ethics Board at the University of Alberta granted permission to conduct this study. Results will be disseminated in scientific journals and conferences, and the MS Society of Alberta. Physical therapists and kinesiologists are important stakeholders and will be targeted during dissemination.

Trial registration number NCT03136744.

Strengths and limitations of this study

- The 'Sit Less with multiple sclerosis (MS)' intervention development was guided by theory and input from persons with MS.
- The 'Sit Less with MS' intervention is internet-based and thus accessible to participants who may have difficulty in travelling.
- The feasibility of conducting a larger trial will be based on standardised criteria regarding process, resource and management metrics.
- The study is a feasibility trial without a comparison group thus limiting strong inferences regarding efficacy.

INTRODUCTION

Individuals with multiple sclerosis (MS) experience a broad range of symptoms such as fatigue, pain, depression, balance and walking disabilities, even in the early stages of the disease, that limit daily functioning, mobility and engagement in life activities.[1 2] Participation in physical activity, particularly exercise training, slows the progression of the disease and improves fatigue, depression, mobility and quality of life.[3–8] Despite the evidence, persons with MS are less physically active than non-disabled peers.[9–11] This pattern of benefit, yet low participation, may support a paradigm change away from promoting moderate-to-vigorous physical activity through exercise training, to focusing on the opposite end of the activity spectrum, sedentary behaviour. This shift to focus on reducing and replacing sedentary behaviour with light physical activity in people with disabilities was proposed in a seminal paper published in Physical Therapy.[12] Such an idea is plausible considering a recent report using the North American Research Committee on MS Registry with 8004 individuals with MS which reported that self-reported sitting time in persons with MS (480 min/day) was double that of the general population (240 min/day).[11] This, therefore, represents an enormous opportunity for behaviour change,

as people with MS spend nearly 8 hours per day sitting! Taken together, consistently low levels of physical activity participation and the problem of too much sitting suggest a new approach is needed.

To date, there are very few interventions targeting sedentary behaviour in MS, and a recent review reported that there was no evidence that physical activity interventions changed sedentary behaviour in MS.[13] This is not surprising as the interventions were not specifically designed to change sedentary behaviour. We located one study that tested a website based-behaviour change intervention that focused on increasing physical activity and reducing sedentary time.[14] One question of the International Physical Activity Questionnaire (IPAQ) was used to measure self-reported sedentary time. Over a period of the 6-month intervention, the intervention group reduced sedentary time by 99 min compared with the waitlist control. The self-report nature of the measurement, and the significant differences in sedentary time of the intervention and control group at baseline limit the conclusions that can be drawn from this study.[14] That research does support future studies whose specific aim is to reduce sedentary behaviour as documented by device-based measures of activity and sedentary behaviour. Sedentary behaviour[15] is a new intervention target, but little clinical research has been done with persons with MS.

The protocol described in this manuscript tackles the challenge of activity promotion by breaking up sitting time and encouraging light intensity activity, an intervention approach that is likely more feasible and sustainable with broad scale impact than programmes that focus on exercise training (ie, structured physical activity at higher intensities). A focus on the reduction of sedentary behaviour is supported by growing evidence of the health risks of too much sitting,[16 17] and is reinforced by the physical activity guidelines for Americans released in November 2018[18] that recommend moving more and sitting less to provide benefit for 'nearly everyone'. Among the general population, sedentary behaviour has adverse effects on health such as increased cardiometabolic risk,[19] depression,[20] type 2 diabetes[21] and mortality,[22 23] even in those who are physically active. Recent work with persons with MS shows that sedentary behaviour is related to blood pressure.[24] In addition to the health benefits of sitting less, research with older adults and those with disability shows that less sitting, and especially more breaks from sitting, is positively associated with less frailty[25] and better mobility.[26] This association makes sense as in order to break up sitting we move from sitting to standing, a movement critical to mobility and function. Thus, interventions that target the reduction of sedentary behaviour may be particularly applicable and beneficial for those with mobility disability.[12]

The primary objectives of the study are (1) to test the feasibility of the 'Sit Less with MS' intervention and (2) to provide preliminary information about efficacy of the intervention for changing sedentary and physical activity behaviours and MS-related symptoms.

METHODS AND ANALYSIS

Study design

The 'Sit Less with MS' study uses a single-group, prepost intervention design to test the feasibility and preliminary efficacy of a novel intervention. The intervention is 15 weeks and divided into two 7 week stages: Sit-Less and Move-More (see figure 1).

The focus during each of the two stages is contained in the names, first sitting less, and then maintaining the reductions in sitting and adding more movement in the second stage. Participants come to the University of Alberta campus at three time points, baseline (week 0), postintervention (week 15) and follow-up (week 22), for

