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MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTER STUDY

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ABSTRACT

Introduction

Stroke survivors usually experience long-lasting functional, emotional, and social consequences that might contribute to sedentary behaviour and participation restrictions, which are important targets to address during rehabilitation. However, the trajectory and inter-relationship between these factors is unknown.

Methods and analysis

Part&Sed is a research project based on an observational study design with 6- and 12-months follow-up in stroke survivors. In addition, a qualitative analysis of the impact of the stroke on the person who has suffered it, validation of the Satisfaction with Daily Occupation-Occupational Balance assessment tool, and analysis of the reliability of the Fitbit Inspire 2 activity tracker wristband will be carried out. Participants will be chronic stroke survivors with independent walking capacity. Sociodemographic and clinical data, physical activity, ambulation, sleep, quality of life, anxiety and depression, community participation, and occupational satisfaction and balance, as well as data provided by the activity tracker wristband, will be collected. In addition, if the participant has a primary caregiver, the caregiver will also be monitored. A priori sample of 130 participants will be required to perform a random-effects multiple regression model. Mixed models for repeated measures will assess the variation over time of the different variables associated with participation and sedentary behaviour. Psychometrics properties (e.g., internal consistency, construct validity, test-retest reliability) of the Satisfaction with Daily Occupation-Occupational Balance will be determined. Additionally, intraclass correlation coefficients and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2. The qualitative analysis process will be carried out using the analysis proposed by Giorgi.

Ethics and dissemination

The study received ethical approval from the regional Research Ethics Committee (PI21/333). The results will be made available via peer-reviewed publications, international conferences, and official channels.

Strengths and limitations of this study

- This large prospective multicentre project examines the multifactorial interaction between physical activity and participation dimensions in Spanish stroke survivors.
- Training sessions on the procedures and administration of the evaluation tools will be conducted to minimize inter-rater variability.
- A novel method for assessing physical activity and sleep parameters in stroke survivors will be explored.
- Stroke survivors with aphasia, no technological knowledge or those living in nursing homes and hospital settings will not be included.
- Physical activity is being monitored by wrist-worn devices which are known to have limitations.

Key Words:

Epidemiological Study, Stroke, Physical Activity, Fitness Trackers, Community Participation, Occupational Participation.

INTRODUCTION

Stroke has an annual global incidence of 12.2 million, being the second leading cause of death in developed countries.[1 2] There is an estimated prevalence of 143 million people living with post-stroke disability, thus becoming the third leading cause of disability worldwide and representing the main need for neurorehabilitation.[3] In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.[1] Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations[4], as well as restrictions in participation in self-care, work, leisure and free time, and social activities.[5-8] Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.[9]

Participation is defined by the International Classification of Functioning, Disability and Health (ICF) as "a person's involvement in life situations" and is the product of an interaction between the individual's health condition and contextual factors.[10] Therefore, participation comprehends meaningful activities performed by individuals in their real environment (e.g., family, or community) that occupy time and that give meaning and purpose to their life.[11] Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.[12 13]

Physical inactivity and sedentary behaviour, are one of the main lifestyle-related risk factors for stroke recurrence.[14] Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)[15] and endorsed by the American Heart Association Council (AHAC)[16]. These recommendations consist of achieving 150 min of moderate-to-vigorous-intensity physical activity per week or 75 min of vigorous-intensity physical activity per week.[17] On the other hand, sedentary behaviour is defined as any waking

behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents (METs), while sitting, reclining, or lying.[18] If the sedentary behaviour is maintained throughout the day or week while being awake, it can be classified as a Sedentary Behaviour Pattern.[19] Adult populations who comply with the physical activity WHO recommendations show a lower risk of death and developing noncommunicable diseases.[20] However, stroke survivors often report sedentary behaviour most of the day, especially in the afternoon and evening.[21] Additionally, the average number of sleep hours is much higher in stroke survivors than in the healthy population, which is associated with cardiovascular morbidity and mortality.[22]

Regarding the factors that contribute to sedentary lifestyles in the stroke population, it has been observed that inpatient stroke survivors in rehabilitation centres are more sedentary.[23 24] However, those living in the community still do not meet a healthy level of physical activity .[25] On the other hand, the fear of falling is associated with sedentary lifestyles,[26 27] to the extent that stroke survivors reduce activities involving standing or walking by 20% on average.[28] In turn, the intensity and frequency of rehabilitation treatment,[23 29] the place of residence and characteristics of the community,[25] social support,[23] years after stroke,[30] initial stroke severity,[31 32] type of hemiparesis, greater cognition,[32-34] better endurance and gait speed,[32-35] are further examples of contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety, depression, and self-efficacy, can play a role.[36 37] This ensemble of factors warrants studies analysing multifactorial relationships and to establish a firm consensus on policies for dealing with the rehabilitation of stroke survivors.

Systematic reviews show that post-stroke interventions do not impact community participation until several years after stroke[38] and that the identification of barriers is key.[39] However, despite the limited evidence regarding the factors that influence participation[30], having an extensive social network he ability to walk for a few hundred

meters or drive are potential facilitators[8]. Additionally, improvements in physical functioning do not necessarily translate into improved participation in work, domestic, social and leisure activities. [40 41] This could be why stroke survivors feel unsatisfied about not recovering pre-stroke participation levels in relevant activities, which may be due to their environment, age, acceptance of the new situation, or degree of affectation;[42] as well as due to the presence of comorbidities related to cognitive impairment and depressive states.[43]

Therefore, aiming at emphasizing social reintegration as a long-term goal,[44] several studies highlight the need to consider other under-investigated factors, such as the influence of the primary caregiver and the family environment;[36] environmental factors such as climate and daylight hours;[33] or the impact of treatments focusing on health education[45] and the person-centred model.[2]

PART&SED-STROKE PROJECT JUSTIFICATION

The stroke population in Europe, Australia, Canada, and the United States is known to have high levels of sedentary lifestyles.[21 25 31 32 46-50] However, there is no solid information about the Spanish population, which would allow the development, as recommended by the WHO, of a specific public health plan for the stroke survivors in Spain. For this reason, longitudinal studies are needed to determine the evolution of the level of physical activity after stroke.[44 46]

The assessment tools included in the present protocol have been selected based on the 2018 Cochrane review authored by Lynch et al.,[51] and by the recommendations of Kwakkel et al.,[52] and its updates in a 2020 Delphi study.[53] Additionally, other reliable assessment tools are needed to ascertain the amount of sedentary time, assess its effect on health, and identify significant predictors of physical activity levels.[14] In this sense, devices with high potential have already been identified at the scientific level,[54 55] and it

is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate monitoring.[56] However, more studies are needed to analyse the potential of new wearable devices to record this physical activity and measure adherence and compliance with physical activity recommendations in the stroke population[57], as well as to assess their suitability and ease of use in the clinical setting by professionals and patients. Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting the recovery of participatory life after stroke, it is relevant that clinicians have validated assessment tools for the stroke population on occupational satisfaction.

The current protocol has also included the Activity Card Sort (ACS), recommended in systematic reviews for the ICF domains of activity and participation in the stroke population.[58 59] Finally, following the recommendations of other studies, other factors such as personal, sociodemographic, and psychological factors that may have an impact on mobility in the community have been considered.[33]

Considering that the current goal of neurorehabilitation is to design and personalize physical activity programs according to the ability, goals, and preferences of the stroke survivor, as well as to encourage long-term lifestyle habits,[60] it is warranted to conduct longitudinal studies investigating the trajectory and the interrelationship between sedentary behaviour and participation in stroke survivors.

Objectives

1. To multidimensionally explore the factors associated with participation and sedentary behaviour in the Spanish stroke survivors.
2. To investigate the influence of sedentary behaviour and individual characteristics of the primary caregiver on the participation and sedentary lifestyle of the Spanish stroke survivors.

3. To analyse the natural fluctuation of participation, sedentary behaviour and associated factors over 12 months in the Spanish stroke survivors.
4. To validate and establish the psychometric properties of the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB) assessment scale for the Spanish stroke survivors.
5. To determine the intra-subject reliability values in the short (1 week) and medium-term (6 months) of the Fitbit Inspire 2 activity tracker wristband and evaluate the construct validity of monitoring physical activity and sleep quality using Fitbit Inspire 2 activity tracker wristband versus the scores obtained in the IPAQ-SF and MOS-Sleep self-reported questionnaires in Spanish stroke survivors.
6. To qualitatively analyse the lived experience of Spanish stroke survivors in terms of barriers and facilitators for the return to physical activity and participation in occupational living, along with the knowledge needed to achieve it.

METHODS

Study design

The present protocol complies with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) recommendations,[61] the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),[62] the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),[63] and the COnsolidated criteria for reporting qualitative studies (COREQ),[64] and the Standards for Reporting Qualitative Research (SRQR).[65]

This study protocol will follow a prospective design with a follow-up of 12 months (figure 1), in which several centres distributed throughout Spain will participate (online supplemental material 1). Specifically, a cross-sectional design will be used to assess factors associated with sedentary behaviours and participation levels in stroke survivors,

including the influence of the primary caregiver. The validation and establishment of the psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will be performed. Additionally, a prospective cohort design will be used to assess the evolution of sedentary and participation behaviours in stroke survivors over time, identifying those factors that may contribute to a modification of these behaviours. Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time frame in which to appreciate meaningful changes. Finally, the life experience of stroke survivors will be investigated through unstructured in-depth interviews and semi-structured interviews, which will be analysed by means of a descriptive phenomenological approach.

Population

The study sample will consist of people who have suffered a stroke and reside in Spain. The inclusion criteria will consist of 1) be over 18 years of age; 2) have a history of stroke with a medical diagnosis for more than 6-months, regardless of its aetiology; 3) outpatient living at home; 4) have cognitive and speech ability to perform and understand the tests to be administered and the purpose of the research project (i.e., no aphasia and a Mini-Mental Cognitive Test score >24;[66]) 5) be able to ambulate with or without aids, which represent an ambulation ability ≥ 3 in the Functional Ambulatory Category[67] *[not applicable for SDO-OB validation]; 6) minimum knowledge and availability of a mobile phone; and 7) accept informed consent. The exclusion criteria will be 1) non-acceptance of participation in the research project by the primary caregiver; 2) not tolerating being monitored with an activity tracker wristband; 3) residing in institutions (e.g., nursing homes); and 4) no commitment to continuity. Missing evaluation sessions, existing a personal or family situation that interferes with data collection, and willingness to discontinue the study were considered withdrawal criteria.

If the stroke survivor has a primary caregiver, the primary caregiver will be invited to participate in the study. A primary caregiver is defined as a person, either a family member or an employee, who spends more than half of their daily time supporting or caring for the stroke survivor.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Contact and recruitment

Centres and Health professionals

The collaborators will be composed of health professionals (physiotherapists and occupational therapists) working in institutions, centres, and associations, as well as self-employed professionals, whose field of action is focused on the neurological rehabilitation of stroke survivors. Specifically, in a first phase, contact will be established via email or telephone with professionals who form part of the research team's network. While in a second phase, general information about the research study will be disseminated through social networks (i.e., Twitter and LinkedIn) to increase the number of potential organizations and professionals collaborating. These collaborators will meet the conditions of residing in different parts of Spain, having extensive experience in neurological rehabilitation, and currently providing care to stroke survivors.

