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Protocol for a pragmatic randomised controlled feasibility study of *MS WorkSmart*: an online intervention for Australians with MS who are employed

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ABSTRACT

Introduction Multiple sclerosis (MS) causes a wide variety of symptoms. Loss of income due to sickness and early retirement comprise one-third of the total cost of MS in Australia. An intervention that maximises work productivity and keeps people with MS in the workforce for longer could provide a large societal cost saving and improve quality of life. The aim is to test the feasibility of delivering and evaluating a 10-week digitally delivered intervention called '*MS WorkSmart*'. Findings will provide insights into participant profiles and address key methodological and procedural uncertainties (recruitment, retention, intervention adherence and engagement, and selection of primary outcome) in preparation for a subsequent definitive trial.

Methods and analysis A parallel-arm randomised controlled feasibility study, comparing those randomised to receive the MS WorkSmart package plus usual care (n=20) to those receiving usual care only (n=20). Australians with MS, aged 18–60 years, who are employed, and self-report work instability will be recruited from the Australian MS Longitudinal Study. Online surveys, at baseline and 1-month postintervention, will include MS-related work productivity loss and risk of job loss, MS work behaviour self-efficacy, health-related quality of life, fatigue severity, MS symptom impact on work, intention to retire due to MS, MS-related work difficulties, and awareness and readiness for change at work. Qualitative feedback will be obtained via a semistructured survey following the intervention (for participants) and via interviews (coaches). Analyses will be primarily descriptive and focus on the feasibility and acceptability of the intervention and study procedures. Progression criteria will guide decisions around whether to progress to a full trial.

Ethics and dissemination The study has been approved by the University of Tasmania Human Research Ethics Committee (H0024544). Findings will be disseminated via publication in peer-reviewed journals, conference presentations and community presentations.

Trial registration number ACTRN12622000826741.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a feasibility randomised controlled study to address key methodological and procedural uncertainties to inform the design of a future definitive trial; it cannot determine the intervention's effectiveness.
⇒ The intervention was collaboratively developed by a team of professionals, including individuals with multiple sclerosis (MS), and experts in MS, psychology and occupational therapy.
⇒ The active involvement of MS Societies will enable the definitive trial to closely emulate real-world implementation.
⇒ The intervention, which aims to enhance self-efficacy related to MS and employment, specifically targets individuals who face a potential risk of job loss.

INTRODUCTION

Multiple sclerosis (MS) is a complex disorder affecting the central nervous system. MS presents itself through a range of symptoms including problems with fatigue, mobility and muscle function, pain, cognition, speech, bladder, and vision. The disease has a substantial impact on work outcomes,[1] which is associated with considerable personal and societal costs.[2] In Australia, for example, over one-third of the overall cost of MS can be attributed to income loss resulting from sickness, and lost wages due to employment status change, occupation change and premature retirement.[3] Consequently, substantial societal cost savings can be achieved by providing support to individuals with MS to help them maintain employment and mitigate the difficulties associated with their work. This would not only yield financial benefits for people with MS but also contribute to an overall improvement in their quality of life.

International studies consistently show that a significant proportion of people with MS face an early exit from the workforce, reduced working hours or changes in employment roles as a direct result of their condition.[4 5] People with MS who become unemployed are

less likely to return to the workforce.[6] Many people with MS also experience a decline in work productivity. In previous work, we highlighted the average productivity loss resulting from presenteeism (working while unwell) to be 10.8% and absenteeism to be 3.4%.[7] These statistics emphasise the significant impact MS has on work-related outcomes and underscore the need for measures to address productivity issues in this population.

The factors that lead to unemployment in MS can be categorised in four broad groups: disease-related factors, working environment factors, work demands and personal factors.[8] Within disease-related factors, fatigue stands out as the most common reason for early retirement, with 61.2%–94.4% reporting it to be their primary reason for leaving employment.[4 9] Fatigue affects approximately 80% of people with MS[10] and often manifests early in the disease process.[11] Research has shown that improvements in fatigue significantly contribute to enhanced working ability, increased work hours and reduced sick leave.[12] Conversely, worsening fatigue is associated with work loss.[12] However, current medications for MS-related fatigue, including amantadine and modafinil, exhibit limited effectiveness, with trials reporting low pooled effect sizes.[13 14]

A multivariable model of unemployment revealed that, alongside fatigue, cognitive problems, mobility-related symptoms, age and education level were all significantly associated with employment status while productivity loss was exclusively influenced by the severity of MS-related symptoms.[7] Our research, aligning with other studies,[6] found that once symptoms were taken into account, factors such as higher disability, longer disease duration and MS type did not significantly predict early retirement and unemployment. These findings indicate that an intervention should focus on understanding which symptoms have the greatest impact on work.

Clinicians and allied health professionals assist people with MS with factors related to the work environment. This includes environmental factors (hot rooms, open plan offices, inaccessible toilets, non-ergonomic workstations), social factors (lack of support from family and friends) and workplace factors (lack of information on legal rights, lack of support with job retention, inflexible employment structures and lack of employer support). While workplace assistance is relatively straightforward to provide and has a significant protective effect on employment,[15 16] services are often accessed when it is already too late.[9] A digital intervention, which gives people information about the accommodations and adjustments that are available to make a significant improvement to how they work, may encourage people to act earlier.

