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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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-065628
Article Type:	Protocol
Date Submitted by the Author:	13-Jun-2022
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Keywords:	Stroke < NEUROLOGY, STROKE MEDICINE, NEUROLOGY, Neurological injury < NEUROLOGY

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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 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.<sup>1 2</sup> 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.<sup>3</sup> In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.<sup>1</sup> Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations<sup>4</sup>, as well as restrictions in participation in self-care, work, leisure and free time, and social activities.<sup>5-8</sup> Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup> Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.<sup>12 13</sup>

Physical inactivity and sedentary behaviour, are one of the main lifestyle-related risk factors for stroke recurrence.<sup>14</sup> Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)<sup>15</sup> and endorsed by the American Heart Association Council (AHAC)<sup>16</sup>. 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.<sup>17</sup> On the other hand, sedentary behaviour is defined as any waking

1  
2  
3 behaviour characterized by an energy expenditure  $\leq 1.5$  metabolic equivalents (METs),  
4  
5 while sitting, reclining, or lying.<sup>18</sup> If the sedentary behaviour is maintained throughout  
6  
7 the day or week while being awake, it can be classified as a Sedentary Behaviour  
8  
9 Pattern.<sup>19</sup> Adult populations who comply with the physical activity WHO  
10  
11 recommendations show a lower risk of death and developing noncommunicable  
12  
13 diseases.<sup>20</sup> However, stroke survivors often report sedentary behaviour most of the day,  
14  
15 especially in the afternoon and evening.<sup>21</sup> Additionally, the average number of sleep hours  
16  
17 is much higher in stroke survivors than in the healthy population, which is associated with  
18  
19 cardiovascular morbidity and mortality.<sup>22</sup>  
20  
21  
22

23  
24 Regarding the factors that contribute to sedentary lifestyles in the stroke  
25  
26 population, it has been observed that inpatient stroke survivors in rehabilitation centres  
27  
28 are more sedentary.<sup>23 24</sup> However, those living in the community still do not meet a  
29  
30 healthy level of physical activity.<sup>25</sup> On the other hand, the fear of falling is associated  
31  
32 with sedentary lifestyles,<sup>26 27</sup> to the extent that stroke survivors reduce activities involving  
33  
34 standing or walking by 20% on average.<sup>28</sup> In turn, the intensity and frequency of  
35  
36 rehabilitation treatment,<sup>23 29</sup> the place of residence and characteristics of the community,<sup>25</sup>  
37  
38 social support,<sup>23</sup> years after stroke,<sup>30</sup> initial stroke severity,<sup>31 32</sup> type of hemiparesis,  
39  
40 greater cognition,<sup>32-34</sup> better endurance and gait speed,<sup>32-35</sup> are further examples of  
41  
42 contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety,  
43  
44 depression, and self-efficacy, can play a role.<sup>36 37</sup> This ensemble of factors warrants  
45  
46 studies analysing multifactorial relationships and to establish a firm consensus on policies  
47  
48 for dealing with the rehabilitation of stroke survivors.  
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52

53  
54 Systematic reviews show that post-stroke interventions do not impact community  
55  
56 participation until several years after stroke<sup>38</sup> and that the identification of barriers is  
57  
58 key.<sup>39</sup> However, despite the limited evidence regarding the factors that influence  
59  
60 participation<sup>30</sup>, having an extensive social network he ability to walk for a few hundred

1  
2 meters or drive are potential facilitators<sup>8</sup>. Additionally, improvements in physical  
3  
4 functioning do not necessarily translate into improved participation in work, domestic,  
5  
6 social and leisure activities.<sup>40 41</sup> This could be why stroke survivors feel unsatisfied about  
7  
8 not recovering pre-stroke participation levels in relevant activities, which may be due to  
9  
10 their environment, age, acceptance of the new situation, or degree of affectation,<sup>42</sup> as well  
11  
12 as due to the presence of comorbidities related to cognitive impairment and depressive  
13  
14 states.<sup>43</sup>  
15  
16  
17

18  
19 Therefore, aiming at emphasizing social reintegration as a long-term goal,<sup>44</sup>  
20  
21 several studies highlight the need to consider other under-investigated factors, such as the  
22  
23 influence of the primary caregiver and the family environment;<sup>36</sup> environmental factors  
24  
25 such as climate and daylight hours;<sup>33</sup> or the impact of treatments focusing on health  
26  
27 education<sup>45</sup> and the person-centred model.<sup>2</sup>  
28  
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## 32 **PART&SED-STROKE PROJECT JUSTIFICATION**

33  
34 The stroke population in Europe, Australia, Canada, and the United States is known to  
35  
36 have high levels of sedentary lifestyles.<sup>21 25 31 32 46-50</sup> However, there is no solid  
37  
38 information about the Spanish population, which would allow the development, as  
39  
40 recommended by the WHO, of a specific public health plan for the stroke survivors in  
41  
42 Spain. For this reason, longitudinal studies are needed to determine the evolution of the  
43  
44 level of physical activity after stroke.<sup>44 46</sup>  
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48  
49 The assessment tools included in the present protocol have been selected based on  
50  
51 the 2018 Cochrane review authored by Lynch et al.,<sup>51</sup> and by the recommendations of  
52  
53 Kwakkel et al.,<sup>52</sup> and its updates in a 2020 Delphi study.<sup>53</sup> Additionally, other reliable  
54  
55 assessment tools are needed to ascertain the amount of sedentary time, assess its effect on  
56  
57 health, and identify significant predictors of physical activity levels.<sup>14</sup> In this sense,  
58  
59 devices with high potential have already been identified at the scientific level,<sup>54 55</sup> and it  
60



1  
2  
3 is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate  
4  
5 monitoring.<sup>56</sup> However, more studies are needed to analyse the potential of new wearable  
6  
7 devices to record this physical activity and measure adherence and compliance with  
8  
9 physical activity recommendations in the stroke population<sup>57</sup>, as well as to assess their  
10  
11 suitability and ease of use in the clinical setting by professionals and patients.  
12  
13 Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband  
14  
15 (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting  
16  
17 the recovery of participatory life after stroke, it is relevant that clinicians have validated  
18  
19 assessment tools for the stroke population on occupational satisfaction.  
20  
21

22  
23 The current protocol has also included the Activity Card Sort (ACS),  
24  
25 recommended in systematic reviews for the ICF domains of activity and participation in  
26  
27 the stroke population.<sup>58 59</sup> Finally, following the recommendations of other studies, other  
28  
29 factors such as personal, sociodemographic, and psychological factors that may have an  
30  
31 impact on mobility in the community have been considered.<sup>33</sup>  
32  
33

34  
35 Considering that the current goal of neurorehabilitation is to design and  
36  
37 personalize physical activity programs according to the ability, goals, and preferences of  
38  
39 the stroke survivor, as well as to encourage long-term lifestyle habits,<sup>60</sup> it is warranted to  
40  
41 conduct longitudinal studies investigating the trajectory and the interrelationship between  
42  
43 sedentary behaviour and participation in stroke survivors.  
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## 48 **Objectives**

- 49  
50 1. To multidimensionally explore the factors associated with participation and  
51  
52 sedentary behaviour in the Spanish stroke survivors.  
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- 54  
55 2. To investigate the influence of sedentary behaviour and individual characteristics  
56  
57 of the primary caregiver on the participation and sedentary lifestyle of the Spanish  
58  
59 stroke survivors.  
60

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,<sup>61</sup> the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),<sup>62</sup> the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),<sup>63</sup> and the COnsolidated criteria for reporting qualitative studies (COREQ),<sup>64</sup> and the Standards for Reporting Qualitative Research (SRQR).<sup>65</sup>

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,

1  
2 including the influence of the primary caregiver. The validation and establishment of the  
3  
4 psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will  
5  
6 be performed. Additionally, a prospective cohort design will be used to assess the  
7  
8 evolution of sedentary and participation behaviours in stroke survivors over time,  
9  
10 identifying those factors that may contribute to a modification of these behaviours.  
11  
12 Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time  
13  
14 frame in which to appreciate meaningful changes. Finally, the life experience of stroke  
15  
16 survivors will be investigated through unstructured in-depth interviews and semi-  
17  
18 structured interviews, which will be analysed by means of a descriptive  
19  
20 phenomenological approach.  
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### 28 **Population**

29  
30 The study sample will consist of people who have suffered a stroke and reside in Spain.  
31  
32 The inclusion criteria will consist of 1) be over 18 years of age; 2) have a history of stroke  
33  
34 with a medical diagnosis for more than 6-months, regardless of its aetiology; 3) outpatient  
35  
36 living at home; 4) have cognitive and speech ability to perform and understand the tests  
37  
38 to be administered and the purpose of the research project (i.e., no aphasia and a Mini-  
39  
40 Mental Cognitive Test score  $>24$ ;<sup>66</sup>) 5) be able to ambulate with or without aids, which  
41  
42 represent an ambulation ability  $\geq 3$  in the Functional Ambulatory Category<sup>67</sup> \*[not  
43  
44 applicable for SDO-OB validation]; 6) minimum knowledge and availability of a mobile  
45  
46 phone; and 7) accept informed consent. The exclusion criteria will be 1) non-acceptance  
47  
48 of participation in the research project by the primary caregiver; 2) not tolerating being  
49  
50 monitored with an activity tracker wristband; 3) residing in institutions (e.g., nursing  
51  
52 homes); and 4) no commitment to continuity. Missing evaluation sessions, existing a  
53  
54 personal or family situation that interferes with data collection, and willingness to  
55  
56 discontinue the study were considered withdrawal criteria.  
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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