All those who will show interest in the study will receive a document that includes information on the objective of the study, criteria for the selection of the sample, functions to be carried out that would imply their commitment to participate and a timetable for data collection. If there is continued interest in participating, a first meeting will be held to provide further information and resolve doubts. After this meeting, the centres and

professionals will express their willingness to participate or not. Each participating centre must sign the collaboration agreement and each professional belonging to these centres must accept the document of commitment to participate in the research. These documents will regulate the anonymized transfer of the data collected for the exclusive use of the research, as well as the commitments and functions of the institutions and professionals involved.

All participating centres will be included in the database to begin the process of homogenizing data collection through videoconference meetings and training sessions. With the aim of facilitating access to information on the study, a secure shared folder has been created in a virtual space containing documents on the study, information sheets for participants, consents, collaboration documents, and manuals of procedures to be followed. In addition, the research team will provide and send a minimum of 2 Fitbit Inspire-2 monitoring wristbands to each collaborating centre.

Stroke survivor participants and primary caregivers

The recruitment process of participants (stroke survivors and their respective caregivers) will be carried out in two phases. Firstly, each of the collaborating centres will be responsible for promoting the existence of the study through their usual internal channels of communication with their users, such as posters, information circulars, and posts on social networks. Each potential participant will be given an information sheet about the research project, and any questions they may have regarding the development of the research project and their participation in it will be answered.

Secondly, those users who voluntarily agree to participate in the study will be assessed by healthcare professionals (occupational therapists and physiotherapists) with training and clinical experience in neurorehabilitation to corroborate compliance with the eligibility criteria. Those who meet the selection criteria will be selected as potential

participants and will be asked to sign the informed consent for inclusion in the study. Once the informed consent is signed, they will be assigned an appointment for the first assessment session within approximately one week. The assessment sessions will be conducted by the same assessors at each centre.

Data collection and security measures

Each collaborator will be responsible for collecting part of the data for participants from their centres. The collection of all the data will be supervised and coordinated by the research team, and the principal investigator will be in direct contact with each collaborator to assist with solving any problems that may arise.

In order to maintain security in the process of collecting data from each participant: 1) each collaborator will be assigned an account and password to access the P4Work application where the data collected from each participant in the study is recorded;[68] and 2) each collaborator will be provided with accounts and passwords that must be assigned to each participant (stroke survivor and their main caregiver) to use the Fitbit application.

Only the collaborators at each centre will know the identity of each participant recruited at their centre. In such a way that the data collected from each participant that the research team will have access to will be assigned to an encrypted and anonymized identity in both the Fitbit and P4Work applications.

Outcome measures

Sociodemographic data

Sociodemographic data will include age, sex, smoker, educational level, economic level, employment status, height and weight, municipality, type of housing, presence of architectural barriers, and home cohabitation.

Clinical data

Clinical data will include information such as age at the time of stroke, type of stroke, damaged cerebral hemisphere, time of evolution, pain experience, other pathologies, current medication, current rehabilitation and hours per week, number of falls in the last six months, use of assistive devices, the Barthel Index,[69] the Fall Efficacy Scale (FES-I),[70] and the modified Rankin scale.[71]

Self-reported physical activity

Self-reported physical activity will be evaluated with the short version of the International Physical Activity Questionnaire (IPAQ-SF). The IPAQ-SF is a self-report scale that aims to determine the level of physical activity in the current period (last seven days) and the time spent sitting down. The final score categorizes physical activity levels into low, moderate, or high physical activity. The IPAQ is a suitable questionnaire for population-based physical activity monitoring. The IPAQ-SF can be used for physical activity prevalence studies to monitor the population and has demonstrated adequate reliability and validity[72 73] and has been used in previous studies with stroke population.[74]

Self-perceived quality and quantity of sleep

Sleep Scale from the Medical Outcomes Study (MOS-Sleep) will be used to assess the most important dimensions of sleep quantitatively and qualitatively as well as to assess potential sleep disturbances. The tool consists of 12 items whose responses are based on a retrospective assessment over the last 4 weeks[75]. The MOS-sleep is a suitable and valid questionnaire to obtain information on multiple aspects of sleep quality. The scale has been shown to have good validity and reliability for the assessment of sleep disturbances.

It is a sensitive assessment tool for detecting the impact of an illness or medication on the different dimensions of sleep [76].

Current health status

Current health status will be evaluated with the self-assessed, health-related, quality of life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component scale, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of these dimensions has five possible answers or levels of severity. In a second part of the questionnaire, respondents are asked to rate their current health status on a scale, where 100 corresponds to "the best health status you can imagine" and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable tool for assessing the quality of life [77].

State of anxiety and depression

The state of anxiety and depression will be evaluated with the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a depression subscale and an anxiety subscale with interspersed items. The items are scored on a 4-point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale, where a higher score indicates greater symptom severity. The HADS is a reliable and valid tool for assessing levels of depression and anxiety [78] and has been used with stroke survivors in previous studies [79].

Degree of community participation

The degree of community participation will be assessed using the Activity Card Sort for the Spanish population (ACS). The ACS is a scale that measures self-perceived participation using photographs reflecting everyday activities. The activities are

categorised into four domains, instrumental activities, leisure activities with low physical demand, leisure activities with high physical demand, and socio-educational activities. It covers eight of the nine domains of participation as defined by the ICF.[10] The final score is the percentage of activities maintained after an illness, which is developed as a quotient between the number of activities carried out before the illness and those carried out at present. The ACS is a reliable and validated tool for measuring the perceived level of participation.[80 81]

Degree of occupational satisfaction and balance

The degree of occupational satisfaction and balance will be assessed with the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-based instrument that assesses 13 different occupational items organised into 4 domains: productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the level of participation in an activity, the occupational satisfaction derived from participating in this activity, the perceived occupational balance within each domain. For each item, the interviewer will determine whether there is participation by the person and then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied and 7 being extremely satisfied). The SDO-OB has good reliability and validity [82].

Physical mobility tests

The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The person will be asked to walk for 10 meters while being timed. The comfortable speed for walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the value of the assessment. The 10MWT is a reliable and validated tool for measuring walking speed.[83]

The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked by the participant in 6 minutes. Standardized guidelines will be followed during the test to give verbal indications concerning the time elapsed and positive reinforcement, without any other indications not allowed by the test. The 6MWT is a reliable and valid tool for measuring distance run, endurance, and aerobic capacity.[84]

Additionally, walking aids and a modified Borg Index (0-10) will be collected after each test.

Activity tracker wristband

The Fitbit Inspire 2 activity tracker will be used to continuously assess the level of activity throughout 14-days. The device is based on a 3-axis accelerometery system that allows monitoring physical activity, number of steps, heart rate, sleep duration, and sleep score. The Fitbit wristbands are considered a valid and reliable tool for monitoring physical activity and sleep hours,[85 86] which are considered a valid procedure in stroke population.[87 88]

Evaluation of caregivers

Sociodemographic data and IPAQ-SF will be collected from primary caregivers during the first interview with study participants who have suffered a stroke. Caregivers will be monitored with the Fitbit activity wristband during the same time as the stroke survivor is monitored.

Assessments and temporality

The evaluations will be carried out in a similar way at 3 points in time over a 12-month period (i.e., baseline, 6- and 12-months). Each evaluation will be composed of different tests and questionnaires grouped by blocks, to avoid saturation of the participants.

Specifically, block 1 will be assessed by the collaborators approximately one week after recruitment, and will consist of sociodemographic data, IPAQ-SF, FES-I, Barthel Index, HADS, and EQ-5D-5L. After completing the assessment of block 1, the Fitbit Inspire 2 activity tracker wristband will be linked to the mobile device for 14 days of 24-hour monitoring. Block 2 will be assessed in the settings of collaborator centres approximately two weeks after completing block 1, coinciding with the return of the activity tracker wristband, and will consist of the ACS, the 6MWT, and the 10MWT. Block 3 will be assessed homogenously in all participants by the principal investigator via teleconference within the period between the blocks 1 and 2, and will consist of clinical data, MOS-Sleep, and SDO-OB (figure 1).

One to two weeks after completing the baseline evaluation, a minimum of 50 participants will complete again the IPAQ-SF, MOS-sleep, and SDO-OB. Additionally, during the follow-up period after baseline, a random sample of around 30 participants will participate in unstructured and semi-structured interviews as part of the qualitative design.

Qualitative design

A qualitative phenomenological design will be followed based on Husserl's framework.[89] Data collection will be completed when the information obtained in the interviews becomes repetitive.[90] First-person data collection instruments (unstructured and semi-structured interviews) and the researcher's field notes will be used simultaneously.[90] Data collection will be conducted in two phases. The first phase of data collection will be conducted through unstructured in-depth interviews. The second phase will be conducted through semi-structured interviews based on the analysis of participants' responses from the first phase, together with questions grouped into 3 research areas: physical activity, participation, and health education.

The analysis proposed by Giorgi will be used.[91] The researcher's field notes will complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.

Different strategies will be followed before and during the data collection process to ensure the methodological rigour and quality of this study (i.e., establishing the positioning of the researchers, triangulation, auditing of the material obtained, and participant verification).

Monitoring of the methodological quality

Given the multicentric nature of the research study, several mechanisms will be implemented to avoid inter-observer bias and reduce random errors as much as possible. Firstly, the assessment protocol is composed of measurement instruments with reliable inter-observer psychometric characteristics, which allows a standardized data collection. Secondly, meetings to unify the protocol for administration of the tools and data collection will be performed, establishing a unification of the evaluation criteria in each of the items of the tools. Thirdly, training sessions on the procedures and administration of the evaluation tools will be conducted both face-to-face and virtually. Additionally, all collaborators will have written manuals that include these standardized and unified procedures. Finally, the project research team will supervise all procedures and solve any potential issues, sharing the relevant information with all collaborators participating.

Sample size

The sample size has been calculated with G*Power (*v3.1.9.4; Heinrich-Heine-University, Dusseldorf, Germany*) based on the requirements of the most demanding research objective in terms of the number of participants (i.e., objective 1). Specifically, after

running a priori analysis with an alpha value of 0.05, a power of 80%, and expecting a coefficient of multiple determination (ρ^2) between 0.30 and 0.50, a total of 130 participants will be required to perform a random-effects multiple regression model with up to 15 variables.

Statistical analysis

The results will be presented in tables and graphs by presenting the mean and standard deviation, or the median and interquartile range values, depending on the normality of the data.

Random-effects multiple regression models will be used to examine the factors associated with the stroke survivor's participation and sedentary behaviour, including the sedentary behaviour and individual characteristics of the primary caregiver.

Mixed models for repeated measures will be used to assess the variation over time of the different variables associated with participation and sedentary behaviour.

In the validation process of the SDO-BO in the Spanish stroke survivors, Cronbach's α statistic will be used to test internal consistency and intraclass correlation coefficients to assess test-retest reliability. In addition, Spearman's rank correlation will be used to assess the construct validity of the SDO-BO compared to EQ-5D-5L and ACS.

Pearson's correlations will be used to assess the construct validity of the activity tracker wearable compared to self-reported measures. Furthermore, intraclass correlation coefficients with a 95% confidence interval, the standard error of measurement, and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2 collected during two-consecutive weeks.

