





BMJ Open Web-based physical activity intervention for people with progressive multiple sclerosis: application of consensus-based intervention development guidance

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ABSTRACT

Objectives People with progressive multiple sclerosis (PwPMS) report that they recognise the benefits of activity on their physical and psychological health but need support to achieve their physical activity goals. We aimed to systematically develop a theoretically informed intervention that would enable PwPMS to more readily engage in regular physical activity.

Design We used an intervention mapping approach to inform intervention development.

Setting We conducted semistructured interviews with PwPMS and their families/carers and physiotherapists recruited from secondary care settings.

Participants Fourteen PwPMS with an Expanded Disability Status Scale score of between 6 and 8 and 7 of their families/carers and 13 physiotherapists and 1 physiotherapy technician participated.

Results Interview data suggested that the development of supportive coaching relationships with physiotherapists could promote the ability of PwPMS to achieve a desirable and achievable physical activity plan. These interview data informed the prototype 'Lifestyle Exercise and Activity Package for Multiple Sclerosis' (LEAP-MS) consisting of a secure multiuser web-based platform (with an education and activity suite, interactive components enabling selection of exercises, goal setting and activity logging), up to six flexible face-to-face or web-based physiotherapy coaching sessions and remote support via an embedded web-based messaging function that all together draw on specific theory-based methods to achieve physical activity behaviour change, namely active learning, reinforcement, modelling, feedback, facilitation, goal setting and guided practice. Implementation is within a multiuser platform accessible to participants, trained physiotherapists and researchers.

Conclusions We have followed an inclusive, systematic and transparent process to develop the LEAP-MS intervention that enables detailed description of components, context and guiding principles to inform ongoing evaluation. Importantly, PwPMS expressed the need for autonomy in developing physical activity plans. This has been achieved through the embedding of self-

Strengths and limitations of this study

- We have followed a systematic process that adheres to consensus-based intervention development guidance.
- Involvement of key stakeholders was central throughout to make the resultant intervention grounded in the particular lived experiences and needs of this underserved patient group.
- Physiotherapy training to use technology in remote consultations and provide self-management support was developed as part of the implementation planning process.
- Members of the patient and public involvement steering committee reviewed the prototype intervention and volunteered to undertake initial feasibility testing to refine the implementation process but further and more extensive user testing would have been preferable.
- Stakeholders were identified from across South Wales and thus perspectives were limited to one locality.

management principles in the design and delivery of the LEAP-MS intervention.

INTRODUCTION/BACKGROUND

Multiple sclerosis (MS) is the most common disabling neurological disease among young adults in the developed world¹ with a wide range of associated symptoms including motor, sensory, visual and autonomic impairments.¹ It affects an estimated 107 000 people in the UK.² These individuals are often high users of health and social care services and self-report low health-related quality-of-life.^{3 4} Around 10% of patients are initially diagnosed with progressive MS and many with an initial relapsing remitting course will

develop progressive MS and advancing disability over time.¹⁵

The benefits of supervised exercise in MS are well established such that physical activity interventions have become a cornerstone of MS rehabilitation with physical, psychological and social domain benefits.^{6,7} Regular physical activity can provide a sense of hope and purpose^{8,9} and people with MS, including those with progressive MS value and perceive benefit from keeping physically active and moving.^{10,11} However, in more recent years, there has been a shift in thinking away from 'exercise training for fitness' towards 'physical activity for health'.¹² To this end, explicitly supporting people with MS with the skills to select or alter their activities and individualise to their preferences, needs, time constraints and values is more likely to achieve a sustained change in behaviour.¹³ Indeed, building self-efficacy through goal setting and mastery along with coaching-style communication and self-monitoring are now well established as critically important determinants of sustained behaviours.⁷

A systematic review (including studies published up until 30 April 2015) identified 19 reports of behavioural change interventions aiming to increase activity and participation in people with MS. Interventions typically incorporated goal setting, barrier identification and information provision and were delivered either face to face, using tele-medicine technology or through unsupervised home-based exercise programmes with written material as support. They were effective in increasing physical activity over the short term, but had no effect on the physical components of quality of life or fatigue and initial increases in physical activity were not sustained in the longer term.¹⁴ Other researchers have previously developed interventions to promote physical activity in MS using a dedicated website and video chats with a coach.^{15,16} However, as with most MS physical activity research to date,^{6,7,10,11,17,18} studies have exclusively focused on patients who are ambulatory, despite non-ambulatory people with MS, with more advanced disease being most at risk of becoming inactive.

Seeking sustainable, cost-effective interventions that promote physical activity behaviours for all, in particular those who struggle with higher levels of disability, is clearly a priority. Furthermore providing clarity on the ways in which physiotherapists are best able to contribute to self-management support for physical activity for people with progressive MS (PwPMS), was highlighted during a research priority setting exercise run by the James Lind Alliance in partnership with the MS Society. Thus, we aimed to develop a theoretically informed physiotherapy intervention, the 'Lifestyle Exercise and Activity Package for Multiple Sclerosis' (LEAP-MS), that would enable PwPMS to more readily engage in regular physical activity both in and out of their homes.

We used intervention mapping,¹⁹ a systematic approach to intervention development, that incorporates theory and evidence-based planning for behavioural change and acknowledges individuals' behaviour as being dependent

on their environment and social context. It has been applied in a range of behaviour change contexts and settings (both clinical and public health) including physical activity promotion in older age individuals,²⁰ self-management interventions for rheumatoid arthritis,^{21,22} and for low back pain²³ and theory-based interventions to promote physical activity in preschool and school age children.^{24,25}

The first step of the intervention development process is the needs assessment which aims to identify areas for change, associated behavioural and environmental factors (barriers) that together inform the definition of intervention context and goals. Here, we report on the initial needs assessment and the subsequent development of LEAP-MS.

METHODS

We used semistructured interviews to explore (1) the experiences of PwPMS (with significant disability limiting their walking and ability to participate in activities of daily living) and their families/carers in accessing and doing physical activity and (2) the perceptions, experiences and training needs of physiotherapists in supporting PwPMS to be physically active.

PwPMS were identified via a tertiary MS centre database, which held records of all persons with MS in the region that had given permission to be contacted about research projects applicable to them. Purposive sampling to ensure a representative balance of gender, age and Expanded Disability Status Scale (EDSS)²⁶ score (with EDSS range between six and eight) was employed. Family members/carers were also invited to participate. Written informed consent was obtained for all research interviews apart from one interview where the participant was unable to hold a pen. In this case consent was verbal and witnessed. Physiotherapists and physiotherapy technicians were recruited via three participating University Health Boards.

Face-to-face interviews were conducted by a post-doctoral neurological physiotherapist with experience working with patients with MS and conducting and tailoring semi-structured interviews with people with a wide range of neurological deficits. Interviews explored past and present physical activity, including facilitators and barriers, support from physiotherapists (or not), experiences/understanding of 'self-management' and their ideas for personalising an invention resource, (see Interview Topic Guide; online supplemental file 1). Interviews with physiotherapists focused on their experiences of supporting PwPMS to be physically active, their understanding of self-management principles and the application of these in everyday practice.

