

Online Research @ Cardiff

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository: https://orca.cardiff.ac.uk/id/eprint/145376/

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Busse, Monica ORCID: https://orcid.org/0000-0002-5331-5909, Playle, Rebecca ORCID: https://orcid.org/0000-0002-2989-1092, Latchem-Hastings, Julie ORCID: https://orcid.org/0000-0001-6738-916X, Button, Kate ORCID: https://orcid.org/0000-0003-1073-9901, Lowe, Rachel, Barlow, Christy ORCID: https://orcid.org/0000-0001-5759-0310, Lloyd, Barry ORCID: https://orcid.org/0000-0003-4763-1726, Dean-Young, Andrew, Poile, Vincent, Dawes, Helen, Davies, Freya ORCID: https://orcid.org/0000-0002-6956-1100, O'Halloran, Rhian, Tallantyre, Emma ORCID: https://orcid.org/0000-0002-3760-6634, Edwards, Adrian ORCID: https://orcid.org/0000-0002-6228-4446, Wood, Fiona ORCID: https://orcid.org/0000-0001-7397-4074 and Jones, Fiona 2022. A web-based life-style, exercise and activity intervention for people with progressive multiple sclerosis results of a single-arm feasibility study. Multiple Sclerosis and Related Disorders 57, 103388. 10.1016/j.msard.2021.103388 file

> Publishers page: https://doi.org/10.1016/j.msard.2021.103388 <https://doi.org/10.1016/j.msard.2021.103388>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies.

See

http://orca.cf.ac.uk/policies.html for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.

> information services gwasanaethau gwybodaeth

A web-based Life-style, Exercise and Activity intervention for People with Progressive Multiple Sclerosis: Results of a Single-Arm Feasibility Study.

Monica Busse^{1*}, Rebecca Playle¹, Julie Latchem-Hastings¹, Kate Button², Rachel Lowe¹, Christy Barlow¹, Barry Lloyd¹, Andrew Dean-Young¹, Vincent Poile¹, Helen Dawes³, Freya Davies⁴, Rhian O'Halloran⁵, Emma Tallantyre⁵, Adrian Edwards⁴, Fiona Wood⁴, Fiona Jones⁶.

1Centre for Trials Research, Cardiff University, 4th floor Neuadd Meirionnydd, Heath Park, Cardiff.

2School of Healthcare Sciences, Cardiff University, Ty Dewi Sant, Heath Park, Cardiff.

3Movement Science Group, Oxford Brookes University, Gipsy Lane, Headington, Oxford.

4PRIME Centre Wales and School of Medicine, Cardiff University, Heath Park, Cardiff.

5Helen Durham Neuro-Inflammatory Centre, University Hospital of Wales, Heath Park, Cardiff

6Faculty of Health and Social Care Science, St George's University of London and Kingston University

BusseME@cardiff.ac.uk\$

\$ corresponding author

Keywords:

Multiple Sclerosis, Physiotherapy, Intervention, Physical Activity, Self-management, feasibility study

Highlights

- Co-designed digital interventions provide unique opportunities to reach underserved groups.
- Our web-based physical activity intervention for people with progressive MS utilised technology to provide a new way of partnership working.
- Users were able to develop valuable skills in self-management support and use of technology and engagement in the intervention was associated with improvements in MSIS-29 scores.
- Delivering and evaluating this novel technology based intervention in a trial setting is feasible; a full effectiveness trial is warranted.

Abstract

Background. People with progressive Multiple Sclerosis often struggle to access appropriate and inclusive support for regular physical activity. The Lifestyle, Exercise and Activity Package (LEAP-MS) intervention, is a co-designed web-based physical activity intervention for people with progressive Multiple Sclerosis (MS). It consists of two key components; (1) web-based physical activity coaching with physiotherapists using self-management support strategies and 2) an interactive web-based platform including a physical activity information suite, an activity selection and planning tool and a participant-physiotherapist messaging system. We aimed to evaluate recruitment, retention and uptake, in a single arm feasibility study.

Methods. Participants with primary or secondary progressive MS with an Expanded Disability Status Scale score of 6 to 8 were recruited. Assessments included the MS Impact Scale (MSIS-29) and measures of participation at baseline, three and six months. All participants received the intervention which consisted of up to six web-based physiotherapyled physical activity **c**oaching sessions alongside access to web-based education and activity suites. Recruitment, retention and uptake data were summarised. Pre-defined progression criteria were used to guide feasibility assessment. Clinical outcome data were analysed descriptively.

Results. Fifty-eight percent (21/36) of those submitting expressions of interest were recruited; 76% completed follow-up. Pre-specified progression criteria for retention were met but recruitment did not meet progression criteria. The intervention achieved set fidelity criteria. At three months, 12 participants (75%) reported improvements in routine activities after the intervention. MSIS-29 physical scores improved by an average of eight points (95% CI -12.6 to -3.3). Improvements were also seen in MSIS-29 psychological scores and fatigue. Some improvements were maintained at six months.

Conclusions. The LEAP-MS intervention is feasible and associated with improvements in MSIS-29 scores. The intervention facilitated partnership working between physiotherapists and people with progressive MS. Users developed valuable skills in supported selfmanagement by focussing on enhancing physical activity to support overall wellbeing. This work has laid the foundations for a large-scale evaluation of a co-designed intervention with potential for far reaching impact on the lives of people with progressive MS.

Word count: 3151

Background.