Ethics and confidentiality

The study protocol has been approved by the regional ethics committee "Comité de Ética de la Investigación de la Comunidad de Aragón" (PI21/333). All patients will receive an information sheet explaining the purpose of the study and the tests and assessments that will be performed if they agree to participate in the study. In addition, once they have agreed to participate in the study, subjects will sign the informed consent form. There will be no financial compensation of any kind to the participants in this project.

Dissemination

Any deviation from the protocol will be presented and justified at the time of publication of the results. Regardless of the outcome, the results will be made available via peer-reviewed publications in open-source journals and relevant international conferences within the field of health and behavioural sciences or neurology, among others.

DECLARATIONS

Authors' contributions

CDA and PBL conceived and planned the project. CDA, PBL, JAA, and VDG, with the collaboration of the rest of the authors, contributed to the design of the study protocol. CDA, ABE, JGR, and PRP contributed to the qualitative study design. CDA, PBL, JBA, RGN, MLR, and VDG contributed to the reliability study design. CDA led the recruitment of participating centres and coordination of the professional collaborators. "Part&Sed collaborators" contributed to checking and testing the protocol design and will conduct the data collection. CDA, PBL, ABE, JBA, JRG, VDG, and NF contributed to writing the article. All authors have read and approved the final manuscript.

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Competing interests

None declared.

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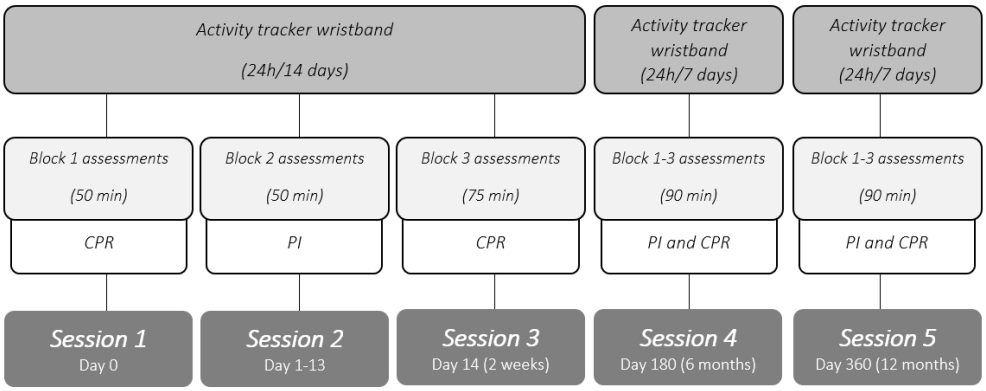
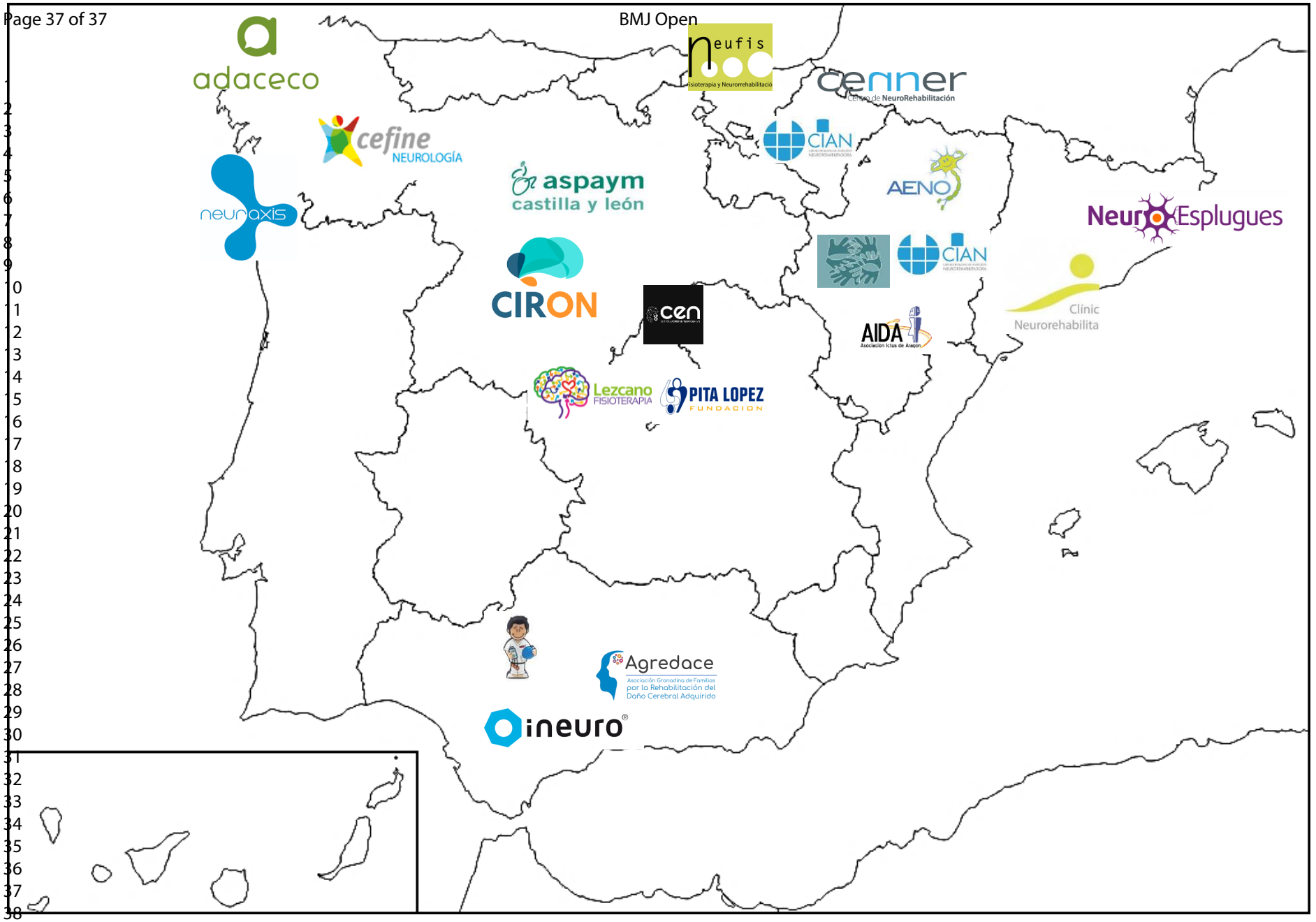
FIGURE LEGEND

Figure 1. Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.



Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

773x314mm (38 x 38 DPI)



Supplementary material 1. Geographical distribution of collaborating centres in Spain.

BMJ Open

MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED-STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTRE STUDY

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MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTRE STUDY

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ABSTRACT

Introduction

Stroke survivors usually experience long-lasting functional, emotional, and social consequences that might contribute to sedentary behaviour and participation restrictions, which are important targets to address during rehabilitation. However, the trajectory and inter-relationship between these factors is unknown.

Methods and analysis

Part&Sed is a research project based on an observational study design with 6- and 12-months follow-up in stroke survivors. In addition, a qualitative analysis of the impact of the stroke on the stroke survivor, validation of the Satisfaction with Daily Occupation-Occupational Balance assessment tool, and analysis of the reliability of the Fitbit Inspire 2 activity tracker wristband will be carried out. Participants will be chronic stroke survivors with independent walking capacity. Sociodemographic and clinical data, physical activity, ambulation, sleep, quality of life, anxiety and depression, community participation, and occupational satisfaction and balance, as well as data provided by the activity tracker wristband, will be collected. In addition, if the participant has a primary caregiver, the caregiver will also be monitored. A minimum of 130 participants will be recruited to conduct a random-effects multiple regression model. Mixed models for repeated measures will assess the variation over time of the different variables associated with participation and sedentary behaviour. Psychometrics properties (e.g., internal consistency, construct validity, test-retest reliability) of the Satisfaction with Daily Occupation-Occupational Balance will be determined. Additionally, intraclass correlation coefficients and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2. The qualitative analysis process will be carried out using the analysis proposed by Giorgi.

Ethics and dissemination

The study received ethical approval from by the Spanish regional ethics committee "Comité de Ética de la Investigación de la Comunidad de Aragón" (PI21/333). The results will be made available via peer-reviewed publications, international conferences, and official channels.

Strengths and limitations of this study

- This large prospective multicentre project examines the multifactorial interaction between physical activity and participation dimensions in Spanish stroke survivors.
- Training sessions on the procedures and administration of the evaluation tools will be conducted to minimize inter-rater variability.
- A novel method for assessing physical activity and sleep parameters in stroke survivors will be explored.
- Stroke survivors with aphasia, no technological knowledge or those living in nursing homes and hospital settings will not be included.
- Physical activity is being monitored by wrist-worn devices which are known to have limitations.

Key Words:

Epidemiological Study, Stroke, Physical Activity, Fitness Trackers, Community Participation, Occupational Participation.

INTRODUCTION

Stroke has an annual global incidence of 12.2 million, being the second leading cause of death in developed countries.[1 2] There is an estimated prevalence of 143 million people living with post-stroke disability, thus becoming the third leading cause of disability worldwide and representing the main need for neurorehabilitation.[3] In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.[1] Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations[4], as well as restrictions in participation in self-care, work, leisure and free time, and social activities.[5-8] Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.[9]

Participation is defined by the International Classification of Functioning, Disability and Health (ICF) as "a person's involvement in life situations" and is the product of an interaction between the individual's health condition and contextual factors.[10] Therefore, participation comprehends meaningful activities performed by individuals in their real environment (e.g., family, or community) that occupy time and that give meaning and purpose to their life.[11] Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.[12 13]

Physical inactivity and sedentary behaviour are one of the main lifestyle-related risk factors for stroke recurrence.[14] Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)[15] and endorsed by the American Heart Association Council (AHAC)[16]. These recommendations consist of achieving 150 minutes of moderate-to-vigorous-intensity physical activity per week or 75 minutes of vigorous-intensity physical activity per week.[17] On the other hand, sedentary behaviour is defined as any waking

behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents (METs), while sitting, reclining, or lying.[18] If the sedentary behaviour is maintained throughout the day or week while being awake, it can be classified as a Sedentary Behaviour Pattern.[19] Adult populations who comply with the physical activity WHO recommendations show a lower risk of death and developing noncommunicable diseases.[20] However, stroke survivors often report sedentary behaviour most of the day, especially in the afternoon and evening.[21] Additionally, the average number of sleep hours is much higher in stroke survivors than in the healthy population, which is associated with cardiovascular morbidity and mortality.[22]

Regarding the factors that contribute to sedentary lifestyles in the stroke population, it has been observed that inpatient stroke survivors in rehabilitation centres are more sedentary.[23 24] However, those living in the community still do not meet a healthy level of physical activity .[25] On the other hand, the fear of falling is associated with sedentary lifestyles,[26 27] to the extent that stroke survivors reduce activities involving standing or walking by 20% on average.[28] In turn, the intensity and frequency of rehabilitation treatment,[23 29] the place of residence and characteristics of the community,[25] social support,[23] years after stroke,[30] initial stroke severity,[31 32] type of hemiparesis, greater cognition,[32-34] better endurance and gait speed,[32-35] are further examples of contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety, depression, and self-efficacy, can play a role.[36 37] This ensemble of factors warrants studies analysing multifactorial relationships and to establish a firm consensus on policies for dealing with the rehabilitation of stroke survivors.

