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

Monica Busse<sup>1\*</sup>, Rebecca Playle<sup>1</sup>, Julie Latchem-Hastings<sup>1</sup>, Kate Button<sup>2</sup>, Rachel Lowe<sup>1</sup>, Christy Barlow<sup>1</sup>, Barry Lloyd<sup>1</sup>, Andrew Dean-Young<sup>1</sup>, Vincent Poile<sup>1</sup>, Helen Dawes<sup>3</sup>, Freya Davies<sup>4</sup>, Rhian O'Halloran<sup>5</sup>, Emma Tallantyre<sup>5</sup>, Adrian Edwards<sup>4</sup>, Fiona Wood<sup>4</sup>, Fiona Jones<sup>6</sup>.

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

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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 self-management 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.

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#### Background.

Multiple sclerosis (MS) is the most common disabling neurological disease among young adults affecting an estimated 107,000 people in the UK<sup>1</sup>. Of these it is estimated that approximately 53,000 have either primary or secondary progressive MS<sup>23</sup> 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-life<sup>4</sup>. We know that people with MS want to keep physically active and moving<sup>5</sup> however people with MS, especially those who are more disabled, find it hard to initiate and maintain activity<sup>6</sup>.

The National Institute for Health and Care Excellence (NICE) Clinical guideline [CG186]<sup>7</sup> 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 PwMS<sup>8</sup>. 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<sup>9,10</sup> 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-efficacy<sup>11</sup> 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 lives<sup>12</sup>. Such approaches promote the seeking of individual solutions to overcome barriers affecting the lives of those living with long term conditions<sup>13</sup>. Goal setting, appropriate communication and self-monitoring are important determinants of sustained physical activity behaviour<sup>14</sup>. 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 disability<sup>15</sup>. 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<sup>22,23</sup>.

**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 score<sup>24</sup> 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 Register<sup>25</sup>, 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 terms<sup>15</sup>. 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)<sup>26</sup>. This would then influence the impact of ill-health on participation, activities, and autonomy as measured by the Oxford Participation and Activities Questionnaire (OxPAQ)<sup>27</sup> and health-related quality-of-life as measured by EQ-5D-5L<sup>28</sup>. 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)<sup>29</sup> and the physical and psychological impact of MS from the patient's perspective as measured by the Multiple Sclerosis Impact Scale (MSIS-29)<sup>29</sup>.

Participants were asked to repeat the online patient-reported outcome measures, plus a modified Patients' Global Impression of Change (PGIC)<sup>30</sup>, 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 practice<sup>16</sup>. Underpinned by both self-regulation theory and social cognitive theory<sup>11,17</sup>, 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<sup>18–21</sup>.

**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 delivery<sup>15</sup>. 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 retention<sup>31</sup> (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'<sup>32</sup>.

**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 course<sup>33</sup>. 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 relevant<sup>34</sup> 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 change<sup>15</sup> 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)<sup>23</sup>. Modifications were required to enable entirely remote delivery<sup>22</sup>. 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 MS<sup>35</sup>. 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.

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

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**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

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Figure 1. Study Flow Chart.



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

| Demographic characteristics                         | ( <b>n</b> ) | n (%) or Mean (SD)                    |
|---|--------------|---------------------------------------|
| Age (years) <sup>a</sup>                            | 21           | 60.9 (9.2)                            |
| Gender at birth (Females: Males)                    | 21           | 15:6 (% female 71.4)                  |
| Ethnicity   | 21           |                                       |
| Welsh/English / Scottish / Northern Irish / British |              | 20 (95,2%)                            |
| Any other White background (White European)         |              | 1 (4.8%)                              |
| Household   | 21           |                                       |
| 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 <sup>a</sup>      | 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   |    | 0                              |
|--|----|--------------------------------|
| Solifenacin  |    | 2 (9.5%)                       |
| Amitriptyline                                      |    | 2 (9.5%)                       |
| Duloxetine   |    | 1 (4.8%)                       |
| Carmabazepine                                      |    | 0                              |
| Beta-Interferon                                    |    | 1 (4.8%)                       |
|  |    |                                |
| 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                           |    | 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%)                        |
| 7.0 (Unable to walk beyond approximately 5m        |    |                                |
| 7.0 (Onable to wark beyond approximately 5m        |    | 5 (25%)                        |
| 7.5 (Unable to take more than a few steps          |    |                                |
| Restricted to wheelchair)                          |    | 4(20%)                         |
| MSIS 20  | 21 | + (2070)                       |
|  | 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         | 49 additional consultations out of a (out of total 105 possible) |
|  |  |
| Frequency and duration of remote physiotherapist       | 57 out of the total 69 consultations                             |
| contacts recorded.                                     | consultation lasted 42 minutes                                   |
| Total number of times (mean (SD)) a user logged in on  | 71 (140)   |
| the system   |  |
| Website log in rates: Number of logins (mean (SD))     | 3 (5)  |
| per month  |  |
| Website log in rates: Total time (mean (SD)) (minutes) | 83 (152)   |
| spent using the LEAP-MS website                        |  |
| Website log in rates: Average time (minutes) spent per | 2 (3)  |
| log in   |  |
| Website log in rates: Longest (mean (SD)) log in       | 16 (30)  |
| session (minutes)                                      |  |
| Website log in rates: Length of time between each log  | 9 (10)   |
| in episode (days)                                      |  |

|               |    | D 1'        |              | <b>C</b> ' 1 |                            | OF AL OT      |
|---------------|----|-------------|--------------|--------------|----------------------------|---------------|
|               | 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                 |               |
|               |    |             |              |              | $\infty$ improvement       |               |
| MSIS-29       | 16 | 45.2 (15.2) | 37.3 (13.7)  | 41.1 (15.3)  | $-12.6$ 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 $0.2^{\infty}$     | -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 <sup>∞</sup>   | -5.2 to 0.7   |
| Physical      |    |             |              |              |                            |               |
| MFIS          | 16 | 15.4 (8.2)  | 13.3 (7.4)   | 12.4 (8.0)   | -4.1 to $1.3^{\infty}$     | -4.5 to -1.5  |
| Cognitive     |    |             |              |              |                            |               |
| MFIS          | 16 | 3.8 (2.0)   | 2.9 (1.4)    | 3.3 (1.6)    | $-1.6$ to $0.4^{\infty}$   | -1.5 to 0.6   |
| Psychological |    |             |              |              |                            |               |
| MFIS Total    | 16 | 41.9 (16.1) | 36.8 (11.8)  | 36.1 (14.1)  | -8.9 to $1.6^{\infty}$     | -10.2 to -1.3 |
| UW-SES-SF     | 16 | 43.1 (9.5)  | 46.4 (8.7)   | 47.8 (9.1)   | $-0.8$ to $7.3^{\infty}$   | 0.2 to 9.2    |
|               |    |             |              |              |                            |               |
| OxPAQ         | 16 | 45.1 (20.9) | 42.7 (19.5)  | 44.2 (21.4)  | -9.6 to 4.9 <sup>∞</sup>   | -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 $1.4^{\infty}$    | -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 $10.2^{\infty}$ | -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 $0.1^{\circ}$     | -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) ( $\infty$  = 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<br>and reaffirming<br>consent | Explanation of and<br>introduction to the<br>LEAP-MS study | Demonstration<br>(where required) of<br>the LEAP-MS<br>platform and its<br>key functions | Evidence of self-<br>management<br>approach taken to<br>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  |
| <b>Reflection</b> *  | 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  |
| <b>Overall Score</b> | 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.