Lifestyle, exercise and activity package for people living with progressive multiple sclerosis (LEAP-MS): Protocol for a Single-Arm Feasibility Study.

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Study Protocol

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Abstract

Background. We have co-designed a tailored blended physiotherapy intervention for people with Progressive Multiple Sclerosis (MS) who often struggle to access support for physical activity. Underpinned by self-management principles, the Lifestyle, Exercise and Activity Package for people with MS intervention, which we call the LEAP-MS intervention, incorporates face-to-face or online physiotherapy coaching sessions with an accompanying online physical activity platform. The LEAP-MS platform is a multi-user system enabling user and physiotherapist to co-create activity plans. The LEAP-MS platform consists of an information and activity suite, interactive components enabling selection of exercises into an activity programme, goal setting, and activity logging. The platform also facilitates online remote support from a physiotherapist through an embedded online messaging function. We aim to evaluate the LEAP-MS platform in a feasibility trial.

Methods. LEAP-MS will be evaluated within a single arm feasibility study with embedded process evaluation. After registration and initial eligible screening, 21 participants will be required to complete baseline self-completion measures. This will be followed by an initial home-based or online coaching session with a physiotherapist (who has received tailored self-management and digital resource training) and access to the online intervention for an initial three-month period. During this period participants are given the option to request up to five further home-based or online physiotherapy coaching sessions. Follow-up questionnaires and semi-structured interviews will be administered three months after baseline with participants and intervention physiotherapists. The LEAP-MS platform will be available to participants for a further three months. Usage of the LEAP-MS platform will be tracked during the full six-month period and final follow up will be conducted six months after baseline.

Discussion. Feasibility outcomes (recruitment, retention, intervention uptake and safety) will be reported. The process evaluation will be undertaken to identify possible mechanisms for any observed effects. The data here will inform full scale evaluations of this co-produced, blended physiotherapy intervention.

Trial registration:

ClinicalTrials.gov NCT03951181. Registered 15th May 2019 https://clinicaltrials.gov/ct2/show/NCT03951181

Background

Multiple sclerosis (MS) is the most common disabling neurological disease among young adults (1) affecting an estimated 107,000 people in the UK (2). Of these it is estimated that 10–15,000 have primary progressive MS (3) and 38,000 have secondary progressive MS (4, 5) which is characterised by the progression of symptoms either independent of relapses or remissions or with superimposed relapses. People with progressive MS (PwPMS) tend to have higher levels of disability than those with relapsing-remitting MS, often have high health and social care needs and self-report low health related quality of life (6, 7). PwPMS experience a wide range of symptoms including motor, sensory, visual, bowel and bladder dysfunction (8). Regular physical activity is generally regarded to be an important component of the long-term management of MS. Positive outcomes of regular physical activity include improved mobility, strength and cognition, and reduced fatigue. There are well-established psychological and social benefits associated with physical activity in MS (9, 10). Engaging in regular physical activity is considered to be a positive way to cope with living with progressive MS (11, 12).

Various physical activity interventions for people with MS have been reported in the literature, ranging from group-based to digital versatile disc (DVD) and web-based interventions (13–17). A recent systematic review explored the effectiveness of these interventions, most of which sought to change participants' behaviours in some way. The authors found that short duration interventions incorporating goal setting, barrier identification and information provision increased physical activity but had no effect on the physical components of quality of life and fatigue (18). Many of the studies reviewed were based on prescribing structured exercise rather than on providing personalised approaches to reducing sedentary behaviour. They did not aim to equip people with the skills to select, progress or alter their own programmes and therefore lacked an underpinning or utilisation of behaviour change theories. Providing support that is tailored to an individual's needs, time constraints and values is more likely to achieve a sustained change in physical activity behaviour (19). Indeed, developing self-determined and self-efficacious physical activity behaviours through goal setting, appropriate communication and self-monitoring are established and critically important determinants of sustained physical activity behaviour (20).

Despite the potential benefits of physical activity and the value placed on supporting people with MS to remain active, there remains little evidence about the benefits of physiotherapy or physical activity for PwPMS who have more advanced disability (21). Most research has focussed on patients who are ambulatory, despite non-ambulatory people with MS being those who are least likely to stay active (9, 20, 22). A systematic review (23) of physiotherapy interventions, including exercise therapy, for the rehabilitation of people with progressive multiple sclerosis published in 2016 reviewed 13 studies (of eight interventions) of variable methodological quality. It concluded that physiotherapy and exercise interventions for PwPMS was potentially of benefit but that fully powered efficacy studies were required. Recently, a home-based, self-managed standing frame programme has been found to be effective in PwPMS (24) however, there is little research into physical activity interventions in PwPMS, which may be explained by difficulties recruiting or retaining individuals with advanced disability into research studies. These challenges, which may be explained by difficulties travelling to appointments and a high prevalence of fatigue and cognitive impairment, are the same ones that must be overcome to enable PwPMS to engage in sustained physical activity. Seeking sustainable, cost-effective interventions that facilitate access to physical activity for all remains a priority.