Systematic reviews show that post-stroke interventions do not impact community participation until several years after stroke[38] and that the identification of barriers is key.[39] However, despite the limited evidence regarding the factors that influence participation[30], having an extensive social network the ability to walk for a few hundred

meters or drive are potential facilitators[8]. Additionally, improvements in physical functioning do not necessarily translate into improved participation in work, domestic, social and leisure activities. [40 41] This could be why stroke survivors feel unsatisfied about not recovering pre-stroke participation levels in relevant activities, which may be due to their environment, age, acceptance of the new situation, or degree of affectation;[42] as well as due to the presence of comorbidities related to cognitive impairment and depressive states.[43]

Therefore, aiming at emphasizing social reintegration as a long-term goal,[44] several studies highlight the need to consider other under-investigated factors, such as the influence of the primary caregiver and the family environment;[36] environmental factors such as climate and daylight hours;[33] or the impact of treatments focusing on health education[45] and the person-centred model.[2]

PART&SED-STROKE PROJECT JUSTIFICATION

The stroke population in Europe, Australia, Canada, and the United States is known to have high levels of sedentary lifestyles.[21 25 31 32 46-50] However, there is no solid information about the Spanish population, which would allow the development, as recommended by the WHO, of a specific public health plan for the stroke survivors in Spain. For this reason, longitudinal studies are needed to determine the evolution of the level of physical activity after stroke.[44 46]

The assessment tools included in the present protocol have been selected based on the 2018 Cochrane review authored by Lynch et al.,[51] and by the recommendations of Kwakkel et al.,[52] and its updates in a 2020 Delphi study.[53] Additionally, other reliable assessment tools are needed to ascertain the amount of sedentary time, assess its effect on health, and identify significant predictors of physical activity levels.[14] In this sense, devices with high potential have already been identified at the scientific level,[54 55] and it

is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate monitoring.[56] However, more studies are needed to analyse the potential of new wearable devices to record this physical activity and measure adherence and compliance with physical activity recommendations in the stroke population[57], as well as to assess their suitability and ease of use in the clinical setting by professionals and patients. Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting the recovery of participatory life after stroke, it is relevant that clinicians have validated assessment tools for the stroke population on occupational satisfaction.

The current protocol has also included the Activity Card Sort (ACS), recommended in systematic reviews for the ICF domains of activity and participation in the stroke population.[58 59] Finally, following the recommendations of other studies, other factors such as personal, sociodemographic, and psychological factors that may have an impact on mobility in the community have been considered.[33]

Considering that the current goal of neurorehabilitation is to design and personalize physical activity programs according to the ability, goals, and preferences of the stroke survivor, as well as to encourage long-term lifestyle habits,[60] it is warranted to conduct longitudinal studies investigating the trajectory and the interrelationship between sedentary behaviour and participation in stroke survivors.

Objectives

1. To multidimensionally explore the factors associated with participation and sedentary behaviour in the Spanish stroke survivors.
2. To investigate the influence of sedentary behaviour and individual characteristics of the primary caregiver on the participation and sedentary lifestyle of the Spanish stroke survivors.

3. To analyse the natural fluctuation of participation, sedentary behaviour and associated factors over 12 months in the Spanish stroke survivors.
4. To validate and establish the psychometric properties of the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB) assessment scale for the Spanish stroke survivors.
5. To determine the intra-subject reliability values in the short (1 week) and medium-term (6 months) of the Fitbit Inspire 2 activity tracker wristband and evaluate the construct validity of monitoring physical activity and sleep quality using Fitbit Inspire 2 activity tracker wristband versus the scores obtained in the IPAQ-SF and MOS-Sleep self-reported questionnaires in Spanish stroke survivors.
6. To qualitatively analyse the lived experience of Spanish stroke survivors in terms of barriers and facilitators for the return to physical activity and participation in occupational living, along with the knowledge needed to achieve it.

METHODS

Study design

The present protocol complies with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) recommendations,[61] the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),[62] the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),[63] and the COnsolidated criteria for reporting qualitative studies (COREQ),[64] and the Standards for Reporting Qualitative Research (SRQR).[65]

This study protocol will follow a prospective design with a follow-up of 12 months (figure 1), in which several centres distributed throughout Spain will participate (online supplemental material 1). Specifically, a cross-sectional design will be used to assess factors associated with sedentary behaviours and participation levels in stroke survivors,

including the influence of the primary caregiver. The validation and establishment of the psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will be performed. Additionally, a prospective cohort design will be used to assess the evolution of sedentary and participation behaviours in stroke survivors over time, identifying those factors that may contribute to a modification of these behaviours. Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time frame in which to appreciate meaningful changes. Finally, the life experience of stroke survivors will be investigated through unstructured in-depth interviews and semi-structured interviews, which will be analysed by means of a descriptive phenomenological approach.

Population

The study sample will consist of people of both sexes who have suffered a stroke and reside in Spain. The inclusion criteria will consist of 1) be over 18 years of age; 2) have a history of stroke with a medical diagnosis for more than 6-months, regardless of its aetiology; 3) outpatient living at home; 4) have cognitive and speech ability to perform and understand the tests to be administered and the purpose of the research project (i.e., no aphasia and a Mini-Mental Cognitive Test score >24;[66]) 5) be able to ambulate with or without aids, which represent an ambulation ability ≥ 3 in the Functional Ambulatory Category[67] *[not applicable for SDO-OB validation]; and 6) availability of a mobile phone with Bluetooth and internet connection. The exclusion criteria will be 1) non-acceptance of participation in the research project by the primary caregiver; 2) not tolerating being monitored with an activity tracker wristband; 3) residing in institutions (e.g., nursing homes); 4) no commitment to continuity; and 5) a history of more than one symptomatic stroke. Missing evaluation sessions, existing a personal or family situation

that interferes with data collection, and willingness to discontinue the study were considered withdrawal criteria.

If the stroke survivor has a primary caregiver, the primary caregiver will be invited to participate in the study. A primary caregiver is defined as a person, either a family member or an employee, who spends more than half of their daily time supporting or caring for the stroke survivor.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Contact and recruitment

Centres and Health professionals

The collaborators will be composed of health professionals (physiotherapists and occupational therapists) working in institutions, centres, and associations, as well as self-employed professionals, whose field of action is focused on the neurological rehabilitation of stroke survivors. Specifically, in a first phase, contact will be established via email or telephone with professionals who form part of the research team's network. While in a second phase, general information about the research study will be disseminated through social networks (i.e., Twitter and LinkedIn) to increase the number of potential organizations and professionals collaborating. These collaborators will meet the conditions of residing in different parts of Spain, having extensive experience in neurological rehabilitation, and currently providing care to stroke survivors.

All those who will show interest in the study will receive a document that includes information on the objective of the study, criteria for the selection of the sample, functions to be carried out that would imply their commitment to participate and a timetable for

data collection. If there is continued interest in participating, a first meeting will be held to provide further information and resolve doubts. After this meeting, the centres and professionals will express their willingness to participate or not. Each participating centre must sign the collaboration agreement and each professional belonging to these centres must accept the document of commitment to participate in the research. These documents will regulate the anonymized transfer of the data collected for the exclusive use of the research, as well as the commitments and functions of the institutions and professionals involved.

All participating centres will be included in the database to begin the process of homogenizing data collection through videoconference meetings and training sessions. With the aim of facilitating access to information on the study, a secure shared folder has been created in a virtual space containing documents on the study, information sheets for participants, consents, collaboration documents, and manuals of procedures to be followed. In addition, the research team will provide and send a minimum of 2 Fitbit Inspire-2 monitoring wristbands to each collaborating centre.

Stroke survivor participants and primary caregivers

The recruitment process of participants (stroke survivors and their respective caregivers) will be carried out in two phases. Firstly, each of the collaborating centres will be responsible for promoting the existence of the study through their usual internal channels of communication with their users, such as posters, information circulars, and posts on social networks. Each potential participant will be given an information sheet about the research project, and any questions they may have regarding the development of the research project and their participation in it will be answered.

Secondly, those users who voluntarily agree to participate in the study will be assessed by healthcare professionals (occupational therapists and physiotherapists) with

training and clinical experience in neurorehabilitation to corroborate compliance with the eligibility criteria. Those who meet the selection criteria will be selected as potential participants and will be asked to sign the informed consent for inclusion in the study. Once the informed consent is signed, they will be assigned an appointment for the first assessment session within approximately one week. The assessment sessions will be conducted by the same assessors at each centre.

Data collection and security measures

Each collaborator will be responsible for collecting part of the data for participants from their centres. The collection of all the data will be supervised and coordinated by the research team, and the principal investigator will be in direct contact with each collaborator to assist with solving any problems that may arise.

In order to maintain security in the process of collecting data from each participant: 1) each collaborator will be assigned an account and password to access the P4Work application where the data collected from each participant in the study is recorded;[68] and 2) each collaborator will be provided with accounts and passwords that must be assigned to each participant (stroke survivor and their main caregiver) to use the Fitbit application.

Only the collaborators at each centre will know the identity of each participant recruited at their centre. In such a way that the data collected from each participant that the research team will have access to will be assigned to an encrypted and anonymized identity in both the Fitbit and P4Work applications.

Outcome measures

Sociodemographic data

Sociodemographic data will include age, sex, smoker, educational level, economic level, employment status, height and weight, municipality, type of housing, presence of architectural barriers, and home cohabitation.

Clinical data

Clinical data will include information such as age at the time of stroke, type of stroke, damaged cerebral hemisphere, time of evolution, pain experience, other pathologies (including number of silent or subclinical strokes), current medication, current rehabilitation and hours per week, number of falls in the last six months, use of assistive devices, the Barthel Index,[69] the Fall Efficacy Scale (FES-I),[70] and the modified Rankin scale.[71]

Self-reported physical activity

Self-reported physical activity will be evaluated with the short version of the International Physical Activity Questionnaire (IPAQ-SF). The IPAQ-SF is a self-report scale that aims to determine the level of physical activity in the current period (last seven days) and the time spent sitting down. The final score categorizes physical activity levels into low, moderate, or high physical activity. The IPAQ is a suitable questionnaire for population-based physical activity monitoring. The IPAQ-SF can be used for physical activity prevalence studies to monitor the population and has demonstrated adequate reliability and validity[72 73] and has been used in previous studies with stroke population.[74]

Self-perceived quality and quantity of sleep

Sleep Scale from the Medical Outcomes Study (MOS-Sleep) will be used to assess the most important dimensions of sleep quantitatively and qualitatively as well as to assess potential sleep disturbances. The tool consists of 12 items whose responses are based on

a retrospective assessment over the last 4 weeks[75]. The MOS-sleep is a suitable and valid questionnaire to obtain information on multiple aspects of sleep quality. The scale has been shown to have good validity and reliability for the assessment of sleep disturbances. It is a sensitive assessment tool for detecting the impact of an illness or medication on the different dimensions of sleep [76].

Current health status

Current health status will be evaluated with the self-assessed, health-related, quality of life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component scale, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of these dimensions has five possible answers or levels of severity. In a second part of the questionnaire, respondents are asked to rate their current health status on a scale, where 100 corresponds to "the best health status you can imagine" and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable tool for assessing the quality of life [77].