The decision of whether people with MS should disclose their condition to their employers and colleagues is complex. While disclosure makes it possible to request workplace accommodations, there is a risk this could result in a perception of decreased capability, leading to potential discrimination or even being forced out of the workplace.[17] Taking into account an individual's personal work circumstances, expectations and responsibilities, as well as finding the best way to disclose an MS diagnosis in the workplace and positively influence one's employer, have been shown to empower individuals to navigate these complex situations and prevent discrimination.[18] In addition, it is important to address negative cognitions that can arise following an MS diagnosis, such as those related to negative self-talk, concerns about future capabilities or perceptions of being less efficient or burdensome.[9 19] Qualitative studies of employed individuals with MS emphasise the importance of addressing these anxieties and potential sources of stress.[18 20]

At the time of starting this project, despite the evident need for self-management interventions specifically designed for people with MS in the workforce, there were no tailored interventions that would address their unique challenges and needs. In collaboration with people with MS, specialists in MS research, IT (information technology), film, professional writing, design, psychology, occupational therapy and experts by experience, we have developed a digital programme called *MS WorkSmart*. The primary objective of this programme is to enhance self-efficacy related to MS and employment by reducing the impact of symptoms, improving communication and negotiation skills, addressing negative cognitions related to MS and work, enhancing coping skills and improving knowledge around workplace modifications and adjustments to accommodate individual needs. *MS WorkSmart* has included some of the principles from FACETS (Fatigue: Applying Cognitive behavioural and Energy effectiveness Techniques to lifeStyle), a rehabilitation programme that aims to improve fatigue in individuals with MS.[21 22] It addresses the work barriers and job adjustments identified in a recent systematic review, including job characteristics, the work environment, social relationships at work, negative work events and lack of information.[23]

MS WorkSmart uses a combination of evidence-based behavioural change techniques to achieve these goals. These techniques include reframing perspectives, fostering a valued self-identity, restructuring the physical environment, reducing negative emotions, establishing habits, engaging in behavioural practice, self-monitoring, problem-solving and action planning.[24] The programme employs engaging, personalised, interactive and practical delivery methods. It caters for a variety of learning styles and uses a mixture of presentation formats. For instance, it incorporates professional videos featuring real-life experiences of experts and individuals with MS, tasks, printable resources and integration with the *My SymptoMS* app (further details below). Online supplemental file 1 provides a description of *MS WorkSmart* using the TIDieR (Template for Intervention Description and Replication) template.

Recognising the variable impact of MS on individuals, *MS WorkSmart* enables participants to personalise their therapy by applying the programme's learning outcomes to their unique circumstances to maximise desired

outcomes. The digital health application, accessible on different devices, is lower cost than face-to-face delivery. Additionally, it is more convenient for Australians with MS, where services are limited for those who live in rural and remote communities, and for those who find it difficult to attend face-to-face sessions.[25] Digital health applications provide substantial benefits to people with MS.[26 27] Participants will also have access to a coach, who will provide guidance and support throughout the programme, to enhance engagement and adherence.[28] A closed Facebook group will be available to foster additional peer learning and enhance connections with others.

AIMS AND OBJECTIVES

The primary objective is to test the feasibility of delivering *MS WorkSmart* and to lay the foundation for a fully powered randomised controlled trial (that will assess the likely treatment effectiveness and cost-effectiveness) of *MS WorkSmart*. The specific aims are as follows:

1. Recruitment: Estimate recruitment rates, eligibility rates and reasons for non-participation.
2. Participant profile: Examine the profiles of eligible participants and compare their profiles to those ineligible and not participating.
3. Retention and engagement: Estimate study retention and adherence rates to *MS WorkSmart* and assess reasons for dropout, where possible.
4. Planning for the fully powered trial: Estimate the delivery costs, variability of outcome measures and preliminary effect sizes to inform sample size requirements and the choice of a primary (or coprimary) outcome measure(s) and gather feedback on the intervention and the need for a booster session 3 months after the intervention.

METHODS AND ANALYSIS

Design

This is an unblinded parallel-arm pragmatic randomised controlled feasibility study with an embedded qualitative component. Participants will be randomised (1:1 ratio) to receive either the *MS WorkSmart* package plus usual care or usual care only. The research plan was informed by the Medical Research Council guidance for the development and evaluation of complex interventions[29] and reporting will follow the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot and feasibility trials[30] and the CONSORT statement for eHealth interventions.[31]

Patient and public involvement

MS WorkSmart has been codesigned with people living with MS, health professionals and stakeholders. A total of 31 people with MS participated in focus groups to discuss the topics of the intervention, and 4 people with MS and four health professionals were featured in the videos. People living with MS and health professionals provided feedback on the intervention and study materials. Some will be involved in the governance of the study. MS Australia and their four-member organisations have been involved as key stakeholders.

Sample size considerations

The proposed sample size of 40 recruited participants fulfils rules of thumb conventions for feasibility studies.[32] With a sample of 40 people (20 in each arm), it is anticipated that about 32 (16 in each arm) will complete the full feasibility study (ie, we will over-recruit to allow for up to 20% not completing outcome measures). This sample size will provide us with sufficient numbers to achieve the aims of this study with the following precision: drop-out rates of around 20% will be estimated with a precision level (ie, distance between the estimate and upper/lower 95% CI limit) of ±12%. With 40 participants recruited, an estimated recruitment rate of around 40% will have a precision level of ±10%.