Interviews were audiorecorded, transcribed verbatim and analysed thematically.²⁷ This involved familiarisation with the data by rereading and annotating transcripts. The data were then systematically searched for recurring themes. Crucially, the researcher did not just look

at recurring themes but also views that were unusual or contradictory. Analytic notes were made and labels (codes) were applied to sections of text. Codes were then grouped into categories of shared meaning. The strength of each initial category was considered, and key themes established through an inductive, latent thematic analysis. Categorical groupings were restructured as the data were revisited and themes which best captured the essence of the data formed. Once the final themes had been established, the data were revisited to ensure that all manifestations of each theme in the dataset had been accounted for.²⁸

Six physiotherapists, 10 PwPMS and 5 family members attended a stakeholder event to contribute to step 4 of the intervention mapping process. They discussed (1) key barriers to physical activity and (2) possible solutions. These individuals were identified through advertising posters in MS specialist clinic areas and a local social media campaign with the support of the local MS Society and our public and patient involvement (PPI) group. Those present were asked to think about physical activities that they could do and those which they could envisage being of interest to others.

In one of four mini workshops attendees explored their readiness (or not) to access and use available technologies.

Patient and public involvement

The research question emerged as a result of a James Lind Alliance Priority Setting Exercise. Patients and the public were involved in the design (interview and

stakeholder event planning), conduct (delivering the stakeholder event and interpretation of the interview data), reporting of this research (developing a communication and producing video summaries of the findings) through an established PPI group. The chair of the PPI group was a member of the study management group attending regular management group meetings. The PPI group remain involved in ongoing dissemination plans for this research.

RESULTS

The interview data (needs assessment) guided each subsequent intervention development step namely: (1) specification of a logic model of change based on anticipated intervention outcomes; performance objectives and behavioural determinants; (2) selection of applicable theory-based intervention methods and practical applications relevant to the determinants specified in (1); (3) development of a prototype intervention based on (2) to (3) as well as the aforementioned stakeholder event; (4) development of an adoption and implementation plan relevant to the specific intervention contexts and (5) design of an evaluation plan to assess process and future effectiveness. Main outcomes from each step of the process are depicted in figure 1.

Step 1: needs assessment

Fourteen PwPMS with an EDSS score of between 6 and 8 and 7 of their families/carers participated in face-to-face

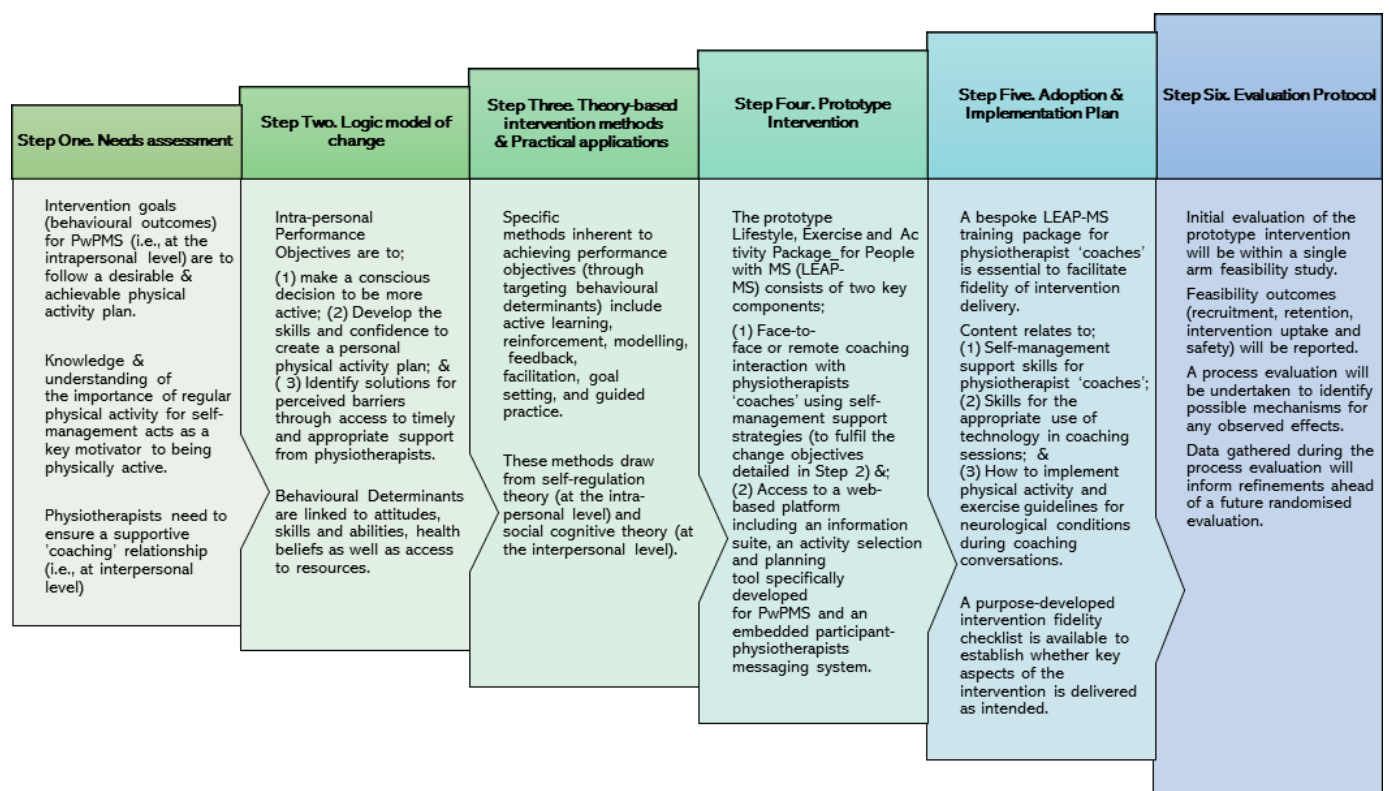


Figure 1 Main outcomes at each step of the six step intervention mapping process. PwPMS, People with progressive Multiple Sclerosis.

interviews. Thirteen physiotherapists and one physiotherapy technician participated in interviews. We identified eight themes from interviews with PwPMS (and families/carers) and three themes from physiotherapist interviews that informed the intervention goals, namely that the PwPMS would develop a desirable and achievable physical activity plan. Critically this would be achieved through the development of a supportive coaching relationship with their physiotherapist.

Table 1 demonstrates the key themes and how they were associated with the overarching LEAP-MS intervention goals (behavioural outcomes), the related change and performance objectives and relevant behavioural determinants at both the intrapersonal level (ie, for the person with PwPMS) and the interpersonal (ie, the physiotherapist). Practical implications for the intervention development are also detailed in table 1.