State of anxiety and depression

The state of anxiety and depression will be evaluated with the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a depression subscale and an anxiety subscale with interspersed items. The items are scored on a 4-point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale, where a higher score indicates greater symptom severity. The HADS is a reliable and valid tool for assessing levels of depression and anxiety [78] and has been used with stroke survivors in previous studies [79].

Degree of community participation

The degree of community participation will be assessed using the Activity Card Sort for the Spanish population (ACS). The ACS is a scale that measures self-perceived participation using photographs reflecting everyday activities. The activities are categorised into four domains, instrumental activities, leisure activities with low physical demand, leisure activities with high physical demand, and socio-educational activities. It covers eight of the nine domains of participation as defined by the ICF.[10] The final score is the percentage of activities maintained after an illness, which is developed as a quotient between the number of activities carried out before the illness and those carried out at present. The ACS is a reliable and validated tool for measuring the perceived level of participation.[80 81]

Degree of occupational satisfaction and balance

The degree of occupational satisfaction and balance will be assessed with the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-based instrument that assesses 13 different occupational items organised into 4 domains: productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the level of participation in an activity, the occupational satisfaction derived from participating in this activity, the perceived occupational balance within each domain. For each item, the interviewer will determine whether there is participation by the person and then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied and 7 being extremely satisfied). The SDO-OB has good reliability and validity [82].

Physical mobility tests

The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The person will be asked to walk for 10 meters while being timed. The comfortable speed for walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the

value of the assessment. The 10MWT is a reliable and validated tool for measuring walking speed.[83]

The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked by the participant in 6 minutes. Standardized guidelines will be followed during the test to give verbal indications concerning the time elapsed and positive reinforcement, without any other indications not allowed by the test. The 6MWT is a reliable and valid tool for measuring distance run, endurance, and aerobic capacity.[84]

Additionally, walking aids and a modified Borg Index (0-10) will be collected after each test.

Furthermore, physical mobility tests will be performed in all centres under similar standardized conditions. Before signing the collaborating agreement, each centre will ensure that it has sufficient space on its premises to carry out the tests.

Activity tracker wristband

The Fitbit Inspire 2 activity tracker will be used to continuously assess the level of activity throughout 14-days. The device is based on a 3-axis accelerometery system that allows monitoring physical activity, number of steps, heart rate, sleep duration, and sleep score. The Fitbit wristbands are considered a valid and reliable tool for monitoring physical activity and sleep hours,[85 86] which are considered a valid procedure in stroke population.[87 88]

Evaluation of caregivers

Sociodemographic data and IPAQ-SF will be collected from primary caregivers during the first interview with study participants who have suffered a stroke. Caregivers will be monitored with the Fitbit activity wristband during the same time as the stroke survivor is monitored.

Assessments and temporality

The evaluations will be carried out in a similar way at 3 points in time over a 12-month period (i.e., baseline, 6- and 12-months). Each evaluation will be composed of different tests and questionnaires grouped by blocks, to avoid saturation of the participants. Specifically, block 1 will be assessed by the collaborators approximately one week after recruitment, and will consist of sociodemographic data, IPAQ-SF, FES-I, Barthel Index, HADS, and EQ-5D-5L. After completing the assessment of block 1, the Fitbit Inspire 2 activity tracker wristband will be linked to the mobile device for 14 days of 24-hour monitoring. Block 2 will be assessed in the settings of collaborator centres approximately two weeks after completing block 1, coinciding with the return of the activity tracker wristband, and will consist of the ACS, the 6MWT, and the 10MWT. Block 3 will be assessed homogenously in all participants by the principal investigator via teleconference within the period between the blocks 1 and 2, and will consist of clinical data, MOS-Sleep, and SDO-OB (figure 1).

One to two weeks after completing the baseline evaluation, a minimum of 50 participants will complete again the IPAQ-SF, MOS-sleep, and SDO-OB. Additionally, during the follow-up period after baseline, a random sample of around 30 participants will participate in unstructured and semi-structured interviews as part of the qualitative design.

Qualitative design

A qualitative phenomenological design will be followed based on Husserl's framework.[89] Data collection will be completed when the information obtained in the interviews becomes repetitive.[90] First-person data collection instruments (unstructured and semi-structured interviews) and the researcher's field notes will be used simultaneously.[90] Data

collection will be conducted in two phases. The first phase of data collection will be conducted through unstructured in-depth interviews. The second phase will be conducted through semi-structured interviews based on the analysis of participants' responses from the first phase, together with questions grouped into 3 research areas: physical activity, participation, and health education.

The analysis proposed by Giorgi will be used.[91] The researcher's field notes will complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.

Different strategies will be followed before and during the data collection process to ensure the methodological rigour and quality of this study (i.e., establishing the positioning of the researchers, triangulation, auditing of the material obtained, and participant verification).

Monitoring of the methodological quality

Given the multicentric nature of the research study, several mechanisms will be implemented to avoid inter-observer bias and reduce random errors as much as possible. Firstly, the assessment protocol is composed of measurement instruments with reliable inter-observer psychometric characteristics, which allows a standardized data collection. Secondly, meetings to unify the protocol for administration of the tools and data collection will be performed, establishing a unification of the evaluation criteria in each of the items of the tools. Thirdly, training sessions on the procedures and administration of the evaluation tools will be conducted both face-to-face and virtually. Additionally, all collaborators will have written manuals that include these standardized and unified procedures. Finally, the project research team will supervise all procedures and solve any potential issues, sharing the relevant information with all collaborators participating.

Sample size

The sample size has been calculated with G*Power (*v3.1.9.4; Heinrich-Heine-University, Dusseldorf, Germany*) based on the requirements of the most demanding research objective in terms of the number of participants (i.e., objective 1). Specifically, after running a priori analysis with an alpha value of 0.05, a power of 80%, and expecting a coefficient of multiple determination (ρ^2) between 0.30 and 0.50, a minimum of 130 participants will be required to perform a random-effects multiple regression model with up to 15 variables. Furthermore, a sample size higher than 73 participants during follow-ups will assure to perform a mixed model for repeated measures a power of 80% and an alfa error of 0.05 to detect a small to medium standardized mean difference (i.e., f = 0.15) and expecting at least a moderate correlation among repeated measures (i.e., r = 0.5).

Statistical analysis

The results will be presented in tables and graphs by presenting the mean and standard deviation, or the median and interquartile range values, depending on the normality of the data.

Random-effects multiple regression models will be used to examine the factors associated with the stroke survivor's participation and sedentary behaviour, including the sedentary behaviour and individual characteristics of the primary caregiver.

Mixed models for repeated measures will be used to assess the variation over time of the different variables associated with participation and sedentary behaviour.

In the validation process of the SDO-BO in the Spanish stroke survivors, Cronbach's α statistic will be used to test internal consistency and intraclass correlation coefficients to assess test-retest reliability. In addition, Spearman's rank correlation will be used to assess the construct validity of the SDO-BO compared to EQ-5D-5L and ACS.

Pearson's correlations will be used to assess the construct validity of the activity tracker wearable compared to self-reported measures. Furthermore, intraclass correlation coefficients with a 95% confidence interval, the standard error of measurement, and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2 collected during two-consecutive weeks.

Limitations

This project has some limitations. Firstly, our population does not stroke survivors with aphasia, an important group who are often excluded from research. Additionally, our population does not include those with limited technical knowledge or people living in nursing homes. Therefore, the generalisability of the results of this study will be limited. This study will not provide insights into physical activity and participation in the acute and subacute phases of stroke recovery, as it only commences in the chronic phase. Finally physical activity is being monitored by wrist-worn devices which are known to have limitations.[87]

Ethics and confidentiality

The study protocol has been designed following the Helsinki statement and approved by the Spanish regional ethics committee "Comité de Ética de la Investigación de la Comunidad de Aragón" (PI21/333). All patients will receive an information sheet explaining the purpose of the study and the tests and assessments that will be performed if they agree to participate in the study. In addition, once they have agreed to participate in the study, subjects will sign the informed consent form. There will be no financial compensation of any kind to the participants in this project.

Dissemination

Any deviation from the protocol will be presented and justified at the time of publication of the results. Regardless of the outcome, the results will be made available via peer-reviewed publications in open-source journals and relevant international conferences within the field of health and behavioural sciences or neurology, among others.

DECLARATIONS

Authors' contributions

CDA and PBL conceived and planned the project. CDA, PBL, JAA, and VDG, with the collaboration of the rest of the authors, contributed to the design of the study protocol. CDA, ABE, JGR, and PRP contributed to the qualitative study design. CDA, PBL, JBA, RGN, MLR, and VDG contributed to the reliability study design. CDA led the recruitment of participating centres and coordination of the professional collaborators. "Part&Sed collaborators" contributed to checking and testing the protocol design and will conduct the data collection. CDA, PBL, ABE, JBA, JRG, VDG, and NF contributed to writing the article. All authors have read and approved the final manuscript.

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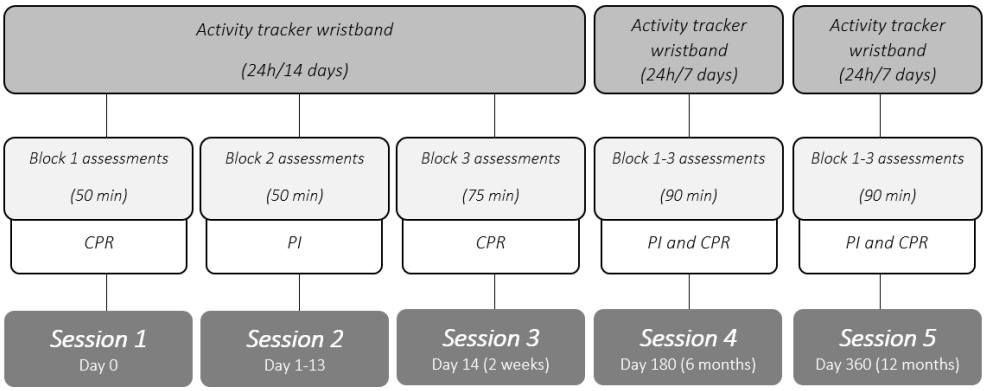
FIGURE LEGEND