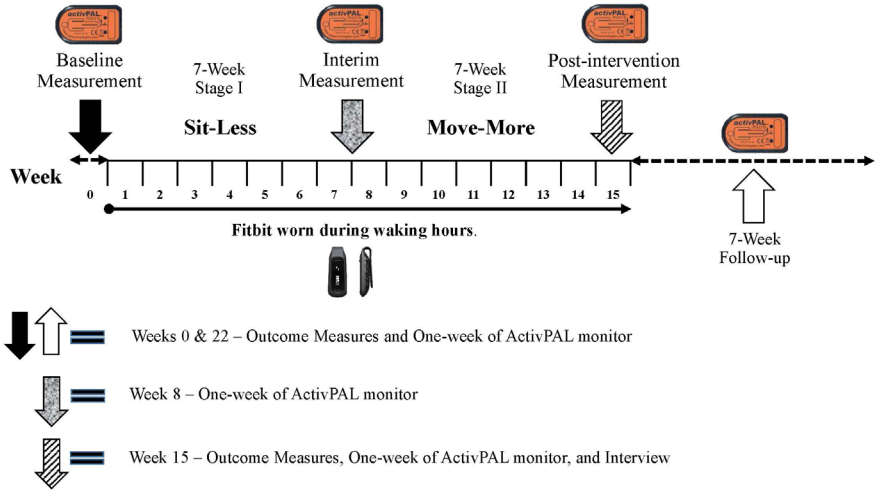

Figure 1 Sit Less with MS programme timeline.

activity and MS-related symptom measurements. Between intervention completion (week 15) and follow-up testing (week 22), there is no participant contact with the research team. Perspectives on participation in the 'Sit Less with MS' intervention are collected through qualitative interviews (with 10 participants) and a feedback questionnaire (all participants).

Preliminary testing of the intervention was done with four participants with MS. The intervention was conducted on a condensed timeline (1 month), using only baseline assessments, two newsletters and four coaching sessions via Skype or phone. Testing increased the understanding of time and data management required, and informed changes to participant materials and data collection procedures. The primary changes include improved participant instructions for Fitbit initialisation and use, more succinct Sit-Less and Move-More messaging on the newsletters, changes to baseline testing procedures related to monitor (ActivPAL3 and Fitbit) education, and increased interventionist practice of monitor troubleshooting.

Participants and recruitment

Participants are included if they meet the following criteria: (1) diagnosis of MS confirmed by the patient's neurologist; (2) diagnosis of MS of at least 1-year duration; (3) mild or moderate neurological disability (defined by Expanded Disability Status Scale (EDSS) score of 1–6.5); (4) relapse free within the previous 3 months; (5) stable in terms of disease modifying drugs and rehabilitation over the previous 6 months; (6) physically inactive (defined as insufficiently active by the health contribution score of less than 14 from the Godin-Shephard Leisure-Time Physical Activity Questionnaire)[27] and (7) able to walk with or without a walking aid for 10 m.

Participants are recruited through community programmes, and the MS Clinic at the University of Alberta. Neurologists in the MS Clinic identify participants who meet the inclusion criteria, and seek consent from potential participants to be contacted by the research team. The research team then follows up with the potential participant directly by phone to confirm eligibility and to discuss the study. At community sites, participants directly contact researchers. Participants sign the informed consent form at the baseline visit. Forty participants will be enrolled. Enrolled participants may continue to attend rehabilitation sessions (physical therapy, occupational therapy) but are asked not to participate in a structured exercise programming during the intervention. Data collection is ongoing at the time of submission of this study protocol.

Intervention

The 'Sit Less with MS' intervention programme is a novel activity behaviour change programme that focuses on interrupting prolonged sitting and replacing it with light physical activity. The intervention was fully developed and operationalised by incorporating the results from interviews with 15 patients with MS[28] and the behavioural strategies and principles from social cognitive theory (SCT).[29] The core determinants of SCT that provide a foundation for behaviour change include knowledge, self-efficacy, outcome expectations, goal setting, perceived environmental or personal facilitators, as well as social and structural barriers. To ensure that the behaviour change techniques outlined by SCT are incorporated into the intervention, the behaviour change taxonomy outlined by Michie *et al*[30] was consulted and translated into an activity behaviour change model for adults with MS (table 1). The components are integrated in the educational materials and weekly coaching sessions with participants throughout the 15-week programme. Table 1 provides information about the incorporation of SCT variables in the intervention (ie, programme manual, newsletters and coaching sessions).

During each week of the programme (excluding weeks 0 and 15), an individual coaching session takes place. A newsletter accompanies each session. The newsletter specific to each SCT component is sent 2–3 days before a scheduled coaching sessions. Newsletters are two pages long and include text, figures and pictures. Specific information about topics in the newsletters, as well as a brief summary of the goals of the related coaching sessions is provided in table 2. The topics are the same for the Sit-Less and Move-More stages; however, the messaging and the vignettes change to target the appropriate stage. The participant is asked to read the newsletter before the coaching session. Coaching sessions occur either through Skype, FaceTime or phone, and take 15–30 min. The goal of these sessions is to facilitate the translation of knowledge and strategies for activity behaviour change based on the core determinants of the SCT, and support accountability and compliance with the intervention.

A Fitbit One is worn throughout the intervention as a self-monitoring tool, starting after baseline ActivPAL3 removal (ie, 1 week after baseline assessment). Participants retain the Fitbit after intervention completion. Self-monitoring occurs slightly differently in the Sit-Less versus the Move-More stage, as described below. The Fitbit One does not provide real-time information about sitting interruptions to the participants, but alarms can be set as a reminder to stand up throughout the day. For review of sedentary time during the Sit-Less stage, participants are instructed to login to the Fitbit website daily to view their daily activity log graphs. The logs show daily activity across time and sedentary periods are displayed with no steps. Participants are taught to use the logs so they can recognise sedentary and active periods, with example graphs provided in the programme manual to assist interpretation. By contrast, in the Move-More stage participants receive real time information about step counts on their phone. During the weekly coaching sessions in both stages, the participants and coaches view and discuss the activity logs together as they provide information about both sedentary time and stepping.