Setting and participants

The intervention will be delivered digitally, with coaching support provided through Zoom and/or telephone. Data collection will occur via online surveys while the initial screening process will be conducted over the telephone. The study focuses on individuals living in Australia with MS who are currently employed. The study will be conducted between May 2023 and February 2024.

Eligibility criteria

The study includes people with (1) a self-reported doctor diagnosis of MS; (2) a medium or high risk of losing employment (MS-Work Instability Score (MS-WIS)>10); (3) regular employment of ≥10 hours/week; (4) aged 18–60 years; (5) access to the internet and (6) adequate English proficiency to complete the study. There is a minimal misclassification between a self-reported doctor diagnosis of MS and a diagnosis that is verified by a doctor. The MS-WIS cut point of 10 has been shown to possess high sensitivity (78%) and specificity (80%) in identifying work instability and has demonstrated good test–retest reliability over time (r=0.88).[33] We will include people with regular employment of ≥10 hours/week (93% of the working MS population), as those working part time are more likely to be at risk of early retirement and may benefit most. Those >60 years are likely to start planning for their retirement. The study excludes people already participating in a symptom management or vocational rehabilitation trial.

Recruitment

Participants will be recruited from the Australian MS Longitudinal Study, managed by IvdM.[5 7 34 35] Employed participants who participated in the 2021 employment survey will be randomly selected and invited to participate via email (or mail if there is no valid email address on file). Those declining the invitation will be asked to provide a reason for not participating. Those who do not respond will be followed up by email and telephone. Invitations

will continue to be sent until a total of 40 eligible volunteer participants are recruited.

Screening, informed consent and randomisation

Potential participants will be contacted for a phone eligibility screening. If there are English proficiency concerns, an example page of the intervention will be provided. Eligible participants will be sent an email containing a link to provide voluntary electronic consent. Randomisation will be automated through REDCap. Individuals will be allocated in a one-to-one ratio to either the intervention or control group, using block randomisation with a block size of four.

Intervention: *MS WorkSmart*

Online supplemental file 1 includes a description of the intervention following the TIDieR checklist. The *MS WorkSmart* intervention package includes access to *MS WorkSmart*, access to the *My SymptoMS* app, coaching support via Zoom/telephone and access to a closed Facebook group.

MS WorkSmart consists of nine modules. Participants will be asked to complete one module per week, with a week's break after module 5. The modules take approximately 1.5–2 hours to complete. Table 1 provides an overview of *MS WorkSmart*.

An accompanying app, *My SymptoMS*, has been developed to aid participants in identifying patterns in their symptoms and determining the impact of behaviours, management strategies or medications on those symptoms. The primary objective of the app is to reduce reliance on health professionals for assistance. It has been specifically designed for smartphones while also being accessible on iPads and computers. Within *MS WorkSmart*, participants will be encouraged to select and monitor the symptoms that have the greatest impact on their work or the symptoms they believe they can manage more effectively. Subsequently, participants will be prompted to identify and track behaviours that may influence the symptoms they have chosen to monitor. The app's visualisation feature will provide feedback on their progress over time.

Coaches, who are registered or provisionally registered psychologists with experience in delivering cognitive–behavioural therapy, will provide support throughout the programme. After completing modules 1, 3, 5, 7 and 9, each participant will have a scheduled Zoom or telephone call with their assigned coach. The calls will address any issues participants may have encountered during the module and related tasks and provide an opportunity to discuss specific concerns and support participants to implement workplace changes. The intervention may empower participants to engage in discussions about work-related matters with their employers or arrange workplace assessments. The involvement of representatives from all Australian MS Societies ensures assistance with referrals to local experts.

A closed Facebook group will be available for participants to engage with and learn from peers. The *MS WorkSmart* Team will create approximately two posts per week, to which participants can respond and interact.

Participants in the intervention arm will also continue to receive their usual care.

Control arm

Control arm participants will receive only usual care, as this approach will evaluate the real-world effectiveness of the intervention.[36] Usual care may vary, ranging from participants not receiving any intervention, information or contact with a health professional, to discussions with an occupational therapist or employment services, or support from a psychologist.

Data collection schedule

Participants will complete outcome measures prior to randomisation, and at 1-month postintervention for the intervention group (with equivalent timings for the control group). In the fully powered trial, 6-month and 12-month postintervention follow-ups will be included to capture changes implemented after the intervention has finished.[37] All responses will be recorded through a secure online REDCap system. Table 2 provides an overview of the schedule of enrolment, intervention and assessments.

Primary and secondary outcomes

The feasibility outcomes are summarised in table 3. Our primary outcomes of interest relate to determining the feasibility and acceptability of MS WorkSmart, including (a) recruitment and eligibility, (b) retention, (c) missing data on outcome measures, (d) acceptability of *MS WorkSmart* intervention components and (e) adherence to the *MS WorkSmart* programme. Our secondary outcomes of interest relate to the planning of the fully powered trial, including (a) selection of primary (or coprimary) outcome measure(s), (b) estimation of the sample size, (c) estimation of delivery costs and (d) obtaining participant feedback for improvements of the intervention and the need for a booster session. The anticipated potential barriers of this intervention include the recruitment (people with MS are not interested in this programme), acceptability of *MS WorkSmart* (people find the *MS WorkSmart* programme challenging and have difficulty completing it), and drop-out in the research surveys, particularly in the control arm (table 4).