Multiple sclerosis (MS) is the most common disabling neurological disease among young adults affecting an estimated 107,000 people in the UK¹. Of these it is estimated that approximately 53,000 have either primary or secondary progressive MS²³ 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, high health and social care needs and self-report low health related quality-of-life⁴. We know that people with MS want to keep physically active and moving⁵ however people with MS, especially those who are more disabled, find it hard to initiate and maintain activity⁶.

The National Institute for Health and Care Excellence (NICE) Clinical guideline [CG186]⁷ encourages people with MS to continue "exercising" for longer term benefits. They further refer to the NICE Public health guideline [PH49] on the importance of behaviour change approaches to elicit longer term benefits of physical activity in MS. Incorporating goal setting, barrier identification and information provision have all been shown to increase physical activity in PwMS⁸. However, to date studies typically involve participants with mild to moderate MS Expanded Disability Status Scale (EDSS) <7) with studies reporting the outcomes of structured exercise interventions, a sub-set of physical activity involving planned, structured and repetitive exercise to maintain or improve muscle strength or physical fitness. To our knowledge, there are only two published reports of self-management interventions (one of which utilised web-based exercises) in PwPMS^{9,10} with more advanced disability. Both studies report promising results, and adherence to web-based physiotherapy supported exercise was shown to be equivalent to individually prescribed activities.

Self-management support interventions in healthcare focus on self-efficacy¹¹ and set out to enable knowledge, skills and confidence for individuals to manage not only their long-term health conditions but also the practical and emotional impact it has on their lives¹². Such approaches promote the seeking of individual solutions to overcome barriers affecting the lives of those living with long term conditions¹³. Goal setting, appropriate communication and self-monitoring are important determinants of sustained physical activity behaviour¹⁴. With this in mind, we used an intervention mapping approach to systematically develop a bespoke physical activity self-management support intervention for PwPMS with advanced disability¹⁵. Within this patient-, family/carer- and community-centred intervention, physiotherapists provided a unique role as a physical activity coach. Our aim was to establish the feasibility of evaluating the developed integrated behaviour change and coaching selfmanagement intervention LEAP-MS. Here we report the results of this initial feasibility study.

Methods.

Objectives. The primary objectives were to establish feasibility of the study in terms of quantitative measures of recruitment, retention, intervention uptake and safety. Secondary objectives were to assess outcomes on a range of measures reflective of disease and functional status.

Design. Single arm (before and after) non-randomised feasibility study with embedded process evaluation (reported separately). For full details see associated protocol paper and adaptations to the protocol to accommodate remote implementation^{22,23}.

Participants and Setting. We aimed to recruit 21 participants with either primary or secondary progressive MS who were aged 18 or over and with an EDSS score²⁴ from 6 to 8. The sample size was based on the 95% confidence interval for an adequate proportion of eligible subjects being recruited (70%). The lower 95% confidence interval was 50% which is the minimum acceptable recruitment proportion.

Participants were required to have capacity to consent to study participation and have access to internet connection at home. Potential participants could be approached about the study via three routes, namely (1) Eldrix HealthContact, the MS database employed at the Helen Durham centre, a tertiary MS specialist centre (2) referral via local physiotherapy teams and (3) via the National MS register in the local region. For routes 2 and 3, information about the study was available via local physiotherapy services or via the UK MS Register²⁵, where potentially eligible participants were invited to complete the online expression of interest.

Eligibility screening and informed consent. All participants who completed an online eligibility checklist received a telephone call from the research team, to discuss study involvement and undergo further eligibility checks. Interested participants were then directed back to the LEAP-MS website and provided with individual user details to complete an online consent form and the baseline assessment.

Assessments. Consented participants were asked to complete a range of patient-reported outcome measures online at baseline, 3 and 6-months post baseline. Selected assessments reflected our proposed logic model of change, linking performance objectives to the proposed intervention outcomes over the short and medium terms¹⁵. In the short term, we anticipated that adherence to the intervention would be achieved through enhanced self-efficacy as assessed by the University of Washington 6-item short form self-efficacy scale (UW-SES-SF) (MS specific)²⁶. This would then influence the impact of ill-health on participation, activities, and autonomy as measured by the Oxford Participation and Activities Questionnaire (OxPAQ)²⁷ and health-related quality-of-life as measured by EQ-5D-5L²⁸. In the longer term, we hypothesised that the intervention would reduce the impact of fatigue on physical, cognitive, and psychosocial functioning as measured by modified form of the Fatigue Impact Scale (MFIS)²⁹ and the physical and psychological impact of MS from the patient's perspective as measured by the Multiple Sclerosis Impact Scale (MSIS-29)²⁹.

Participants were asked to repeat the online patient-reported outcome measures, plus a modified Patients' Global Impression of Change (PGIC)³⁰, at 3 months and 6 months postbaseline. In this, they were asked to indicate their degree of change using one of five responses (much better, slightly better, the same, slightly worse, much worse) in relation to their routine activities, emotional well-being, and social engagement.

Email reminders were sent two weeks before and two weeks after the expected assessment completion date. Participants received a telephone reminder if they had not logged on in the 2 weeks before the expected assessment date. At the end of the initial intervention period (3 months) participants and their treating physiotherapists were asked to participate in a semi-structured interview aimed at eliciting experiences and reflections on the intervention, and the process of its delivery (data reported separately).

The LEAP-MS Intervention. The LEAP-MS intervention (<u>www.leapms.org</u>) consists of two key components; (1) face-to-face or web-based physical activity coaching with physiotherapists using self-management support strategies and 2) an interactive web-based platform including an information suite, an activity selection and planning tool specifically developed for PwPMS and a participant-physiotherapist messaging system. Participants used the platform to complete study assessments and access the interactive education and activity selection and planning tool. They are also able to contact their intervention physiotherapist via a messaging function to seek guidance or request consultations. Physiotherapists used the platform to record consultation notes, respond to participants' requests and to view participant activity and goal setting. The study team used the platform to evaluate participant engagement with the intervention and to manage data throughout the study.