Step 2: developing a logic model of change

We produced a logic model of change (figure 2) which linked performance objectives to behavioural determinants that would lead to the proposed intervention outcomes over the short and medium term. Intrapersonal (for the PwPMS) performance objectives focused around three main areas—first, making a conscious decision to be more active; second, developing the skills and confidence to create a personal physical activity plan, which would include identifying suitable physical activities,²⁹ weighing up the risks and benefits of each activity in relation to health, and to be confident in trying new things and third—identifying solutions for perceived barriers through access to timely and appropriate support from physiotherapists. A key dependency was that the physiotherapists themselves recognised the importance of personalised and tailored self-management support for physical activity and that they had the knowledge, confidence and skills to do so.

Step 3: selection of applicable theory-based intervention methods and applications

Recognising the need for specific methods to achieve physical activity behaviour change, for example, active learning, reinforcement, modelling, feedback, facilitation, goal setting and guided practice,³⁰ we drew from two underlying programme theories: social cognitive theory and self-regulation theory. Social cognitive theory is a widely adopted theoretical framework used in physical activity interventions.^{31 32} Within social cognitive theory, behaviour is an outcome of the interaction of personal, social and physical factors within the environment and knowledge of self that will influence health beliefs and behaviours. The key construct within social cognitive theory is that of self-efficacy, defined as ‘a belief about individual capability to perform a certain behaviour’.³¹ Other critical constructs are in relation to exploring health beliefs, outcome expectations, barriers and facilitators and using knowledge of self in goal setting.^{33–36} Specific methods inherent in social cognitive theory-based

interventions are goal mastery, active learning, reinforcement, modelling, feedback, facilitation and guided practice.³⁷

Self-regulation theory argues that illness representations, beliefs and social and cultural contexts drive behavioural and emotional responses.³⁸ Representations of the illness are personally evaluated, and individuals will typically respond to awareness of an issue by developing an action plan achieved through guided practice and goal setting.³⁷ Online supplemental tables 1 and 2 depict the matrix of performance objectives, behavioural determinants and change objectives with associated theory-based methods, parameters and practical applications at the intrapersonal and interpersonal levels.

Step 4: designing and producing the intervention

The way in which PwPMS wanted to engage with physiotherapists was a critical factor in intervention design. Discussions at our stakeholder event highlighted that physiotherapy input in supporting physical activity engagement was warranted but ownership (autonomy) was critical to ongoing engagement. The presence of physiotherapists was only useful if they could recognise specific contexts and work with PwPMS to address their concerns. Flexible needs-driven communication with physiotherapists was preferred; those who saw physiotherapists as key motivators to their level of activity preferred more regular, scheduled contact.

Participants in our stakeholder event detailed extensive variety in activities which interested them indicating a requirement for a vast ‘library’ of activity ‘ideas’ to meet the needs of a very diverse population. The event confirmed our interview findings that a technological solution would be welcomed but that such a solution would require interactive functionality that could be personalised with text, audio and visual options for providing information, as well as access to remote support from physiotherapists. Many stakeholders had multiple personal technologies that they used daily in their home and most accessed the internet regularly to gain support and information about MS. Attendees were quick to suggest technological solutions to engaging with both activities and therapists and envisaged various features they would like to see in web-based tools—especially for the support of memory and motivation. They also identified that technology offered the potential for personalisation in a way that other methods could not.

The LEAP-MS intervention (www.leapms.org) was thus designed to consist of two key components: (1) face-to-face or web-based coaching with physiotherapists using self-management support strategies (to fulfil the change objectives detailed in step 2) and (2) a web-based platform including an information suite, an activity selection and planning tool specifically developed for PwPMS and a participant-physiotherapist messaging system (see figure 3). It was developed as a multiuser system that enables the pairing of MS participant and physiotherapist accounts. It promotes self-management and

Table 1 Themes and key messages identified from interviews with PwPMS (and families/carers) and physiotherapists as well as associated LEAP-MS intervention goals, change objectives and practical considerations

Theme	Key messages	Intervention goals (behavioural outcomes)	Change objectives	Practical implications
Experience of information at point of diagnosis	How diagnosis was delivered and remembered by the participant was often influential in shaping their initial attitude towards their condition and could also impact on their long-term attitude towards physical activity.	Person with MS follows a desirable and achievable physical activity plan	Decide to be more active with MS	The need to provide information about how physical activity could help the management of MS symptoms and 'myth bust' long entrenched understandings shaped the inclusion of an 'Information Suite' within the LEAP-MS activity package and formed part
Relationship with physical activity and exercise pre-MS and post-MS	The relationships and attitudes PwPMS had with physical activity, sport and exercise before their MS diagnosis could impact on their attitudes towards physical activity following diagnosis.			
Perception of the impact of physical activity on MS symptoms	Those who were clear that physical activity helped them manage their symptoms were more engaged with physical activity than those who could not see how it could help them.			
Motivation	What did and did not motivate PwPMS to be physically active was highly individual—but included the ability to recognise how physical activity could help manage MS symptoms and the input of healthcare professions and peers.		Identify solutions for perceived barriers	Recognising the individuality of 'motivation'—we included a range of functions and features in the LEAP-MS intervention including goal setting and self-progress monitoring, the option of meeting with physiotherapists up to six times and the ability for physiotherapists to view participants plans. This sense of being monitored by healthcare professions was seen as a key motivator for doing regular activities discussed.
Fear, falls and fatigue	The single biggest barriers to activity for people with progressive MS were either fatigue or a fear of falling.			We included information and advice about exercise and the management of fatigue in an 'Information Suite'. We carefully selected activities including lots of seated options to enable activity with very low risk for those for whom either fear or risk of falling was high in the web platforms' 'Activities Suite' and ensured key safety information and reminders were populated throughout the platform.
Therapies and interactions with healthcare professionals	Past and present interactions with physiotherapists and other healthcare professionals also played a part in attitudes towards physical activity.			We trained physiotherapists to take a self-management approach to their coaching sessions with participants which focused on enhancing physical activity rather than solving a particular problem or issue. Using self-management and focusing on enhancing well-being rather than looking at problems provided the opportunity for the participant-physiotherapy relationship to be re-set.
Reliance and risk	Most were happy to take measured risks but took support from (and spoke about the importance of support given by) partners and family members to help them mitigate risks as much as possible.		Create own personalised physical Activity plan	Recognising the importance of exercising together we recommended exercise with others on the LEAP-MS platform and for example, included activities which could be carried out with children to provide options for families to be active together. We provided basic safety information in the 'Information Suite' and through the use of self-management techniques in physiotherapy coaching sessions, supported (and skilled) PwPMS to make their own judgements about safety and mitigating risks.
Finance and facilities	PwPMS could be hampered from participating in physical activity due to issues of access to facilities or finance. Participants expressed confidence in the use of technology for a range of social and work purposes. While none were using these devices to support physical activity, the potential of online engagement to support physical activity was largely welcomed.			We ensured that LEAP-MS content and/or activities suggested were primarily: (1) free, (2) could be done at home or in open public spaces and/or (3) did not rely on expensive equipment. LEAP-MS provided alternative ways to meet with physiotherapists (eg, over zoom).
Physiotherapists as experts	Physiotherapists recognised the importance of physical activity in the management of MS symptoms, but were less confident in the application of exercise principles specific to the needs of people with long term neurological conditions.	Physiotherapist efficiently supports people with MS to engage in a desirable and achievable physical activity plan	Demonstrate confidence to develop a shared approach to exercise prescription, knowledge and skills to shape programmes to fit with individual needs	We developed a training package for physiotherapists which included asynchronous self-study of exercise principles for people with long term neurological conditions.
Focus on individual problems rather than on physical activity	Physiotherapists explained that there was little opportunity for physical activity', general fitness or exercise to be a central focus of a session due to service structure and provision.		Endorse creative and individualised physical activity planning in LEAP-MS consultations	LEAP-MS offered intervention physiotherapists a new way to engage with PwPMS purely about physical activity rather than for 'referred' problems.
Self-management approaches to physical activity	Self-management as an approach was well accepted by those we interviewed but the level of skill and experience of using this approach varied significantly within our cohort.			Part of the LEAP-MS physiotherapy training package included bespoke self-management training delivered over two half day face-to-face sessions.