Despite the limited evidence about the benefits of physical activity for PwPMS, we know that people with MS, including those with progressive MS, want to keep physically active and moving (11, 25). However, people with MS, especially those who are more disabled, find it hard to start and to maintain activity (26). Many require support to remain physically active and often do not receive enough support (26). When people with MS are asked about their needs, physiotherapist-led support for physical activity ranks highly (27–29) with many needing support to identify physical activity that is suited to them (30, 31). Physiotherapists' training and experience mean that they are ideally placed to support physical activity and exercise prescription and are often promoted as exercise experts (32). This expert role, however, may paradoxically foster reliance on physiotherapists and although many physiotherapists have a thorough

knowledge of risk factors, pathology and their effects on all systems, they may not necessarily be confident in exercise physiology and prescription. Indeed, the first barrier to promoting activity in PwPMS may come not from the individual themselves, but from the professionals with whom they engage (33, 34).

Here we present the protocol for the LEAP-MS single arm feasibility trial and embedded process evaluation. LEAP-MS is a co-designed blended physiotherapy digital intervention underpinned by a self-management approach. Our primary objective is to establish the feasibility of the LEAP-MS intervention. Secondary to this, we will validate the underpinning intervention logic model through both qualitative assessment of intervention processes and descriptive evaluation of acceptability and patient-reported outcomes.

Methods

STUDY DESIGN SUMMARY AND SETTING

This is a single arm feasibility study with an embedded process evaluation. Those who are eligible and consent to participate in the study will complete a series of assessments at baseline, 3 and 6 months; during this time they will also have access to the LEAP-MS blended physiotherapy intervention (see Figure 1; participant flow diagram). The intervention will be delivered online and, where possible, in the community. Community based delivery is reliant upon the current COVID-19 pandemic social distancing requirements being lifted and/or local physiotherapy provision.

The intervention is made up of physiotherapy coaching sessions (delivered via a secure web video conferencing system or in person where possible) and an online platform. The online platform is made up of a series of co-produced resources and functions. These include online interactive education, an activity selection and planning tool, specifically developed for PwPMS and a participant-physiotherapist messaging system. The activity selection and planning tool includes tailored physical activity ideas and interactive functions enabling the development of personalised activity programmes, goal setting and activity logs. The online platform works in conjunction with face-to-face or online coaching sessions and facilitates remote support (via the online platform messaging system) from trained physiotherapists.

Population. We will recruit 21 participants with either primary or secondary progressive multiple sclerosis (as defined by the Lublin classification) (35) who are aged 18 or over and who have an Expanded Disability Status Scale (EDSS) score (36) between 6 and 8. Participants will be required to have capacity to consent to study participation on their own behalf and have access to mobile, wireless or wired internet connection at home. We will exclude any individuals with relapsing-remitting or non-progressive MS, are unable to understand written and spoken English, or are pregnant or planning a pregnancy.

The sample size is based on the 95% confidence interval for an adequate proportion of eligible subjects being recruited (70%). The lower 95% confidence interval is 50% which is the minimum acceptable recruitment proportion.

Recruitment. There will be three routes for informing potential participants about the study: (1) Eldrix HealthContact; (2) Outpatient physiotherapy services or (3) MS Society branch and national MS register publicity in the local region.

1. Eldrix HealthContact is a tertiary centre MS database where PwPMS who meet the inclusion criteria and who have also given consent to be contacted about research will be identified by authorised Eldrix HealthContact users. A selection of those identified (based on EDSS scores in potentially eligible range) will be sent a study information sheet.
2. Physiotherapists at the two participating Health Boards will screen all MS outpatients for eligibility during the recruitment phase. Those eligible and interested in participating will be provided with an information sheet about the study.
3. Information about the study will be made available via the local branch of the MS Society (within the boundaries of the two participating Health Boards) and the national MS register inviting interested participants to complete the online expression of interest.