After the baseline assessments, participants were paired with an intervention physiotherapist who contacted the participant to arrange the first coaching session, after which the full LEAP-MS online tool was released to the participant. Activities implicit within the intervention include active learning, reinforcement, modelling, feedback, facilitation, goal setting, and guided practice¹⁶. Underpinned by both self-regulation theory and social cognitive theory^{11,17}, behaviour change theories operating at the intra-personal and interpersonal level respectively are integrated within both face to face/ web based physiotherapy coaching and an associated web based platform. Performance objectives focus around three main areas first, that the PwPMS make a conscious decision to be more active; second, they develop the skills and confidence to create a personal physical activity plan, and third – they become adept at identifying solutions for perceived barriers through access to timely and appropriate support from physiotherapists. Intervention physiotherapists used one-to-one physical activity coaching strategies to support self-management, focussed on exploration of goal setting and support for selection/modification of meaningful physical activities enabling PwPMS to build their personalised activity plan^{18–21}.

Physiotherapy Training. Eight physiotherapists received bespoke LEAP-MS training, which focussed on the provision of self-management support to participants alongside the use of technology in consultations and updates on physical activity and exercise guidelines for neurological conditions. Further resources to help structure remote interactions (https://www.bridgesselfmanagement.org.uk/covid-19-resources/) were made available to ensure standardisation of coaching interactions regardless of mode of delivery. Therapists

were able to access conversation-based scripts to guide their coaching conversations and had the opportunity to practice coaching conversations and receive peer review.

Intervention Fidelity. Fidelity was assessed in two parts – first using a components checklist in relation to each part of LEAP-MS initial recorded intervention sessions – 1. checking eligibility and reaffirming consent, 2. explanation of the study, 3. demonstration of the platform and its key functions and 4. evidence of a self-management ethos taken to the consultation. In addition, a purpose-developed fidelity checklist was used to score knowledge and skills evidenced by physiotherapists during intervention delivery¹⁵. At least one initial video-recorded coaching session and one follow-up session were observed by a qualitative researcher to enable completion of the fidelity checklist for each intervention physiotherapist (n=8). The presence and consistency of self-management language used across six domains (problem solving, goal setting, reflection, knowledge of MS and physical activity, communication style, and engagement with the technology) were also assessed.

Feasibility Progression criteria. A traffic light system of progression criteria for recruitment and retention³¹ (see Table 2) guided our decisions as to future evaluations. Intervention uptake and safety were not formal progression criteria but were closely monitored and considered in final recommendations.

Safety was assessed using an online process of self-reporting by the participant. Participants were asked to self-report any incidents of falls, fatigue, increased muscle soreness or sprain, or other incidents they felt relevant, and whether the incidents required medical intervention. In this patient population, exacerbations of existing MS symptoms with potential for hospitalisation due to secondary complications, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems were defined as 'expected'³².

Analysis. All proportions were tabulated with 95% confidence intervals alongside the study flow chart, which detailed the reasons for exclusion, refusal and dropout. Intervention uptake is reported descriptively. There was no defined minimum dataset for the clinical secondary outcomes. Data completeness of each patient-reported outcome measure was tabulated to further inform our assessment of feasibility. Distributions of the outcome scores were tabulated with 95% confidence intervals at baseline and follow-up time points.

Governance. This study was approved by the Research Ethics Committee (REC) For Wales (Wales REC 6), REC reference: 19/WA/1095, and received research and development (R&D) approval from the appropriate Health Boards in Wales.

Results.

Twenty-one participants with progressive MS (15 females; mean (SD) age 60.9) were recruited (see Table 2). There was a good representation across the range of EDSS scores from EDSS 6 to EDSS 7.5. No participants with EDSS 8 were recruited. Most participants used assistive devices, had home adaptations and had been living with MS for more than 15 years. Only one participant was in full-time employment and only one lived alone.

At baseline, mean (SD) scores on the MSIS-29 physical and psychological sub-scale were 49.5 (16.5) and 26.9 (15.4) respectively [possible range 0-100; with higher scores indicating greater disease impact]. Mean (SD) MFIS physical, cognitive and psychological sub-scales scores were respectively 23.5 (8.6) [possible range of 0-36]; 15.2 (7.8) [possible range of 0-40] and 3.7 (2.0) [possible range 0-8]. Mean (SD) self-efficacy score was 43.1 (8.6). Scores on the OxPAQ routine activities, emotional well-being and social engagement domains were 50.1 (21.0); 31.4 (22.1) and 32.4 (27.6) respectively [possible range 0-100; with higher scores indicating inferior health status].

<Table 1 here>

Recruitment. The study was open to recruitment from 13.08.2020 for 11 weeks, achieving an average recruitment rate of 1.9 participants per week. Of the initial 36 expressions of interest received, three were ineligible, one uncontactable, and 11 did not complete all the baseline assessments and could therefore not be assigned to a physiotherapist. Fifty-eight percent (21/36) of those submitting online permission to contact forms were eligible, consented and completed all baseline forms. The pre-specified criterion for recruitment, namely 70%, was thus not fully met, but was above the cut off of 50% indicating lack of feasibility, suggesting that further work is required to optimise the recruitment process.