Outcome measures

There are two candidate coprimary outcome measures for a future definitive trial. The first of these is of high relevance to society and the second to the person with MS: (1) Work productivity loss will be measured using the Work Productivity and Activity Impairment Questionnaire: MS, which captures both absenteeism and presenteeism (% of work time missed due to MS symptoms and % of impairment while working due to MS symptoms). It has demonstrated sensitivity to change in other long-term conditions.[38 39] We will extend the 7-day recall period to

Table 1 Overview *MS WorkSmart* programme

Module	Learning objectives/outcomes	Estimated duration (minute)		
		Videos	Text	Tasks
1 Your work	This introduction module discusses the factors that may impact on employment and quality of life more broadly. Participants will gain insights into their MS, including an understanding of their symptoms, their clinical care team and the medications they may be using. Additionally, the module covers important aspects of employment, such as the participant's type of work, working hours any barriers they may face in their workplace, the reasons behind their decision to work, the implications of not working and their overall work satisfaction.	30	30	15–30
2 Your symptoms	This module helps participants to gain an understanding of the symptoms that have the greatest impact on their work. It introduces a six-step plan for managing symptoms effectively. The plan encompasses the following aspects: prevention through proactive planning and setting boundaries, analysing patterns in symptoms and identifying contributing factors, recognising warning signs that indicate a potential issue, acknowledging the presence or worsening of symptoms, taking action to mitigate and improve those symptoms, and devising a plan for recovery when a break becomes necessary.	30	60	30–40
3 Smart talk	This module focuses on the significance of effective communication and explores the various factors that influence it. Participants will gain insights into articulating their MS to others. Furthermore, the module provides a set of thought-provoking questions designed to assist participants in planning and conducting important conversations related to their MS.	20	40	30–60
4 Disclosure	This module provides guidance on disclosing one's MS to various individuals, including employers, colleagues, friends and family. Participants will understand that disclosure is not a singular event but rather an ongoing process. They will be encouraged to carefully consider the reasons behind their decision to disclose or not, evaluate the safety of disclosure, determine the appropriate amount of information to share, learn effective strategies for disclosing and identify the optimal timing for disclosure. Participants will have the opportunity to apply the communication skills they have acquired throughout the module.	25	40	60–90
5 Smart facts	This module highlights the significance of acquiring and effectively communicating factual information. Participants will gain insights into the importance of understanding relevant facts about themselves, including their MS condition and their personality traits related to self-care. By gaining this knowledge, participants may be motivated to take necessary actions and make informed decisions. The module will also deepen the understanding of how to use factual information to effectively communicate needs within the workplace.	17	37	20–40
6 Transforming thoughts	This module strives to foster a transformative shift in participants' perspectives on workplace challenges and life with MS overall. It emphasises the influence of thoughts on actions and outcomes. Participants will learn to recognise and identify thoughts that may contribute to undesirable results or hinder their progress. Furthermore, the module provides guidance on how to effectively change those thoughts to promote more positive and beneficial outcomes.	30	30	40–60
7 Mindful living	This module provides support to participants in identifying stressors present in their workplace and broader life. It aims to equip them with strategies and techniques to effectively reduce the impact of these stressors. Participants will gain insights into recognising the factors that contribute to stress, whether work-related or related to other aspects of their lives.	20	40	30–45
8 Smart work	This module focuses on the practical changes that participants can make within the workplace. It covers the various workplace accommodations and adjustments that may be relevant and provides examples of when requests may or may not be reasonable. It also covers the funding and supports that are available for people with a disability.	20	40	40–45
9 Your future	The final module focuses on helping participants plan for the future, incorporating the knowledge and skills they have gained throughout *MS WorkSmart*. It emphasises both short-term and long-term implementation of their learnings. Participants will explore strategies to prevent reverting to old habits and ensure the sustainability of positive changes. In addition, the module addresses the challenge of planning for an uncertain future.	15	45	60–90

MS, multiple sclerosis.

4 weeks to reduce the influence of unusual weeks, which does not reduce its validity and is in line with other studies.[40] (2) Risk of job loss will be measured using the MS-WIS, capturing key aspects that the intervention targets: (1) the physical and cognitive aspects of MS and their impact on work; (2) the working environment/organisational aspects; (3) social aspects of the working environment and (4) psychological aspects of working.[33] Analogous scales have been developed for rheumatoid arthritis and ankylosing spondylitis, which have been

Table 2 Schedule of enrolment, intervention and assessments for the *MS WorkSmart* feasibility study