There are two primary intervention coaches who are both licensed physical therapists. One backup intervention

Table 1 Behaviour change techniques in the 'Sit Less with MS' intervention based on the determinants of social cognitive theory (SCT)

		SCT determinants					
Behavioural taxonomy	**Practical strategies for delivery**	**Knowledge**	**Self-efficacy**	**Outcome expectations**	**Goal setting**	**Facilitators**	**Barriers**
Information about behaviour	Programme manual Newsletters Coaching sessions	*					
Information about consequences and benefits	Newsletters Coaching sessions	*		*			
Information about others' approval	Newsletters Coaching sessions	*				*	*
Prompt intention formation	Newsletters Coaching sessions	*					
Prompt barrier identification	Newsletters Coaching sessions	*					*
Encouragement	Newsletters Fitbit Coaching sessions		*			*	
Graded tasks	Programme manual Coaching sessions		*		*		
Provide instructions	Programme manual Newsletters Coaching sessions	*					
Model behaviour	Newsletters Coaching sessions		*				
Goal setting	Programme manual Newsletters Coaching sessions		*		*		
Review goals	Coaching sessions		*	*	*	*	*
Prompt self-monitoring	Programme manual Newsletters Fitbit Coaching sessions		*		*		
Provide feedback	ActivPAL Fitbit Coaching sessions	*	*		*		
Teach to use cues	Newsletters Coaching sessions	*					
Agree behavioural contract	Programme manual Newsletters Coaching sessions	*		*			
Prompt practice	Programme manual Newsletters Coaching sessions				*		
Follow-up prompts	Fitbit Coaching sessions					*	
Social support	Newsletters					*	
Identification of a role model	Newsletters Coaching sessions		*			*	
Prompt self-talk	Programme manual Newsletters Coaching sessions		*				
Relapse prevention	Coaching sessions	*	*				

Table 2 E-newsletter topics and goals of the accompanying coaching sessions

Weekly topic	E-newsletter topics	Coaching session goals
Familiarisation	No newsletter sent.	Introduction of the intervention coach, programme and Fitbit.
Outcome expectations	What benefits can I expect by interrupting prolonged sitting/moving more?	Increase the participants' knowledge of the risks of sitting, and the benefits of moving more.
Setting goals	Why should I set sit-less/move-more goals?	Set activity goals. Develop goal achievement plan.
Self-monitoring	How can keeping track of my activity help me to interrupt my sitting/move more?	Learn about the benefits and specific strategies to self-monitor activity throughout the day.
Self-efficacy	What is self-efficacy? What does it have to do with interrupting and reducing prolonged sitting/moving more?	Foster the belief that the participant can persevere with their behaviour change even when faced with obstacles, and that they have control over their activity behaviour.
Overcoming barriers	How can I identify and remove barriers to interrupting prolonged sitting/moving more?	Evaluate and reflect on physical, emotional, social and environmental barriers to activity behaviour change. Discuss and establish strategies to overcome barriers.
Finding facilitators	What is a facilitator? How will finding facilitators help me to maintain my sit-less/move-more habits?	Evaluate and reflect on personal, social and environmental facilitators to activity behaviour change.

coach was trained to fill in during holiday leave or illness. Interventionists take part in training sessions prior to beginning the coaching sessions and over the course of the study. Scripts guide the coaching sessions and ensure that the same key messages are communicated to each participant. Both training and use of scripts helps to ensure fidelity of the intervention. Fidelity will be assessed using basic metrics such as number of sessions completed, any deviations from the intended weekly schedule and the length of each session. Fidelity is also assessed using the detailed notes that the intervention coaches complete after every intervention session. Two primary components in each intervention coaching session that are expected to be present are (1) discussion of the tenet of SCT addressed in each session and (2) discussion and exploration of activity monitor (Fitbit results) and adjustment of goals as needed. Intervention notes will be reviewed and primary intervention components present will be recorded. This process will be completed by a research team member who is not involved with the intervention (ie, not an intervention coach), and the principal investigator (PM). The percentage of participants that receive at least 80% of the primary intervention components throughout the intervention will be reported. In addition, a total of 8–10 intervention sessions will be audio recorded and transcribed. The main purpose of the recordings is to allow spot checking for intervention components. The recordings are also used as a teaching tool during the intervention, which helps to ensure that interventionists use similar approaches. Finally, use of the Fitbit is an important part of the intervention. Its use will be tracked by one research assistant using Fitabase. Intervention coaches also track the participant's use of the Fitbit wearing via the Fitbit website. Participants will be reminded to wear the Fitbit if it is apparent they are not wearing it (ie, no steps). The total number of valid Fitbit days (Fitbit worn for at least 10 hours) over the course of the intervention will be recorded.