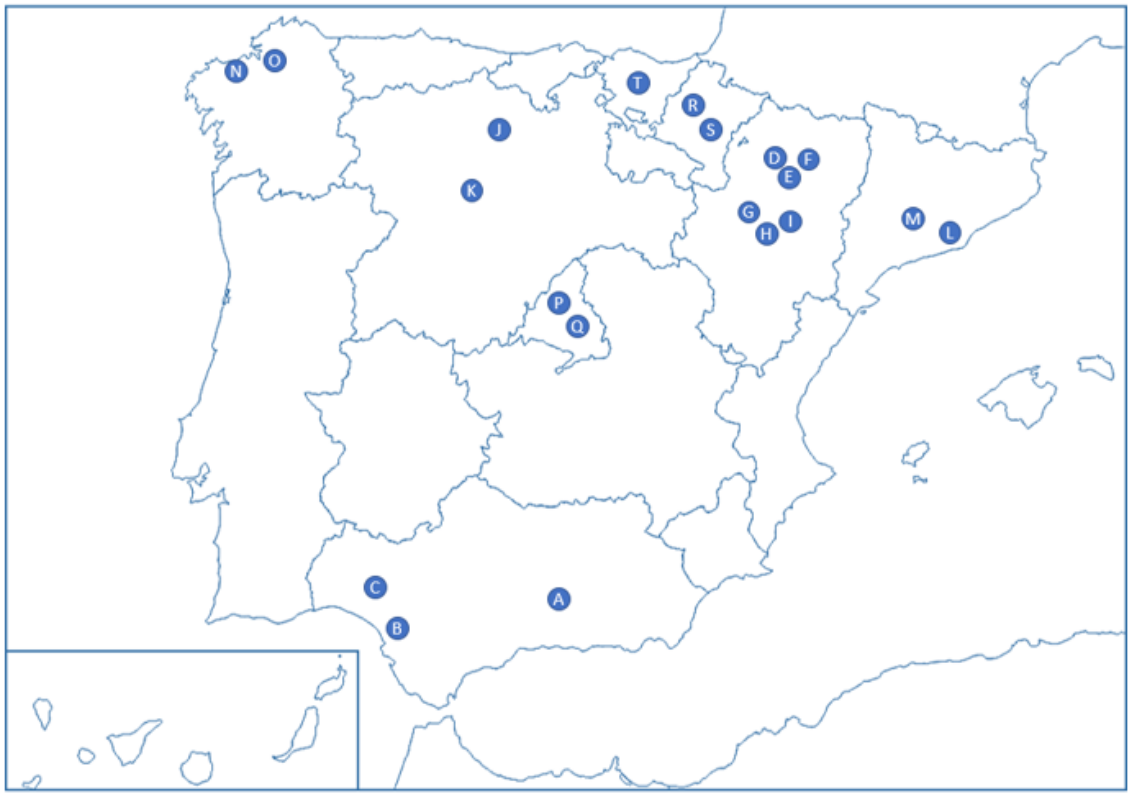
Figure 1. Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.



Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

773x314mm (38 x 38 DPI)

SPAIN REGION	CITY	CENTER NAME
Andalucía	Granada	AGREDACE (A)
Andalucía	San Lucar de barrameda	Freelance Physiotherapist (B)
Andalucía	Sevilla	INEURO (C)
Aragón	Huesca	AENO (D)
Aragón	Huesca	Hospital Provincial Sagrado Corazón de Jesús (E)
Aragón	Huesca	Hospital Universitario San Jorge (F)
Aragón	Zaragoza	AIDA (G)
Aragón	Zaragoza	Grupo 5 CIAN Zaragoza (H)
Aragón	Zaragoza	Rehabilitación El Carmen (I)
Castilla y León	Burgos	ASPAYM (J)
Castilla y León	Valladolid	CIRON (K)
Cataluña	Esplugues de Llobregat	NeuroEsplugues (L)
Cataluña	San Cugat del Vallés	Clínica de neurorrehabilitación (M)
Galicia	A Coruña	ADACECO (N)
Galicia	Ferrol	NEURAXIS (O)
Madrid	Collado Villalba	Fundación Pita López (P)
Madrid	Madrid	Freelance Physiotherapist (Q)
Navarra	Pamplona	Grupo 5 CIAN Navarra (R)
Navarra	Pamplona	CENNER (S)
Pais Vasco	Vitoria	NEUFIS (T)



Supplementary material 1. List of participating centres in relation to their geographical location in Spain.

BMJ Open

MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED-STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTRE STUDY

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Protocol paper for BMJ Open

MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTRE STUDY

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ABSTRACT

Introduction

Stroke survivors usually experience long-lasting functional, emotional, and social consequences that might contribute to sedentary behaviour and participation restrictions, which are important targets to address during rehabilitation. However, the trajectory and inter-relationship between these factors are unknown.

Methods and analysis

Part&Sed is a research project based on an observational study design with 6- and 12-months follow-ups in stroke survivors. In addition, a qualitative analysis of the impact of the stroke on the stroke survivor, validation of the Satisfaction with Daily Occupation-Occupational Balance assessment tool, and analysis of the reliability of the Fitbit Inspire 2 activity tracker wristband will be carried out. Participants will be chronic stroke survivors with independent walking capacity. Sociodemographic and clinical data, physical activity, ambulation, sleep, quality of life, anxiety and depression, community participation, and occupational satisfaction and balance, as well as data provided by the activity tracker wristband, will be collected. In addition, if the participant has a primary caregiver, the caregiver will also be monitored. A minimum of 130 participants will be recruited to conduct a random-effects multiple regression model. Mixed models for repeated measures will assess the variation over time of the different variables associated with participation and sedentary behaviour. Psychometrics properties (e.g., internal consistency, construct validity, test-retest reliability) of the Satisfaction with Daily Occupation-Occupational Balance will be determined. Additionally, intraclass correlation coefficients and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2. The qualitative analysis process will be carried out using the analysis proposed by Giorgi.

Ethics and dissemination

The study received ethical approval from the Spanish regional ethics committee "Comité de Ética de la Investigación de la Comunidad de Aragón" (PI21/333). The results will be made available via peer-reviewed publications, international conferences, and official channels.

Strengths and limitations of this study

- This large prospective multicentre project examines the multifactorial interaction between physical activity and participation dimensions in Spanish stroke survivors.
- Training sessions on the procedures and administration of the evaluation tools will be conducted to minimize inter-rater variability.
- A novel method for assessing physical activity and sleep parameters in stroke survivors will be explored.
- Stroke survivors with aphasia, no technological knowledge or those living in nursing homes and hospital settings will not be included.
- Physical activity is being monitored by wrist-worn devices which are known to have limitations.

Key Words:

Epidemiological Study, Stroke, Physical Activity, Fitness Trackers, Community Participation, Occupational Participation.

INTRODUCTION

Stroke has an annual global incidence of 12.2 million, being the second leading cause of death in developed countries.[1 2] There is an estimated prevalence of 143 million people living with post-stroke disability, thus becoming the third leading cause of disability worldwide and representing the main need for neurorehabilitation.[3] In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.[1] Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations[4], as well as restrictions in participation in self-care, work, leisure and free time, and social activities.[5-8] Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.[9]

Participation is defined by the International Classification of Functioning, Disability and Health (ICF) as "a person's involvement in life situations" and is the product of an interaction between the individual's health condition and contextual factors.[10] Therefore, participation comprehends meaningful activities performed by individuals in their real environment (e.g., family or community) that occupy time and give meaning and purpose to their life.[11] Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.[12 13]

Physical inactivity and sedentary behaviour are one of the main lifestyle-related risk factors for stroke recurrence.[14] Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)[15] and endorsed by the American Heart Association Council (AHAC)[16]. These recommendations consist of achieving 150 minutes of moderate-to-vigorous-intensity physical activity per week or 75 minutes of vigorous-intensity physical activity per week.[17] On the other hand, sedentary behaviour is defined as any waking

behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents (METs), while sitting, reclining, or lying.[18] If the sedentary behaviour is maintained throughout the day or week while being awake, it can be classified as a Sedentary Behaviour Pattern.[19] Adult populations who comply with the WHO recommendations for physical activity show a lower risk of death and developing non-communicable diseases.[20] However, stroke survivors often report sedentary behaviour most of the day, especially in the afternoon and evening.[21] Additionally, the average number of sleep hours is much higher in stroke survivors than in the healthy population, which is associated with cardiovascular morbidity and mortality.[22]

Regarding the factors that contribute to sedentary lifestyles in the stroke population, it has been observed that inpatient stroke survivors in rehabilitation centres are more sedentary.[23 24] However, those living in the community still do not meet a healthy level of physical activity.[25] On the other hand, the fear of falling is associated with sedentary lifestyles,[26 27] to the extent that stroke survivors reduce activities involving standing or walking by 20% on average.[28] In turn, the intensity and frequency of rehabilitation treatment,[23 29] the place of residence and characteristics of the community,[25] social support,[23] years after stroke,[30] initial stroke severity,[31 32] the type of hemiparesis, greater cognition,[32-34] better endurance and gait speed,[32-35] are further examples of contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety, depression, and self-efficacy, can play a role.[36 37] This ensemble of factors warrants studies analysing multifactorial relationships and establishing a firm consensus on policies for the rehabilitation of stroke survivors.

Systematic reviews show that post-stroke interventions do not impact community participation until several years after stroke[38] and that identifying barriers is key.[39] However, despite the limited evidence regarding the factors that influence participation[30], having an extensive social network and the ability to walk for a few hundred meters or

drive are potential facilitators[8]. Additionally, improvements in physical functioning do not necessarily translate into improved participation in work, domestic, social, and leisure activities. [40 41] This could be why stroke survivors feel unsatisfied about not recovering pre-stroke participation levels in relevant activities, which may be due to their environment, age, acceptance of the new situation, or degree of affectation;[42] as well as due to the presence of comorbidities related to cognitive impairment and depressive states.[43]

Therefore, aiming at emphasizing social reintegration as a long-term goal,[44] several studies highlight the need to consider other under-investigated factors, such as the influence of the primary caregiver and the family environment;[36] environmental factors such as climate and daylight hours;[33] or the impact of treatments focusing on health education[45] and the person-centred model.[2]

PART&SED-STROKE PROJECT JUSTIFICATION

The stroke population in Europe, Australia, Canada, and the United States is known to have high levels of sedentary lifestyles.[21 25 31 32 46-50] However, there is no solid information about the Spanish population, which would allow the development, as recommended by the WHO, of a specific public health plan for the stroke survivors in Spain. For this reason, longitudinal studies are needed to determine the evolution of the level of physical activity after stroke.[44 46]

The assessment tools included in the present protocol have been selected based on the 2018 Cochrane review authored by Lynch et al.,[51] and by the recommendations of Kwakkel et al.,[52] and its updates in a 2020 Delphi study.[53] Additionally, other reliable assessment tools are needed to ascertain the amount of sedentary time, assess its effect on health, and identify significant predictors of physical activity levels.[14] In this sense, devices with high potential have already been identified at the scientific level,[54 55] and it

is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate monitoring.[56] However, more studies are needed to analyse the potential of new wearable devices to record this physical activity and measure adherence or compliance with physical activity recommendations in the stroke population[57], as well as to assess their suitability and ease of use in the clinical setting by professionals and patients. Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting the recovery of participatory life after stroke, it is relevant that clinicians have validated assessment tools for the stroke population on occupational satisfaction.

The current protocol has also included the Activity Card Sort (ACS), recommended in systematic reviews for the ICF domains of activity and participation in the stroke population.[58 59] Finally, following the recommendations of other studies, other factors such as personal, sociodemographic, and psychological factors that may have an impact on mobility in the community have been considered.[33]

Considering that the current goal of neurorehabilitation is to design and personalise physical activity programs according to the ability, goals, and preferences of the stroke survivor, as well as to encourage long-term lifestyle habits,[60] it is warranted to conduct longitudinal studies investigating the trajectory and the interrelationship between sedentary behaviour and participation in stroke survivors.

Objectives

1. To multidimensionally explore the factors associated with participation and sedentary behaviour in Spanish stroke survivors.
2. To investigate the influence of sedentary behaviour and individual characteristics of the primary caregiver on the participation and sedentary lifestyle of Spanish stroke survivors.

