STUDY PROTOCOL

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Research title: Using one App as a guide to lumbopelvic stability exercises in patients with chronic stroke: a pilot study of a randomized clinical trial

1. Glossary of acronyms

QoL: Quality of Life

App: Mobile application

ADL: Activities of Daily Living

2. Introduction:

Stroke continues to be one of the leading causes of death and disability in the Spanish adult population, with the presentation of various sequelae, such as impaired mobility and a consequent reduction in Quality of Life (QoL). These sequelae, which can be chronic, generate significant spending and a saturation of social and health services. With the growth in the number of cases, the development of new rehabilitation approaches and updating to the current social context becomes pertinent, such as the incorporation of telerehabilitation to assist individuals who have suffered a stroke.

3. Background and current status of the topic:

Stroke, defined by the World Health Organization as the rapid development of clinical signs of local or global disturbance of brain function, for more than 24 hours or leading to death, without any other apparent cause than vascular origin, it is the most well-known and frequent cerebrovascular disease in the adult population (1). In Spain, according to data from the National Statistics Institute, death in adults from cerebrovascular disease continues to be one of the leading causes of death in our country, with about 30% of cases (2) .

Stroke is also one of the leading causes of disability in the adult population, generating a significant expense and saturation of social and health services, both in the acute and chronic phase, since its symptoms are usually permanent to a greater or lesser extent. degree. Among these symptoms one can find language disorders or cognitive alterations, but the most common is the sensory-motor alteration of the half of the body opposite to the brain injury(3) . These alterations lead to a significant reduction in QoL since they provide the patient with great disabilities in different areas of their life. In 2013,

Schmid et al. Associated the balance deficit and the risk of falls with a low QoL level in patients with stroke in its chronic phase (4) .

Faced with the possible sequelae of stroke, survivors often attend neurorehabilitation programs in which physical therapy, psychology, speech therapy, among others, depending on the needs of the individual, participate. In relation to sensory and motor rehabilitation, which is usually the responsibility of physiotherapy, one of the fundamental therapeutic objectives is to achieve optimal trunk control and sitting balance since it is known that the low performance of the trunk musculature, specifically its delayed and asynchronous activation due to the resulting hemiparesis, is associated with poor postural balance and gait instability (5) . Known studies support the idea that trunk stability plays a critical role in maintaining balance both in sitting and standing, functional mobility, gait, and increased QoL in individuals with stroke (6,7,8).

Being aware of the growth in the number of cases, the impact on the health of individuals and their resulting disability, it would be advisable to study and develop new effective means to respond to the growing demand for individuals with stroke, such as the use of digital technologies for therapeutic exercises to intensify rehabilitation even at home. Its use can facilitate access to information and guidelines for rehabilitative treatment by patients and their families or caregivers, provide greater intensity to therapies and increase the involvement of individuals in the rehabilitation process. On the other hand, it would also allow continuous therapeutic follow-up without the need for displacement and the perpetuation of the rehabilitation of permanent sequelae and their secondary sequelae. With this vision and knowing that the use of electronic and digital devices, such as the smartphone or tablet, is becoming more frequent, it is hoped that these will be considered as a possible therapeutic resource.

From this concept telerehabilitation arises, as a rehabilitation method in which professionals use telecommunications devices to provide intervention, assessment and support strategies for disabled people who are at home. This is a feasible method and has the advantages of providing flexibility of time and space, reducing inequality in medical care, improving the quality of care, and reducing costs in human resources, transportation, and facilities (9) . In the market you can find mobile applications (App) for neurorehabilitation such as language rehabilitation, cognitive disorders and incentives for physical activity. However, these apps are usually incomplete and depersonalized, and

their results compared to conventional therapies in a clinical setting are inconclusive (10) . In a current systematic review, published in 2018, no App has been found that contemplates personalized functional physical rehabilitation for individuals with Stroke (11) . For this reason, it is convenient to find an App that contemplates motor rehabilitation customized to the abilities of users with Stroke.

The idea of introducing telerehabilitation in the physiotherapy services of care for chronic patients, has the intention of improving health care services and optimizing human resources while promoting the rehabilitation process of the sequelae of individuals. Apart from the continuous contact channel between medical personnel and users and means of monitoring clinical evolution, it becomes pertinent to study this type of digital tools as a means of personalized prescription of therapeutic exercise for the home, especially in chronic situations that saturate rehabilitation services. This research study will provide information on the effectiveness of using an App as a means of personalized prescription of therapeutic exercises to be carried out at home, especially lumbopelvic stabilization exercises whose evidence is known. Thus, it is expected to study the level of adherence to telerehabilitation by individuals with stroke in its chronic phase, along with analyzing clinical results related to balance and its influence on participation in Activities of Daily Living (ADL) and QoL.