LEAP-MS, Lifestyle Exercise and Activity Package for Multiple Sclerosis; MS, multiple sclerosis; PwPMS, People with progressive Multiple Sclerosis.

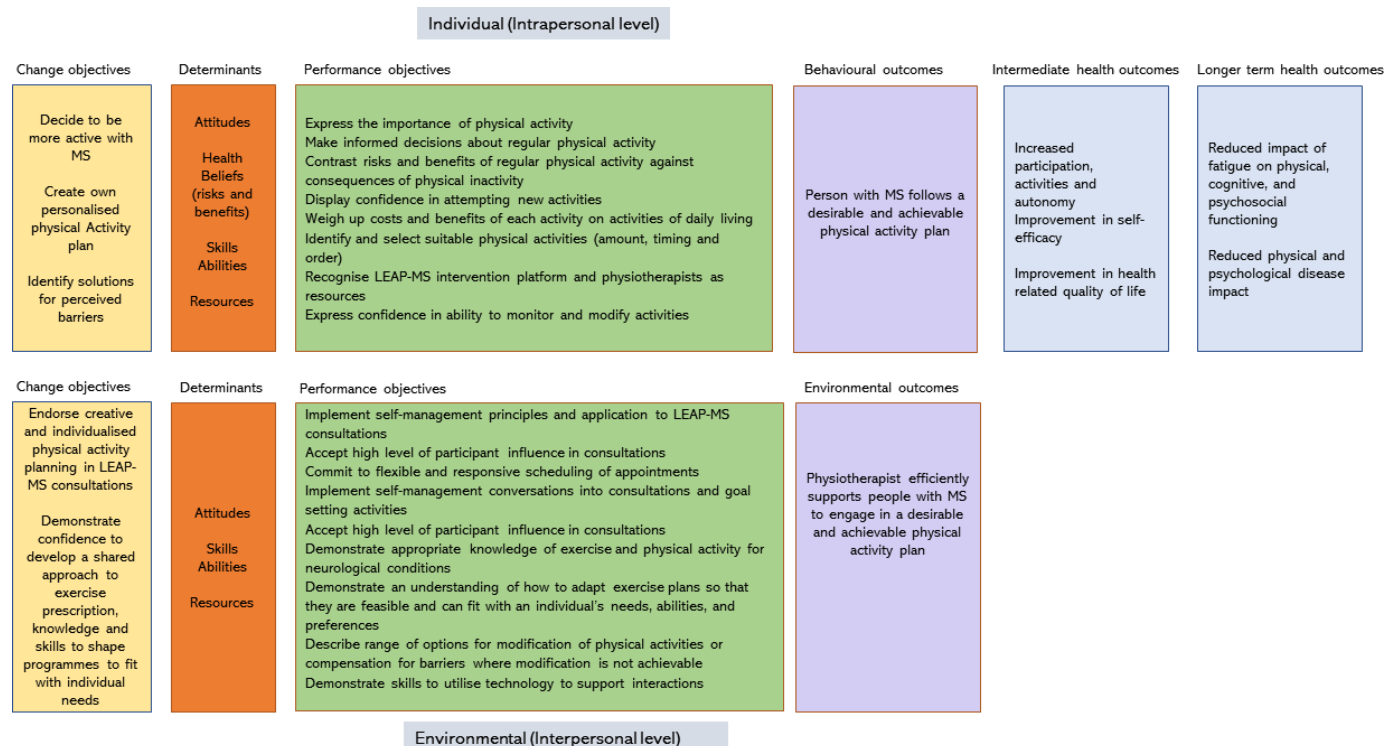


Figure 2 Logic model of change for the intervention detailing change objectives determinants, performance objectives and proposed behavioural (intrapersonal) and environmental (interpersonal) outcomes leading to intermediate and longer-term health outcomes for the person with multiple sclerosis (MS). LEAP-MS, Lifestyle Exercise and Activity Package for Multiple Sclerosis.

autonomous behaviour supported by physiotherapist as needed. In-platform messaging enables the physiotherapist to see and discuss participant choices, aims and progress building on a previous successfully tested multiuser system (TRAK^{39 40}).

The physical activity coaching approach is a development of an existing work book-based physical activity coaching intervention for people with Huntington's disease.⁴¹ It promotes self-management skills through the use of coaching techniques and strategies as part of a Bridges self-management approach.⁴² In coaching sessions, PwPMS will learn how to navigate the LEAP-MS website, choose personal activities, set goals and log weekly activity. Physiotherapists will draw on their professional knowledge and skills of safe, appropriate physical activity and exercise specific to MS both verbally (face to face or remote) and through directing participants to the LEAP-MS web-based platform. Depending on needs and areas of importance identified by the PwPMS, they will encourage self-management approached through the discussion of strategies to anticipate and overcome barriers to physical activity and explore options for self-monitoring (including activity trackers and logs). They may also share examples of other PwPMS who have experienced similar challenges when initiating a new exercise programme—with discussion of how they overcame these, thus using modelling as a potential source of self-efficacy. After the initial session, physiotherapists will review any progress, safety concerns and progression of exercise as requested or initiated by the PwPMS and provide

appropriate feedback for activity selection, attempts and engagement in regular physical activity. PwPMS can also use the inbuilt messaging function to communicate with their paired physiotherapist to seek additional support if needed.

Step 5: planning for adoption and implementation

A bespoke LEAP-MS training package⁴³ which ensures skill development in provision of self-management support skills for physiotherapist⁴² alongside the appropriate use of technology in coaching sessions and application of physical activity and exercise guidelines for neurological conditions has been developed.⁴⁴ The initial content was achieved through the conduct of a 2 day interactive training session, attended by physiotherapists likely to deliver the intervention in the subsequent evaluation, underpinned by Bridges Self-Management principles and delivered by Bridges Social Enterprise (<http://www.bridgesselfmanagement.org.uk/>). This workshop was video recorded and prepared for use as a final online training package accessed via the LEAP-MS multimedia online learning resource. Given the emergent challenges in rehabilitation service delivery during the COVID-19 pandemic,^{45–47} and the anticipated move to greater use of remote intervention delivery, further resources (<https://www.bridgesselfmanagement.org.uk/covid-19-resources/>) to help structure remote interactions were made available as part of the final training package so as to ensure standardisation of coaching interactions

Personal Challenges

Once you've completed a aim make sure you log it by clicking on the star (★).