1  
2 professionals will express their willingness to participate or not. Each participating centre  
3  
4 must sign the collaboration agreement and each professional belonging to these centres  
5  
6 must accept the document of commitment to participate in the research. These documents  
7  
8 will regulate the anonymized transfer of the data collected for the exclusive use of the  
9  
10 research, as well as the commitments and functions of the institutions and professionals  
11  
12 involved.  
13  
14

15  
16 All participating centres will be included in the database to begin the process of  
17  
18 homogenizing data collection through videoconference meetings and training sessions.  
19  
20 With the aim of facilitating access to information on the study, a secure shared folder has  
21  
22 been created in a virtual space containing documents on the study, information sheets for  
23  
24 participants, consents, collaboration documents, and manuals of procedures to be  
25  
26 followed. In addition, the research team will provide and send a minimum of 2 Fitbit  
27  
28 Inspire-2 monitoring wristbands to each collaborating centre.  
29  
30  
31

### 32 33 34 *Stroke survivor participants and primary caregivers*

35  
36 The recruitment process of participants (stroke survivors and their respective caregivers)  
37  
38 will be carried out in two phases. Firstly, each of the collaborating centres will be  
39  
40 responsible for promoting the existence of the study through their usual internal channels  
41  
42 of communication with their users, such as posters, information circulars, and posts on  
43  
44 social networks. Each potential participant will be given an information sheet about the  
45  
46 research project, and any questions they may have regarding the development of the  
47  
48 research project and their participation in it will be answered.  
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52  
53 Secondly, those users who voluntarily agree to participate in the study will be  
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55 assessed by healthcare professionals (occupational therapists and physiotherapists) with  
56  
57 training and clinical experience in neurorehabilitation to corroborate compliance with the  
58  
59 eligibility criteria. Those who meet the selection criteria will be selected as potential  
60

1  
2 participants and will be asked to sign the informed consent for inclusion in the study.  
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4  
5 Once the informed consent is signed, they will be assigned an appointment for the first  
6  
7 assessment session within approximately one week. The assessment sessions will be  
8  
9 conducted by the same assessors at each centre.  
10

### 11 12 13 14 **Data collection and security measures**

15  
16 Each collaborator will be responsible for collecting part of the data for participants from  
17  
18 their centres. The collection of all the data will be supervised and coordinated by the  
19  
20 research team, and the principal investigator will be in direct contact with each  
21  
22 collaborator to assist with solving any problems that may arise.  
23

24  
25 In order to maintain security in the process of collecting data from each  
26  
27 participant: 1) each collaborator will be assigned an account and password to access the  
28  
29 P4Work application where the data collected from each participant in the study is  
30  
31 recorded;<sup>68</sup> and 2) each collaborator will be provided with accounts and passwords that  
32  
33 must be assigned to each participant (stroke survivor and their main caregiver) to use the  
34  
35 Fitbit application.  
36  
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38  
39 Only the collaborators at each centre will know the identity of each participant  
40  
41 recruited at their centre. In such a way that the data collected from each participant that  
42  
43 the research team will have access to will be assigned to an encrypted and anonymized  
44  
45 identity in both the Fitbit and P4Work applications.  
46  
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### 50 51 **Outcome measures**

#### 52 53 *Sociodemographic data*

54  
55 Sociodemographic data will include age, sex, smoker, educational level, economic level,  
56  
57 employment status, height and weight, municipality, type of housing, presence of  
58  
59 architectural barriers, and home cohabitation.  
60

### 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,<sup>69</sup> the Fall Efficacy Scale (FES-I),<sup>70</sup> and the modified Rankin scale.<sup>71</sup>

### 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<sup>72 73</sup> and has been used in previous studies with stroke population.<sup>74</sup>

### 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<sup>75</sup>. 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.

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2  
3 It is a sensitive assessment tool for detecting the impact of an illness or medication on the  
4  
5 different dimensions of sleep <sup>76</sup>.  
6  
7

### 8 9 Current health status

10  
11 Current health status will be evaluated with the self-assessed, health-related, quality of  
12  
13 life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component  
14  
15 scale, including mobility, self-care, usual activities, pain/discomfort, and  
16  
17 anxiety/depression. Each of these dimensions has five possible answers or levels of  
18  
19 severity. In a second part of the questionnaire, respondents are asked to rate their current  
20  
21 health status on a scale, where 100 corresponds to "the best health status you can imagine"  
22  
23 and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable  
24  
25 tool for assessing the quality of life <sup>77</sup>.  
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### 32 33 State of anxiety and depression

34  
35 The state of anxiety and depression will be evaluated with the Hospital Anxiety and  
36  
37 Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a  
38  
39 depression subscale and an anxiety subscale with interspersed items. The items are scored  
40  
41 on a 4-point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale,  
42  
43 where a higher score indicates greater symptom severity. The HADS is a reliable and  
44  
45 valid tool for assessing levels of depression and anxiety <sup>78</sup> and has been used with stroke  
46  
47 survivors in previous studies <sup>79</sup>.  
48  
49  
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### 53 54 Degree of community participation

55  
56 The degree of community participation will be assessed using the Activity Card Sort for  
57  
58 the Spanish population (ACS). The ACS is a scale that measures self-perceived  
59  
60 participation using photographs reflecting everyday activities. The activities are



1  
2 categorised into four domains, instrumental activities, leisure activities with low physical  
3 demand, leisure activities with high physical demand, and socio-educational activities. It  
4  
5 covers eight of the nine domains of participation as defined by the ICF.<sup>10</sup> The final score  
6  
7 is the percentage of activities maintained after an illness, which is developed as a quotient  
8  
9 between the number of activities carried out before the illness and those carried out at  
10  
11 present. The ACS is a reliable and validated tool for measuring the perceived level of  
12  
13 participation.<sup>80 81</sup>

### 20 21 Degree of occupational satisfaction and balance

22  
23 The degree of occupational satisfaction and balance will be assessed with the Satisfaction  
24  
25 with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-  
26  
27 based instrument that assesses 13 different occupational items organised into 4 domains:  
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29 productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the  
30  
31 level of participation in an activity, the occupational satisfaction derived from  
32  
33 participating in this activity, the perceived occupational balance within each domain. For  
34  
35 each item, the interviewer will determine whether there is participation by the person and  
36  
37 then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied and 7  
38  
39 being extremely satisfied). The SDO-OB has good reliability and validity.<sup>82</sup>

### 44 45 46 Physical mobility tests

47  
48 The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The  
49  
50 person will be asked to walk for 10 meters while being timed. The comfortable speed for  
51  
52 walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the  
53  
54 value of the assessment. The 10MWT is a reliable and validated tool for measuring  
55  
56 walking speed.<sup>83</sup>

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3 The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked  
4 by the participant in 6 minutes. Standardized guidelines will be followed during the test  
5 to give verbal indications concerning the time elapsed and positive reinforcement, without  
6 any other indications not allowed by the test. The 6MWT is a reliable and valid tool for  
7 measuring distance run, endurance, and aerobic capacity.<sup>84</sup>  
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14 Additionally, walking aids and a modified Borg Index (0-10) will be collected  
15 after each test.  
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### 18 19 20 21 Activity tracker wristband

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23 The Fitbit Inspire 2 activity tracker will be used to continuously assess the level of activity  
24 throughout 14-days. The device is based on a 3-axis accelerometry system that allows  
25 monitoring physical activity, number of steps, heart rate, sleep duration, and sleep score.  
26 The Fitbit wristbands are considered a valid and reliable tool for monitoring physical  
27 activity and sleep hours,<sup>85 86</sup> which are considered a valid procedure in stroke  
28 population.<sup>87 88</sup>  
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### 39 40 Evaluation of caregivers

41 Sociodemographic data and IPAQ-SF will be collected from primary caregivers during  
42 the first interview with study participants who have suffered a stroke. Caregivers will be  
43 monitored with the Fitbit activity wristband during the same time as the stroke survivor  
44 is monitored.  
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### 50 51 52 53 Assessments and temporality

54  
55 The evaluations will be carried out in a similar way at 3 points in time over a 12-month  
56 period (i.e., baseline, 6- and 12-months). Each evaluation will be composed of different  
57 tests and questionnaires grouped by blocks, to avoid saturation of the participants.  
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2 Specifically, block 1 will be assessed by the collaborators approximately one week after  
3 recruitment, and will consist of sociodemographic data, IPAQ-SF, FES-I, Barthel Index,  
4 HADS, and EQ-5D-5L. After completing the assessment of block 1, the Fitbit Inspire 2  
5 activity tracker wristband will be linked to the mobile device for 14 days of 24-hour  
6 monitoring. Block 2 will be assessed in the settings of collaborator centres approximately  
7 two weeks after completing block 1, coinciding with the return of the activity tracker  
8 wristband, and will consist of the ACS, the 6MWT, and the 10MWT. Block 3 will be  
9 assessed homogenously in all participants by the principal investigator via teleconference  
10 within the period between the blocks 1 and 2, and will consist of clinical data, MOS-  
11 Sleep, and SDO-OB (figure 1).  
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25 One to two weeks after completing the baseline evaluation, a minimum of 50  
26 participants will complete again the IPAQ-SF, MOS-sleep, and SDO-OB. Additionally,  
27 during the follow-up period after baseline, a random sample of around 30 participants  
28 will participate in unstructured and semi-structured interviews as part of the qualitative  
29 design.  
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### 40 **Qualitative design**