Measures

Measures related to process, resources, management and scientific aspects of the study are assessed. Process outcomes provide information about the success and feasibility of recruitment strategies. Resource and management metrics address some of the administrative aspects of conducting this type of research, such as communication time with participants and time for data entry. Scientific metrics provide information about participant experience, safety, burden and adherence during the intervention, and the effect size and clinical meaningfulness of any change in activity behaviour or MS-related symptoms.

Process, resource and management metrics

All contacts with potential participants, the numbers of eligible and ineligible participants, refusal reasons and the flow of participants (including withdrawals) during the programme are recorded. These records allow reporting of reach and retention. The programme itself is internet-based thus most communications (ie, requiring staff resources) related to scheduling of coaching sessions are done via email or by phone. Contacts with the participants are recorded throughout the programme. Time for data entry and cleaning is recorded.

Demographic, anthropometric and clinical measures

Demographic and anthropometric information about age, gender, the highest level of education, smoking history, chronic health conditions, medications, use of walking aids, walking distance, type of MS, date of MS diagnosis, weight and height are collected. Body mass index is calculated as weight (kg)/height (m).[2] The EDSS score

is used to characterise impairment and is a valid measure of impairment that is widely used in clinical research.[31] The EDSS is administered by a physical therapist or physician. Patient Determined Disease Steps (PDDS) scale[32 33] is also used to determine the level of mobility disability in adults with MS. The PDDS has been validated in persons with MS[34] and contains a single item for measuring self-reported neurological impairment ranging from 0 (normal) through 8 (bedridden).

Symptom, physical activity and sedentary behaviour measures

Measures are described below in the categories of physical performance, MS-related symptoms, and physical activity and sedentary behaviour. All measures are completed at three time points (baseline, postintervention and follow-up), except ActivPAL3 which is also measured midintervention. Measurements at each timepoint are completed in a 2-hour in-person session.

Physical performance

Walking capacity, walking speed and physical function are measured. Walking capacity is measured with the Six-minute Walk Test (6MWT),[35] asking participants to walk a 30 m track as fast and as far as possible for 6 min. The standard protocol from the American Thoracic Society[36] is adapted for use with persons with MS, as discussed by Goldman *et al*.[37] Participants are permitted to use their walking aids if necessary. The distance walked in 6 min is recorded and reported in metres. Walking speed is measured by the timed 10 m Walk Test (10MWT).[38] Participants walk a distance of 14 m at their usual speed with their usual walking aids. The time required to complete the intermediate 10 m is measured. The 2 m available prior to the marked 10 m distance is to control for acceleration. Three repetitions are completed and the average time is used to calculate walking speed in metres/s. The Short Physical Performance Battery[39] is a functional test that incorporates repeated chair stands, balance tests and walking speed. Tests are timed and scores correspond with time ranges as published.[39] For example, participants who complete the 4 m walking speed test in less than 4.82 s receive two points on the walking speed domain. The test is a valid measure of function in those with MS.[40] The total score, out of a maximum of 12, will be reported and is a combined score of the three domains. Higher scores represent better function.

MS-related symptoms

Fatigue, depression, pain, sleep disturbance, cognition and change in quality of life are MS-related symptoms frequently reported in those with MS,[41 42] and measured in this study. The National Multiple Sclerosis Society recommends their measurement in clinical studies.[43] The impact of fatigue on day-to-day function is measured using the Fatigue Severity Scale (FSS). This measure is a self-report scale with nine questions answered on a 7-point Likert scale. The FSS has well-established reliability and validity for use with persons with MS.[44] The FSS score is reported as one total score which is the mean of the nine items. Scores range from 1 to 7 and higher scores indicate greater impact of fatigue on daily life. The Modified Fatigue Impact Scale (MFIS) is also used to assess the impact of fatigue in terms of physical, cognitive and psychosocial functioning. Participants are asked to score 21 items, using a 5-item Likert scale, on how often fatigue affected them in the past 4 weeks. The MFIS has an excellent reliability among people with MS, and it assesses the high levels of fatigue better than other fatigue questionnaires.[45] Total scores on the subscales are reported, along with an aggregate score which is the sum of the three subscales. Scores range from 0 to 84 with higher scores indicating greater impact from fatigue. Depression is measured using the Hospital Anxiety and Depression Scale (HADS).[46] This is a 14-item questionnaire that includes seven items for anxiety and seven for depression, with items scored on a scale of 0 to 3. The HADS is a valid measure of both anxiety and depression.[47] Anxiety and depression subscale scores are the summed scores of the items related to anxiety and depression, and are reported separately. Higher scores represent more anxiety or depression. Pain is measured using the short form McGill Pain Questionnaire.[48] This questionnaire asks participants to respond to 15 different descriptors of pain (eg, throbbing and splitting), indicating whether they have none, mild, moderate or severe pain related to that descriptor. This questionnaire is a widely used valid measure of subjective pain.[49] The total pain rating index will be reported and is the sum of scores from 0 to 3 related to the 15 descriptors of pain. Scores range from 0 to 45 and higher scores indicate greater amounts of perceived pain. Sleep is measured using the Pittsburgh Sleep Quality Index. This questionnaire gathers information about sleep habits in the previous month and uses 19 self-rated questions.[50] Question scores are combined to form 7 'component' scores, each of which has a range of 0–3 points (0=no difficulty, and 3=severe difficulty). The seven component scores are then added to yield one 'global' score with a range of 0–21 points. A score of zero indicates no difficulty sleeping while a score of 21 indicates severe difficulties in all areas. Cognition is measured using the Symbol Digit Modalities Test (SDMT). The SDMT has been shown to be sensitive to cognitive impairment in MS.[51] This test was originally developed for use with persons with Huntington's disease and was adapted for use with persons with MS.[52] It specifically measures psychomotor speed, attention and integration of information. It is the standard outcome used to measure cognitive processing speed in persons with MS, nationally and internationally. The score reported is a proportion of correct responses to total responses over the 90 s test, which represents both cognitive speed and accuracy. Finally, quality of life is measured by the Medical Outcomes Study Short-Form Health Survey.[53] This questionnaire consists of 36 questions and provides information on eight domains of health (physical function, role

limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitation due to emotional problems and mental health). Eight domain scores, scaled to a maximum of 100, are reported. Higher scores indicate better domain-specific quality of life.

Physical activity and sedentary behaviour

Physical activity level is measured using the Godin-Shephard Leisure-Time Physical Activity Questionnaire during screening and at all time points in the trial. It provides a self-report of leisure-time physical activity.[27 54] During the intervention, participants wear a Fitbit One during waking hours. The Fitbit One provides immediate feedback about step count (as described earlier). Treacy and colleagues tested the validity of the Fitbit One against several monitors and found the Fitbit One worn at the ankle had the best agreement with direct observation.[55] It provided accurate step count even for slower walking speeds. The waist-worn Fitbit One has acceptable accuracy, and better accuracy is associated with faster walking speeds.[55 56] In our study, participants with slower walking speeds (<0.8 m/s) wear the Fitbit on their ankle, while the remainder of participants are given the choice of ankle or waist placement.

Sedentary behaviour and steps per day are objectively measured by the ActivPAL3 at baseline, midintervention, postintervention and follow-up. The monitor is worn on the stronger thigh of the participant with non-allergenic waterproof tape (3M Tegaderm Film) for seven continuous days. The ActivPAL3 uses proprietary algorithms to classify time spent in sitting/lying, standing and stepping, and transitions between postures.[57 58] Accuracy in classifying posture and transitions between postures has been reported to be 100% in older adults and those with the disability.[59] Two primary sedentary behaviour outcomes will be reported, including breaks per day (transitions from sit to stand), and the total volume of sitting time per day. Measurement of breaks is important as they are analogous to the functional task of sitting to standing, and breaking up long bouts of sitting has been identified as a particularly important behavioural target. Total daily sitting time is the volume variable historically measured in sedentary behaviour research and has been repeatedly shown in research with non-disabled populations to be associated with health risk factors.[19 60] Steps per day is the primary physical activity outcome. Information about clinically important step per day are available for people with MS.[61] Participants are asked to record their bed-time and sleep-time in a log book during ActivPAL3 measurement time periods, and throughout the intervention. They also record information in their log about falls. The primary outcomes from ActivPAL3(breaks per day, total sedentary time and steps per day) will be generated using the R package (PAactivpal).[62] Outcomes are reported with respect to waking time, determined using the methods of Chastin and colleagues[63] and the participant logs, prior to analysis in R.

Box 1 Topics addressed during survey and in interviews to explore the participants experience of the 'Sit Less with MS' Programme

Participant perspectives of:

- Weekly intervention coaching sessions, including integration of weekly newsletters.
- Self-monitoring using the Fitbit.
- Changes in activity during the programme.
- Changes (if any) experienced during the programme (probe for changes in multiple sclerosis-related symptoms as needed).
- Confidence to make changes in activity.
- Intentions or plans to continue with activity goals.
- Aspects of programme that could be changed to improve the programme.
- Programme delivery (ie, primarily through internet).
- Sit-Less and Move-More messaging.
- General satisfaction.

Participant perspectives

Formative evaluation of the internet-based activity behaviour change programme is undertaken after the 15-week programme through an online survey and one-on-one interviews. The survey asks for perceptions of the programme using 20 questions rated using a 5-point Likert-type scale. All participants receive a link to a short survey after the 15-week intervention. To gain a deeper understanding of participant experiences, 10 participants are purposively recruited (to ensure a distribution of age and level of disability) to participate in a one-on-one interview. The interview is conducted over the phone or a video-conferencing medium, audio recorded and transcribed verbatim. It focuses on perceptions of specific components of the programme (coaching sessions, use of Fitbit and newsletters), as well as how the intervention might be modified for future trials. Box 1 provides an overview of the topics included in the survey and interviews.

Patient and public involvement

Persons with MS were consulted in the first and second phases of this project as part of the development and preliminary testing of the intervention. We interviewed 15 persons with MS to increase our understanding of their perspectives on sedentary behaviour and how it could be changed.[28] Persons with MS also participated in preliminary testing and modification of the intervention and study procedures, prior to the feasibility trial. These processes are described at the end of the Study Design section. Formative information about activity from the ActivPAL3 and the Fitbit are shared and discussed with participants throughout the trial to increase their understanding of current activity behaviour. Throughout the trial, participants are being asked if they would like to receive publications related to the results of the study. Those who have requested that information will receive publications directly by email. Results will also be shared

through social media, and through the MS Society of Alberta.