Aim: Be able to make it round the shops on my own By When: 25th September 2020

ADD A NEW AIM

My plan

In this section you will see all the activities you have selected

Take a look at what you've chosen and add some details - when would you like to do these activities? How long do you want to do the activity for or how many times?

Once you've done an activity make sure you log it by clicking on the star (★).

Activity	When	How long for/ How many times	Achieved
core strengthening routine 1	Mondays	10 minutes	★
MojoMoves main session 1	Saturday	1 session	★

Information Suite

LEAP-MS is about supporting you to be physically active. This section includes information about physical activity and MS, how to choose new activities that are right for you and how you can overcome challenges you might face in starting new activities.

Browse through the information categories and take a look at the information below to learn more about why physical activity is important for people with MS and how being physically active can help manage MS symptoms.

Activity Categories: CARDIO-VASCULAR, STRENGTH & ENDURANCE, FLEXIBILITY, CORE STABILITY, BALANCE, CO-ORDINATION & SENSATION, MS & PHYSICAL ACTIVITY, EATING, DRINKING & NUTRITION, MANAGING PAIN & TONE, ACTIVITY & PELVIC HEALTH, BENEFITS OF EQUIPMENT & TECHNOLOGY, CHOOSING ACTIVITIES FOR ME, OVER...

Contact my physio

In this section you can contact your physio if you'd like to ask them any questions about the activities you are doing. This service is available to you for 3 months.

Your physio is: **Andrew**

Write your message here:

Activity Log Table:

Activity	When	How long for/ How many times	Achieved	Times completed
MojoMoves	2020 10:14			
MojoMoves	2020 05:56			
Leg strengt	2020 05:55			
MojoMove	2020 05:54			
MojoMove	2020 05:54			
MojoMoves main session 1	2020 19:58	Two times each week	2 out of 10	1-10 minutes
Leg strengthening routine	2020 19:49			
MojoMoves main session 1	2020 19:48	Between 3 and 5 times a week	4 out of 10	31-40 minutes
Aerobics session 4	2020 19:45	Every day	1 out of 10	1-10 minutes
Activities at the gym	2020 19:36	Every day	1 out of 10	1-10 minutes

Extra Notes: This is a test submission on the UAT server

Figure 3 The web-based platform which includes multimedia education about being active with MS, tailored physical activity ideas and interactive functions enabling the development of personalised activity programmes, goal setting and activity logs. Unlike other physiotherapy-based web-based activity platforms for other conditions or general education platforms, the platform has a paired account function in which people with MS can be paired with their physiotherapist. Critically, rather than the physiotherapist selecting and prescribing activities, the person with MS has complete choice and control of this process. MS, multiple sclerosis.

regardless of mode of delivery (online or face to face in the home).

The key knowledge and skills required by physiotherapists to deliver the intervention informed specific training and the onwads planning for fidelity evaluation were captured in a purpose-developed fidelity checklist (online supplemental table 3). They include understanding of exercise principles and physical activity specifically for neurological conditions and those needed to facilitate the central approach of self-management, the ability to implement coaching conversations underpinned by self-management principles and language, having an understanding of how to adapt/modify exercise plans so that they are feasible and can fit with an individual's needs, and abilities, favourable attitudes and the technical skills to support PwPMS to use web-based tools.

Step 6: evaluation plan

In line with the Medical Research Council Framework for Development and Evaluation of complex interventions,^{48 49} LEAP-MS will be evaluated within a single arm feasibility study with embedded process evaluation.⁴³ After registration and initial eligible screening, 21 participants will be required to complete baseline self-report measures after which they will be able to access the intervention for an initial 3-month period. During this period, participants are given the option to request up to five further home-based or online physiotherapy coaching sessions as found acceptable in previous physical activity interventions using components of this intervention.⁴¹

Follow-up questionnaires and semistructured interviews will be administered 3 months after baseline with participants and intervention physiotherapists. The LEAP-MS platform will be available to participants for a further



3 months. Use of the LEAP-MS platform will be tracked during the full 6-month period and final follow-up will be conducted 6 months after baseline. Given the detailed development process followed it will be possible for the intervention to be fully described in line with the 'Template for Intervention Description and Repliation' checklist.⁵⁰ Feasibility outcomes (recruitment, retention, intervention fidelity, uptake (website usage statistics) and safety) will be reported and the process evaluation will explore participant experiences of the intervention and explore possible mechanisms for any observed effects.

DISCUSSION

Remote technologies to support the delivery of medical, mental health and rehabilitation services have been documented for many years and, with the ever-growing refinement and accessibility of technologies within the home, so has the interest of service users in remote delivery of health-based services.⁵¹ Telephone and web-based consultations for physiotherapy or musculoskeletal based assessment/outpatient triage has been in use for several decades,⁵² and the use of 'wearables'—personal activity devices to monitor and motivate activity—account for much contemporary digital discussion in therapeutic literature.^{53–55}

A vast array of digital technologies has been harnessed to support all aspects of MS care.⁵⁶ Examples include those which focus particularly on physical activity via web-based units of self-directed learning combined with exercise programmes prescribed by a physiotherapist and a texting or email service,⁵⁷ in-clinic prescribed exercise programmes combined with home-based automated prompt systems delivering reminders,⁵⁸ web-displayed physiotherapy-prescribed exercise routines alongside telephone calls or web-based asynchronous communication with physiotherapists.^{59–61}

None of these interventions however focus on people with high levels of disability and impairment and they do not combine real-time web conferencing to support patient–physiotherapist communication. Within this context, the LEAP-MS is unique in providing a tailored physical activity self-management support intervention for PwPMS with severe disability. The strong expression from PwPMS about autonomy and the ethos and embedding of self-management principles that was evident throughout this intervention mapping process was central to design and delivery of the LEAP-MS intervention. The resultant LEAP-MS intervention focuses on coaching PwPMS to consider and plan their own opportunities for physical activity through eliciting, acknowledging, and discussing participants' perceptions and experiences of physical activity.^{33–36} It seeks to ensure PwPMS have control over when and how they access physiotherapist input including home-based, face-to-face or on-line (video based) coaching sessions. These coaching strategies directly support self-management through promoting goal setting and development of a personalised activity

plan⁴¹ as part of a Bridges self-management approach.⁴² In this, key sources of self-efficacy, goal mastery and modelling are integral to coaching interactions, as both mediator of change and an anticipated outcome.