41 A qualitative phenomenological design will be followed based on Husserl's framework.<sup>89</sup>  
42 Data collection will be completed when the information obtained in the interviews  
43 becomes repetitive.<sup>90</sup> First-person data collection instruments (unstructured and semi-  
44 structured interviews) and the researcher's field notes will be used simultaneously.<sup>90</sup> Data  
45 collection will be conducted in two phases. The first phase of data collection will be  
46 conducted through unstructured in-depth interviews. The second phase will be conducted  
47 through semi-structured interviews based on the analysis of participants' responses from  
48 the first phase, together with questions grouped into 3 research areas: physical activity,  
49 participation, and health education.  
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3 The analysis proposed by Giorgi will be used.<sup>91</sup> The researcher's field notes will  
4 complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA  
5 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.  
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10 Different strategies will be followed before and during the data collection process  
11 to ensure the methodological rigour and quality of this study (i.e., establishing the  
12 positioning of the researchers, triangulation, auditing of the material obtained, and  
13 participant verification).  
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### **Monitoring of the methodological quality**

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

52 The sample size has been calculated with G\*Power (v3.1.9.4; *Heinrich-Heine-University,*  
53 *Dusseldorf, Germany*) based on the requirements of the most demanding research  
54 objective in terms of the number of participants (i.e., objective 1). Specifically, after  
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2 running a priori analysis with an alpha value of 0.05, a power of 80%, and expecting a  
3 coefficient of multiple determination ( $r^2$ ) between 0.30 and 0.50, a total of 130  
4 participants will be required to perform a random-effects multiple regression model with  
5 up to 15 variables.  
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### 11 12 13 **Statistical analysis**

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16 The results will be presented in tables and graphs by presenting the mean and standard  
17 deviation, or the median and interquartile range values, depending on the normality of the  
18 data.  
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23 Random-effects multiple regression models will be used to examine the factors  
24 associated with the stroke survivor's participation and sedentary behaviour, including the  
25 sedentary behaviour and individual characteristics of the primary caregiver.  
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30 Mixed models for repeated measures will be used to assess the variation over time  
31 of the different variables associated with participation and sedentary behaviour.  
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35 In the validation process of the SDO-BO in the Spanish stroke survivors,  
36 Cronbach's  $\alpha$  statistic will be used to test internal consistency and intraclass correlation  
37 coefficients to assess test-retest reliability. In addition, Spearman's rank correlation will  
38 be used to assess the construct validity of the SDO-BO compared to EQ-5D-5L and ACS.  
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44 Pearson's correlations will be used to assess the construct validity of the activity  
45 tracker wearable compared to self-reported measures. Furthermore, intraclass correlation  
46 coefficients with a 95% confidence interval, the standard error of measurement, and  
47 minimum detectable change will be calculated to assess intra-subject reliability of  
48 physical activity and sleep parameters recorded by the Fitbit Inspire 2 collected during  
49 two-consecutive weeks.  
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### **Ethics and confidentiality**

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3 The study protocol has been approved by the regional ethics committee “Comité de Ética  
4 de la Investigación de la Comunidad de Aragón” (PI21/333). All patients will receive an  
5 information sheet explaining the purpose of the study and the tests and assessments that  
6  
7 will be performed if they agree to participate in the study. In addition, once they have  
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9 agreed to participate in the study, subjects will sign the informed consent form. There will  
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11 be no financial compensation of any kind to the participants in this project.  
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### 18 **Dissemination**

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

### **Funding**

This work was supported by “Ayudas a Proyectos Internos de Investigación Universidad San Jorge curso 2021-2022” grant number 2122037. PB-L is supported by the Grant FPU19/05237. The funders did not have any role in this study.

### **Acknowledgments**

We thank all the collaborating centres involved for the recruitment of study participants: ADACECO (Asociación de Daño Cerebral de A Coruña) in A Coruña, AENO (Asociación de Enfermos Neurológicos Oscense) in Huesca, AGREDACE (Asociación de Daño Cerebral Adquirido de Granada) in Granada. AIDA (Asociación de Ictus de Aragón) in Zaragoza, ASPAYM (Asociación de personas con lesión medular y otras discapacidades física) in Burgos, CEFINE (Rehabilitación Neurológica Cefine) in A Coruña, CEN (Centro Europeo de Neurociencias) in Madrid, CENNER (Centro de NeuroRehabilitación, Nutrición y Fisioterapia) in Pamplona, Centro de neurorrehabilitación (Clinica de Rehabilitación Neurológica Sant Cugat) in San Cugat del Valles, CIRON (Centro Integral de Rehabilitación ON) in Valladolid, Freelance Physiotherapist in Madrid and SanLucar de Barrameda, FUNDACIÓN PITA LÓPEZ (Centro de Neurorehabilitación de Daño Cerebral Adquirido) in Madrid, Grupo 5 CIAN Navarra (Centro Integral de Atención Neurorehabilitadora) in Pamplona, Grupo 5 CIAN Zaragoza (Centro Integral de Atención Neurorehabilitadora) in Zaragoza, INEURO (Neurorrehabilitación y Atención al Neurodesarrollo) in Sevilla, , NEUFIS (Centro de Fisioterapia y Neurorrehabilitación) in Vitoria, NEURAXIS (Rehabilitación Neurológica



1  
2 y Desarrollo Infantil) in Ferrol, NEUROESPLUGAS (Centre de Rehabilitació  
3  
4 Neurològica) in Esplugues de Llobregat, Rehabilitación El Carmen in Zaragoza.  
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For peer review only

## REFERENCES

1. GBD SC. Global, regional, and national burden of stroke and its risk factors, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet Neurology* 2021;**20**(10):795-820.
2. World Health A. Framework on integrated, people-centred health services: report by the Secretariat. Geneva: World Health Organization, 2016.
3. Cieza A, Causey K, Kamenov K, et al. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2021;**396**(10267):2006-17.
4. Viktorisson A, Reinholdsson M, Danielsson A, et al. Pre-stroke physical activity in relation to post-stroke outcomes - linked to the International Classification of Functioning, Disability and Health (ICF): A scoping review. *Journal of rehabilitation medicine* 2022;**54**:jrm00251.
5. Lee Y, Nicholas ML, Connor LT. Identifying emotional contributors to participation post-stroke. *Topics in stroke rehabilitation* 2021:1-13.
6. Svensson JS, Westerlind E, Persson HC, et al. Occupational gaps 5 years after stroke. *Brain and behavior* 2019;**9**(3):e01234.
7. Singam A, Ytterberg C, Tham K, et al. Participation in Complex and Social Everyday Activities Six Years after Stroke: Predictors for Return to Pre-Stroke Level. *PloS one* 2015;**10**(12):e0144344.
8. Norlander A, Carlstedt E, Jönsson AC, et al. Long-Term Predictors of Social and Leisure Activity 10 Years after Stroke. *PloS one* 2016;**11**(2):e0149395.
9. Kennedy C, Bernhardt J, Churilov L, et al. Factors associated with time to independent walking recovery post-stroke. *Journal of neurology, neurosurgery, and psychiatry* 2021;**92**(7):702-08.