Activity or measures	Invitation and screening	Preintervention	During intervention (10 weeks)	1 month postintervention
Invitation to participate; reasons non-participation	✓			
Eligibility assessment	✓			
Consent process	✓			
Randomisation	✓			
Access to *MS WorkSmart* intervention (*MS WorkSmart* programme, coaching, My SymptoMS App, closed Facebook group, usual care)			•	
Work Productivity and Activity Impairment Questionnaire: Multiple Sclerosis (MS)		•/○		•/○
MS-Work Instability Score		•/○		•/○
MS Work Behaviour Self-Efficacy Scale		•/○		•/○
European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) and EQ-5D-5L-Psychosocial		•/○		•/○
Modified Fatigue Impact Scale-5, impact of symptoms on work		•/○		•/○
Workload, work ability, likelihood of reducing working hours, likelihood of changing work type, likelihood of stopping with work, unpaid work.		•/○		•/○
MS Work Difficulties Questionnaire-23		•/○		•/○
MS Work Change Awareness Scale		•/○		•/○
New General Self-Efficacy Scale (for validation only)		•/○		•/○
Other measures: age, sex, city of residence, relationship status, highest education level, occupational category, whether self-employed, physical/mental demand of job, job satisfaction, workload, unpaid work, MS disclosed, work preference, personal and family income, number dependents, age first MS symptoms, age diagnosis, disease duration, type of MS, disability, disease modifying therapy use, relapse last 4 weeks.		•/○		
Adverse events			••••	
Any additional symptom management and vocational rehabilitation interventions received				•/○
Feedback on individual *MS WorkSmart* modules			••••	
Feedback on the *MS WorkSmart* online intervention materials (content, format, usefulness, ease of use and duration), coaching, Facebook group, My SymptoMS App, primary outcome measures.				•
Feedback from coaches via interviews (logistical processes, amount and types of support provided, inclusion/exclusion criteria, whether a booster session may be required)				✓
Costs of delivering the intervention (time spent coaching; meeting and training time)			••••	

•=participants in the intervention group; ○=participants in the usual care group.

used successfully to measure improvements in response to interventions.[41 42]

We have developed an MS Work Behaviour Self-Efficacy Scale, specifically for *MS WorkSmart*, to assess self-efficacy related to MS and employment, including symptom management, communicating about MS, arranging workplace adjustments and accommodations, reducing negative cognitions (ie, negative thoughts), and stress reduction and self-care activities. It has 31 items, which are rated on a 6-point Likert-type scale (1=strongly disagree and 6=strongly agree). This scale will be validated against the more generic Work Self-Efficacy Scale; an 8-item scale which assesses beliefs in ability to manage daily work tasks.[43]

Table 3 Feasibility outcomes

Feasibility objective	Outcomes (and how measured)
Assess the feasibility and acceptability of *MS WorkSmart*	Recruitment, eligibility and profile ► Number of participants screened, number of eligible participants, number of participants enrolled, number randomised (determined from study records) and profile of participants (determined from survey data). Retention ► Number of participants lost to follow-up (with reasons, if known) (determined from study records). Missing data on outcome measures ► Number of missing data for outcome measures (determined from questionnaires with missing rates logged in study records). Acceptability of *MS WorkSmart* intervention components ► Feedback on the acceptability of intervention components, including the digital intervention and associated tasks, coaching sessions, optional closed Facebook group and *My SymptoMS* app (determined from participant feedback surveys, module feedback during coaching sessions, and interviews with coaches post intervention). Adherence to the *MS WorkSmart* programme ► Number completed modules, quizzes and tasks (determined by programme records).
Plan for the fully powered trial	Selection of primary outcome measure ► The choice of the primary outcome measure is guided by the importance of different outcome measures (determined from participant feedback surveys), the response rates and % missing data of outcome measures (determined from study records) and the preliminary effect size estimates of the outcome measures (determined by questionnaire responses). Sample size ► The sample size is estimated from the SD of continuous primary outcomes measures (determined by the questionnaire data), lost to follow-up data and missing data (determined from questionnaires and study records). Delivery costs ► Coach and staff time (determined from study records). Intervention improvement and uncertainties ► Intervention feedback (determined by feedback survey). ► Need for booster session (determined by feedback survey).

We will use the European Quality of Life with five Dimensions and five Levels (EQ-5D-5L) and EQ-5D-5L-Psychosocial to assess health-related quality of life.[44 45] The EQ-5D-5L has items on mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D-5L-Psychosocial has four additional items from the Assessment of Quality of Life scale (sleep, energy, close relationships and social isolation).[45]

Fatigue will be assessed via the Modified Fatigue Impact Scale-5. The impact of key symptoms on work will be assessed (whether they had the symptom in the last 4 weeks (yes/no) and the impact on work (0–10 rating scale, 0=no impact on work activities, 10=extreme impact and preventing most work activities)), including fatigue, pain, cognitive symptoms, walking difficulties, feelings of depression, feelings of anxiety, bladder problems, bowel

Table 4 Progression criteria to guide decisions for the fully powered trial

Progression measure	Progression criteria (traffic light metric)
Potential issue: People with MS are not interested in this programme. ► Percentage of eligible people interested in participating.	>30% (green) 10%–30% (amber) <10% (red)
Potential issue: People with MS find the *MS WorkSmart* programme challenging and have difficulty in completing it. ► Percentage of people randomised to the *MS WorkSmart* arm who complete >60% of the material, quizzes and tasks. This excludes participants who were prevented of completing the programme due to a serious and lasting adverse event unrelated to the intervention.	>60% (green) 40%–60% (amber) <40% (red)
Potential issue: Drop-out in the research surveys is too high, particularly in the control arm. ► Percentage of people who complete the postintervention survey, stratified by intervention arm.	>70% (green) 50%–70% (amber) <50% (red)

problems, sensory symptoms, spasticity, vision and an option to record other symptoms that have an impact on work.