We followed the GUIDance for the rEporting of intervention Development framework to provide a comprehensive description of each step of the intervention development process.⁶² The context, purpose and target population were clearly defined and we used the six step intervention mapping process⁶³ to develop a theoretically informed intervention. We ensured participation of all stakeholders throughout the process both through the conduct of interviews to inform the needs assessment and at the intervention design stage when we hosted a stakeholder event with a view to ensuring acceptability and relevance of our outputs. Interview participants and stakeholders were identified from across South Wales. Three members of our PPI steering committee reviewed the prototype intervention and engaged in initial feasibility testing to help the team refine implementation plans although we have yet to establish optimal delivery mode (face to face or remote are both options) and dose (participants can elect to receive up to six coaching sessions) and we cannot be sure that we have captured relevant content across all stages of progressive MS. While the ascertainment of views were limited to those in one single geographical area, the views expressed by our participants were well aligned to that reported in the literature in terms of barriers and facilitators of physical activity in PwPMS.^{17 29 36} Future associated studies will need to incorporate views of PwPMS from a broader spread of localities with specific reference to the role of physiotherapist coaches in providing self-management support for physical activity in PwPMS.

LEAP-MS is a bespoke intervention that addresses the fundamental, individual, and relational barriers to maintaining meaningful activity that are not routinely considered in directed and structured physiotherapy interventions. It is now ready for initial evaluation in a single-arm feasibility and acceptability study with embedded process evaluation (<https://clinicaltrials.gov/ct2/show/NCT03951181>). It is our view that our ongoing emphasis on codesign will ensure intervention acceptability and adherence and this initial evaluation will seek to provide robust user experience data which will inform further intervention refinement ahead of full-scale evaluation.

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LEAP-MS Topic guide

Interviews for people with multiple sclerosis

Version 1.0

This topic guide is for researcher use only. It will not be shown to participants.

Each section has several key open questions – asked with a view to eliciting a narrative response and to let participants tell their story in their own way so that what is most important to the person is foregrounded by them. A series of more specific questions detailed below can be used for probing further as required.

For those participants who suffer with fatigue, the interviewer will prioritise the questions highlighted in yellow after they have given the person being interviewed the opportunity to tell them a bit about themselves.

This interview schedule has also been written with the possibility of participants using communication aids and the need for the interviewer to ask more closed questions in these instances. This is reflected in the prompting sections indicated in blue. Such prompts will not however be used in the main.

Introduction

- 1) Tell me a bit about yourself? (prompt if appropriate ‘what are your interests?’, ‘can you tell me a bit about your family’, what do you do/did you do for work? or do you like [list activities as appropriate for response – take cues from home environment])
- 2) Could you please tell me a bit about when you were diagnosed with MS and about your journey so far, living with MS?

Opening questions – Physical Activity

[This opening section aims to find out about the general level of activity that the interviewee currently engages with, what they think constitutes physical activity and what it means to them]

- 3) What do you think of as ‘physical activity’? and what does it mean to you?
[offer a selection of choices if person is unable to give open response - e.g. a) vigorous exercise or playing sport, b) anything that raises your heart rate, c) anything that involves physical effort for an individual]

- 4) What physical activity are you able to do at the moment?
[list options if required focussing on activities of daily living in the first instance]
- 5) Do you think of these things as 'exercise'? – and if not, what is the difference for you between physical activity and exercise?
- 6) In terms of being physically active - what have you done this morning? [Have you got from bed to chair using your sliding board/transfer aid?, washed your face and hands, stood in the shower, reached across to grab a box of cereal for breakfast etc. – take cues from the environment and info thus far about how to pitch this list]
- 7) What have you been doing recently?
- 8) Are there physical activities you've been doing up until recently but you are unable to do at the moment?
- 9) Is there anything you miss about [activity]?
- 10) How do you find getting out and about?
- 11) What do you do?

Barriers and facilitators to physical activity

[Picking up on what has been said in response to the above questions, the aim of this section of questioning is to draw out specifically what helps and hinders, what is a barrier to and what/who facilitates physical activity]

- 12) What helps you to do [activity]?
[Give range of potential facilitators in the given context – probe on the basis of any positive response – apply this strategy to the two questions below as required]
- 13) What support do you have to be physically active at the moment?
- 14) Is there some form of activity that you think you would be able to do if you had some/more assistance? What is that – and what help would you need to be able to do it?
- 15) What gets in the way of you being more physically active?

Exercise/physical activity with others

[Due to the likely need of this patient group for day to day support – this section explores the interviewees relationship with activity and others].

- 16) You have mentioned [family/friends] – what do you do together?
- 17) How do these people help you in your life and how do you help them?
- 18) Are there things you would like to do with those people that you can't do?
- 19) What prevents you from doing those things?

What is available to you locally?

[Aim of this section is to find out what the interviewee is able to access locally and what they can't, what they know about local facilities that may support physical activity]

- 20) Can you tell me about things, places, activities, groups that are available for you locally? [Research area in which interviewee lives ahead of interview and take list of nearby accessible facilities to list if required]
- 21) Do you access/use any of these things yourself? If so, why and if not, why not?
- 22) Do you know about [tell them anything I know about local to them that they haven't mentioned] – would you be interested in trying out any of those?
- 23) If no, why not?

Relationship with exercise

[Aim of these questions is to draw out the persons life long relationship with physical activity and whether how they think about activity has changed with their MS one way or the other]

- 24) Did you enjoy being active when you were younger? [rephrase if the person is very young]
- 25) What did you do? Did you play any sport, go to exercise classes or dance for example? [provide a range of examples and narrow down as positive responses received to gain detail]
- 26) Has having MS changed how you think or feel about exercise? And being physically active?

Exercise and MS

[Aim of this section is to draw out the beliefs that patient holds about being physically active and the benefits or not of being active for their condition].

- 27) What do you tend to get told or advised in relation to exercise?
- 28) Is any of this information helpful?

MS, Physical activity and self-management

[The aim of this section is to draw out MS participants perceptions of physiotherapy provision and models of support in relation to exercise. This is key as we need to be clear whether or not the people we interview have the same wishes and goals as those consulted with who called for more self- management support for people with MS – on which this project is built]

- 29) How supported do you feel by health care professionals to be physically active?
- 30) Who do you think is best placed to support you with being physically active?
- 31) What is your experience of physiotherapy? [is your experience of physiotherapy positive, negative etc]
- 32) Have you ever heard of 'self-management'? – Self management is....
- 33) Do you think self-managing with the occasional guidance of a physiotherapists would be helpful for you? – do you prefer other ways?

Change

[The aim of this section is to provide information about MS and physical activity and ask if this information changes the perspective of the individual about what physical activity is and what it could be in the context of their lives. This section is divided into two sections - for someone with low engagement and someone with high engagement]

- 34) [For someone with limited engagement with activity] If I said that being physically active includes [i.e. standing, transferring into your chair, sitting forward, reaching, using your hands to play games, picking things off the supermarket shelf and putting them in the trolley, breathing exercises, going out and meeting people -turning your head and shaking hands] would that change how you think about physical activity?
- 35) [For someone with high engagement with PA] What would you say to other people with MS who aren't as active as you – what would you advise them to help them to start being more active?

- 36) What do you think would help you increase your own level of physical activity?