- 1  
2  
3 10. World Health Organization. International Classification of Functioning, Disability  
4  
5 and Health (ICF). *Geneva: World Health Organization, 2001*
- 6  
7 11. Wu Cy, Lin Kc. Defining occupation: A comparative analysis. *Journal of*  
8  
9 *Occupational Science* 1999;**6**(1):5-12.
- 10  
11 12. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
12  
13 domain & process, 4th edition. *The American journal of occupational therapy :*  
14  
15 *official publication of the American Occupational Therapy Association* 2020;**74**
- 16  
17 13. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
18  
19 domain & practice, 2nd edition. *The American journal of occupational therapy :*  
20  
21 *official publication of the American Occupational Therapy Association*  
22  
23 2008;**62**(6):625-83.
- 24  
25 14. English C, Manns PJ, Tucak C, et al. Physical activity and sedentary behaviors in  
26  
27 people with stroke living in the community: a systematic review. *Phys Ther*  
28  
29 2014;**94**(2):185-96.
- 30  
31 15. Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines  
32  
33 on physical activity and sedentary behaviour. *British journal of sports medicine*  
34  
35 2020;**54**(24):1451-62.
- 36  
37 16. Gordon NF, Gulanick M, Costa F, et al. Physical activity and exercise  
38  
39 recommendations for stroke survivors: an American Heart Association scientific  
40  
41 statement from the Council on Clinical Cardiology, Subcommittee on Exercise,  
42  
43 Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing;  
44  
45 the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke  
46  
47 Council. *Circulation* 2004;**109**(16):2031-41.
- 48  
49 17. WHO. Physical activity strategy for the WHO European Region 2016–2025, WHO-  
50  
51 Europe, 2015. 2015
- 52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 18. Letter to the editor: standardized use of the terms "sedentary" and "sedentary  
4  
5 behaviours". *Appl Physiol Nutr Metab* 2012;**37**(3):540-2.  
6
- 7  
8 19. Chastin SF, Granat MH. Methods for objective measure, quantification and analysis  
9  
10 of sedentary behaviour and inactivity. *Gait & posture* 2010;**31**(1):82-6.  
11
- 12  
13 20. Ekelund U, Tarp J, Steene-Johannessen J, et al. Dose-response associations between  
14  
15 accelerometry measured physical activity and sedentary time and all cause  
16  
17 mortality: systematic review and harmonised meta-analysis. *BMJ (Clinical*  
18  
19 *research ed)* 2019;**366**:l4570.  
20
- 21  
22 21. English C, Wondergem R, Hendrickx W, et al. People with Stroke Are Most  
23  
24 Sedentary in the Afternoon and Evening. *Cerebrovasc Dis* 2022:1-6.  
25
- 26  
27 22. Ezeugwu VE, Manns PJ. Sleep Duration, Sedentary Behavior, Physical Activity, and  
28  
29 Quality of Life after Inpatient Stroke Rehabilitation. *Journal of stroke and*  
30  
31 *cerebrovascular diseases : the official journal of National Stroke Association*  
32  
33 2017;**26**(9):2004-12.  
34
- 35  
36 23. Barrett M, Snow JC, Kirkland MC, et al. Excessive sedentary time during in-patient  
37  
38 stroke rehabilitation. *Topics in stroke rehabilitation* 2018;**25**(5):366-74.  
39
- 40  
41 24. Bernhardt J, Dewey H, Thrift A, et al. Inactive and Alone. 2004;**35**(4):1005-09.  
42
- 43  
44 25. Hassett L, Ada L, Hellweg S, et al. Active and sedentary bouts in people after stroke  
45  
46 and healthy controls: An observational study. *Physiother Res Int*  
47  
48 2020;**25**(3):e1845.  
49
- 50  
51 26. Hellström K, Lindmark B, Wahlberg B, et al. Self-efficacy in relation to impairments  
52  
53 and activities of daily living disability in elderly patients with stroke: a prospective  
54  
55 investigation. *Journal of rehabilitation medicine* 2003;**35**(5):202-7.  
56
- 57  
58 27. Salbach NM, Mayo NE, Robichaud-Ekstrand S, et al. Balance self-efficacy and its  
59  
60 relevance to physical function and perceived health status after stroke. *Archives*  
*of physical medicine and rehabilitation* 2006;**87**(3):364-70.

- 1  
2  
3 28. Hanna E, Janssen H, Crowfoot G, et al. Participation, Fear of Falling, and Upper Limb  
4  
5 Impairment are Associated with High Sitting Time in People with Stroke. *Occup*  
6  
7 *Ther Health Care* 2019;**33**(2):181-96.  
8  
9  
10 29. Hebert D, Lindsay MP, McIntyre A, et al. Canadian stroke best practice  
11  
12 recommendations: Stroke rehabilitation practice guidelines, update 2015.  
13  
14 *International journal of stroke : official journal of the International Stroke Society*  
15  
16 2016;**11**(4):459-84.  
17  
18  
19 30. Thilarajah S, Mentiplay BF, Bower KJ, et al. Factors Associated With Post-Stroke  
20  
21 Physical Activity: A Systematic Review and Meta-Analysis. *Archives of physical*  
22  
23 *medicine and rehabilitation* 2018;**99**(9):1876-89.  
24  
25  
26 31. English C, Healy GN, Coates A, et al. Sitting time and physical activity after stroke:  
27  
28 physical ability is only part of the story. *Topics in stroke rehabilitation*  
29  
30 2016;**23**(1):36-42.  
31  
32  
33 32. English C, Healy GN, Coates A, et al. Sitting and Activity Time in People With  
34  
35 Stroke. *Phys Ther* 2016;**96**(2):193-201.  
36  
37  
38 33. Hendrickx W, Riveros C, Askim T, et al. Identifying factors associated with sedentary  
39  
40 time after stroke. Secondary analysis of pooled data from nine primary studies.  
41  
42 *Top Stroke Rehabil* 2019;**26**(5):327-34.  
43  
44  
45 34. Mountain A, Patrice Lindsay M, Teasell R, et al. Canadian Stroke Best Practice  
46  
47 Recommendations: Rehabilitation, Recovery, and Community Participation  
48  
49 following Stroke. Part Two: Transitions and Community Participation Following  
50  
51 Stroke. *International journal of stroke : official journal of the International Stroke*  
52  
53 *Society* 2020;**15**(7):789-806.  
54  
55  
56 35. Fini NA, Bernhardt J, Holland AE. Low gait speed is associated with low physical  
57  
58 activity and high sedentary time following stroke. *Disability and rehabilitation*  
59  
60 2021;**43**(14):2001-08.

- 1  
2  
3 36. Hall J, Morton S, Fitzsimons CF, et al. Factors influencing sedentary behaviours after  
4  
5 stroke: findings from qualitative observations and interviews with stroke  
6  
7 survivors and their caregivers. *BMC public health* 2020;**20**(1):967.  
8  
9  
10 37. Espenberger KR, Fini NA, Peiris CL. Personal and social factors that influence  
11  
12 physical activity levels in community-dwelling stroke survivors: A systematic  
13  
14 review of qualitative literature. *Clinical rehabilitation* 2021;**35**(7):1044-55.  
15  
16  
17 38. Becker I, Maleka MD, Stewart A, et al. Community reintegration post-stroke in New  
18  
19 Zealand: understanding the experiences of stroke survivors in the lower South  
20  
21 Island. *Disability and rehabilitation* 2020:1-8.  
22  
23  
24 39. Wesselhoff S, Hanke TA, Evans CC. Community mobility after stroke: a systematic  
25  
26 review. *Topics in stroke rehabilitation* 2018;**25**(3):224-38.  
27  
28  
29 40. O'Brien AN, Wolf TJ. Determining work outcomes in mild to moderate stroke  
30  
31 survivors. *Work (Reading, Mass)* 2010;**36**(4):441-7.  
32  
33  
34 41. Kaskutas V. Stroke Rehabilitation. A function-based approach. St. Louis, Missouri.  
35  
36 2016:224-236.  
37  
38  
39 42. Engel-Yeger B, Tse T, Josman N, et al. Scoping Review: The Trajectory of Recovery  
40  
41 of Participation Outcomes following Stroke. *Behavioural neurology*  
42  
43 2018;**2018**:5472018.  
44  
45  
46 43. Kapoor A, Lanctôt KL, Bayley M, et al. "Good Outcome" Isn't Good Enough:  
47  
48 Cognitive Impairment, Depressive Symptoms, and Social Restrictions in  
49  
50 Physically Recovered Stroke Patients. *Stroke* 2017;**48**(6):1688-90.  
51  
52  
53 44. Norlander A, Iwarsson S, Jönsson AC, et al. Participation in social and leisure  
54  
55 activities while re-constructing the self: understanding strategies used by stroke  
56  
57 survivors from a long-term perspective. *Disability and rehabilitation* 2021:1-9.  
58  
59  
60 45. Stern BZJTOJoOT. Critical Reflections on Self-Management Support in Chronic  
Disease: The Value of Occupational Therapy in Health Promotion. 2018

- 1  
2  
3 46. Fini NA, Holland AE, Keating J, et al. How Physically Active Are People Following  
4  
5 Stroke? Systematic Review and Quantitative Synthesis. *Phys Ther*  
6  
7 2017;**97**(7):707-17.  
8
- 9 47. Mahendran N, Kuys SS, Brauer SG. Recovery of ambulation activity across the first  
10  
11 six months post-stroke. *Gait Posture* 2016;**49**:271-76.  
12  
13
- 14 48. Hendrickx W, Riveros C, Askim T, et al. An Exploration of Sedentary Behavior  
15  
16 Patterns in Community-Dwelling People With Stroke: A Cluster-Based Analysis.  
17  
18 *Journal of neurologic physical therapy : JNPT* 2021;**45**(3):221-27.  
19  
20
- 21 49. Tieges Z, Mead G, Allerhand M, et al. Sedentary behavior in the first year after stroke:  
22  
23 a longitudinal cohort study with objective measures. *Archives of physical*  
24  
25 *medicine and rehabilitation* 2015;**96**(1):15-23.  
26  
27
- 28 50. Paul L, Brewster S, Wyke S, et al. Physical activity profiles and sedentary behaviour  
29  
30 in people following stroke: a cross-sectional study. *Disability and rehabilitation*  
31  
32 2016;**38**(4):362-7.  
33  
34
- 35 51. Lynch EA, Jones TM, Simpson DB, et al. Activity monitors for increasing physical  
36  
37 activity in adult stroke survivors. *The Cochrane database of systematic reviews*  
38  
39 2018;**7**(7):Cd012543.  
40  
41
- 42 52. Kwakkel G, Lannin NA, Borschmann K, et al. Standardized measurement of  
43  
44 sensorimotor recovery in stroke trials: Consensus-based core recommendations  
45  
46 from the Stroke Recovery and Rehabilitation Roundtable. *International journal*  
47  
48 *of stroke : official journal of the International Stroke Society* 2017;**12**(5):451-61.  
49  
50
- 51 53. Pohl J, Held JPO, Verheyden G, et al. Consensus-Based Core Set of Outcome  
52  
53 Measures for Clinical Motor Rehabilitation After Stroke-A Delphi Study.  
54  
55 *Frontiers in neurology* 2020;**11**:875.  
56  
57
- 58 54. Fini NA, Holland AE, Keating J, et al. How is physical activity monitored in people  
59  
60 following stroke? *Disability and rehabilitation* 2015;**37**(19):1717-31.