Retention. Twenty-one participants completed the baseline assessments and were assigned to a physiotherapist. One participant withdrew from the study before any physiotherapist contact for personal reasons. Sixteen participants (76 %) completed both the 3-month and 6-month follow-up assessments (**see Figure 1, Table 2**). The pre-specified criterion for retention was met.

<Figure 1 here>

<Table 2 here>

Core elements of the LEAP-MS intervention were evident in all observed physiotherapy sessions (see supplementary Table 2). The use of a coaching style was present, but varied between intervention physiotherapists and across domains. Intervention physiotherapists evidenced consistent self-management language and phrasing when supporting goal setting (median score 4) and in eliciting reflection (median scores 3.5). Using self-management language in relation to technology use was the weakest domain (median score 2) (see Supplementary Table 3).

Intervention uptake/ Adherence. Twenty participants completed the initial consultation. One participant withdrew after three sessions due to an unrelated hospital admission which was reported as a SAE. Nineteen participants (90.5% of those recruited) thus received the intervention as intended. Forty-nine additional consultations (median 2; range 0-5) were requested and completed by the remaining 19 participants. Adherence data are presented in Table 5.

<Table 3 here>

Harms. There was one SAE reported, a hospital admission for a comorbidity. This was reviewed and confirmed to be not related to the intervention.

Self-reported outcomes. Twelve out of 16 participants (75%) were at least slightly better in terms of OxPAQ domains of routine activities and 11 out of 16 (69%) were at least slightly **better** in relation to emotional well-being domains after the intervention. Ten out of 16 (62%) reported no change or worsening in terms of social engagement after the intervention.

At the three months follow-up, scores on the MSIS-29 physical scale were on average eight points (95% CI -12.6 to -3.3) lower than those at baseline, indicating a promising improvement in MS impact. A similar pattern of change was seen on MSIS-29 psychological scores along with improvements in fatigue as measured by the modified form of the Fatigue Impact Scale. Some of the improvements, most notably the MSIF Physical and Cognitive scores, were maintained at the 6-months follow-up (see Table 8).

<Table 4 here>

Discussion

Here we report the results from a single arm evaluation of a novel web-based technology intervention evaluation. Participants were encouraged to learn more about aspects of their condition and about physical activity. They were able to access an information suite including advice from experts, short videos and reflections from peers. The intervention also provided a multitude of ideas for remaining physically active as well as video based examples of structured exercise programmes suitable for people with advanced disability. As well as building their own plans, participants were able to set goals and monitor their progress as they participated in their own bespoke, self-determined programme of physical activity. This could focus either on structured and planned exercise or more broadly on physical activity as recommended for people with Multiple Sclerosis throughout the disease course³³. Uniquely, the LEAP-MS intervention had a paired account function in which people with MS can be paired with their physiotherapist to respond to participants' requests and to view participant activity and goal setting.

Our results suggest that the intervention was feasible and acceptable and resulted in improvements in terms of MS impact in the direction that was expected. Despite not meeting

the pre-specified criterion for upper cut off for recruitment (58% rather than the target 70%), recruitment was still above the minimum defined recruitment rates for feasibility. It may be that for future studies, particularly those which involve self-referral, that recruitment rates from expression of interest to consent should be lower than we had initially proposed. Once recruited, we were able to demonstrate good retention at six months follow-up assessment. The average magnitude of change in the MSIS-29 physical reported at the 3-months follow-up point was clinically relevant³⁴ and the changes in the other outcome measures were in the expected direction that is indicative of positive intervention impact. Importantly, these changes were in line with our hypothesised logic model of change¹⁵ but as a single arm evaluation, we cannot assume that these outcomes are causally related to the LEAP-MS intervention.

This study was due to open to recruitment at the same time as the onset of the first wave of the COVID-19 pandemic in the UK (March 2020)²³. Modifications were required to enable entirely remote delivery²². Whilst our mode of recruitment was reliant on accurate reporting of disability by potential participants, there are clear benefits of a remote study such as outs in terms of reaching participants who would otherwise not be recruited to clinical studies. This approach to self-referral is thus critical to the inclusive research agenda and should be considered in future studies.

The completion of the online forms appeared to be the most challenging aspect of the study for participants, with 31% starting the assessments but not completing them, despite two telephone reminders and a follow-up email. The provision of study information to potentially eligible participants relied entirely on written information (post or email). Under typical conditions (i.e. not in a pandemic where all face-to-face elective consultations were halted), we would have anticipated at least one opportunity for the study to be discussed with a referring clinician to ensure that potential participants understood what it involved. Participants did not have this opportunity although they were able to discuss participation with the study team. We believe that this may have resulted in at least some who submitted online permission-to-contact forms not progressing to the next stages.

In future studies, we believe a multi-media resource explaining what participants can expect if they enrol in the study and the eligibility criteria would help to optimise the recruitment process. Additionally, we propose further remote (telephone) support in completing the online questionnaires, alongside the option for postal completion and return for those who request this. It is worth recognising that cognitive impairment and computer literacy may have affected attrition. Having the option for postal questionnaire completion may be important in certain instances.

Physical activity trials to date have tended to exclude those with PwPMS and advanced disability. In LEAP-MS, we have addressed one aspect of inclusivity, namely the recruitment of more disabled PwPMS, but there remains the need to optimise the intervention for greater inclusivity for under-represented groups for example Black, Asian and minority ethnic populations, people with lower health literacy, those without internet etc), particularly given

the increasing emphasis on preventive exercise interventions in MS³⁵. The LEAP-MS intervention has critical potential to maintain mobility, health and life quality in PwPMS with potential cost savings. With optimisation of recruitment process and the web-based intervention elements, we now propose progression to a fully powered, randomised controlled evaluation.