All potential participants who are interested in participating will be required to complete an online expression of interest form and eligibility checklist via the LEAP-MS website. We will monitor population characteristics of those who express an interest in participating, with a particular focus on gender and levels of disability. The expression of interest form will remain open until such time as eligibility has been confirmed for the entire recruited participant cohort. This will take the form of a two-stage process. First, prior to the initial target sample size being recruited, those who submit an expression of interest, will receive an automatically generated response from the system, thanking them for their interest, explaining that eligibility will be assessed in the order of received expression of interests and that the study team will contact them in due course. Second, once eligibility has been confirmed for the entire participant cohort and the study has closed to recruitment, the expression of interest page will disabled however interested individuals will be able to provide their contact details to receive study updates and results.

Eligibility screening and informed consent. All participants who complete an online eligibility checklist and are deemed potentially eligible will receive a telephone call from the research team, to discuss what participation in the study involves and provide participants with an opportunity to ask any questions. During the call, the member of the research team will also complete a further eligibility checklist and eligibility will be fully confirmed at the first coaching session with the physiotherapist. Those participants who are interested in the study will be directed back to the LEAP-MS website and provided with individual user details to complete an online consent form. Once the consent form has been submitted online, participants will be directed to complete the baseline assessment battery.

Assessments. All consented participants will be required to complete a range of patient-reported outcome measures directly online at baseline, 3 and 6-months post baseline (plus or minus 2 weeks; see Table 1: Schedule of enrolment, interventions and assessments). The modified form of the Fatigue Impact Scale (MFIS) (37) will provide an assessment of fatigue in terms of physical, cognitive, and psychosocial functioning. The Multiple Sclerosis Impact Scale (MSIS-29) will measure the physical and psychological impact of MS from the patient's perspective (38). The EQ-5D-5L will provide an indication of health-related quality of life (39). The Oxford Participation and Activities Questionnaire (OxPAQ) will provide an assessment of the impact of ill-health on participation, activities and autonomy (40) and the University of Washington 6-item short form self-efficacy scale (UW-SES-SF) (MS specific) will provide an indication of self-efficacy (41).

After the baseline assessments have been completed by the participant, their online user account will be paired with an intervention physiotherapist's account. This physiotherapist will then contact the participant to arrange the first coaching session, after which the full LEAP-MS online tool will be released to the participant.

Participants will be asked to repeat the online patient-reported outcome measures, plus a modified Patients' Global Impression of Change (PGIC) (42), at 3 months and 6 months post-baseline. Automatic prompts will be provided to the registration email address at the start of the follow-up data collection window (2 weeks before and 2 weeks after the expected assessment completion date). Participants will receive a telephone reminder if they have not logged on in the 2 weeks prior to the expected assessment completion date. Electronic data capture will be standard across all study remote processes using an online platform developed by the Centre for Trials Research using a bespoke Structured Query Language (SQL) database. A study-specific data management plan has been developed to ensure the security and confidentiality of all participant data and that high-quality data is available for ongoing analyses.

At the end of the initial intervention period (3 months) participants and their treating physiotherapists will be asked to participate in a semi-structured interview aimed at eliciting experiences and reflections on the intervention, and the process of its delivery (content, design, language, adaptability to personal needs and recommendations for the future). Given the small sample size of this feasibility study, everyone who consents to being interviewed will be interviewed, even if they withdraw from the intervention (see process evaluation).

Table 1: Schedule of enrolment, interventions and assessments

	STUDY PERIOD					
	Screening	Baseline	Intervention		Follow-up	
Timepoint	-4 weeks - 0	0	0-3 months	3-6 months	3 months	6 months
Screening						
Pre-screening – EldrixHealthContact Database	X					
Pre-screening – Physiotherapy outpatient clinics	X					
Self-assessment online eligibility check	X					
Eligibility screen & discuss the study (telephone call from research team)	X					
Online informed consent	X					
Eligibility confirmed at physiotherapy coaching session			X			
Intervention						
Physiotherapy coaching sessions (up to 6 sessions)			X			
LEAP-MS activity web-based platform			X	X		
Assessments						
MFIS		X			X	X
MSIS-29		X			X	X
EQ-5D-5L		X			X	X
OxPAQ		X			X	X
UW-SES-SF		X			X	X
PGIC					X	X
Semi-structured interview					X	

LEAP-MS Intervention. The aim of the LEAP-MS intervention is to provide improved awareness of achievable, relevant and interesting activities and exercises for PwPMS. It will also provide an opportunity for sharing experiences of participating and enable shared management and monitoring (self and physiotherapist) of activities and exercises. It is a blended physiotherapy intervention made up of 1) a co-produced, encrypted multi-user web-based platform accessible to participants and physiotherapists and 2) coaching sessions with intervention physiotherapists delivered via a secure web video conferencing system, or in person, in the participants home. Intervention physiotherapists are trained on self-management principles and practice, use of technology in coaching sessions and physical activity and exercise guidelines for neurological conditions. As this is a blended intervention including a web-based platform, participants will require computer skills (or a carer companion who can assist them is needed), and internet access for the duration of their study participation.