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2  
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53  
54  
55  
56  
57  
58  
59  
60
55. Kringle EA, Skidmore ER, Terhorst L, et al. Sedentary behavior patterns over 6 weeks among ambulatory people with stroke. *Topics in stroke rehabilitation* 2021;**28**(7):537-44.
56. Fini NA, Holland AE, Bernhardt J, et al. How Many Hours of Device Wear Time Are Required to Accurately Measure Physical Activity Post Stroke? *International journal of environmental research and public health* 2022;**19**(3)
57. Levy T, Laver K, Killington M, et al. A systematic review of measures of adherence to physical exercise recommendations in people with stroke. *Clinical rehabilitation* 2019;**33**(3):535-45.
58. Kessler D, Egan M. A Review of Measures to Evaluate Participation Outcomes Post-Stroke. 2012;**75**(9):403-11.
59. Tse T, Douglas J, Lentin P, et al. Measuring participation after stroke: a review of frequently used tools. *Archives of physical medicine and rehabilitation* 2013;**94**(1):177-92.
60. Fini NA, Bernhardt J, Said CM, et al. How to Address Physical Activity Participation After Stroke in Research and Clinical Practice. *Stroke* 2021;**52**(6):e274-e77.
61. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**(7624):806-8.
62. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010;**19**(4):539-49.
63. Kottner J, Audigé L, Brorson S, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *J Clin Epidemiol* 2011;**64**(1):96-106.



- 1  
2  
3 64. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research  
4  
5 (COREQ): a 32-item checklist for interviews and focus groups. *International*  
6  
7 *journal for quality in health care : journal of the International Society for Quality*  
8  
9 *in Health Care* 2007;**19**(6):349-57.
- 10  
11 65. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative  
12  
13 research: a synthesis of recommendations. *Academic medicine : journal of the*  
14  
15 *Association of American Medical Colleges* 2014;**89**(9):1245-51.
- 16  
17 66. Lobo A, Saz P, Marcos G, et al. [Revalidation and standardization of the cognition  
18  
19 mini-exam (first Spanish version of the Mini-Mental Status Examination) in the  
20  
21 general geriatric population]. *Medicina clinica* 1999;**112**(20):767-74.
- 22  
23 67. Van Bloemendaal M, Bout W, Bus SA, et al. Validity and reproducibility of the  
24  
25 Functional Gait Assessment in persons after stroke. *Clinical rehabilitation*  
26  
27 2019;**33**(1):94-103.
- 28  
29 68. Bellosta-López P, Domenech-Garcia V, Palsson TS, et al. European knowledge  
30  
31 alliance for innovative measures in prevention of work-related musculoskeletal  
32  
33 pain disorders (Prevent4Work Project): protocol for an international mixed-  
34  
35 methods longitudinal study. *BMJ Open* 2021;**11**(9):e052602.
- 36  
37 69. Gao Y, Wang Y, Li D, et al. Disability assessment in stroke: Relationship among the  
38  
39 pictorial-based Longshi Scale, the Barthel Index, and the modified Rankin Scale.  
40  
41 *Clinical rehabilitation* 2021;**35**(4):606-13.
- 42  
43 70. Lomas-Vega R, Hita-Contreras F, Mendoza N, et al. Cross-cultural adaptation and  
44  
45 validation of the Falls Efficacy Scale International in Spanish postmenopausal  
46  
47 women. *Menopause (New York, NY)* 2012;**19**(8):904-8.
- 48  
49 71. Quinn TJ, Dawson J, Walters MR, et al. Reliability of the Modified Rankin Scale.  
50  
51 2009;**40**(10):3393-95.
- 52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 72. Craig CL, Marshall AL, Sjöström M, et al. International physical activity  
4 questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*  
5 2003;**35**(8):1381-95.  
6  
7  
8  
9  
10 73. SC. Mantilla Toloza AG-C. El Cuestionario Internacional de Actividad Física. Un  
11 instrumento adecuado en el seguimiento de la actividad física poblacional. *Revista*  
12 *Iberoamericana de Fisioterapia y Kinesiología* 2007;**10**(1):48-52.  
13  
14  
15  
16 74. Phusuttatam T, Saengsuwan J, Kittipanya-Ngam P. Development and Preliminary  
17 Validation of a Stroke Physical Activity Questionnaire. *Stroke Res Treat*  
18 2019;**2019**:6764834.  
19  
20  
21  
22  
23 75. Rejas J, Ribera MV, Ruiz M, et al. Psychometric properties of the MOS (Medical  
24 Outcomes Study) Sleep Scale in patients with neuropathic pain. *European journal*  
25 *of pain (London, England)* 2007;**11**(3):329-40.  
26  
27  
28  
29  
30 76. Hays RD, Martin SA, Sesti AM, et al. Psychometric properties of the Medical  
31 Outcomes Study Sleep measure. *Sleep medicine* 2005;**6**(1):41-4.  
32  
33  
34  
35 77. Ramos-Goñi JM, Rivero-Arias O, Errea M, et al. Dealing with the health state 'dead'  
36 when using discrete choice experiments to obtain values for EQ-5D-5L health  
37 states. *The European journal of health economics : HEPAC : health economics in*  
38 *prevention and care* 2013;**14 Suppl 1**(Suppl 1):S33-42.  
39  
40  
41  
42  
43  
44 78. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta psychiatrica*  
45 *Scandinavica* 1983;**67**(6):361-70.  
46  
47  
48  
49 79. Ayis SA, Ayerbe L, Ashworth M, et al. Evaluation of the Hospital Anxiety and  
50 Depression Scale (HADS) in screening stroke patients for symptoms: Item  
51 Response Theory (IRT) analysis. *Journal of affective disorders* 2018;**228**:33-40.  
52  
53  
54  
55 80. Alegre-Muelas C, Alegre-Ayala J, Huertas-Hoyas E, et al. Spanish Transcultural  
56 Adaptation of the Activity Card Sort. *Occupational therapy international*  
57 2019;**2019**:4175184.  
58  
59  
60