Helping others and new physical activity resource/models

[The aim of this section is to explore what the person might want from services and what type of resource(s) they might engage with]

Based on what the person has said about their experiences – use that as a base to discuss models of therapy delivery and the potential for self-management resources with physiotherapy support. Ask directly if they have any ideas for resources before asking the below]

- 37) Do you currently use a smart phone, tablet or computer? [probe with questions about their level of confidence and the type of things they use these technologies for]
- 38) Have you used a paper-based workbook for anything in your life recently? If so, how did you get on?
- 39) Could you see yourself using an online resource alongside support from a physiotherapist to help you be more active?
- 40) Would this be something you feel you could and would be willing to use together?
- 41) What would you like to see on such as resource?
- 42) How would you want to track your progress?
- 43) How would you know if something was helping you?
- 44) Any thoughts about how the resource should be put together?

LEAP-MS Topic guide

Interviews for physiotherapists

Version 1.0

This interview schedule is divided into 6 core areas. Key questions are highlighted in yellow which will be prioritised if the health care professional being interviewed is short of time.

The majority of the questions posed here are written in order to generate a narrative response. Most experiential based questions have been tested in other interviews with health care professionals working with people with a range of neurological conditions. Questions which refer to self-management have largely been piloted in studies with health care professionals working specifically with people with secondary progressive MS conducted by members of our team.

Introduction

- 1) Can you tell me a bit about yourself, your career to date as a physiotherapist/physiotherapy assistant [prompt around their pathway into neurological physiotherapy and to specialising in MS if relevant]

- 2) Can you tell me a bit about your current place of work and the services your place of work offer/provide for people with progressive MS?

- 3) What does it mean to you to work in this field/with this patient group?

- 4) What do you find most rewarding and most challenging in your work with this group?

MS patients and exercise

- 5) What does 'physical activity' mean to you in the context of people with progressive MS?

- 6) What barriers do these patients face in being physically active?

- 7) In your experience, what helps people with progressive MS remain as active as possible or re-start some form of activity?

8) How do you feel physiotherapists support people with progressive MS to be physically active?

9) Could the profession do more or work differently with this patient group in your opinion?

10) What would you do or change about your work with these patients if there were no restrictions on your time or money etc?

If the professional has not spontaneously given patient examples then....

11) Can you tell me some stories about how people with progressive MS that you have worked with or heard about has successfully been able to be physically active?

12) Can you give me some examples where it's been very difficult to support a person with progressive MS to remain active or engage them in being as physically active as they could be?

Self-management

10) What does the term 'self-management' mean to you?

11) What do you think of the ideas behind self-management?

MS and self-management

12) What do you think about using self-management techniques with people with progressive MS?

13) Have you used any self-management techniques with patients recently? Can you give me an example of a situation where you felt it worked well and a situation where it didn't work so well?

If they have not used self-management with patients then:

14) Can you think about a patient you are working with at the moment/have worked with who has progressive MS that you think self-management is appropriate for?

15) Can you think about a patient where self-management wouldn't be appropriate?

16) Have you ever tried to use self-management with patients with cognitive impairment? Can you tell me about your experience of doing that?

Self-management training and education

17) Have you had any training about/on self-management? - What did you learn from it/think of it?

18) [If training received] From the training you received – what worked well for you? What did you find worked well to support your learning? Do you feel you have further learning needs? How could those be best met?

[If training not received] Would you be interested in training about self-management? How do you learn best? [e.g. do you like lecture style teaching, workshops, a weekly course face-to-face or online?]

Physical activity and the community

19) Are you aware of accessible places or tailored activities carried out locally that may support this patient group to be more physically active? Can you tell me about them?

The intervention and approach

As you know, part of the LEAP-MS study is looking at developing an online intervention to support PwPMS to be more physically active. We anticipate that the intervention might be a type of online workbook with a range of physical activities as suggestions to be carried out with others e.g. games parents can play with their children/grandchildren and individually, tips about getting out and accessible places and schemes, exercise regimes (or links to those already established), sections to set aims/goals etc.

We are suggesting the exploration of a model where such a resource is used in conjunction with support from a physiotherapist where the patient would receive an initial consultation from a physiotherapist where activity needs were discussed and the resource introduced to them. Initial goals could be set and an initial period of time be given for the patient to explore the resource and begin trying different things. They would then be reviewed by therapist either at a set date or on a self-referral basis.

We would trial this idea with a small amount of people to check if any intervention developed was acceptable to patients and physiotherapists – and evaluate its impact/usability. If positive, the intervention and model would be put forward for a full trial.

20) What do you think should be included within such a resource?

21) Can you envisage the model working?

22) What could improve the chances of it being successful? What barriers should we be aware of?

23) Is there anything else you'd like to add? Or anything else you'd like to say, that I haven't yet asked you about?

Supplementary Table 1. Performance objectives, behavioural determinants and change objectives for the specific behavioural outcomes (intervention goals) at the intra-personal level with theory-based methods, parameters and practical applications for the PwPMS at the intrapersonal level.

Behavioural Outcomes at the Intrapersonal level: Person with MS follows a desirable and achievable PA plan					
Change Objectives	Determinants	Performance Objectives	Theory-based methods	Parameters	Practical applications
Decide to be more active with MS	Attitudes	Make informed decisions about regular physical activity.	Active learning: Encouraging learning from goal driven and activity-based experience .	Time, information, skills.	Persons with MS participate in initial coaching sessions where they will be encouraged to discuss their perceptions and experiences of physical activity with a view to developing a personalised activity plan.
	Skills & abilities				
	Health beliefs (risks and benefits of health behaviours)	Contrast risks and benefits of regular physical activity against consequences of physical inactivity.	Reinforcement: linking a positive behaviour to relevant consequence that increases the behaviour's rate frequency or probability.	Reinforcement needs to be tailored and follow the behaviour in time.	
Create own personalised Physical Activity plan	Attitudes	Display confidence in attempting new activities.	Goal setting: Prompting planning what the person will do, including a definition of goal-directed behaviours that result in the target behaviour.	Commitment to the goal; goals that are difficult but available within the individual's skill level.	Persons with MS will learn how to navigate the LEAP-MS website, a multi-user website system consisting of an information and activity suite, interactive components enabling selection of exercises into an activity programme, goal setting, and activity logging choose personal goals and log weekly activity. Persons with MS will be able to request up to six further coaching sessions to review goals and progress. They will also be able to utilise the inbuilt messaging function to seek timely support about specific questions.
			Modelling: Providing an appropriate model being reinforced for the desired action.	Attention, self- efficacy and skills, identification with model	
	Health beliefs (risks and benefits of health behaviours)	Weigh up costs and benefits of each activity on activities of daily living.	Reinforcement: linking a positive behaviour to relevant consequence that increases the behaviour's rate.	Reinforcement needs to be tailored and follow the behaviour in time.	
	Skills & abilities	Identify and select suitable physical activities (dose , timing and order).	Feedback: Giving information to individuals regarding the extent to which they are accomplishing learning or performance, or the extent to which performance is having an impact.	Feedback needs to be individual, follow the behaviour in time, and be specific.	
Identify solutions for perceived barriers	Attitudes	Recognise the intervention platform and physiotherapists as resource.	Facilitation: Creating an environment that makes the action easier or reduces barriers to action.	Requires real changes in the environment instead of in the perceptions of the environment Requires the identification of barriers and facilitators and the power for making the appropriate changes.	Physiotherapists elicit, acknowledge, and discuss participants' perceptions and experiences of physical activity. Physiotherapists use self-management strategies, promote goal setting and selection/modification physical activities to build a personalised activity plan. Physiotherapists share information about physical activity and exercise specific to MS both verbally (face to face or remote) and through directing participants to the digital tool. They may discuss strategies to anticipate and overcome barriers to physical activity and explore options for self-monitoring (including activity trackers and logs). This may include sharing common challenges that others face when initiating a new exercise programme – and how they overcame these as well as discussing management of fatigue and pain and reviewing options to minimise falls risk. After the initial session, physiotherapists review progress, discuss safety concerns and progression of exercise as requested/initiated by the person with MS and provide appropriate feedback for activity selection, attempts and engagement in regular physical activity.
	Resources				
	Skills & abilities	Express confidence in ability to monitor and modify activities.	Active learning: Encouraging learning from goal driven and activity-based experience . Guided practice: Prompting individuals to rehearse and repeat the behaviour various times, discuss the experience, and provide feedback.	Time, information, skills. Subskill demonstration, instruction, and enactment with Individual feedback; requires supervision by an experienced person.	