4. Objectives:

This project has the following proposed objectives:

- To analyze the adherence to the treatment of the App
- To evaluate the effectiveness of an intervention of lumbopelvic stability exercises performed at home, through the use of an App, compared to usual therapy.

5. Hypothesis:

The hypothesis of the present study project is: to. The use of an App, adapted to the abilities and needs of individuals with stroke, improves adherence to its use for carrying out specific therapeutic exercises. b. Muscular stability exercises of the lumbopelvic area performed at home monitored by means of an App improve the

perception of the QoL of individuals who have suffered a stroke in the chronic phase of their evolution compared to the usual follow-up of this type of individuals. c. Muscular stability exercises of the lumbopelvic area performed at home monitored by an App increase the functionality and participation in the ADL of individuals who have suffered a stroke in the chronic phase of their evolution compared to the usual follow-up of this type of individuals. d. Muscular stability exercises of the lumbopelvic area performed at home monitored by an App improve the balance in sitting and standing and reduce the number of falls of individuals who have suffered a stroke in the chronic phase of their evolution compared to the usual monitoring of this type of individuals. and. Muscular stability exercises of the lumbopelvic area performed at home monitored by means of an App improve the gait of individuals who have suffered a stroke in the chronic phase of their evolution compared to the usual follow-up of this type of individuals.

6. Material and methods:

For this study, the Farmalarm App of the Inmovens group - Vall d´Hebrón Hospital will be used, adapted and updated by the main researchers of this study. The App will have the “rehabilitation” option where the user can consult the description of the exercise and view a demonstration video so that it can be carried out correctly at home, independently or with the help of a third person. The researchers will be responsible for The researcher of this study will also be registered as administrator of the App with permission to create users, contact them directly through chat or video-call and personalize the exercise program for each user. On the other hand, they will also have permission to consult the use data of the App by users. The App will also contemplate the option of confirming the completion of each proposed exercise and a small survey related to the effort used to complete it. The data obtained from these options will facilitate the customization of the exercise program.

The exercises that will be carried out with the App, in this study phase (Table 1), are described in previous works by the author Rosa Cabanas and colobradores (6). All possible exercises (description and demonstration video) will be included in the administration platform of the App and according to the capabilities of each user, the prescription of some exercises or others will be made, respecting their progression. In this

way, the aim is to personalize the therapeutic exercise program for each user, as well as modify the number of repetitions suggested and add facilitating or hindering suggestions to the same exercise.

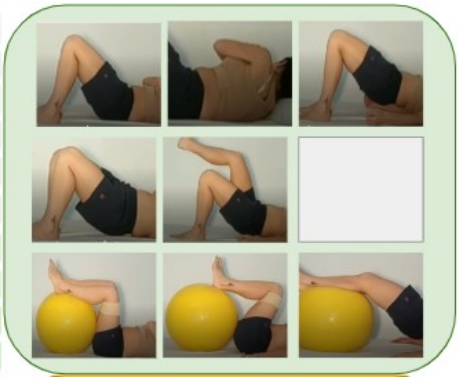
Supino	Báscula pélvica antero-posterior Rotación de tronco superior Puente pélvica Puente con movimiento lateral Puente unilateral derecho Puente unilateral izquierdo Rotación del tronco inferior Flexión y extensión de rodillas Puente en pelota unilateral derecha Puente en pelota unilateral izquierda	
Sedestación	Báscula pélvica antero-posterior Rotación de tronco superior Báscula pélvica medio-lateral Rotación tronco inferior Flexión lateral del tronco Alcance anterior Alcance lateral derecho Alcance diagonal derecho Alcance lateral izquierdo Alcance diagonal izquierdo	
Sedestación en pelota	Báscula pélvica antero-posterior Rotación de tronco superior Báscula pélvica medio-lateral Rotación tronco inferior Flexión lateral del tronco Alcance anterior Alcance lateral derecho Alcance diagonal derecho Alcance lateral izquierdo Alcance diagonal izquierdo	

Table 1: Stability exercises of the lumbopelvic region

In this simple blind randomized controlled pilot study, participants will be recruited from users of the rehabilitation center where the study will be carried out (Neurorehabilitation Clinic - Sant Cugat del Vallés). To carry out this study, there is already an agreement signed between the Neurorehabilitation Clinic and the International University of Catalonia.

The following participation criteria have been defined for this pilot study Inclusion criteria:

• Medical diagnosis of stroke with cortical or subcortical, ischemic or hemorrhagic involvement with more than 6 months of evolution

• Clinical symptoms of hemiplegia or hemiparesis

• Over 18 years of age

• Ability to understand and execute simple instructions

• Score equal to or less than 10 in the Spanish version of the Trunk Impairment Scale 2.0

• Be a frequent user of smartphone or tablet. Failing this, the direct family member / caregiver is considered.

Exclusion criteria:

• Appearance of any disease or aggravation of any of the comorbidities that the patient presents that prevents rehabilitation (example: dialysis)

• Suffer a second episode of Stroke.