- 1  
2  
3 81. Hartman-Maeir A, Eliad Y, Kizoni R, et al. Evaluation of a long-term community  
4 based rehabilitation program for adult stroke survivors. *NeuroRehabilitation*  
5 2007;**22**(4):295-301.  
6  
7  
8  
9  
10 82. Vidaña-Moya L, Eklund M, Merchán-Baeza JA, et al. Cross-Cultural Adaptation,  
11 Validation and Reliability of the Spanish Satisfaction with Daily Occupations-  
12 Occupational Balance (SDO-OB): An Evaluation Tool for People with Mental  
13 Disorders. *International journal of environmental research and public health*  
14 2020;**17**(23)  
15  
16  
17  
18  
19  
20  
21 83. Tyson S, Connell L. The psychometric properties and clinical utility of measures of  
22 walking and mobility in neurological conditions: a systematic review. *Clinical*  
23 *rehabilitation* 2009;**23**(11):1018-33.  
24  
25  
26  
27  
28 84. Macchiavelli A, Giffone A, Ferrarello F, et al. Reliability of the six-minute walk test  
29 in individuals with stroke: systematic review and meta-analysis. *Neurological*  
30 *sciences : official journal of the Italian Neurological Society and of the Italian*  
31 *Society of Clinical Neurophysiology* 2021;**42**(1):81-87.  
32  
33  
34  
35  
36  
37 85. Ringeval M, Wagner G, Denford J, et al. Fitbit-Based Interventions for Healthy  
38 Lifestyle Outcomes: Systematic Review and Meta-Analysis. *J Med Internet Res*  
39 2020;**22**(10):e23954.  
40  
41  
42  
43  
44 86. Feehan LM, Geldman J, Sayre EC, et al. Accuracy of Fitbit Devices: Systematic  
45 Review and Narrative Syntheses of Quantitative Data. *JMIR Mhealth Uhealth*  
46 2018;**6**(8):e10527.  
47  
48  
49  
50  
51 87. Klassen TD, Simpson LA, Lim SB, et al. "Stepping Up" Activity Poststroke: Ankle-  
52 Positioned Accelerometer Can Accurately Record Steps During Slow Walking.  
53 *Phys Ther* 2016;**96**(3):355-60.  
54  
55  
56  
57  
58  
59  
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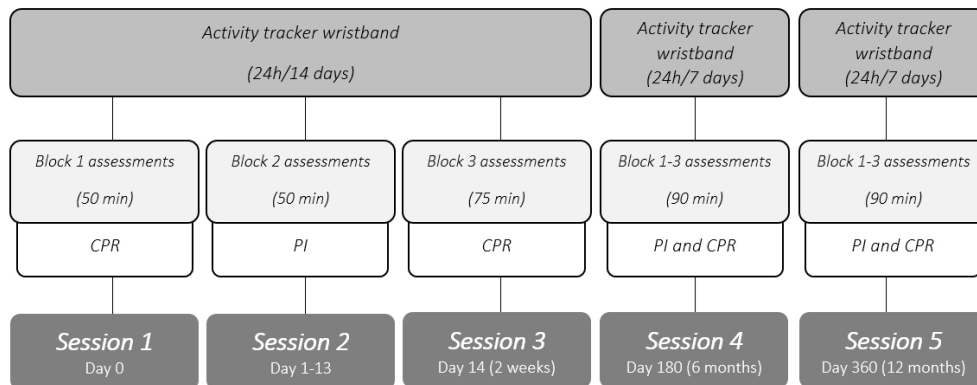
- 1  
2  
3 88. Klassen TD, Semrau JA, Dukelow SP, et al. Consumer-Based Physical Activity  
4  
5 Monitor as a Practical Way to Measure Walking Intensity During Inpatient Stroke  
6  
7 Rehabilitation. *Stroke* 2017;**48**(9):2614-17.  
8
- 9 89. Kim H-K, Jun M, Rhee S, et al. Husserlian phenomenology in Korean nursing  
10  
11 research: analysis, problems, and suggestions. *J Educ Eval Health Prof*  
12  
13 2020;**17**:13-13.  
14  
15
- 16 90. Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3:  
17  
18 Sampling, data collection and analysis. *The European journal of general practice*  
19  
20 2018;**24**(1):9-18.  
21  
22
- 23 91. Giorgi A. The Theory, Practice, and Evaluation of the Phenomenological Method as  
24  
25 a Qualitative Research Procedure. *Journal of Phenomenological Psychology*  
26  
27 1997;**28**(2):235-60.  
28  
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3 **FIGURE LEGEND**  
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5 **Figure 1.** Study timeline design. CPR: Collaborating Professional Researcher; PI:  
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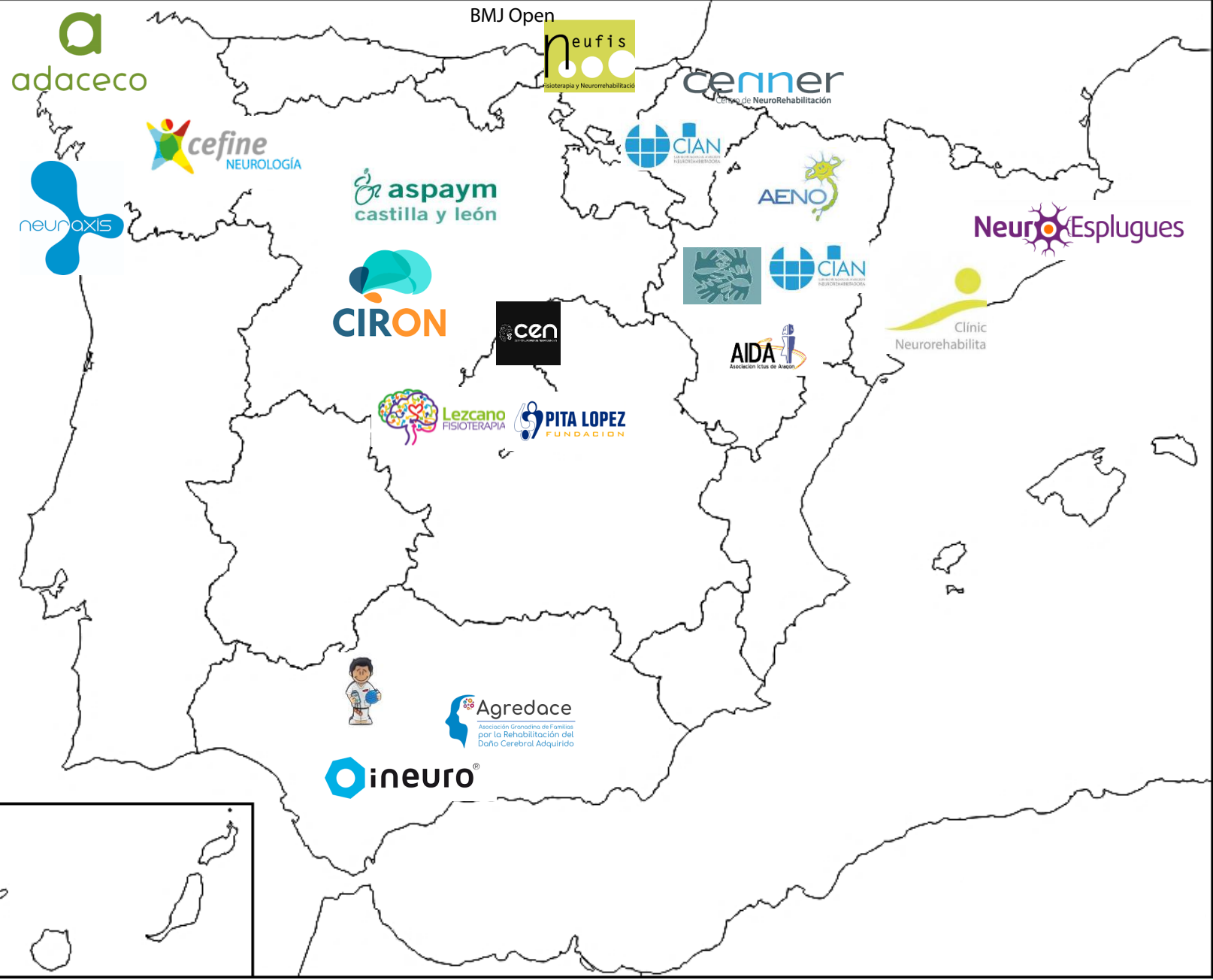
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Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

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39 **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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-065628.R1
Article Type:	Protocol
Date Submitted by the Author:	20-Dec-2022
Complete List of Authors:	de Diego-Alonso, Cristina; Universidad San Jorge Alegre-Ayala, Jorge; Centro Europeo de Neurociencias Buesa, Almudena; San Jorge University - University Campus of the Walqa Technology Park, Blasco-Abadía, Julia; Universidad San Jorge, Department of Physiotherapy Lopez-Royo, Maria Pilar; Universidad San Jorge, Roldán-Pérez, Patricia; Universidad San Jorge Giner-Nicolás, Rafael; Universidad San Jorge Collaborators group, Part&Sed-Stroke; Part&Sed Collaborators group Gueita-Rodríguez, Javier; Universidad Rey Juan Carlos, Physiotherapy, Occupational Therapy, Rehabilitation and Physical Medicine. Fini, Natalie; University of Melbourne, School of Health Sciences , Physiotherapy; Alfred Health, Physiotherapy Domenech-García, Victor ; University of San Jorge Faculty of Health Sciences, Department of Physiotherapy Bellosta-López, Pablo; University of San Jorge Faculty of Health Sciences, Department of Physiotherapy
<b>Primary Subject Heading</b>:	Neurology
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, STROKE MEDICINE, NEUROLOGY, Neurological injury < NEUROLOGY

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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 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.<sup>1 2</sup> 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.<sup>3</sup> In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.<sup>1</sup> Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations<sup>4</sup>, as well as restrictions in participation in self-care, work, leisure and free time, and social activities.<sup>5-8</sup> Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup> Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.<sup>12 13</sup>

Physical inactivity and sedentary behaviour are one of the main lifestyle-related risk factors for stroke recurrence.<sup>14</sup> Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)<sup>15</sup> and endorsed by the American Heart Association Council (AHAC)<sup>16</sup>. 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.<sup>17</sup> On the other hand, sedentary behaviour is defined as any waking

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3 behaviour characterized by an energy expenditure  $\leq 1.5$  metabolic equivalents (METs),  
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5 while sitting, reclining, or lying.<sup>18</sup> If the sedentary behaviour is maintained throughout  
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7 the day or week while being awake, it can be classified as a Sedentary Behaviour  
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9 Pattern.<sup>19</sup> Adult populations who comply with the physical activity WHO  
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11 recommendations show a lower risk of death and developing noncommunicable  
12  
13 diseases.<sup>20</sup> However, stroke survivors often report sedentary behaviour most of the day,  
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15 especially in the afternoon and evening.<sup>21</sup> Additionally, the average number of sleep hours  
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17 is much higher in stroke survivors than in the healthy population, which is associated with  
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19 cardiovascular morbidity and mortality.<sup>22</sup>  
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24 Regarding the factors that contribute to sedentary lifestyles in the stroke  
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26 population, it has been observed that inpatient stroke survivors in rehabilitation centres  
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28 are more sedentary.<sup>23 24</sup> However, those living in the community still do not meet a  
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30 healthy level of physical activity.<sup>25</sup> On the other hand, the fear of falling is associated  
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32 with sedentary lifestyles,<sup>26 27</sup> to the extent that stroke survivors reduce activities involving  
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34 standing or walking by 20% on average.<sup>28</sup> In turn, the intensity and frequency of  
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36 rehabilitation treatment,<sup>23 29</sup> the place of residence and characteristics of the community,<sup>25</sup>  
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38 social support,<sup>23</sup> years after stroke,<sup>30</sup> initial stroke severity,<sup>31 32</sup> type of hemiparesis,  
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40 greater cognition,<sup>32-34</sup> better endurance and gait speed,<sup>32-35</sup> are further examples of  
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42 contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety,  
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44 depression, and self-efficacy, can play a role.<sup>36 37</sup> This ensemble of factors warrants  
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46 studies analysing multifactorial relationships and to establish a firm consensus on policies  
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48 for dealing with the rehabilitation of stroke survivors.  
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54 Systematic reviews show that post-stroke interventions do not impact community  
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56 participation until several years after stroke<sup>38</sup> and that the identification of barriers is  
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58 key.<sup>39</sup> However, despite the limited evidence regarding the factors that influence  
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60 participation<sup>30</sup>, having an extensive social network the ability to walk for a few hundred