Acknowledgements. We would like to acknowledge Barbara Stensland and the team of Public Involvement and Engagement (PPIE) partners at each stage of this study and our PPIE co-applicant. We would also like to acknowledge the support from the UK MS Register, based in Population Data Science in Swansea University Medical School in communicating the study information to potentially eligible participants in the register.

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

Funding. This study has been funded by the Multiple Sclerosis Society (grant number 81). Funds have been provided for study management, researcher and clinician time, basic equipment (such as printing), to support public and patient involvement (PPI) and the development and evaluation of the LEAP-MS intervention. The Centre for Trials Research receives infrastructure funding from Health and Care Research Wales and Cancer Research UK. HD is supported by the Elizabeth Casson Trust and the NIHR Oxford Health Biomedical Research Centre.

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. The authors declare that there are no competing interests.

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.

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

JLH 1A;1B;2A;2B;3A;3B RP 1A;1B;2A;2B;3A;3B KB 1A;1B;2A;2B;3A;3B RL 1A; 1B; 2A;2B;3A;3B CB 1A; 1B; 2A; 2B; 3B BL 1A; 1B; 2A; 2B; 3B BL 1A; 1B; 2A; 2B; 3B ADY 1B; 2B; 3B VP RL 1A; 1B; 2B; 3B HD 1A; 2B; 3B FD 1A; 2B; 3B ROH 1A; 2B; 3B ET 1A; 2B; 3B AE 1A; 2B; 3B FW 1A; 2B; 3B FJ 1A; 2B; 3B

References.

- 1. MS in the UK | Multiple Sclerosis Society UK. https://www.mssociety.org.uk/care-and-support/resources-and-publications/publications-search/ms-in-the-uk.
- Primary progressive MS. *MS Trust* https://www.mstrust.org.uk/a-z/primary-progressivems.
- Khurana, V., Sharma, H. & Medin, J. Estimated prevalence of secondary progressive multiple sclerosis in the USA and Europe: results from a systematic literature search (P2.380). *Neurology* 90, (2018).
- Ernstsson, O. *et al.* Cost of Illness of Multiple Sclerosis A Systematic Review. *PLOS* ONE 11, e0159129 (2016).
- Malcomson, K. S., Lowe-Strong, A. S. & Dunwoody, L. What can we learn from the personal insights of individuals living and coping with multiple sclerosis? *Disabil Rehabil* 30, 662–674 (2008).
- Davies, F. *et al.* 'You are just left to get on with it': qualitative study of patient and carer experiences of the transition to secondary progressive multiple sclerosis. *BMJ Open* 5, e007674 (2015).
- Recommendations | Multiple sclerosis in adults: management | Guidance | NICE. https://www.nice.org.uk/guidance/cg186/chapter/Recommendations#ms-symptommanagement-and-rehabilitation.
- Sangelaji, B. *et al.* The effectiveness of behaviour change interventions to increase physical activity participation in people with multiple sclerosis: a systematic review and meta-analysis. *Clin Rehabil* 30, 559–576 (2016).
- Freeman, J. *et al.* Assessment of a home-based standing frame programme in people with progressive multiple sclerosis (SUMS): a pragmatic, multi-centre, randomised, controlled trial and cost-effectiveness analysis. *Lancet Neurol* 18, 736–747 (2019).

- Donkers, S. J., Nickel, D., Paul, L., Wiegers, S. R. & Knox, K. B. Adherence to Physiotherapy-Guided Web-Based Exercise for Persons with Moderate-to-Severe Multiple Sclerosis: A Randomized Controlled Pilot Study. *Int J MS Care* 22, 208–214 (2020).
- Bandura, A. Health Promotion by Social Cognitive Means. *Health Educ Behav* 31, 143–164 (2004).
- 12. Putting it into practice: building knowledge, skills and confidence | A practical guide to self-management support. *Health Foundation* https://reader.health.org.uk/practical-guide-to-self-management-support/putting-it-into-practice-building-knowledge-skills-and-confidence.
- Making the change. *The Health Foundation* https://www.health.org.uk/publications/making-the-change.
- Backus, D. Increasing Physical Activity and Participation in People With Multiple Sclerosis: A Review. *Arch Phys Med Rehabil* 97, S210-217 (2016).
- Busse, M. *et al.* Web-based physical activity intervention for people with progressive multiple sclerosis: application of consensus-based intervention development guidance.
 BMJ Open 11, e045378 (2021).
- 16. Kok, G. *et al.* A taxonomy of behaviour change methods: an Intervention Mapping approach. *Health Psychol Rev* **10**, 297–312 (2016).
- Cameron, L. D. & Leventhal (PhD.), H. *The Self-regulation of Health and Illness Behaviour*. (Psychology Press, 2003).
- Joseph, R. P., Ainsworth, B. E., Mathis, L., Hooker, S. P. & Keller, C. Utility of Social Cognitive Theory in Intervention Design for Promoting Physical Activity among African-American Women: A Qualitative Study. *Am J Health Behav* 41, 518–533 (2017).