We will also assess (1) the perceived likelihood of withdrawing from work entirely, (2) the likelihood of reducing the amount of hours worked due to MS and (3) the likelihood of changing the type of work performed due to MS (in the 'next 12 months' and in the 'next 5 years') using a 5-point Likert-type scale, ranging from 'very unlikely' to 'very likely'.

We have developed an MS Work Change Awareness Scale, specifically for *MS WorkSmart*, to assess awareness and readiness for change at work. It is based on the theory of the Change Awareness Questionnaire.[46 47] It includes 21 items (6-point Likert-type scales, strongly disagree-strongly agree) with subscores related to three stages: the precontemplation, contemplation and action stages, with subscores for each stage.

We are including 19 items of the MS Work Difficulties Questionnaire-23, developed by CI Honan, assessing key domains of work barriers/difficulties in the last 4 weeks including cognitive/psychological barriers and physical barriers.[48]

See table 2 for any additional measures captured in the study.

Intervention adherence and fidelity measures

Adherence and content completion will be primarily assessed using the data analytics of *MS WorkSmart* (completion of modules and quizzes and tasks). Coach-specific information will be used to cross-validate the analytics data, including the dates of Zoom sessions, the support provided and the level of feedback on completed modules. The *My SymptoMS* data provide data on the engagement with symptom tracking and behaviour modification. In terms of fidelity, all Zoom/telephone calls will be recorded, and an independent rater will conduct fidelity checks on 20% of calls to rate treatment adherence, integrity and fidelity to ensure the coaches are implementing the intervention as intended.

Reporting and management of adverse events

Given the nature of the intervention, no serious adverse reactions are anticipated. The National Health and Medical Research Council of Australia's definitions of adverse events will be used.[49] Adverse events could include a deterioration in a participant's physical or psychological health, an accidental injury, or adverse actions or discrimination in the workplace associated with engaging with or implementing aspects of the intervention. During each support session, coaches will ask whether anything unusual or unexpected happened since the last contact. If a participant reports a possible adverse event, its severity and causal relationship to the intervention will be established and recorded, with a final decision made by CH and BVT. Adverse events will be discussed in team meetings, including the need for active involvement and follow-up. Suspected serious adverse events will be reported within 24 hours to CH, BH and IvdM. IvdM will report serious adverse events to the ethics committee within 7 days of being informed of such an event.[49]

Process evaluation

To ensure the intervention meets the needs of the endusers and to refine the trial processes, we will seek feedback from coaches and participants randomised to the intervention. First, at the end of each coaching session, the coach will ask for feedback in relation to the just-completed modules, including what was helpful and not so helpful.

Second, a feedback survey for participants randomised to the intervention arm will provide data on (1) the length of the programme; (2) the ease of use of the programme; (3) any features that were particularly liked or disliked; (4) any recommendations for improvements; (5) the amount of coach contact and whether additional coach contact was required; (6) whether any unintended negative consequences occurred; (7) any perceived impacts of the programme and (8) the perceived and importance of different outcomes.

Third, the coaches will be interviewed about their experiences, including logistical processes, the amount and types of support provided, inclusion/exclusion criteria, and need for a booster session. The interviews will be recorded and transcribed verbatim. From this information, potential modifications will be identified. They will be balanced against the literature, and advantages/disadvantages will be discussed with the study steering group after which a final decision will be made.

Study management

IvdM will have overall responsibility for study conduct and will liaise closely with the coinvestigators. The project coordinator (AH) and two support coaches will deal with the day-to-day management and coordination of the study and will have meetings with IvdM and CH every 2 weeks. CH (Psychologist registered with the Australian Health Practitioner Regulation Agency with practice endorsement in Clinical Neuropsychology, and Psychology Board of Australia Approved Supervisor) and BVT (Neurologist) will be responsible for managing adverse events. The steering committee will meet monthly and will include all authors, as well as representatives from the four-member organisations of MS Australia and at least two people with MS.

Analysis

Analyses will be primarily descriptive. We will report on the number of individuals eligible, enrolled, randomised and lost to follow-up in a CONSORT diagram. Data related to recruitment, attrition, outcome measures, questionnaire return rates and intervention adherence will be presented using summary statistics (with 95% CIs, where appropriate). Participant profiles between groups will be compared using t-tests and χ^2 tests. To estimate preliminary signals of efficacy to guide the selection of primary and secondary outcomes and

inform sample size requirements for a future definitive trial, we will use linear mixed models, with the post-treatment time point as the outcome and the baseline measure as a covariate as well as other baseline covariates that differ by treatment arm. We will present adjusted mean between-group differences with 95% CIs. The cost of delivering the intervention will be estimated from the coaching time, and meeting and training time. The internal consistency of the new scales will be determined using Cronbach's alpha with additional analysis to remove non-performing items. Construct validity will be determined using correlations between the MS Work Behaviour Self-Efficacy Scale and the New General Self-Efficacy Scale. Qualitative data will be analysed thematically using a five-stage framework method.[50]

Progression criteria to guide decisions for the fully powered trial

Table 4 presents the traffic light system of progression criteria that will guide decisions for the fully powered trial.[51] Intervention safety is not a formal progression criterion but will be closely monitored and considered in final recommendations. Modifications will be considered when the progression criteria are amber or red. For any red progression criteria, if the study team does not believe that the modifications will substantially improve the metric, the study will not continue to a fully powered trial.