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2 meters or drive are potential facilitators<sup>8</sup>. Additionally, improvements in physical  
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4 functioning do not necessarily translate into improved participation in work, domestic,  
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6 social and leisure activities.<sup>40 41</sup> This could be why stroke survivors feel unsatisfied about  
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8 not recovering pre-stroke participation levels in relevant activities, which may be due to  
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10 their environment, age, acceptance of the new situation, or degree of affectation,<sup>42</sup> as well  
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12 as due to the presence of comorbidities related to cognitive impairment and depressive  
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14 states.<sup>43</sup>  
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19 Therefore, aiming at emphasizing social reintegration as a long-term goal,<sup>44</sup>  
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21 several studies highlight the need to consider other under-investigated factors, such as the  
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23 influence of the primary caregiver and the family environment;<sup>36</sup> environmental factors  
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25 such as climate and daylight hours;<sup>33</sup> or the impact of treatments focusing on health  
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27 education<sup>45</sup> and the person-centred model.<sup>2</sup>  
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## 32 **PART&SED-STROKE PROJECT JUSTIFICATION**

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34 The stroke population in Europe, Australia, Canada, and the United States is known to  
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36 have high levels of sedentary lifestyles.<sup>21 25 31 32 46-50</sup> However, there is no solid  
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38 information about the Spanish population, which would allow the development, as  
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40 recommended by the WHO, of a specific public health plan for the stroke survivors in  
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42 Spain. For this reason, longitudinal studies are needed to determine the evolution of the  
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44 level of physical activity after stroke.<sup>44 46</sup>  
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49 The assessment tools included in the present protocol have been selected based on  
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51 the 2018 Cochrane review authored by Lynch et al.,<sup>51</sup> and by the recommendations of  
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53 Kwakkel et al.,<sup>52</sup> and its updates in a 2020 Delphi study.<sup>53</sup> Additionally, other reliable  
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55 assessment tools are needed to ascertain the amount of sedentary time, assess its effect on  
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57 health, and identify significant predictors of physical activity levels.<sup>14</sup> In this sense,  
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59 devices with high potential have already been identified at the scientific level,<sup>54 55</sup> and it  
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3 is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate  
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5 monitoring.<sup>56</sup> However, more studies are needed to analyse the potential of new wearable  
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7 devices to record this physical activity and measure adherence and compliance with  
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9 physical activity recommendations in the stroke population<sup>57</sup>, as well as to assess their  
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11 suitability and ease of use in the clinical setting by professionals and patients.  
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13 Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband  
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15 (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting  
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17 the recovery of participatory life after stroke, it is relevant that clinicians have validated  
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19 assessment tools for the stroke population on occupational satisfaction.  
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23  
24 The current protocol has also included the Activity Card Sort (ACS),  
25  
26 recommended in systematic reviews for the ICF domains of activity and participation in  
27  
28 the stroke population.<sup>58 59</sup> Finally, following the recommendations of other studies, other  
29  
30 factors such as personal, sociodemographic, and psychological factors that may have an  
31  
32 impact on mobility in the community have been considered.<sup>33</sup>  
33  
34

35  
36 Considering that the current goal of neurorehabilitation is to design and  
37  
38 personalize physical activity programs according to the ability, goals, and preferences of  
39  
40 the stroke survivor, as well as to encourage long-term lifestyle habits,<sup>60</sup> it is warranted to  
41  
42 conduct longitudinal studies investigating the trajectory and the interrelationship between  
43  
44 sedentary behaviour and participation in stroke survivors.  
45  
46  
47

## 48 **Objectives**

- 49  
50 1. To multidimensionally explore the factors associated with participation and  
51  
52 sedentary behaviour in the Spanish stroke survivors.  
53
- 54  
55 2. To investigate the influence of sedentary behaviour and individual characteristics  
56  
57 of the primary caregiver on the participation and sedentary lifestyle of the Spanish  
58  
59 stroke survivors.  
60

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,<sup>61</sup> the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),<sup>62</sup> the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),<sup>63</sup> and the COnsolidated criteria for reporting qualitative studies (COREQ),<sup>64</sup> and the Standards for Reporting Qualitative Research (SRQR).<sup>65</sup>

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,



1  
2 including the influence of the primary caregiver. The validation and establishment of the  
3  
4 psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will  
5  
6 be performed. Additionally, a prospective cohort design will be used to assess the  
7  
8 evolution of sedentary and participation behaviours in stroke survivors over time,  
9  
10 identifying those factors that may contribute to a modification of these behaviours.  
11  
12 Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time  
13  
14 frame in which to appreciate meaningful changes. Finally, the life experience of stroke  
15  
16 survivors will be investigated through unstructured in-depth interviews and semi-  
17  
18 structured interviews, which will be analysed by means of a descriptive  
19  
20 phenomenological approach.  
21  
22  
23  
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27

### 28 **Population**

29  
30 The study sample will consist of people of both sexes who have suffered a stroke and  
31  
32 reside in Spain. The inclusion criteria will consist of 1) be over 18 years of age; 2) have  
33  
34 a history of stroke with a medical diagnosis for more than 6-months, regardless of its  
35  
36 aetiology; 3) outpatient living at home; 4) have cognitive and speech ability to perform  
37  
38 and understand the tests to be administered and the purpose of the research project (i.e.,  
39  
40 no aphasia and a Mini-Mental Cognitive Test score  $>24$ ;<sup>66</sup>) 5) be able to ambulate with  
41  
42 or without aids, which represent an ambulation ability  $\geq 3$  in the Functional Ambulatory  
43  
44 Category<sup>67</sup> \*[not applicable for SDO-OB validation]; and 6) availability of a mobile  
45  
46 phone with Bluetooth and internet connection. The exclusion criteria will be 1) non-  
47  
48 acceptance of participation in the research project by the primary caregiver; 2) not  
49  
50 tolerating being monitored with an activity tracker wristband; 3) residing in institutions  
51  
52 (e.g., nursing homes); 4) no commitment to continuity; and 5) a history of more than one  
53  
54 symptomatic stroke. Missing evaluation sessions, existing a personal or family situation  
55  
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60

1  
2  
3 that interferes with data collection, and willingness to discontinue the study were  
4  
5 considered withdrawal criteria.  
6

7 If the stroke survivor has a primary caregiver, the primary caregiver will be invited  
8  
9 to participate in the study. A primary caregiver is defined as a person, either a family  
10  
11 member or an employee, who spends more than half of their daily time supporting or  
12  
13 caring for the stroke survivor.  
14  
15

### 16 17 18 **Patient and public involvement** 19

20 Patients or the public were not involved in the design, conduct, reporting, or  
21  
22 dissemination plans of this research.  
23  
24  
25

### 26 27 28 **Contact and recruitment** 29

#### 30 *Centres and Health professionals* 31

32 The collaborators will be composed of health professionals (physiotherapists and  
33  
34 occupational therapists) working in institutions, centres, and associations, as well as self-  
35  
36 employed professionals, whose field of action is focused on the neurological  
37  
38 rehabilitation of stroke survivors. Specifically, in a first phase, contact will be established  
39  
40 via email or telephone with professionals who form part of the research team's network.  
41  
42 While in a second phase, general information about the research study will be  
43  
44 disseminated through social networks (i.e., Twitter and LinkedIn) to increase the number  
45  
46 of potential organizations and professionals collaborating. These collaborators will meet  
47  
48 the conditions of residing in different parts of Spain, having extensive experience in  
49  
50 neurological rehabilitation, and currently providing care to stroke survivors.  
51  
52  
53

54  
55 All those who will show interest in the study will receive a document that includes  
56  
57 information on the objective of the study, criteria for the selection of the sample, functions  
58  
59 to be carried out that would imply their commitment to participate and a timetable for  
60

1  
2 data collection. If there is continued interest in participating, a first meeting will be held  
3  
4 to provide further information and resolve doubts. After this meeting, the centres and  
5  
6 professionals will express their willingness to participate or not. Each participating centre  
7  
8 must sign the collaboration agreement and each professional belonging to these centres  
9  
10 must accept the document of commitment to participate in the research. These documents  
11  
12 will regulate the anonymized transfer of the data collected for the exclusive use of the  
13  
14 research, as well as the commitments and functions of the institutions and professionals  
15  
16 involved.  
17  
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19

20  
21 All participating centres will be included in the database to begin the process of  
22  
23 homogenizing data collection through videoconference meetings and training sessions.  
24  
25 With the aim of facilitating access to information on the study, a secure shared folder has  
26  
27 been created in a virtual space containing documents on the study, information sheets for  
28  
29 participants, consents, collaboration documents, and manuals of procedures to be  
30  
31 followed. In addition, the research team will provide and send a minimum of 2 Fitbit  
32  
33 Inspire-2 monitoring wristbands to each collaborating centre.  
34  
35  
36  
37  
38