Data management

Data from the study are handled in accordance with the ethical procedures as laid out by the Health Research Ethics Board at the University of Alberta. All staff involved with the project are trained in the appropriate and ethical management of research data. Graduate students are required to complete an 8-hour academic integrity and ethics training programme as part of their programme. Participant confidentiality is maintained through the use of subject id numbers in databases, and any research team communications. Weekly research team meetings are used to reinforce processes related to data management and participant confidentiality. Data will be entered by one research assistant. A separate research assistant will then check for accuracy of entry (from raw data to database). The final data set will be maintained at the University of Alberta in the principal investigator's laboratory in an encrypted file, on password protected computer.

DATA ANALYSIS

Most of the analysis related to feasibility metrics will be descriptive related to recruitment and retention (eg, number of participants approached, number of participants enrolled and number of participants retained), and communication (eg, frequency). Scientific feasibility metrics related to treatment effect will be determined as follows. Descriptive statistics (mean, SD) will be used to characterise the sample. A linear mixed models analysis will be used to determine whether there are changes over time for activity and symptom measures. Effect sizes will be calculated for each of the sedentary behaviour and the MS-related symptom outcomes. SPSS will be used for all quantitative analysis. Thematic analysis will be used to analyse the postintervention interviews, identifying common themes and perceptions about the intervention. The analysis of the survey will be descriptive (eg, frequency).

The decision to continue to the next stage of this work (ie, to conduct a trial with a control group) will be related to safety, reported fatigue, participant satisfaction, completion rates and actual change in sedentary behaviour. The messaging of this novel intervention is the opposite of energy conservation messages persons with MS receive. It further encourages people who may have balance problems to stand up frequently. Thus, it is important to report adverse events (primarily falls), and fatigue. Our criteria include (1) safety defined as no falls specifically related to the intervention, (2) at least 80% of participants report no increase in self-reported fatigue (determined by fatigue questionnaires as well as intervention coach notes regarding self-report of fatigue from participants), (3) participant satisfaction as determined by responses on two questions on the postintervention questionnaire, one regarding satisfaction, the other asking if the participant would recommend the programme to others (80% of participants agree or strongly agree) and (4) participant attrition of 20% at most. Finally, the prepost change in sedentary behaviour will directly inform a power analysis by providing an evidence-based effect size for estimating the appropriate sample size for an efficacy and then effectiveness trial.

DISSEMINATION

The 'Sit Less with MS' study tests a novel sedentary behaviour intervention designed specifically for persons with MS. Dissemination of the results from this study may be a first step towards important changes in the way activity is promoted among persons with MS. The programme is a shift away from a singular focus on moderate-to-vigorous intensity activity to a broader, and perhaps more feasible approach that encourages reductions in sedentary behaviour and increases in light-intensity activity. This approach may allow greater numbers of those with MS to receive the benefits of activity they may be missing out on if only the usual moderate-to-vigorous activity programme is recommended. The results will inform future activity promotion work which is a critically important research area, especially because MS is a progressive disease usually diagnosed at a relatively young age. People with MS live many years managing the symptoms of MS and this new approach may play an important role in management. Results will be disseminated in peer-reviewed journals and to the scientific community through conferences. The Alberta and Northwest Territories Division of the MS Society of Canada is an active division supporting people with MS. We will work with them, through attendance at the annual conference and presentations at MS events across Alberta or nationally, to present and engage the MS population in the interpretation of our results and on the next steps.

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Contributors PM and RWM conceived and designed the study and are co-principal investigators. RWM, PM and SA developed the intervention and all materials related to the intervention (program manual, newsletters, intervention coach scripts, etc). JR is one of the intervention coaches and assisted with the development and revision of intervention materials during the development phase. PM and SA lead the day-to-day operations of the trial, including recruitment and data collection. PM and RWM will colead the process and scientific metric evaluation. SA wrote the first draft of the manuscript. PM led all subsequent revisions of the manuscript. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study protocol is approved by the institutional Health Research Ethics Board at the University of Alberta (Pro000667657), the Northern Alberta Clinical Trials and Research Centre, and the Alberta Health Services Edmonton Zone (operational approval for recruitment through the Northern Alberta MS Clinic).