The LEAP-MS online platform.

The platform is specifically developed for PwPMS and includes regularly updated multimedia education about being active with PMS, tailored physical activity ideas and interactive functions enabling the development of personalised activity programmes, goal setting and activity logs.

The LEAP-MS platform enables access and data input options via desktop computers, laptops, tablets or smart phones. Participants, physiotherapists and the research team all have different access to and editing permissions for the LEAP-MS platform. Participants use the platform to register, complete eligibility forms, consent, baseline and follow-up measures, input safety information, as well as to access the interactive education and activity selection and planning tool. They are also enabled to contact their intervention physiotherapist via a messaging function to ask questions, seek guidance or request coaching sessions. Physiotherapists use the platform to record coaching session notes, respond to participant questions and requests and to view participant activity

selections and goal setting. The platform is also used by the study team to evaluate participant engagement with the intervention and to manage data throughout the study.

Participant use of the LEAP-MS platform and interaction with physiotherapists.

In the initial 3-month intervention period, participant use of the LEAP-MS platform works in conjunction with support from intervention-trained physiotherapists and includes a user pairing facility where patient users are paired with an intervention physiotherapist. The physiotherapist can view the activity selections and goals set by the patient participant and provide coaching and support to engage with participants in setting small targets and incorporating physical activity into their everyday life. The web-based platform also has an inbuilt messaging function to enable participants to contact their physiotherapist in the initial 3-month period to ask questions, seek guidance about activity engagement and request up to six coaching sessions. Coaching sessions will be conducted at participants homes or online dependent on participant preference whilst accommodating any local restrictions (e.g. social distancing during COVID-19 or staff availability). When conducted online, coaching sessions will be conducted via a secure web video conferencing system. All interactions (whether in person, via web video conferencing or via the in-built platform messaging system) will operationalise a supported self-management approach to regular physical activity. Physiotherapists will not be required to respond immediately to communication through the platform, but will schedule regular time slots to respond to LEAP-MS communication, as they would with other forms of patient communication – such as returning telephone calls from outpatients or family members. They will aim to respond within 5 working days. A pre-specified inactivity period 21 days on the website by any one participant will automatically be logged and flagged to the corresponding patient participant's physiotherapist, who will then contact the participant to offer any further support.

Interactions between participant and physiotherapist using the in-built platform messaging function will be captured by the study database. Notes of coaching sessions will be recorded in the web-platform and downloaded for adding to patient notes. Where face-to-face coaching sessions are conducted, intervention physiotherapists will be required to detail distance travelled, mode of travel time and face-to-face contact time. For coaching sessions delivered via web video conferencing, only video conferencing time will be detailed.

Physiotherapy Training. All intervention physiotherapists will receive bespoke LEAP-MS training, which focusses on the provision of self-management support to participants alongside the use of technology in coaching sessions and updates on physical activity and exercise guidelines for neurological conditions. The initial training package was developed through the conduct of a two-day interactive workshop 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. Additional associated information is also provided including guidance on use of technology in coaching sessions, what to expect when using the LEAP platform along with potential challenges and solutions. Given the emergent challenges in rehabilitation service delivery during the COVID-19 pandemic, 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 was made available as part of the final training package so as to ensure standardisation of coaching interactions regardless of mode of delivery (online or face to face in the home). Core principles of exercise physiology and prescription for people with long-term neurological conditions are also covered throughout the training (43,44).

The physiotherapists who complete the training will be invited to participate in the LEAP-MS study as 'intervention physiotherapists'. All those who consent to taking part will have access to conversation-based scripts that they can use to guide their coaching conversations (primarily for online use). They will also have the opportunity to practice coaching conversations and receive peer review. They will be asked to take part in interviews to share their experience of intervention training and intervention delivery.

Safety. We will assess and record any adverse events that may be reported.

Expected Adverse Events (AEs): In this patient population, hospitalisation due to MS, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems are expected. This information will be self-reported by patients online and will not be subject to expedited reporting. The physical activity intervention does not specifically involve any heavy load-bearing exercise or heavy eccentric muscle activity. However, some minor muscle soreness or muscular strain may occur in the few days following the initiation of a new exercise programme or increased physical activity. This would normally resolve spontaneously and would not require any specific interventions or additional medical care but will be noted as a potential expected related AE if reported during the 3-month intervention period. Falls and fatigue are an expected AE as part of the clinical condition but will be monitored for the duration of the intervention.