Supplementary Table 2. Performance objectives, behavioural determinants and change objectives for the specific behavioural outcomes at the interpersonal level with theory-based methods, parameters and practical applications for the physiotherapist supporting the person with MS at the interpersonal level.

Behavioural Outcomes at the Interpersonal level: Physiotherapist efficiently supporting people with MS to engage in a desirable and achievable physical activity plan					
Change Objective	Determinants	Performance Objectives	Methods	Parameters	Practical applications
Endorse creative and individualised physical activity planning in consultations	Attitudes	Describe self-management principles and application to consultations.	Modelling: Providing an appropriate model being reinforced for the desired action.	Appropriate models will vary by environmental level and community.	Bespoke Physiotherapy Training Package with training on self-management principles and skills with a view to empowering patient participants to self-select and modify activities, to have strategies in place to overcome challenges, hurdles, or setbacks. Trained coaches will utilise a blended physiotherapy approach (including the digital platform) within the physio-patient consultation (including appointment setting and self-referral options).
		Accept high level of participant influence in consultations.	Guided practice: Prompting individuals to rehearse and repeat the behaviour various times, discuss the experience, and provide feedback.	Subskill demonstration, instruction, and enactment with individual feedback; requires supervision by an experienced person.	
		Commit to flexible and responsive scheduling of appointments.	Reinforcement: linking a positive behaviour to relevant consequence that increases the behaviour's rate frequency or probability.	Reinforcement needs to be tailored and follow the behaviour in time.	
	Skills and Abilities	Implement self-management into consultations and goal setting activities.	Active learning.	Time, information, skills.	
	Resources	Demonstrate skills to utilise technology to support interactions.	Active learning.	Time, information, skills.	
Demonstrate confidence to develop a shared approach to exercise prescription, knowledge, and skills to shape programmes to fit with individual needs	Skills and Abilities	Demonstrate appropriate knowledge of exercise and physical activity for neurological conditions.	Active learning.	Time, information, skills.	Coaches will confidently develop an exercise plan together with the person with MS, that aligns with their abilities, and aspirations and incorporates key self-management principles and will identify a range of ways to tailor exercise plans for person with MS informed by evidence-based guidelines and available training resources/materials.
		Demonstrate an understanding of how to adapt exercise plans so that they are feasible and can fit with an individual's needs, abilities, and preferences.	Active learning.	Time, information, skills.	
	Resources	Describe range of options for modification of physical activities or compensation for barriers where modification is not achievable.	Active learning.	Time, information, skills.	

Supplementary Table 3. Purpose-developed fidelity checklist to **score** key knowledge and skills required by physiotherapists over the duration of intervention delivery (but at a minimum across initial and first follow-up session).

Item	Description	To what extent was this item demonstrated				
		not at all 0	1	2	3	a great extent 4
Problem solving	<p>Ensuring focus on the person's with MS knowledge of self in relation to health beliefs and outcome expectations.</p> <p>Use of open-ended, coaching style questions <i>"What's the thing that bothers you the most at the moment...?"</i> <i>"What's one small thing you could do that might help?"</i> <i>"What has worked before?"</i> <i>"How confident do you feel about...?"</i></p>					
Goal setting	<p>Encouraging ways to incorporate regular physical activity that is feasible and can fit with an individual's preferences, needs and abilities.</p> <p>Use of <u>open-ended</u>, coaching style questions <i>"What do you want to be able to do?"</i> <i>"What do you want to change?"</i> <i>"What are the things stopping you at the moment?"</i> <i>"What would it take for you to do.....?"</i> <i>"What's one small thing you'd like to work on over the next week?"</i> <i>"What would you like to get back to doing?"</i> <i>"How confident are you now that you can do....?"</i></p>					
Reflection	<p>Encouraging reflection on what works for the individual in their own circumstances and in relation to the progression of activity plans.</p> <p>Use of <u>open-ended</u>, coaching style questions <i>"How does that make you feel?"</i> <i>"What's going well?"</i> <i>"What could you have done differently?"</i> <i>"What have you tried already?"</i></p>					

Knowledge of MS and physical activity	<p>Demonstration of relevant and appropriate knowledge of exercise and physical activity for neurological conditions applied to coaching sessions when required (including frequency, intensity, time and type and supporting modification for symptoms and variability in condition.</p> <p>Use of <u>open-ended</u>, coaching style questions <i>"What would you like to know?"</i> <i>"How would you like that information?"</i> <i>"What is your understanding of?"</i> <i>"What are your concerns?"</i> <i>"What is stopping you from doing more now?"</i></p>	
Communication style (overall impression)	<p>Use of open-ended questions, coaching style, not directing sessions, but deciding on content together based on the things the individual wants to work on. This should reflect an acceptance of high level of participant influence in consultations and a commitment to flexible and responsive scheduling of appointments.</p>	
Engagement with technology (overall impression)	<p>Evidence of coaching style applied to technology skills and use of technology to support interactions and access to web-based resources.</p> <p>Problem solving/ trouble shooting in case of technical queries that the participant has for example, if the participant says....." I couldn't find..., I wasn't able to update/ add/ remove..., how do I email? ...</p> <p>Demonstration and coaching to support technical problem solving and reflection during coaching <i>"Where on the LEAP-MS website do you think you would find information about that type of activity?"</i> <i>"How confident are you to update your plan?"</i> <i>"What support do you need to amend your plan?"</i></p> <p>Evidence that the physiotherapist coach is confident with website functionality for example discussing any amendments participants have made to aims/ challenges and activity list since previous coaching session, showing that they know the linkage and structure of the website and encourage usage of different functionality.</p> <p>Evidence of ability to respond to emails and keep contemporaneous intervention notes.</p>	
<p>Contextual summary for overall scoring (including details of number of sessions and participants observed and timing of sessions).</p>		