3. To analyse the natural fluctuation of participation, sedentary behaviour and associated factors over 12 months in Spanish stroke survivors.
4. To validate and establish the psychometric properties of the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB) assessment scale for Spanish stroke survivors.
5. To determine the intra-subject reliability values in the short (1 week) and medium-term (6 months) of the Fitbit Inspire 2 activity tracker wristband and evaluate the construct validity of monitoring physical activity and sleep quality using Fitbit Inspire 2 activity tracker wristband versus the scores obtained in the IPAQ-SF and MOS-Sleep self-reported questionnaires in Spanish stroke survivors.
6. To qualitatively analyse the lived experience of Spanish stroke survivors in terms of barriers and facilitators for the return to physical activity and participation in occupational living, along with the knowledge needed to achieve it.

METHODS

Study design

The present protocol complies with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) recommendations,[61] the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),[62] the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),[63] and the COnsolidated criteria for reporting qualitative studies (COREQ),[64] and the Standards for Reporting Qualitative Research (SRQR).[65]

This study protocol will follow a prospective design with a follow-up of 12 months (figure 1), in which several centres distributed throughout Spain will participate (online supplemental material 1). Specifically, a cross-sectional design will be used to assess factors associated with sedentary behaviours and participation levels in stroke survivors,

including the influence of the primary caregiver. The validation and establishment of the psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will be performed. Additionally, a prospective cohort design will be used to assess the evolution of sedentary and participation behaviours in stroke survivors over time, identifying those factors that may contribute to a modification of these behaviours. Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time frame in which to appreciate meaningful changes. Finally, the life experience of stroke survivors will be investigated through unstructured in-depth interviews and semi-structured interviews, which will be analysed by means of a descriptive phenomenological approach.

Population

The study sample will consist of people of both sexes who have suffered a stroke and reside in Spain. The inclusion criteria will consist of 1) being over 18 years of age; 2) having a history of stroke with a medical diagnosis for more than 6-months, regardless of its aetiology; 3) outpatient living at home; 4) having cognitive and speech ability to perform and understand the tests to be administered and the purpose of the research project (i.e., no aphasia and a Mini-Mental Cognitive Test score >24;[66]) 5) being able to ambulate with or without aids, which represent an ambulation ability ≥ 3 in the Functional Ambulatory Category[67] *[not applicable for SDO-OB validation]; and 6) availability of a mobile phone with Bluetooth and internet connection. The exclusion criteria will be 1) non-acceptance of participation in the research project by the primary caregiver; 2) not tolerating being monitored with an activity tracker wristband; 3) residing in institutions (e.g., nursing homes); 4) no commitment to continuity; and 5) a history of more than one symptomatic stroke. Missing evaluation sessions, existing a personal or family situation

that interferes with data collection, and willingness to discontinue the study were considered withdrawal criteria.

If the stroke survivor has a primary caregiver, the primary caregiver will be invited to participate in the study. A primary caregiver is defined as a person, either a family member or an employee, who spends more than half of their daily time supporting or caring for the stroke survivor.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Contact and recruitment

Centres and Health professionals

The collaborators will be composed of health professionals (physiotherapists and occupational therapists) working in institutions, centres, and associations, as well as self-employed professionals, whose field of action is focused on the neurological rehabilitation of stroke survivors. Specifically, in the first phase, contact will be established via email or telephone with professionals who form part of the research team's network. While in the second phase, general information about the research study will be disseminated through social networks (i.e., Twitter and LinkedIn) to increase the number of potential organizations and professionals collaborating. These collaborators will meet the conditions of residing in different parts of Spain, having extensive experience in neurological rehabilitation, and currently providing care to stroke survivors.

All those who will show interest in the study will receive a document that includes information on the objective of the study, criteria for the selection of the sample, functions to be carried out that would imply their commitment to participate, and a timetable for

data collection. If there is continued interest in participating, a first meeting will be held to provide further information and resolve doubts. After this meeting, the centres and professionals will express their willingness to participate. Each participating centre must sign the collaboration agreement, and each professional belonging to these centres must accept the commitment document to participate in the research. These documents will regulate the transfer of the anonymized data collected for research use, as well as the commitments and functions of the institutions and professionals involved.

Participating centres will be instructed in homogenizing data collection through videoconference meetings and training sessions. With the aim of facilitating access to information on the study, a secure shared folder has been created in a virtual space containing documents on the study, information sheets for participants, consents, collaboration documents, and manuals of procedures to be followed. In addition, the research team will provide and send a minimum of 2 Fitbit Inspire-2 monitoring wristbands to each collaborating centre.

Stroke survivor participants and primary caregivers

The recruitment process of participants (stroke survivors and their respective caregivers) will be carried out in two phases. Firstly, each of the collaborating centres will be responsible for promoting the existence of the study through their usual internal channels of communication with their users, such as posters, information circulars, and posts on social networks. Each potential participant will be given an information sheet about the research project, and any questions they may have regarding the development of the research project and their participation in it will be answered.

Secondly, those users who voluntarily agree to participate in the study will be assessed by healthcare professionals (occupational therapists and physiotherapists) with training and clinical experience in neurorehabilitation to corroborate compliance with the

eligibility criteria. Those who meet the selection criteria will be selected as potential participants and will be asked to sign the informed consent for inclusion in the study. Once the informed consent is signed, they will be assigned an appointment for the first assessment session within approximately one week. The same assessors will conduct the assessment sessions at each centre.

Data collection and security measures

Each collaborator will be responsible for collecting part of the data for participants from their centres. The collection of all the data will be supervised and coordinated by the research team, and the principal investigator will be in direct contact with each collaborator to assist with solving any problems that may arise.

In order to maintain security in the process of collecting data from each participant: 1) each collaborator will be assigned an account and password to access the P4Work application where the data collected from each participant in the study is recorded;[68] and 2) each collaborator will be provided with accounts and passwords that must be assigned to each participant (stroke survivor and their main caregiver) to use the Fitbit application.

Only the collaborators at each centre will know the identity of each participant recruited at their centre. In such a way, the research team will have access to anonymized data in both the Fitbit and P4Work applications.

Outcome measures

Sociodemographic data

Sociodemographic data will include age, sex, smoking, educational level, economic level, employment status, height and weight, municipality, type of housing, presence of architectural barriers, and home cohabitation.

Clinical data

Clinical data will include information such as age at the time of stroke, type of stroke, damaged cerebral hemisphere, time of evolution, pain experience, other pathologies (including the number of silent or subclinical strokes), current medication, current rehabilitation and hours per week, number of falls in the last six months, use of assistive devices, the Barthel Index,[69] the Fall Efficacy Scale (FES-I),[70] and the modified Rankin scale.[71]

Self-reported physical activity

Self-reported physical activity will be evaluated with the short version of the International Physical Activity Questionnaire (IPAQ-SF). The IPAQ-SF is a self-report scale that aims to determine the level of physical activity in the current period (last seven days) and the time spent sitting down. The final score categorizes physical activity levels into low, moderate, or high physical activity. The IPAQ is a suitable questionnaire for population-based physical activity monitoring. The IPAQ-SF can be used for physical activity prevalence studies to monitor the population and has demonstrated adequate reliability and validity[72 73] and has been used in previous studies with stroke population.[74]

Self-perceived quality and quantity of sleep

Sleep Scale from the Medical Outcomes Study (MOS-Sleep) will be used to assess the most important dimensions of sleep quantitatively and qualitatively as well as to assess potential sleep disturbances. The tool consists of 12 items whose responses are based on a retrospective assessment over the last 4 weeks[75]. The MOS-sleep is a suitable and valid questionnaire to obtain information on multiple aspects of sleep quality. The scale has been shown to have good validity and reliability for the assessment of sleep disturbances.

It is a sensitive assessment tool for detecting the impact of an illness or medication on the different dimensions of sleep [76].

Current health status

Current health status will be evaluated with the self-assessed, health-related, quality of life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component scale, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of these dimensions has five possible answers or levels of severity. In the second part of the questionnaire, respondents are asked to rate their current health status on a scale, where 100 corresponds to "the best health status you can imagine" and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable tool for assessing the quality of life [77].

State of anxiety and depression

The state of anxiety and depression will be evaluated with the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a depression and anxiety subscale with interspersed items. The items are scored on a 4-point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale, where a higher score indicates greater symptom severity. The HADS is a reliable and valid tool for assessing levels of depression and anxiety [78] and has been used with stroke survivors in previous studies [79].

Degree of community participation

The degree of community participation will be assessed using the Activity Card Sort for the Spanish population (ACS). The ACS is a scale that measures self-perceived participation using photographs reflecting everyday activities. The activities are

categorised into four domains, instrumental activities, leisure activities with low physical demand, leisure activities with high physical demand, and socio-educational activities. It covers eight of the nine domains of participation as defined by the ICF.[10] The final score is the percentage of activities maintained after an illness, which is developed as a quotient between the number of activities carried out before the illness and those carried out at present. The ACS is a reliable and validated tool for measuring the perceived level of participation.[80 81]

Degree of occupational satisfaction and balance

The degree of occupational satisfaction and balance will be assessed with the Satisfaction with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-based instrument that assesses 13 different occupational items organised into 4 domains: productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the level of participation in an activity, the occupational satisfaction derived from participating in this activity, and the perceived occupational balance within each domain. For each item, the interviewer will determine whether there is participation by the person and then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied and 7 being extremely satisfied). The SDO-OB has good reliability and validity [82].

Physical mobility tests

The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The person will be asked to walk for 10 meters while being timed. The comfortable speed for walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the value of the assessment. The 10MWT is a reliable and validated tool for measuring walking speed.[83]

The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked by the participant in 6 minutes. Standardized guidelines will be followed during the test to give verbal indications concerning the time elapsed and positive reinforcement without any other indications not allowed by the test. The 6MWT is a reliable and valid tool for measuring distance run, endurance, and aerobic capacity.[84]

Additionally, walking aids and a modified Borg Index (0-10) will be collected after each test.

Furthermore, physical mobility tests will be performed in all centres under similar standardized conditions. Before signing the collaborating agreement, each centre will ensure sufficient space on its premises to carry out the tests.

Activity tracker wristband

The Fitbit Inspire 2 activity tracker will be used to assess the level of activity throughout 14-days continuously. The device is based on a 3-axis accelerometery system that monitors physical activity, number of steps, heart rate, sleep duration, and sleep score. The Fitbit wristbands are considered a valid and reliable tool for monitoring physical activity and sleep hours,[85 86] which are considered a valid procedure in stroke survivors.[87 88]

Evaluation of caregivers

Sociodemographic data and IPAQ-SF will be collected from primary caregivers during the first interview with study participants who have suffered a stroke. Caregivers will be monitored with the Fitbit activity wristband while the stroke survivor is monitored.

Assessments and temporality

The evaluations will be carried out similarly at 3 points in time over a 12-month period (i.e., baseline, 6- and 12-months). Each evaluation will be composed of different tests and questionnaires grouped by blocks, to avoid saturation of the participants. Specifically, block 1 will be assessed by the collaborators approximately one week after recruitment, consisting of sociodemographic data, IPAQ-SF, FES-I, Barthel Index, HADS, and EQ-5D-5L. After completing the assessment of block 1, the Fitbit Inspire 2 activity tracker wristband will be linked to the mobile device for 14 days of 24-hour monitoring. Block 2 will be assessed in the settings of collaborator centres approximately two weeks after completing block 1, coinciding with the return of the activity tracker wristband, and will consist of the ACS, the 6MWT, and the 10MWT. Block 3 will be assessed homogenously in all participants by the principal investigator via teleconference within the period between the blocks 1 and 2, and will consist of clinical data, MOS-Sleep, and SDO-OB (figure 1).