- 19. Shamizadeh, T., Jahangiry, L., Sarbakhsh, P. & Ponnet, K. Social cognitive theorybased intervention to promote physical activity among prediabetic rural people: a cluster randomized controlled trial. *Trials* **20**, 98 (2019).
- 20. Stacey, F. G., James, E. L., Chapman, K. & Lubans, D. R. Social cognitive theory mediators of physical activity in a lifestyle program for cancer survivors and carers: findings from the ENRICH randomized controlled trial. *International Journal of Behavioral Nutrition and Physical Activity* **13**, 49 (2016).
- Uszynski, M. K. *et al.* Social Cognitive Theory Correlates of Physical Activity in Inactive Adults with Multiple Sclerosis. *Int J MS Care* 20, 129–135 (2018).
- 22. Lowe, R. *et al.* Lifestyle, Exercise and Activity Package for People living with Progressive Multiple Sclerosis (LEAP-MS): adaptions during the COVID-19 pandemic and remote delivery for improved efficiency. *Trials* **22**, 286 (2021).
- 23. Latchem-Hastings, J. *et al.* Lifestyle, exercise and activity package for people living with progressive multiple sclerosis (LEAP-MS): protocol for a single-arm feasibility study. *Pilot and Feasibility Studies* **7**, 111 (2021).
- Kurtzke, J. F. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). *Neurology* 33, 1444–1452 (1983).
- Middleton, R. M. *et al.* Validating the portal population of the United Kingdom Multiple Sclerosis Register. *Multiple Sclerosis and Related Disorders* 24, 3–10 (2018).
- 26. Amtmann, D. *et al.* University of Washington self-efficacy scale: a new self-efficacy scale for people with disabilities. *Arch Phys Med Rehabil* **93**, 1757–1765 (2012).
- Morley, D., Dummett, S., Kelly, L. & Jenkinson, C. Measuring improvement in health-status with the Oxford Participation and Activities Questionnaire (Ox-PAQ).
 Patient Relat Outcome Meas 10, 153–156 (2019).

- 28. Herdman, M. *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* **20**, 1727–1736 (2011).
- 29. Fisk, J. D. *et al.* Measuring the functional impact of fatigue: initial validation of the fatigue impact scale. *Clin Infect Dis* **18 Suppl 1**, S79-83 (1994).
- Kamper, S. J., Maher, C. G. & Mackay, G. Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. *J Man Manip Ther* 17, 163–170 (2009).
- Avery, K. N. L. *et al.* Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 7, e013537 (2017).
- 32. Safety reporting. *Health Research Authority* https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/.
- Rosalind Kalb *et al.* Exercise and lifestyle physical activity recommendations for
 people with multiple sclerosis throughout the disease course. Multiple Sclerosis Journal 26 (12) 1459–1469 (2020).
- Costelloe, L. *et al.* The patient knows best: significant change in the physical component of the Multiple Sclerosis Impact Scale (MSIS-29 physical). *Journal of Neurology, Neurosurgery & amp; Psychiatry* 78, 841–844 (2007).
- Dalgas, U., Langeskov-Christensen, M., Stenager, E., Riemenschneider, M. & Hvid,
 L. G. Exercise as Medicine in Multiple Sclerosis-Time for a Paradigm Shift: Preventive,
 Symptomatic, and Disease-Modifying Aspects and Perspectives. *Curr Neurol Neurosci Rep* 19, 88 (2019).

List of Figure Legends

Figure 1. Study Flow Chart.

List of Table Legends

Table 1. MS participants demographic and clinical characteristics at baseline.

Table 2. Results of Feasibility Evaluation against pre-set progression criteria

Table 3. Intervention Uptake.

Table 4. Descriptive summaries for patient reported outcomes at each time point

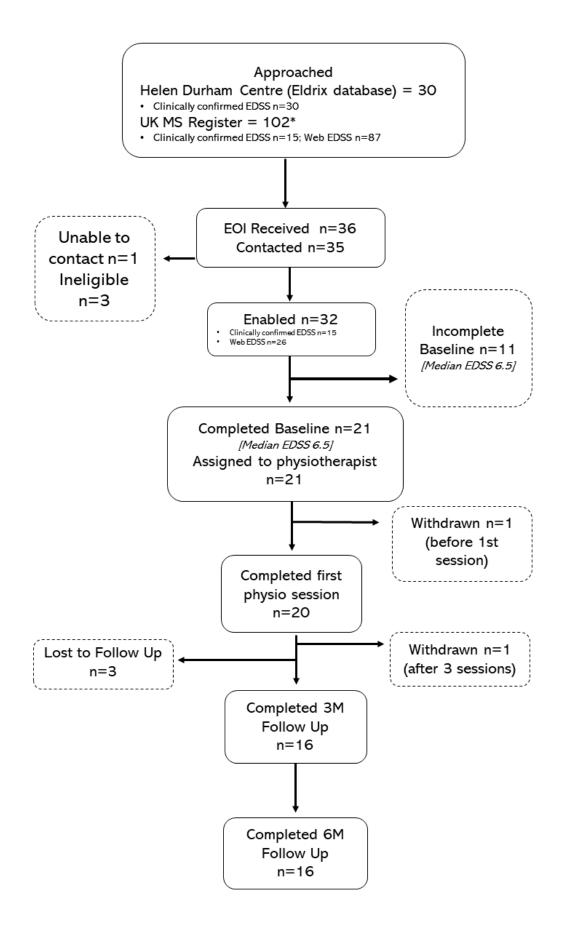
Supplementary Tables

Supplementary Table 1. Data completion rates for patient reported outcomes at each time point

Supplementary Table 2. Intervention components checklist scores

Supplementary Table 3. Application of self-management language and overall communication style across five domains within intervention delivery.

Figure 1. Study Flow Chart.