Procedure: Participants will be asked to use the LEAP-MS platform to self-report any incidents of falls, fatigue, increased muscle soreness or sprain, or other incident they feel is relevant, and whether the incident required medical intervention. Selecting that medical intervention was required will trigger an automated prompt to the paired physiotherapist. Similarly, no activity on the online platform for 3 weeks will also trigger an automated prompt to the paired physiotherapist. Once prompted, the paired physiotherapist will contact the participant to discuss the incident. All serious adverse events (SAEs) that occur between the time of consent and the 3 months follow-up must be reported immediately to the Centre for Trials Research (within 24 hours of knowledge of the event) by the intervention therapist using a dedicated SAE form, unless the SAE is specified as not requiring immediate reporting.

Planned Analyses. The primary objectives are to establish feasibility of the study in terms of quantitative measures of recruitment, retention, intervention uptake and safety (see Table 2). All proportions will be tabulated with 95% confidence intervals alongside the CONSORT chart, which will detail the reasons for exclusion, refusal and dropout. Intervention uptake will be reported descriptively. There is no defined minimum dataset for the clinical secondary outcomes. Data completeness of each patient-reported outcome measure will be tabulated and will further inform our assessment of feasibility. Distributions of the outcomes scores will be investigated and appropriate summary measures for the whole group tabulated with 95% confidence intervals at baseline and follow-up time points. An assessment of attrition bias will be made via tabulation of baseline characteristics for those with complete follow-up data and those who

were not followed-up. No formal hypothesis tests will be carried out in the analyses, however factors such as disease severity (as represented by EDSS scores) and self-efficacy (measured by UW-SES) that may plausibly impact on adherence and retention will be explored with graphical displays. The traffic light system (green, amber, red) of progression criteria as proposed by Avery et al (2017) (45) will be utilised (see Table 2) to guide our decisions as to future evaluations. If at the end of the study the feasibility progression criteria are achieved, then the recommendation would be to move to a randomised evaluation. Modifications in the trial processes or the intervention may be required if progression criteria are not fully achieved. If there is not an identifiable reason or remediable action that can be taken, then progression to a full trial would not be recommended. Intervention uptake and safety are not formal progression criteria but will be closely monitored and considered in any final recommendations. Intervention uptake will be reflected by (1) the percentage of initial coaching sessions completed, number of additional physiotherapy coaching sessions requested and completed, and the number of remote physiotherapist contacts recorded and (2) frequency and duration of weekly logged physical activity. Website log in rates and length of time between each log in episode will provide supplemental information on intervention uptake. Safety will be assessed using an online process of self-reporting by the participant and from any SAE forms completed by the intervention therapist.

Table 2. Feasibility outcomes

Feasibility outcome	Measurement	Green	Amber	Red
Recruitment rate	Percentage of those submitting online permission to contact forms who are eligible and who consent to participation.	70%	50 - 69%	Less than 50%
Retention rate	Percentage of individuals who complete the 3-month follow-up assessments.	70%	50 - 69%	less than 50%

PROCESS EVALUATION

The process evaluation will help us to provide an understanding of the acceptability and fidelity of the intervention, identify possible mechanisms for any observed effects and learn about any adaptations made by the participants (PwPMS and physiotherapists) in undertaking the programme. Acceptability assessment will focus on content, design, language and adaptability to personal needs. It will be assessed through the analysis of any remote contact between participants and physiotherapists as well as semi-structured interviews (conducted either face to face or via the secure web video conferencing system) with participants who completed the intervention and physiotherapists who delivered the intervention. In physiotherapist interviews, we will collect detailed demographic information so we can understand how their characteristics (work setting, previous experience, previous training) influences their approach, experience of the training and delivering the intervention.

Fidelity of the LEAP-MS intervention delivery will be assessed using independent analysis of audio-recorded and/or observed (sampled) sessions, analysis of participants' online activity logs and participant-physiotherapist communications. Five or six initial coaching sessions (approximately 25% of initial coaching sessions) and between 5 and 10 follow-up coaching sessions (dependent on participant consent) will be observed and audio-recorded if conducted face-face. Coaching sessions conducted via web video conferencing, will be recorded using an in-built recording function.