One to two weeks after completing the baseline evaluation, a minimum of 50 participants will complete the IPAQ-SF, MOS-sleep, and SDO-OB again. Additionally, during the follow-up period after baseline, a random sample of around 30 participants will participate in unstructured and semi-structured interviews as part of the qualitative design.

Qualitative design

A qualitative phenomenological design will be followed based on Husserl's framework.[89] Data collection will be completed when the information obtained in the interviews becomes repetitive.[90] First-person data collection instruments (unstructured and semi-structured interviews) and the researcher's field notes will be used simultaneously.[90] Data collection will be conducted in two phases. The first phase of data collection will be conducted through unstructured in-depth interviews. The second phase will be conducted

through semi-structured interviews based on the analysis of participants' responses from the first phase, together with questions grouped into 3 research areas: physical activity, participation, and health education.

The analysis proposed by Giorgi will be used.[91] The researcher's field notes will complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.

Different strategies will be followed before and during the data collection process to ensure the methodological rigour and quality of this study (i.e., establishing the positioning of the researchers, triangulation, auditing of the material obtained, and participant verification).

Monitoring of the methodological quality

Given the multicentric nature of the research study, several mechanisms will be implemented to avoid inter-observer bias and reduce random errors as much as possible. Firstly, the assessment protocol comprises measurement instruments with reliable inter-observer psychometric characteristics, allowing a standardized data collection. Secondly, meetings will be held to unify the protocol for the administration of the tools and data collection, establishing a unification of the evaluation criteria for each tool. Thirdly, training sessions on the procedures and administration of the evaluation tools will be conducted both face-to-face and virtually. Additionally, all collaborators will have written manuals that include these standardized and unified procedures. Finally, the project research team will supervise all procedures and solve any potential issues, sharing the relevant information with all collaborators participating.

Sample size

The sample size has been calculated with G*Power (*v3.1.9.4; Heinrich-Heine-University, Dusseldorf, Germany*) based on the requirements of the most demanding research objective in terms of the number of participants (i.e., objective 1). Specifically, after running a priori analysis with an alpha value of 0.05, a power of 80%, and expecting a coefficient of multiple determination (ρ^2) between 0.30 and 0.50, a minimum of 130 participants will be required to perform a random-effects multiple regression model with up to 15 variables. Furthermore, a sample size higher than 73 participants during follow-ups will be sufficient to perform a mixed model for repeated measures with a power of 80% and an alpha error of 0.05 to detect a small to medium standardized mean difference (i.e., f = 0.15) and expecting at least a moderate correlation among repeated measures (i.e., r = 0.5).

Statistical analysis

The results will be presented in tables and graphs by presenting the mean and standard deviation, or the median and interquartile range values, depending on the normality of the data.

Random-effects multiple regression models will be used to examine the factors associated with the stroke survivor's participation and sedentary behaviour, including the sedentary behaviour and individual characteristics of the primary caregiver.

Mixed models for repeated measures will be used to assess the variation over time of the different variables associated with participation and sedentary behaviour.

In the validation process of the SDO-BO in the Spanish stroke survivors, Cronbach's α statistic will be used to test internal consistency and intraclass correlation coefficients to assess test-retest reliability. In addition, Spearman's rank correlation will be used to assess the construct validity of the SDO-BO compared to EQ-5D-5L and ACS.

Pearson's correlations will be used to assess the construct validity of the activity tracker wearable compared to self-reported measures. Furthermore, intraclass correlation coefficients with a 95% confidence interval, the standard error of measurement, and minimum detectable change will be calculated to assess intra-subject reliability of physical activity and sleep parameters recorded by the Fitbit Inspire 2 collected during two-consecutive weeks.

Limitations

This project has some limitations. Firstly, our population does not include stroke survivors with aphasia, an important group who are often excluded from research. Additionally, our population does not include those with limited technical knowledge or people living in nursing homes. Therefore, the generalisability of the results of this study will be limited. This study will not provide insights into physical activity and participation in the acute and subacute phases of stroke recovery, as it only commences in the chronic phase. Finally, physical activity is being monitored by wrist-worn devices which are known to have limitations.[87]

Ethics and confidentiality

The study protocol has been designed following the Helsinki statement and approved by the Spanish regional ethics committee "Comité de Ética de la Investigación de la Comunidad de Aragón" (PI21/333). All patients will receive an information sheet explaining the purpose of the study and the tests and assessments that will be performed if they agree to participate in the study. In addition, subjects will sign the informed consent form once they have agreed to participate in the study. There will be no financial compensation of any kind to the participants in this project.

Dissemination

Any deviation from the protocol will be presented and justified at the time of publication of the results. Regardless of the outcome, the results will be made available via peer-reviewed publications in open-source journals and relevant international conferences within the field of health and behavioural sciences or neurology, among others.

DECLARATIONS

Authors' contributions

CDA and PBL conceived and planned the project. CDA, PBL, JAA, and VDG, with the collaboration of the rest of the authors, contributed to the design of the study protocol. CDA, ABE, JGR, and PRP contributed to the qualitative study design. CDA, PBL, JBA, RGN, MLR, and VDG contributed to the reliability study design. CDA led the recruitment of participating centres and coordination of the professional collaborators. "Part&Sed collaborators" contributed to checking and testing the protocol design and will conduct the data collection. CDA, PBL, ABE, JBA, JRG, VDG, and NF contributed to writing the article. All authors have read and approved the final manuscript.

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Competing interests

None declared.

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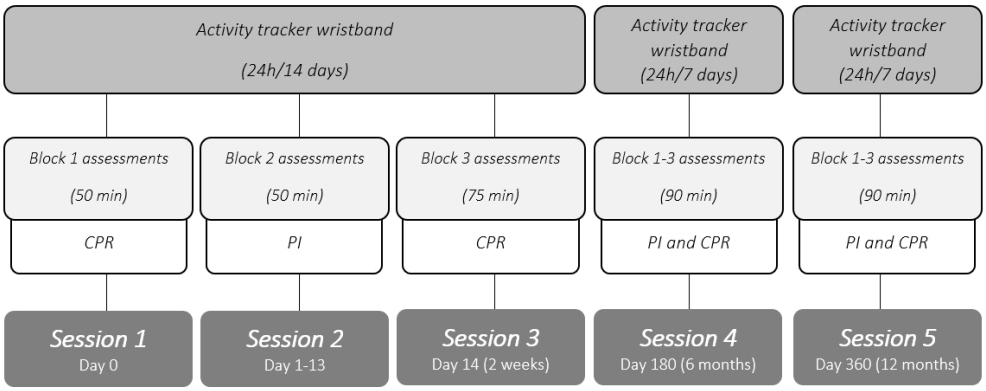
FIGURE LEGEND

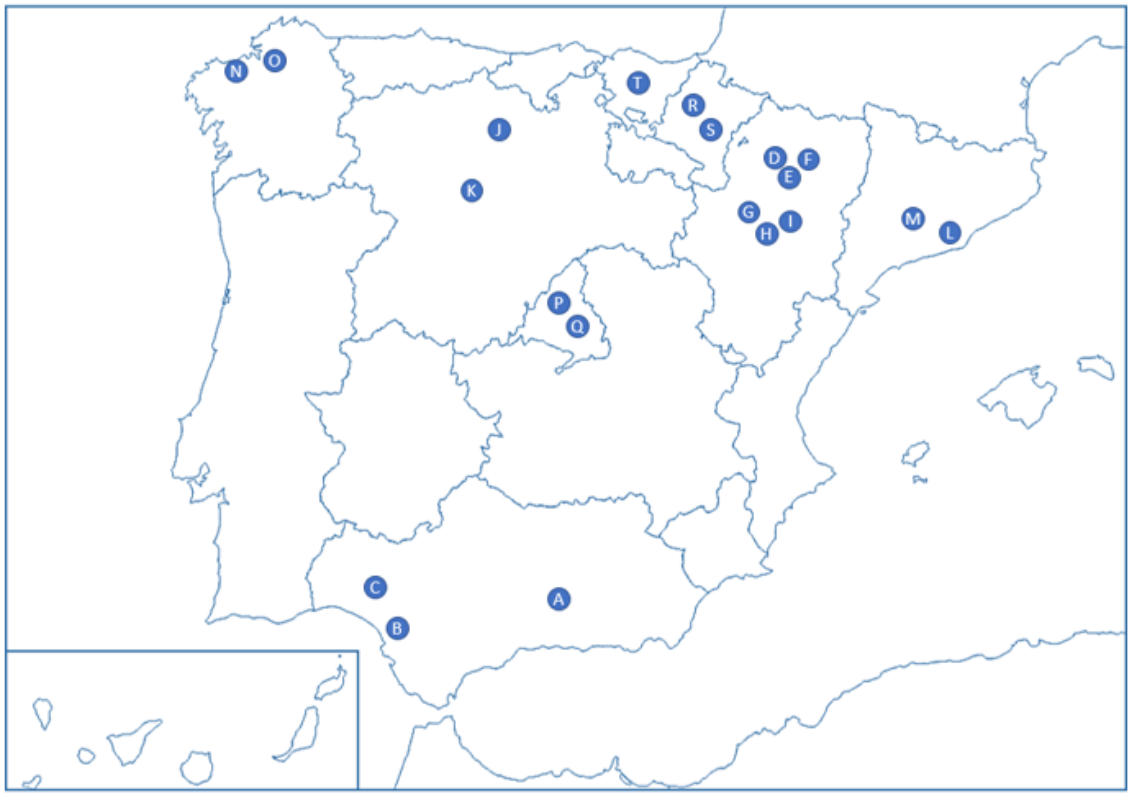
Figure 1. Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.



Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

773x314mm (38 x 38 DPI)

SPAIN REGION	CITY	CENTER NAME
Andalucía	Granada	AGREDACE (A)
Andalucía	San Lucar de barrameda	Freelance Physiotherapist (B)
Andalucía	Sevilla	INEURO (C)
Aragón	Huesca	AENO (D)
Aragón	Huesca	Hospital Provincial Sagrado Corazón de Jesús (E)
Aragón	Huesca	Hospital Universitario San Jorge (F)
Aragón	Zaragoza	AIDA (G)
Aragón	Zaragoza	Grupo 5 CIAN Zaragoza (H)
Aragón	Zaragoza	Rehabilitación El Carmen (I)
Castilla y León	Burgos	ASPAYM (J)
Castilla y León	Valladolid	CIRON (K)
Cataluña	Esplugues de Llobregat	NeuroEsplugues (L)
Cataluña	San Cugat del Vallés	Clínica de neurorrehabilitación (M)
Galicia	A Coruña	ADACECO (N)
Galicia	Ferrol	NEURAXIS (O)
Madrid	Collado Villalba	Fundación Pita López (P)
Madrid	Madrid	Freelance Physiotherapist (Q)
Navarra	Pamplona	Grupo 5 CIAN Navarra (R)
Navarra	Pamplona	CENNER (S)
Pais Vasco	Vitoria	NEUFIS (T)



Supplementary material 1. List of participating centres in relation to their geographical location in Spain.