Demographic characteristics	(n)	n (%) or Mean (SD)
Age (years) ^a	21	60.9 (9.2)
Gender at birth (Females: Males)	21	15:6 (% female 71.4)
Ethnicity	21	
Welsh/ English / Scottish / Northern Irish / British	L	20 (95.2%)
Any other White background (White European)		1 (4.8%)
Household	21	X XX X XX X_X
Just me		1 (4.8%)
Myself and my partner		15 (71.4%)
Myself and my child/children (include		3 (14.3%)
those adopted or fostered)		× /
Myself, my partner and a child/children		2 (9.5%)
Dependents (% yes)	21	3 (14.3%)
Adaptations / equipment (% yes)	21	
Ramps		7 (33.3%)
Rails		11 (52.4%)
Stairlift		6 (28.6%)
Raised Toilet seat		6 (28.6%)
Sliding board		1 (4.8%)
Lift		3 (14.3%)
Wet room		8 (38.1%)
Perching stool		8 (38.1%)
Walking frame		9 (42.9%)
Outdoor Wheeled walker		11 (52.4%)
Self-propel wheelchair		13 (61.9%)
Mobility scooter		12 (57.1%)
Electric wheelchair		6 (28.6%)
Employment status	21	
House Person		2 (9.5%)
Employed (Full Time)		1 (4.8%)
Employed (Part Time)		1 (4.8%)
Unemployed		1 (4.8%)
Retired		16 (76.2%)
Number of years with diagnosed MS ^a	20	17.7 (11.7)
Medication for MS symptoms (all categories)	21	
No medication		2 (9.5%)
Baclofen		9 (42.9%)
Gabapentin		7 (33.3%)
Pregabalin		1 (4.8%)

Oxybutynin		
Solifenacin		2(9.5%)
Amitriptyline Duloxetine		2(9.5%)
		1 (4.8%)
Carmabazepine Beta-Interferon		1 (4.8%)
		1 (4.070)
Method for accessing the LEAP-MS website	21	
Mobile		4 (19%)
Desktop		3 (14.3%)
Tablet		6 (28.6%)
Laptop		10 (47.6%)
Clinical characteristics	1	Mean (SD), Median [IQR]
EDSS	20	
6.0 (Requires a walking aid: cane, crutch, etc. to		5 (25%)
walk about 100m with or without resting)		
6.5 (Requires two walking aids: pair of canes,		6 (30%)
crutches, etc. to walk about 20m without resting)		
7.0 (Unable to walk beyond approximately 5m		5 (25%)
even with aid. Essentially restricted to wheelchair)		5 (2570)
7.5 (Unable to take more than a few steps.		4 (2007)
Restricted to wheelchair)		4 (20%)
MSIS-29	21	
Physical sub-scale		49.5 (16.5), 48.8 [37.5, 61.3]
Psychological sub-scale		26.9 (15.4), 30.6 [16.7, 36.1]
MFIS	21	
Physical subscale		23.5 (8.6), 27 [20, 29.5]
Cognitive sub-scale		15.2 (7.8), 19 [6.5, 21.5]
Psychosocial sub-scale		3.7 (2.0), 4 [2, 5]
Total MFIS Score		42.4 (16.1), 46 [37.0, 54.5]
UW-SES-SF	21	43.1 (8.6), 42.6 [35.6, 47.1]
OxPAQ	21	
Routine Activities Domain		50.1 (21.0), 53.6 [32.1, 67.9]
Emotional Well-Being Domain		31.4 (22.1), 30.0 [15.0, 45.0]
Social Engagement Domain		32.4 (27.6), 25.0 [9.4, 50.0]
EQ-5D-5L	21	
Health today score		60.7 (19.3), 60 [41.5, 78.0]
EQ5D score		0.6 (0.2), 0.6 [0.5, 0.7]

EDSS Expanded Disability Status Scale, MSIS-29 Multiple Sclerosis Impact Scale, MFIS Modified Fatigue Impact Scale, UW-SES-SF University of Washington 6-item short form self-efficacy scale, OxPAQ Oxford Participation and Activities Questionnaire, EQ-5D-5L Five-level EuroQol-5 dimensions health state utility scale.

Table 2. Results of Feasibility Evaluation against pre-set progression criteria

Parameter		Progression criteria
		(traffic light metric)
Recruitment: Percentage of	58%	Green 70%
those submitting online		Amber 50-69%
permission to contact forms		Red less than 50%
who were eligible and who		
consented to participation		
Recruitment pathway:	Helen Durham Centre (Eldrix	
Proportion from each of the	database): n=4	
possible recruitment	The UK MS Register register: n=17	
pathways	Local physiotherapy teams: n=0	
Three month retention rate:	76%	Green 70%
Percentage of individuals		Amber 50-69%
who complete the 3 month		Red less than 50%
follow-up assessments		
Six month retention rate:	76%	
Percentage of individuals		
who complete the 6 month		
follow-up assessments		

