Impact of a tele-rehabilitation program on people with multiple sclerosis: Multicenter, randomized, clinical study.

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1. Introduction

Multiple sclerosis (MS) is an autoimmune disease of the central nervous system that is the leading non-traumatic cause of disability in young adults. It affects women two to three times more than men and presents with heterogeneous clinical manifestations, depending on the neurological areas involved, which complicates its management and requires individualized treatments and specialized care (1). Access to conventional rehabilitation is limited by multiple factors, such as the early onset of the disease during productive stages, the difficulty of balancing work and family life, limited mobility, lack of transportation, and the geographical dispersion of healthcare centers (2). These conditions, together with functional and social barriers, negatively affect therapeutic adherence.

Given this situation, home-based telerehabilitation (HBR) has emerged as an effective alternative, allowing remote monitoring of patients and eliminating physical, logistical, and geographical obstacles, while also providing support to caregivers (3,4).

According to the WHO, HRDT improves access to health services, allowing for a more personalized approach (5-8). It is not intended to replace face-to-face rehabilitation, but rather to complement it, being especially useful in patients with lesser disabilities, as it enhances treatment and promotes preventive activities through the use of advanced technologies (3,6,9).

TRHB has proven effective in patients with acquired brain damage, improving functionality, mobility, and therapeutic acceptance (10,11). In MS, although more evidence is needed, preliminary studies indicate benefits in gait, balance, and cognitive functions such as memory and language (12).

The present study aims to evaluate the impact of a TRHB program in people with MS.

2. Objectives

2.1 Main objective

- To assess the safety and occurrence of adverse effects during the TRHB program.

2.2 Secondary objectives

- To assess the level of adherence to the TRHB program.

- To determine the impact of a telerehabilitation program on the level of physical activity and self-efficacy regarding exercise in patients with multiple sclerosis.

- Observe the impact on levels of anxiety, depression, and fatigue.

- Observe the impact on health-related quality of life.

• Evaluate the effectiveness of the TRHB intervention in terms of walking speed and balance.

• Assess the degree of satisfaction of the participants.

3. Methodology

3.1 Study design

This is a single-blind, randomized clinical study with a control group.

• Intervention group: I conducted 24 tele-rehabilitation sessions (S24) three times a week using the platform for 8 weeks.

• Control group: received a guide with general recommendations on physical activity.

3.2 Inclusion criteria

• Diagnosis of multiple sclerosis confirmed according to the 2017 McDonald criteria.

• Availability of technological means to conduct the sessions online (computer, laptop, or tablet compatible with the Rehub-DyCare® platform).

• Cognitive ability to understand and sign the informed consent form, and functional autonomy to perform the intervention.

• EDSS score equal to or less than 6.5.

3.3 Exclusion criteria

• Participation in an active rehabilitation program at the time of starting the intervention.

• Having undergone rehabilitation in the two months prior to the start of the study.

• Presence of physical or psychological comorbidities that interfere with participation in the program.

3.4 Selection of participants

The invitation to participate was sent via email to people with multiple sclerosis (MS) registered in the Multiple Sclerosis Foundation (FEM) database who had authorized contact. Subsequently, individual telephone contact was made

to provide further information and confirm interest in participating. In addition, some patients were invited from the outpatient clinics of the participating centers.

Participant recruitment was carried out in strict chronological order of response to the survey and/or invitation

from the outpatient clinics. Participants came from the FEM rehabilitation centers – CEMCAT (Barcelona), FEM Lleida, and FEM Reus. Those who agree to participate receive detailed information about the study verbally and in writing, and are asked to sign an informed consent form (ICF), in accordance with current regulations.

Once the informed consent form has been signed, each patient is randomly assigned to the intervention or control group, without the evaluator knowing the assignment.

The evaluations are carried out at three points in time:

- T1: Initial evaluation, before starting the intervention.

- T2: Intermediate evaluation, at the end of the intervention (8 weeks after T1).

- T3: Final evaluation, 8 weeks after T2 (follow-up phase).

The evaluations were performed by physical therapists specializing in MS, blinded to the assigned intervention group, at the following centers: CEMCAT (n=64), FEM Lleida (n=5), and FEM Reus (n=6).

3.5 Randomization and masking

After signing the informed consent form, participants were randomized using a block randomization system, with assignment by sealed envelopes. In this way, only they and the physical therapist in charge of the intervention knew which group they had been assigned to,

thus ensuring the blinding of the evaluators.

3.6 Intervention

TRHB was carried out from each patient's home using the ReHub platform from DyCare (Spain). The program included 24 rehabilitation sessions, distributed over 3 sessions per week for 8 weeks. Although it was recommended that they be carried out on Mondays, Wednesdays, and Fridays,

participants were able to adjust the days according to their convenience.

The objective of the sessions was to work on strength, mobility, proprioception, and balance, adapting the intensity in a personalized way. Follow-up was performed every two weeks, with additional supervision in the first week to correctly calibrate the initial load. In each session, perceived pain was assessed using the VAS scale and fatigue level using the Modified Borg scale, seeking to maintain the perceived effort between 6 and 7 points. The platform includes more than 2,000 exercises, from which an initial exercise itinerary was constructed and subsequently adapted to each patient according to their level of resistance. Throughout the intervention, the load and variety of exercises were progressively adjusted. The progressive increase in load in the

intervention group was achieved by increasing the number of sets and/or repetitions, decreasing the recovery time, or increasing the number of exercises in the session, depending on each individual's abilities.

3.6.1 Intervention group (IG):

- Received a guide on how to use the ReHub platform at T1.

- Performed 24S of personalized TRHB for 8 weeks, with follow-up every two weeks by the therapist.

- In T2, a guide with recommendations is provided to continue physical activity independently without support from the platform.

- Follow-up after each session to adapt the workload and monitor possible incidents (between T1-T2).

3.6.2 Control group (CG):

- Received a guide with recommendations for physical activity in T1.

- Does not participate in structured sessions; only follows their usual daily activities.

- In T2, the importance of continuing with physical activity is reinforced.

4. Statistical analysis

For the description of demographic variables, measures of central tendency were used. Depending on the type of variable, the mean and standard deviation were used, as well as the median and range.

To compare two means, the Kolmogorov-Smirnov test was used to check the normality of the different variables. Descriptive statistics of frequencies and percentages were calculated for the qualitative variables, and the mean and dispersion for the quantitative variables for each of the two groups. The sociodemographic and clinical variables and the level of PA were compared between the control and intervention groups using a $\chi 2$ test for

qualitative variables and a Student's t-test for quantitative variables that are normally distributed or a Mann-Whitney U test if they are not.