• Fractures in any of the lower extremities or important structural alterations in the trunk.

• Death

30 participants will be recruited. No sample calculation will be performed as it is a convenience sample for a pilot study and it is a value very close to the total number of users with Strokes of the center where the study will be carried out. Another limiting factor of the sample is that the users will be monitored daily or weekly by an investigator assuming a ratio of 30 users / 1 therapist. In the recruitment process, patients will be informed about the study, they will be asked to sign an informed consent and the randomization between the experimental group and the control group will be done by computerized lottery and with the following interventions:

Experimental Group: Use of App for the daily performance (Monday to Friday) of lumbopelvic stability exercises (Table 1) apart from the usual physiotherapy treatment for 3 months.

Control Group: Regular physical therapy treatment.

The information on the usual physiotherapy treatment will be collected together with the variables to be studied. At the end of the study, the description of the usual treatment, neuromotor development treatment, will be disclosed, which usually includes techniques for modulating the muscle tone of the affected body, postural control exercises, facilitation of functional movement and practice of tasks including walking.

To guarantee the blinding characteristic, the evaluations will be carried out by a third non-investigating person. The following variables will be studied through selected tests and questionnaires:

• Adherence to the use of the App by individuals from the EG: Data extracted by the administration panel of the App and System Usability Scale. Optimal use (100%) is considered 5 days / week, that is, a use from 0 to 20 days in 12 weeks months will be considered low adherence (0-33%), from 21 to 40 days (33-66%) regular adherence and 41 to 60 days (66-100% :) good adherence.

• QoL: EuroQol 5 dimensions 5 levels.

• Participation in AVD: Barthel Index.

• Functionality: Rankin scale.

• Sitting balance: Spanish versions of the Trunk Impairment Scale 2.0 and Function in Sitting Test.

• Standing balance: Spanish version of the Postural Assessment Scale for Stroke Patients, Berg Scale

• Record of the number of falls.

• Gait: stepping section of the Brunel Balance Assessment test and if they reach a score of 6 they will be evaluated with the G-Walk accelerometer (duration of double and individual support, cadence of the step, gait speed, stride length, length of step and elaborate steps).

For statistical analysis, all subjects will be included, regardless of subsequent events such as protocol violations, lost data, or loss to follow-up. Qualitative and quantitative descriptive statistics will be used to characterize the sample depending on categorical (eg.: sex) or numerical (eg.: age) variables. In the analysis of results, the missing data will be imputed applying the imputation criterion of the last observation made. The distribution of the sample will be calculated according to the Shapiro-Wilk test and parametric and / or non-parametric tests will be used to calculate the significance of the results. The significance level (p) will be 0.05, that is, a confidence level of 95% and 5% of acceptable error. For the purpose of this study, it is proposed to analyze the difference between means and standard deviations of the variables both at the initial time and at 6 and 12 weeks. Its statistical significance will be calculated by the Student's t test or the Mann-Whitney U test for paired data. For the analysis of the effectiveness of the interventions, the evolution obtained in the different groups will be compared with the same statistical tests for independent samples. To assess the correlation between variables, the calculation of Pearson's coefficient and / or Spearman's coefficient will be used.

7. Analysis of results:

According to the existing literature, performing muscle exercises for lumbopelvic stabilization leads to improvements in the balance in sitting, standing and gait in individuals with stroke. These results can be translated into the increase in participation in the ADL and the increase in the CV, factors to be taken into account in these individuals since their sequelae are usually highly limiting and chronic.

Usually, individuals who have suffered a stroke receive rehabilitation, by different disciplines where we find physiotherapy, according to their conditions and needs and with the common objective of achieving the maximum level of autonomy. Knowing that stroke patients can present chronic sequelae, their rehabilitation is perpetuated over time. It is thought that the use of an App can provide continuity to rehabilitation in its chronic phase, monitor and accompany the clinical evolution of the patient by the therapist. On the other hand, one can think that perhaps it is a method that allows reducing the resources, expenses in transfers and occupation of the rehabilitation center by chronic users.

The App will provide specific guidelines for carrying out lumbo-pelvic stabilization exercises and the possibility of viewing demonstration videos, with this it is intended to facilitate and encourage the performance of muscle exercises by the patient independently or with the help of a family member or caregiver. On the other hand, the patient will find a means that allows him to be in direct contact with the therapist in case of doubts about his rehabilitation process, as well as the therapist can contact the patient to monitor and follow up. In case of observing high levels of adherence to the use of the App as well as better results compared to conventional therapy, the use of the App as a new tool in neurorehabilitation can be considered. Even if chronicity leads us to think about maintaining physical condition, it is planned to find better results among individuals who will use the App as a therapeutic accompaniment for autonomous performance of muscle exercises for lumbopelvic stabilization adjacent to regular physical therapy.

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