Table 3. Intervention Uptake

Intervention Uptake Parameter	
Percentage of initial consultations completed	95% (20 initial consultations)
Additional physiotherapy consultation sessions requested and completed	49 additional consultations out of a (out of total 105 possible)
Frequency and duration of remote physiotherapist contacts recorded.	57 out of the total 69 consultations were recorded. The average consultation lasted 42 minutes
Total number of times (mean (SD)) a user logged in on the system	71 (140)
Website log in rates: Number of logins (mean (SD)) per month	3 (5)
Website log in rates: Total time (mean (SD)) (minutes) spent using the LEAP-MS website	83 (152)
Website log in rates: Average time (minutes) spent per log in	2 (3)
Website log in rates: Longest (mean (SD)) log in session (minutes)	16 (30)
Website log in rates: Length of time between each log in episode (days)	9 (10)

	n	Baseline	Three months	Six months	95% CI	95% CI
		Mean (SD)	Mean (SD)	Mean (SD)	Baseline to 3	Baseline to
					months	6 months
					∟no change	
					∞ improvement	
MSIS-29	16	45.2 (15.2)	37.3 (13.7)	41.1 (15.3)	$-12.6 \text{ to } -3.3^{\infty}$	-9.4 to 1.1
Physical						
MSIS-29	16	25.5 (13.1)	20.7 (12.7)	22.2 (18.4)	-9.9 to 0.2^{∞}	-9.5 to 2.9
Psychological						
MFIS	16	22.8 (8.2)	20.6 (5.2)	20.5 (6.3)	-4.2 to 0.9^{∞}	-5.2 to 0.7
Physical						
MFIS	16	15.4 (8.2)	13.3 (7.4)	12.4 (8.0)	-4.1 to 1.3^{∞}	-4.5 to -1.5
Cognitive						
MFIS	16	3.8 (2.0)	2.9 (1.4)	3.3 (1.6)	-1.6 to 0.4^{∞}	-1.5 to 0.6
Psychological						
MFIS Total	16	41.9 (16.1)	36.8 (11.8)	36.1 (14.1)	-8.9 to 1.6^{∞}	-10.2 to -1.3
UW-SES-SF	16	43.1 (9.5)	46.4 (8.7)	47.8 (9.1)	-0.8 to 7.3^{∞}	0.2 to 9.2
OxPAQ	16	45.1 (20.9)	42.7 (19.5)	44.2 (21.4)	-9.6 to 4.9^{∞}	-10.6 to 1.2
Routine						
Activities						
Domain						
OxPAQ	16	29.4 (20.0)	22.5 (18.8)	24.7 (20.0)	-15.1 to 1.4^{∞}	-10.6 to 1.2
Emotional						
Well-Being						
Domain						
OxPAQ	16	28.1 (25.4)	24.6 (22.6)	28.9 (27.5)	-17.2 to 10.2^{∞}	-12.3 to
Social						13.9
Engagement						
Domain						
EQ-5D-5L	16	0.6 (0.1)	0.7 ((0.1)	0.6 (0.2)	-0.04 to 0.1°	-0.1 to 0.1
Your health	16	62.0 (18.4)	62.3 (20.9)	63.1 (21.2)	-11.6 to 12.1∟	-6.4 to 8.7
today						

EDSS Expanded Disability Status Scale, MFIS Modified Fatigue Impact Scale (higher scores indicate *greater* fatigue), MSIS-29 Multiple Sclerosis Impact Scale (higher scores indicate *greater* disease impact), UW-SES-SF University of Washington 6-item short form self-efficacy scale (higher scores indicate *greater* self-efficacy), OxPAQ Oxford Participation and Activities Questionnaire (higher scores indicate *inferior* health status), EQ-5D-5L Five-level EuroQol-5 dimensions health state utility scale (higher scores indicate *superior* health status) (∞ = improvement)

Supplementary Table 1. Data completion rates for patient reported outcomes at each time point

	Baseline	Three months	Six months
EDSS	20/21 (95.2%)	n/a	n/a
MSIS-29 Physical sub-scale	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
MSIS-29 Pyschological sub-scale	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
MFIS total score	21/21 (100%)	17/21 (81.0%)	17/21 (81.0%)
OxPAQ Routine Activities	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
Domain			
OxPAQ Emotional Well-Being	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
Domain			
OxPAQ Social Engagement	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
Domain			
UW-SES-SF	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
EQ-5D-5L	21/21 (100%)	16/21 (76.2%)	16/21 (76.2%)
PGIC		16/21 (76.2%)	16/21 (76.2%)

EDSS Expanded Disability Status Scale, MFIS Modified Fatigue Impact Scale, MSIS-29 Multiple Sclerosis Impact Scale, UW-SES-SF University of Washington 6-item short form self-efficacy scale, OxPAQ Oxford Participation and Activities Questionnaire, EQ-5D-5L Five-level EuroQol-5 dimensions health state utility scale, PGIC Modified Patients' Global Impression of Change

Supplementary Table 2. Intervention components checklist scores

Physiotherapist	Eligibility check and reaffirming consent	Explanation of and introduction to the LEAP-MS study	Demonstration (where required) of the LEAP-MS platform and its key functions	Evidence of self- management approach taken to overall consultation
1	Y	Y	Y	Y
2	Y	Y	Y	Y
3	Y	Y	Y	Y
4	Y	Y	Y	Y
5	Y	Y	Y	Y
6	Y	Y	Y	Y
7	Y	Y	*N/A	Y
8	Y	Y	Y	Y

*In this instance in both participant sessions observed – participants demonstrated independence in using the site and did not need further explanation or support.

Supplementary Table 3. Communication and coaching style across five domains within intervention delivery

Intervention	1	2	3	4	5	6	7	8
physiotherapist								
Problem solving*	3	2	3	4	2	2	3	4
Goal setting*	4	2	4	4	2	4	4	3
Reflection*	4	3	4	4	1	3	4	3
Knowledge of MS and	3	2	4	4	2	2	2	3
Physical Activity*								
Engagement with	2	1	3	4	1	3	**N/A	2
Technology*								
Communication style*	4	2	4	4	2	3	4	3
Overall Score	20	12	22	24	10	17	17	18

*Scoring follows a 5 point scale: 0 = not at all - 4 = a great extent. **In this instance in both participant sessions observed – participants demonstrated independence in using the site and did not need further explanation or support.