Actions observed during face-face observations will be captured using basic proxemic sketches (stick people drawings), kinesics (Kinesics refers to the nonverbal movement related elements of communication in the creation and sustaining of social interactions), alongside standard ethnographic notations (the description of actions/happenings as the observer sees them) (46). The proxemic and kinesics sketches will serve to record the physical and spatial interactions between patient, physiotherapist and intervention technology, to assist the charting of how learning is delivered and 'gets done' through the coaching sessions. If the intervention is delivered remotely, coaching sessions will be recorded and analysed directly.

This range of data collection methods has been selected to enable a comprehensive and multi-faceted description of the experience of those taking part, a nuanced understanding of intervention delivery and usage. The multiple methods selected will also act as a robust form of triangulation.

All qualitative data collection for the process evaluation will be carried out by a research team member with qualitative research experience. All data will initially be separated into their 'type', i.e. speech, text or action (observation), with appropriate methods of analysis applied to each type of data. Interviews, recorded coaching sessions and observations will be analysed thematically initially (47). Should the coaching sessions component of the intervention be found to be central to the usage of the online platform, discourse analysis may be conducted to better capture and understand the impact of interaction and communication between patient participant and physiotherapist. Data collected from text-based online interaction (emails between patient participant and physiotherapist, goal setting and activity records) will be considered as 'personal documents' and subject to textual analysis methods.

Due to the focus of this process evaluation on the use of each component of the intervention, the personal documentation will be initially subjected to content analysis – with a more detailed thematic analysis applied if required (48), to assist final synthesis and triangulation should the depth of the data warrant it. Key findings from each type of data set will be compared and contrasted, drawing out similarities, differences and any contradictions. Data will be reviewed in light of any contradictions and will guide a member checking process with participants, which will be conducted prior to the write-up and dissemination of findings.

Findings will be separated into process and outcome data ready for reporting but with consideration being given to where/if the doing of any process is a major contributor to the outcomes or perceived experience of participants. At this point, we will explore possible mechanisms for any observed effects (both for the person with MS and the intervention physiotherapist) so as to validate change objectives, behavioural outcomes and patient-reported intermediate and longer-term outcomes as depicted in the proposed intervention logic model (Figure 2). There are training needs for physiotherapy staff in delivering this

intervention. These are reflected in the physiotherapy component of the logic model as are aspects related to the broader context within which this intervention will be implemented.

Discussion

The LEAP-MS platform is a multi-user system enabling participants and physiotherapist to co-create activity plans. The LEAP-MS platform consists of an information and activity suite, interactive components enabling selection of exercises to create an activity programme, goal setting, and activity logging. The platform also facilitates remote support from a physiotherapist through an embedded online messaging function. Our experience here lays the basis for the development of multi-user platforms that can be adapted according to population and trial design.

As the secure, encrypted multi-user web-based platform will be accessible to participants, physiotherapists and researchers with data input options via desktop computers, laptops, tablets or smart phones, participants are able to use the platform to register, complete eligibility forms, consent, baseline and follow-up measures as well as to access the intervention. Participants, physiotherapists and research administrators all have different access and editing level permissions within the platform. It is also used by the study team to evaluate participant engagement with the intervention and to manage data throughout the study.

Our ambition has been to co-design a model for physical activity self-management support for PwPMS that is patient-, family/carer- and community-centred with physiotherapists providing a unique role as a coach and partner throughout the whole disease trajectory (49). Self-management approaches are associated with a reduced reliance on health professionals and an increased sense of autonomy and control over an individual's condition. Such approaches are also characterised by upskilling the individual to anticipate potential barriers to achieving any specified goals and to problem solve in the face of such challenges. Any programme, based on self-management principles should then, at its heart, address the fundamental, individual and relational barriers that typical physio-led interventions may pose. Upskilling physiotherapists' self-management support skills alongside exercise prescription knowledge, sharing expertise and working collaboratively with people living with progressive MS to define strategies and activity plans is more likely to promote physical activity behaviour change (50).

Unlike other physiotherapy-based online activity platforms for other conditions or general education platforms, the LEAP-MS 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. The physiotherapist can view participant activity logs, but advise only as required by the person with MS. Furthermore, the patient-facing element of the LEAP-MS intervention platform combines multimedia educational content, activity provision, activity monitoring and goal setting. It includes an online hub for physiotherapists, which draws together self-management training and provides a space for multimedia exercise in long-term neurological conditions.

Evaluation of feasibility, including intervention uptake as measured by login rates and duration, and acceptability in terms of content, design, language and adaptability to personal needs will inform modification and future evaluation. Findings from the feasibility study will be disseminated to participants, health care professionals and the public via a series of outputs. These include a lay summary of findings to be sent to participants and published on university and funder websites for public viewing, formal research reports, peer-reviewed publications and conference papers to share findings with health care professionals.