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. Rommer PS, Eichstädt K, Ellenberger D, *et al*. Symptomatology and symptomatic treatment in multiple sclerosis: Results from a nationwide MS registry. *Mult Scler* 2018:135245851879958.
2. Marrie RA, Horwitz RI. Emerging effects of comorbidities on multiple sclerosis. *Lancet Neurol* 2010;9:820–8.
3. Motl RW. Benefits, safety, and prescription of exercise in persons with multiple sclerosis. *Expert Rev Neurother* 2014;14:1429–36.
4. Sandroff BM, Dlugonski D, Weikert M, *et al*. Physical activity and multiple sclerosis: new insights regarding inactivity. *Acta Neurol Scand* 2012;126:256–62.
5. Dalgas U, Stenager E. Exercise and disease progression in multiple sclerosis: can exercise slow down the progression of multiple sclerosis? *Ther Adv Neurol Disord* 2012;5:81–95.
6. Latimer-Cheung AE, Martin Ginis KA, Hicks AL, *et al*. Development of evidence-informed physical activity guidelines for adults with multiple sclerosis. *Arch Phys Med Rehabil* 2013;94:1829–36.
7. Cederberg KL, Motl RW, McAuley E. Physical activity, sedentary behavior, and physical function in older adults with multiple sclerosis. *J Aging Phys Act* 2018;26:177–82.
8. Pearson M, Dieberg G, Smart N. Exercise as a therapy for improvement of walking ability in adults with multiple sclerosis: a meta-analysis. *Arch Phys Med Rehabil* 2015;96:1339–48.
9. Ezeugwu V, Klaren RE, A Hubbard E, *et al*. Mobility disability and the pattern of accelerometer-derived sedentary and physical activity behaviors in people with multiple sclerosis. *Prev Med Rep* 2015;2:241–6.
10. Motl RW, McAuley E, Snook EM. Physical activity and multiple sclerosis: a meta-analysis. *Mult Scler* 2005;11:459–63.
11. Sasaki JE, Motl RW, Cutter G, *et al*. National estimates of self-reported sitting time in adults with multiple sclerosis. *Mult Scler J Exp Transl Clin* 2018;4:205521731875436.
12. Manns PJ, Dunstan DW, Owen N, *et al*. Addressing the nonexercise part of the activity continuum: a more realistic and achievable approach to activity programming for adults with mobility disability? *Phys Ther* 2012;92:614–25.
13. Coulter EH, Bond S, Dalgas U, *et al*. The effectiveness of interventions targeting physical activity and/or sedentary behaviour in people with Multiple Sclerosis: a systematic review. *Disabil Rehabil* 2018:1–19.
14. Klaren RE, Hubbard EA, Motl RW. Efficacy of a behavioral intervention for reducing sedentary behavior in persons with multiple sclerosis: a pilot examination. *Am J Prev Med* 2014;47:613–6.
15. Tremblay MS, Aubert S, Barnes JD, *et al*. Sedentary Behavior Research Network (SBRN) - Terminology Consensus Project process and outcome. *Int J Behav Nutr Phys Act* 2017;14:75.
16. Owen N, Healy GN, Matthews CE, *et al*. Too much sitting: the population health science of sedentary behavior. *Exerc Sport Sci Rev* 2010;38:105–13.
17. Tremblay MS, Colley RC, Saunders TJ, *et al*. Physiological and health implications of a sedentary lifestyle. *Appl Physiol Nutr Metab* 2010;35:725–40.
18. Piercy KL, Troiano RP, Ballard RM, *et al*. The physical activity guidelines for Americans. *JAMA* 2018;320:2020–8.
19. Healy GN, Matthews CE, Dunstan DW, *et al*. Sedentary time and cardio-metabolic biomarkers in US adults: NHANES 2003-06. *Eur Heart J* 2011;32:590–7.
20. Vallance JK, Winkler EA, Gardiner PA, *et al*. Associations of objectively-assessed physical activity and sedentary time with depression: NHANES (2005-2006). *Prev Med* 2011;53:284–8.
21. Wilmot EG, Edwardson CL, Achana FA, *et al*. Sedentary time in adults and the association with diabetes, cardiovascular disease and death: systematic review and meta-analysis. *Diabetologia* 2012;55:2895–905.
22. Biswas A, Oh PI, Faulkner GE, *et al*. Sedentary time and its association with risk for disease incidence, mortality, and hospitalization in adults: a systematic review and meta-analysis. *Ann Intern Med* 2015;162:123–32.
23. Katzmarzyk PT, Lee IM. Sedentary behaviour and life expectancy in the USA: a cause-deleted life table analysis. *BMJ Open* 2012;2:e000828.
24. Hubbard EA, Motl RW, Fernhall B. Sedentary behavior and blood pressure in patients with multiple sclerosis. *Int J MS Care* 2018;20:1–8.
25. Del Pozo-Cruz B, Mañas A, Martín-García M, *et al*. Frailty is associated with objectively assessed sedentary behaviour patterns in older adults: Evidence from the Toledo Study for Healthy Aging (TSHA). *PLoS One* 2017;12:e0183911.
26. Mañas A, Del Pozo-Cruz B, García-García FJ, *et al*. Role of objectively measured sedentary behaviour in physical performance, frailty and mortality among older adults: A short systematic review. *Eur J Sport Sci* 2017;17:940–53.
27. Amireault S, Godin G. The Godin-Shephard leisure-time physical activity questionnaire: validity evidence supporting its use for classifying healthy adults into active and insufficiently active categories. *Percept Mot Skills* 2015;120:604–22.
28. Aminian S, Ezeugwu VE, Motl RW, *et al*. Sit less and move more: perspectives of adults with multiple sclerosis. *Disabil Rehabil* 2017:1–8.
29. Bandura A. Health promotion by social cognitive means. *Health Educ Behav* 2004;31:143–64.
30. Michie S, Richardson M, Johnston M, *et al*. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
31. Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). *Neurology* 1983;33:1444–52.
32. Hohol MJ, Orav EJ, Weiner HL. Disease steps in multiple sclerosis: a simple approach to evaluate disease progression. *Neurology* 1995;45:251–5.
33. Hohol MJ, Orav EJ, Weiner HL. Disease steps in multiple sclerosis: a longitudinal study comparing disease steps and EDSS to evaluate disease progression. *Mult Scler* 1999;5:349–54.
34. Marrie RA, Goldman M. Validity of performance scales for disability assessment in multiple sclerosis. *Mult Scler* 2007;13:1176–82.
35. Pilutti LA, Dlugonski D, Sandroff BM, *et al*. Gait and six-minute walk performance in persons with multiple sclerosis. *J Neurol Sci* 2013;334(1-2):72–6.
36. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002;166:111–7.
37. Goldman MD, Marrie RA, Cohen JA. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. *Mult Scler* 2008;14:383–90.
38. Graham JE, Ostir GV, Fisher SR, *et al*. Assessing walking speed in clinical research: a systematic review. *J Eval Clin Pract* 2008;14:552–62.
39. Guralnik JM, Simonsick EM, Ferrucci L, *et al*. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol* 1994;49:M85–M94.
40. Motl RW, Chaparro G, Hernandez ME, *et al*. Physical function in older adults with multiple sclerosis: an application of the short physical performance battery. *J Geriatr Phys Ther* 2018;41:155–60.
41. Marrie RA, Hanwell H. General health issues in multiple sclerosis: comorbidities, secondary conditions, and health behaviors. *Continuum* 2013;19:1046–57.
42. Kister I, Bacon TE, Chamot E, *et al*. Natural history of multiple sclerosis symptoms. *Int J MS Care* 2013;15:146–56.
43. National Multiple Sclerosis Socieity. Clinical study measures. 2018. https://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-Researchers/Clinical-Study-Measures (accessed 18 Aug 2018).
44. Krupp LB, LaRocca NG, Muir-Nash J, *et al*. The fatigue severity scale. Application to patients with multiple sclerosis and systemic lupus erythematosus. *Arch Neurol* 1989;46:1121–3.
45. Amtmann D, Bamer AM, Noonan V, *et al*. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57:159–66.
46. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
47. Marrie RA, Zhang L, Lix LM, *et al*. The validity and reliability of screening measures for depression and anxiety disorders in multiple sclerosis. *Mult Scler Relat Disord* 2018;20:9–15.
48. Melzack R. The short-form McGill pain questionnaire. *Pain* 1987;30:191–7.
49. Hawker GA, Mian S, Kendzerska T, *et al*. Measures of adult pain: Visual analog scale for pain (vas pain), numeric rating scale for pain (nrs pain), mcgill pain questionnaire (mpq), short-form mcgill pain questionnaire (sf-mpq), chronic pain grade scale (cpgs), short form-36 bodily pain scale (sf-36 bps), and measure of intermittent