Ethics and dissemination

The study has been approved by the University of Tasmania Human Research Ethics Committee (H0024544). The results of this study will be presented at conferences and published in scientific journals. The findings will also be presented in lay language and disseminated via the Australian MS Longitudinal Study and MS Australia and made available to all participants.

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REFERENCES

1 Vitturi BK, Rahmani A, Dini G, *et al*. Occupational outcomes of people with multiple sclerosis: a scoping review. *BMJ Open* 2022;12:e058948.
2 Paz-Zulueta M, Parás-Bravo P, Cantarero-Prieto D, *et al*. A literature review of cost-of-illness studies on the economic burden of multiple sclerosis. *Mult Scler Relat Disord* 2020;43.
3 Ahmad H, Campbell JA, van der Mei I, *et al*. The increasing economic burden of multiple sclerosis by disability severity in Australia in 2017: results from updated and detailed data on types of costs. *Mult Scler Relat Disord* 2020;44:102247.
4 Moore P, Harding KE, Clarkson H, *et al*. Demographic and clinical factors associated with changes in employment in multiple sclerosis. *Mult Scler* 2013;19:1647–54.
5 Van Dijk PA, Kirk-Brown AK, Taylor B, *et al*. Closing the gap: longitudinal changes in employment for Australians with multiple sclerosis. *Mult Scler* 2017;23:1415–23.
6 Julian LJ, Vella L, Vollmer T, *et al*. Employment in multiple sclerosis. Exiting and re-entering the work force. *J Neurol* 2008;255:1354–60.
7 Chen J, Taylor B, Palmer AJ, *et al*. Estimating MS-related work productivity loss and factors associated with work productivity loss in a representative Australian sample of people with multiple sclerosis. *Mult Scler* 2019;25:994–1004.
8 Sweetland J, Howse E, Playford ED. A systematic review of research undertaken in vocational rehabilitation for people with multiple sclerosis. *Disabil Rehabil* 2012;34:2031–8.
9 Simmons RD, Tribe KL, McDonald EA. Living with multiple sclerosis: longitudinal changes in employment and the importance of symptom management. *J Neurol* 2010;257:926–36.
10 Williams AE, Vietri JT, Isherwood G, *et al*. Symptoms and association with health outcomes in relapsing-remitting multiple sclerosis: results of a US patient survey. *Mult Scler Int* 2014;2014:203183.
11 Klevan G, Jacobsen CO, Aarseth JH, *et al*. Health related quality of life in patients recently diagnosed with multiple sclerosis. *Acta Neurol Scand* 2014;129:21–6.
12 Raggi A, Covelli V, Schiavolin S, *et al*. Work-related problems in multiple sclerosis: a literature review on its Associates and determinants. *Disabil Rehabil* 2016;38:936–44.
13 Asano M, Finlayson ML. Meta-analysis of three different types of fatigue management interventions for people with multiple sclerosis: exercise, education, and medication. *Mult Scler Int* 2014;2014:798285.
14 Nourbakhsh B, Revirajan N, Morris B, *et al*. Safety and efficacy of Amantadine, Modafinil, and methylphenidate for fatigue in multiple sclerosis: a randomised, placebo-controlled, crossover, double-blind trial. *Lancet Neurol* 2021;20:38–48.
15 Frndak SE, Kordovski VM, Cookfair D, *et al*. Disclosure of disease status among employed multiple sclerosis patients: association with negative work events and accommodations. *Mult Scler* 2015;21:225–34.
16 Kirk-Brown AK, Van Dijk PA, Simmons RD, *et al*. Disclosure of diagnosis of multiple sclerosis in the workplace positively affects employment status and job tenure. multiple sclerosis (Houndmills. *Mult Scler* 2014;20:871–6.
17 Roessler R, Rumrill P, Hennessey M, *et al*. The employment discrimination experiences of adults with multiple sclerosis. *J Rehabil* 2011;77:20–30.
18 Jellie B, Sweetland J, Riazi A, *et al*. Staying at work and living with MS: A qualitative study of the impact of a vocational rehabilitation intervention. *Disabil Rehabil* 2014;36:1594–9.
19 Rumrill Jr. PD, Koch LC, Wohlford S. Job retention strategies for individuals with multiple sclerosis. *J Vocat Rehabil* 2013;39:127–35.
20 Johnson KL, Yorkston KM, Klasner ER, *et al*. The cost and benefits of employment: A qualitative study of experiences of persons with multiple sclerosis. *Arch Phys Med Rehabil* 2004;85:201–9.