List Of Abbreviations

LEAP-MS	Lifestyle, Exercise and Activity Package for people with Multiple Sclerosis
MS	Multiple Sclerosis
	People with progressive MS
DVD	digital versatile disc
EDSS	Expanded Disability Status Scale
MFIS	Modified form of the Fatigue Impact Scale (MFIS)
MSIS-29	Multiple Sclerosis Impact Scale
EQ-5D-5L	(a health-related quality of life outcome measure)
OxPAQ	Oxford Participation and Activities Questionnaire
UW-SES	University of Washington 6-item short form self-efficacy scale
PGIC	Patients' Global Impression of Change
AE	Adverse Event
SAE	Serious Adverse Event
NHS	National Health Service
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TIDieR	Template for Intervention Description and Replication
CONSORT	Consolidated Standards of Reporting Trials

Trial Status

The trial is sponsored by Cardiff University (resgov@cardiff.ac.uk) and is set up. Recruitment will commence on 01.06.2020 and is anticipated to end in 30.09.2020. This manuscript has been drafted according to version 1.1 (12/05/2020) of the trial protocol. The protocol has been written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (see Figure 2 and Additional File 1); the intervention is described according to the Template for Intervention Description and Replication (TIDieR) checklist (see Additional File 2); and the final report will follow the Consolidated Standards of Reporting Trials (CONSORT) statement (Extension for Pilot and Feasibility Studies). Study results will be published on ClinicalTrials.gov and in peer-reviewed literature.

Declarations

Ethics approval and consent to participate

This study was approved on 25th June 2019 by the Research Ethics Committee (REC) For Wales (Wales REC 6), recognised by the United Kingdom. Ethics Committee Authority (UKECA). REC reference: 19/WA/1095. This centralised Ethics Committee approved the study in all the sites. All sites within the UK received research and development (R&D) approval from the appropriate Health Boards. Study participants will provide informed consent via the online platform (see methods section).

Consent for publication

Not applicable

Availability of data and materials. We aim to make our research data available wherever possible, subject to regulatory approvals, any terms and conditions placed upon us from external providers, patient confidentiality and all laws concerning the protection of personal information.

Competing interests. All authors have no competing interests to declare.

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Authors' contributions

1) Research project: A. Conception, B. Organization

2) Statistical and Data Analysis: A. Design, B Review and Critique;

3) Manuscript: A. Writing of the first draft, B. Review and Critique.