and constant osteoarthritis pain (icoap). *Arthritis Care Res* 2011;63(S11).
50. Buysse DJ, Reynolds CF, Monk TH, *et al*. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28:193–213.
51. López-Góngora M, Querol L, Escartín A. A one-year follow-up study of the Symbol Digit Modalities Test (SDMT) and the Paced Auditory Serial Addition Test (PASAT) in relapsing-remitting multiple sclerosis: an appraisal of comparative longitudinal sensitivity. *BMC Neurol* 2015;15:1):1.
52. Benedict RHB, Smerbeck A, Parikh R, *et al*. Reliability and equivalence of alternate forms for the Symbol Digit Modalities Test: implications for multiple sclerosis clinical trials. *Mult Scler* 2012;18:1320–5.
53. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30:473–83.
54. Godin G. The Godin-Shephard leisure-time physical activity questionnaire. *Health Fit J Can* 2011;4:18–22.
55. Treacy D, Hassett L, Schurr K, *et al*. Validity of different activity monitors to count steps in an inpatient rehabilitation setting. *Phys Ther* 2017;97:581–8.
56. Balto JM, Kinnett-Hopkins DL, Motl RW. Accuracy and precision of smartphone applications and commercially available motion sensors in multiple sclerosis. *Mult Scler J Exp Transl Clin* 2016;2:205521731663475.
57. Kozey-Keadle S, Libertine A, Lyden K, *et al*. Validation of wearable monitors for assessing sedentary behavior. *Med Sci Sports Exerc* 2011;43:1561–7.
58. Lyden K, Kozey Keadle SL, Staudenmayer JW, *et al*. Validity of two wearable monitors to estimate breaks from sedentary time. *Med Sci Sports Exerc* 2012;44:2243–52.
59. Taraldsen K, Askim T, Sletvold O, *et al*. Evaluation of a body-worn sensor system to measure physical activity in older people with impaired function. *Phys Ther* 2011;91:277–85.
60. Healy GN, Dunstan DW, Salmon J, *et al*. Objectively measured light-intensity physical activity is independently associated with 2-h plasma glucose. *Diabetes Care* 2007;30:1384–9.
61. Motl RW, Pilutti LA, Learmonth YC, *et al*. Clinical importance of steps taken per day among persons with multiple sclerosis. *PLoS One* 2013;8:e73247.
62. Lyden K, Keadle SK, Staudenmayer J, *et al*. The activPALTM accurately classifies activity intensity categories in healthy adults. *Med Sci Sports Exerc* 2017;49:1022–8.
63. Chastin SFM, Culhane B, Dall PM. Comparison of self-reported measure of sitting time (IPAQ) with objective measurement (activPAL). *Physiol Meas* 2014;35:2319–28.