21 Thomas S, Thomas PW, Nock A, *et al*. Development and preliminary evaluation of a cognitive behavioural approach to fatigue management in people with multiple sclerosis. *Patient Educ Couns* 2010;78:240–9.
22 Thomas S, Thomas PW, Kersten P, *et al*. A pragmatic parallel arm multi-centre randomised controlled trial to assess the effectiveness and cost-effectiveness of a group-based fatigue management programme (FACETS) for people with multiple sclerosis. *J Neurol Neurosurg Psychiatry* 2013;84:1092–9.
23 Vitturi BK, Rahmani A, Dini G, *et al*. Work barriers and job adjustments of people with multiple sclerosis: A systematic review. *J Occup Rehabil* 2023;33:450–62.
24 West R, Michie S. A Guide to Development and Evaluation of Digital Behaviour Interventions in Healthcare. London: Silverback Publishing, 2016.
25 Firth N. Effectiveness of psychologically focused group interventions for multiple sclerosis: A review of the experimental literature. *J Health Psychol* 2014;19:789–801.
26 Marziniak M, Brichetto G, Feys P, *et al*. The use of Digital and remote communication Technologies as a tool for multiple sclerosis management. *JMIR Rehabil Assist Technol* 2018;5:e5.
27 Bonnechère B, Rintala A, Spooren A, *et al*. Is mHealth a useful tool for self-assessment and rehabilitation of people with multiple sclerosis. *Brain Sci* 2021;11:1187.
28 van Kessel K, Wouldes T, Moss-Morris R. A New Zealand pilot randomized controlled trial of a web-based interactive self-management programme (Msinvigor8) with and without email support for the treatment of multiple sclerosis fatigue. *Clin Rehabil* 2016;30:454–62.
29 Skivington K, Matthews L, Simpson SA, *et al*. A new framework for developing and evaluating complex interventions: update of medical research Council guidance. *BMJ* 2021;374:n2061.
30 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
31 Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of web-based and mobile health interventions. *J Med Internet Res* 2011;13:e126.
32 Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301–8.
33 McFadden E, Horton MC, Ford HL, *et al*. Screening for the risk of job loss in multiple sclerosis (MS): development of an MS-specific work instability scale (MS-WIS). *Mult Scler* 2012;18:862–70.
34 Bessing B, Hussain MA, Claflin SB, *et al*. Changes in multiple sclerosis symptoms are associated with changes in work productivity of people living with multiple sclerosis. *Mult Scler* 2021;27:2093–102.
35 Bessing B, Claflin SB, Taylor BV, *et al*. Estimating the impact of work difficulties, work self-efficacy and work psychological safety on MS-related work productivity loss. *Mult Scler* 2022;28:1983–96.
36 Freedland KE, Mohr DC, Davidson KW, *et al*. Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosom Med* 2011;73:323–35.
37 Thomas PW, Thomas S, Kersten P, *et al*. One year follow-up of a pragmatic multi-centre randomised controlled trial of a group-based fatigue management programme (FACETS) for people with multiple sclerosis. *BMC Neurol* 2014;14:109.
38 Reilly MC, Gooch KL, Wong RL, *et al*. Validity, Reliability and responsiveness of the work productivity and activity impairment questionnaire in Ankylosing Spondylitis. *Rheumatology (Oxford)* 2010;49:812–9.
39 Reilly MC, Gerlier L, Brabant Y, *et al*. Validity, reliability, and responsiveness of the work productivity and activity impairment questionnaire in Crohn's disease. *Clin Ther* 2008;30:393–404.
40 Sanderson K, Tilse E, Nicholson J, *et al*. Which Presenteeism measures are more sensitive to depression and anxiety *J Affect Disord* 2007;101:65–74.
41 Macedo AM, Oakley SP, Panayi GS, *et al*. Functional and work outcomes improve in patients with rheumatoid arthritis who receive targeted, comprehensive occupational therapy. *Arthritis Rheum* 2009;61:1522–30.
42 Emery P, Smolen JS, Ganguli A, *et al*. Effect of Adalimumab on the work-related outcomes scores in patients with early rheumatoid arthritis receiving methotrexate. *Rheumatology (Oxford)* 2016;55:1458–65.
43 Chen G, Gully SM, Eden D. Validation of a new general self-efficacy scale. *Organizational Research Methods* 2001;4:62–83.
44 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
45 Campbell JA, Ahmad H, Chen G, *et al*. Validation of the EQ-5D-5L and Psychosocial bolt-Ons in a large cohort of people living with multiple sclerosis in Australia. *Qual Life Res* 2023;32:553–68.
46 Lam CS, McMahon BT, Priddy DA, *et al*. Deficit awareness and treatment performance among traumatic head injury adults. *Brain Inj* 1988;2:235–42.
47 Lam CS, Chan F, McMahon BT. Factorial structure of the change assessment questionnaire for individuals with traumatic head-injuries. *Rehabilit Psychol* 1991;36:189–99.
48 Honan CA, Brown RF, Hine DW. The multiple sclerosis work difficulties questionnaire (MSWDQ): development of a shortened scale. *Disabil Rehabil* 2014;36:635–41.
49 Council NHaMR. Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods, 2016. Available: https://www.nhmrc.gov.au/guidelines-publications/eh59
50 Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.
51 Avery KNL, Williamson PR, Gamble C, *et al*. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 2017;7:e013537.