JLH 1A 1B 2A 2B 3A 3B

ER 1A 1B 3A 3B

KB 1A 1B 3B

FJ 1A 1B 2A 2B 3B

RL 1A 1B 3B

HD 1A 1B 2A 2B 3B

FW 1A 1B 2A 2B 3B

FD 1A 1B 2A 2B 3B

VP 1A 1B 2A 2B 3B

RO 1A 1B 2A 2B 3B

BS 1A 1B 2A 2B 3B

ET 1A 1B 2A 2B 3B

RP 1A 1B 2A 2B 3B

AE 1A 1B 2A 2B 3B

MB 1A 1B 2A 2B 3A 3B

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Figures

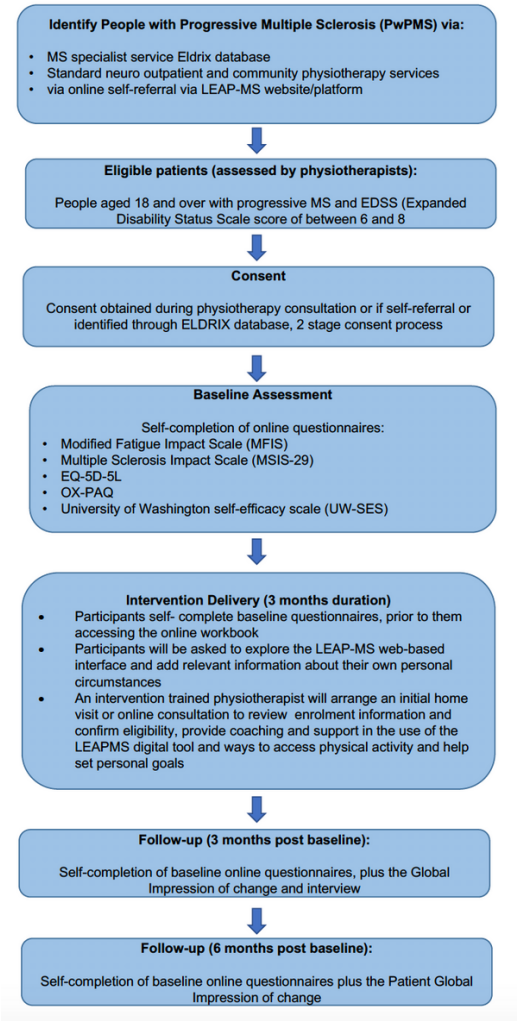

Figure 1

Participant flow diagram

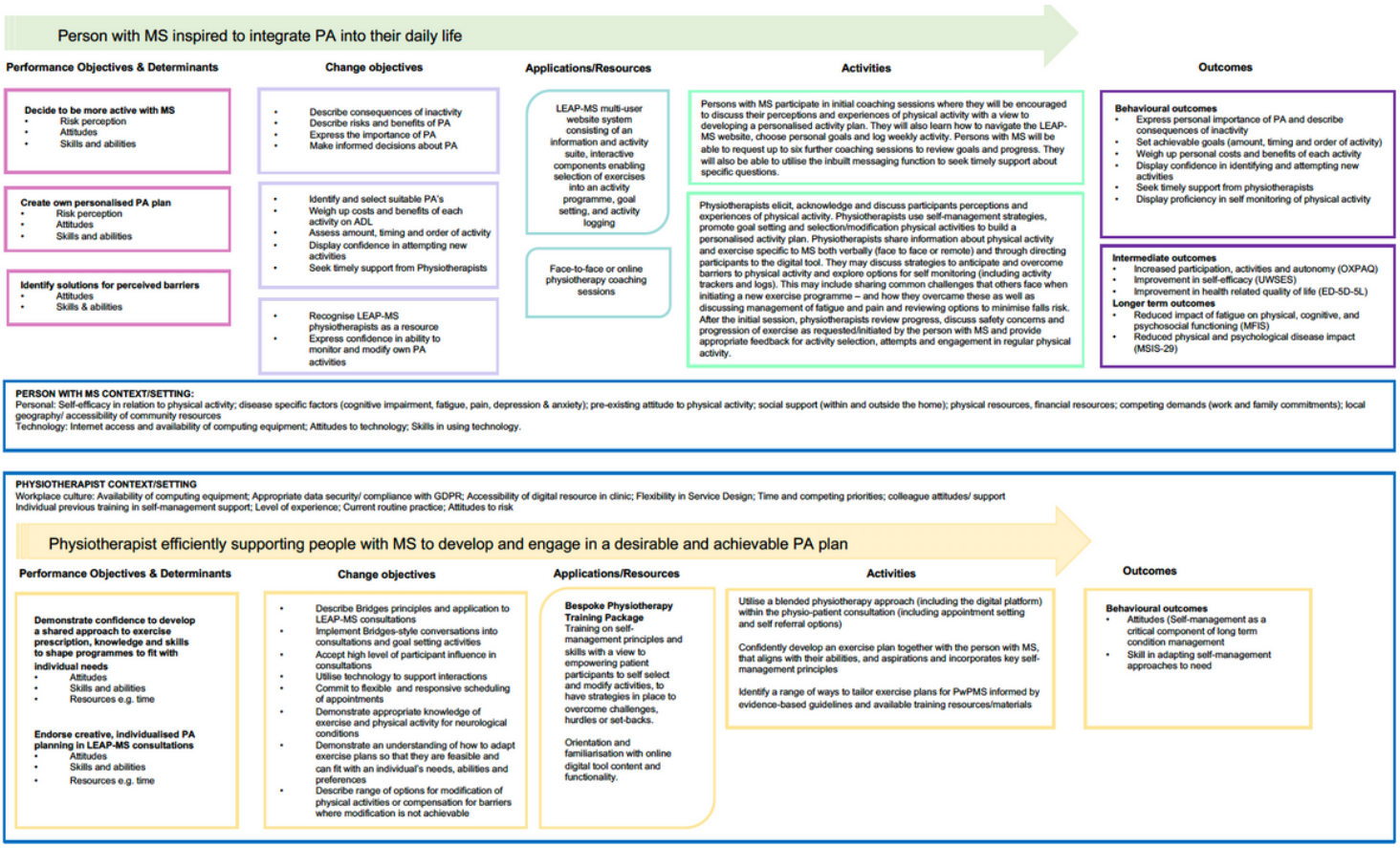

Figure 2

LEAP-MS Intervention logic model detailing objectives, activities and outcomes of PwPMS and the intervention physiotherapist.

Supplementary Files

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