#### 39 *Stroke survivor participants and primary caregivers*

40  
41 The recruitment process of participants (stroke survivors and their respective caregivers)  
42  
43 will be carried out in two phases. Firstly, each of the collaborating centres will be  
44  
45 responsible for promoting the existence of the study through their usual internal channels  
46  
47 of communication with their users, such as posters, information circulars, and posts on  
48  
49 social networks. Each potential participant will be given an information sheet about the  
50  
51 research project, and any questions they may have regarding the development of the  
52  
53 research project and their participation in it will be answered.  
54  
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56

57  
58 Secondly, those users who voluntarily agree to participate in the study will be  
59  
60 assessed by healthcare professionals (occupational therapists and physiotherapists) with

1  
2  
3 training and clinical experience in neurorehabilitation to corroborate compliance with the  
4  
5 eligibility criteria. Those who meet the selection criteria will be selected as potential  
6  
7 participants and will be asked to sign the informed consent for inclusion in the study.  
8  
9 Once the informed consent is signed, they will be assigned an appointment for the first  
10  
11 assessment session within approximately one week. The assessment sessions will be  
12  
13 conducted by the same assessors at each centre.  
14  
15  
16  
17

### **Data collection and security measures**

18  
19  
20 Each collaborator will be responsible for collecting part of the data for participants from  
21  
22 their centres. The collection of all the data will be supervised and coordinated by the  
23  
24 research team, and the principal investigator will be in direct contact with each  
25  
26 collaborator to assist with solving any problems that may arise.  
27  
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29

30  
31 In order to maintain security in the process of collecting data from each  
32  
33 participant: 1) each collaborator will be assigned an account and password to access the  
34  
35 P4Work application where the data collected from each participant in the study is  
36  
37 recorded;<sup>68</sup> and 2) each collaborator will be provided with accounts and passwords that  
38  
39 must be assigned to each participant (stroke survivor and their main caregiver) to use the  
40  
41 Fitbit application.  
42  
43

44  
45 Only the collaborators at each centre will know the identity of each participant  
46  
47 recruited at their centre. In such a way that the data collected from each participant that  
48  
49 the research team will have access to will be assigned to an encrypted and anonymized  
50  
51 identity in both the Fitbit and P4Work applications.  
52  
53  
54

### **Outcome measures**

#### **Sociodemographic data**

1  
2 Sociodemographic data will include age, sex, smoker, educational level, economic level,  
3  
4 employment status, height and weight, municipality, type of housing, presence of  
5  
6 architectural barriers, and home cohabitation.  
7  
8  
9

### 10 11 Clinical data

12  
13 Clinical data will include information such as age at the time of stroke, type of stroke,  
14  
15 damaged cerebral hemisphere, time of evolution, pain experience, other pathologies  
16  
17 (including number of silent or subclinical strokes), current medication, current  
18  
19 rehabilitation and hours per week, number of falls in the last six months, use of assistive  
20  
21 devices, the Barthel Index,<sup>69</sup> the Fall Efficacy Scale (FES-I),<sup>70</sup> and the modified Rankin  
22  
23 scale.<sup>71</sup>  
24  
25  
26  
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28  
29

### 30 31 Self-reported physical activity

32  
33 Self-reported physical activity will be evaluated with the short version of the International  
34  
35 Physical Activity Questionnaire (IPAQ-SF). The IPAQ-SF is a self-report scale that aims  
36  
37 to determine the level of physical activity in the current period (last seven days) and the  
38  
39 time spent sitting down. The final score categorizes physical activity levels into low,  
40  
41 moderate, or high physical activity. The IPAQ is a suitable questionnaire for population-  
42  
43 based physical activity monitoring. The IPAQ-SF can be used for physical activity  
44  
45 prevalence studies to monitor the population and has demonstrated adequate reliability  
46  
47 and validity<sup>72 73</sup> and has been used in previous studies with stroke population.<sup>74</sup>  
48  
49  
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### 53 54 Self-perceived quality and quantity of sleep

55  
56 Sleep Scale from the Medical Outcomes Study (MOS-Sleep) will be used to assess the  
57  
58 most important dimensions of sleep quantitatively and qualitatively as well as to assess  
59  
60 potential sleep disturbances. The tool consists of 12 items whose responses are based on

1  
2 a retrospective assessment over the last 4 weeks<sup>75</sup>. The MOS-sleep is a suitable and valid  
3  
4 questionnaire to obtain information on multiple aspects of sleep quality. The scale has  
5  
6 been shown to have good validity and reliability for the assessment of sleep disturbances.  
7  
8 It is a sensitive assessment tool for detecting the impact of an illness or medication on the  
9  
10 different dimensions of sleep <sup>76</sup>.  
11  
12  
13  
14  
15

### 16 Current health status

17  
18 Current health status will be evaluated with the self-assessed, health-related, quality of  
19  
20 life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component  
21  
22 scale, including mobility, self-care, usual activities, pain/discomfort, and  
23  
24 anxiety/depression. Each of these dimensions has five possible answers or levels of  
25  
26 severity. In a second part of the questionnaire, respondents are asked to rate their current  
27  
28 health status on a scale, where 100 corresponds to "the best health status you can imagine"  
29  
30 and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable  
31  
32 tool for assessing the quality of life <sup>77</sup>.  
33  
34  
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36  
37  
38

### 39 State of anxiety and depression

40  
41 The state of anxiety and depression will be evaluated with the Hospital Anxiety and  
42  
43 Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a  
44  
45 depression subscale and an anxiety subscale with interspersed items. The items are scored  
46  
47 on a 4-point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale,  
48  
49 where a higher score indicates greater symptom severity. The HADS is a reliable and  
50  
51 valid tool for assessing levels of depression and anxiety <sup>78</sup> and has been used with stroke  
52  
53 survivors in previous studies <sup>79</sup>.  
54  
55  
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59

### 60 Degree of community participation

1  
2  
3 The degree of community participation will be assessed using the Activity Card Sort for  
4 the Spanish population (ACS). The ACS is a scale that measures self-perceived  
5 participation using photographs reflecting everyday activities. The activities are  
6 categorised into four domains, instrumental activities, leisure activities with low physical  
7 demand, leisure activities with high physical demand, and socio-educational activities. It  
8 covers eight of the nine domains of participation as defined by the ICF.<sup>10</sup> The final score  
9 is the percentage of activities maintained after an illness, which is developed as a quotient  
10 between the number of activities carried out before the illness and those carried out at  
11 present. The ACS is a reliable and validated tool for measuring the perceived level of  
12 participation.<sup>80 81</sup>

### Degree of occupational satisfaction and balance

25  
26  
27  
28  
29  
30 The degree of occupational satisfaction and balance will be assessed with the Satisfaction  
31 with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-  
32 based instrument that assesses 13 different occupational items organised into 4 domains:  
33 productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the  
34 level of participation in an activity, the occupational satisfaction derived from  
35 participating in this activity, the perceived occupational balance within each domain. For  
36 each item, the interviewer will determine whether there is participation by the person and  
37 then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied and 7  
38 being extremely satisfied). The SDO-OB has good reliability and validity<sup>82</sup>.

### Physical mobility tests

53  
54  
55 The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The  
56 person will be asked to walk for 10 meters while being timed. The comfortable speed for  
57 walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the  
58  
59  
60

1  
2  
3 value of the assessment. The 10MWT is a reliable and validated tool for measuring  
4  
5 walking speed.<sup>83</sup>  
6

7 The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked  
8  
9 by the participant in 6 minutes. Standardized guidelines will be followed during the test  
10  
11 to give verbal indications concerning the time elapsed and positive reinforcement, without  
12  
13 any other indications not allowed by the test. The 6MWT is a reliable and valid tool for  
14  
15 measuring distance run, endurance, and aerobic capacity.<sup>84</sup>  
16  
17

18  
19 Additionally, walking aids and a modified Borg Index (0-10) will be collected  
20  
21 after each test.  
22

23 Furthermore, physical mobility tests will be performed in all centres under similar  
24  
25 standardized conditions. Before signing the collaborating agreement, each centre will  
26  
27 ensure that it has sufficient space on its premises to carry out the tests.  
28  
29  
30

### 31 32 Activity tracker wristband 33

34 The Fitbit Inspire 2 activity tracker will be used to continuously assess the level of activity  
35  
36 throughout 14-days. The device is based on a 3-axis accelerometry system that allows  
37  
38 monitoring physical activity, number of steps, heart rate, sleep duration, and sleep score.  
39  
40 The Fitbit wristbands are considered a valid and reliable tool for monitoring physical  
41  
42 activity and sleep hours,<sup>85 86</sup> which are considered a valid procedure in stroke  
43  
44 population.<sup>87 88</sup>  
45  
46  
47  
48  
49

### 50 51 Evaluation of caregivers 52

53 Sociodemographic data and IPAQ-SF will be collected from primary caregivers during  
54  
55 the first interview with study participants who have suffered a stroke. Caregivers will be  
56  
57 monitored with the Fitbit activity wristband during the same time as the stroke survivor  
58  
59 is monitored.  
60



### **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 homogeneously 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.<sup>89</sup> Data collection will be completed when the information obtained in the interviews becomes repetitive.<sup>90</sup> First-person data collection instruments (unstructured and semi-structured interviews) and the researcher's field notes will be used simultaneously.<sup>90</sup> Data

1  
2 collection will be conducted in two phases. The first phase of data collection will be  
3  
4 conducted through unstructured in-depth interviews. The second phase will be conducted  
5  
6 through semi-structured interviews based on the analysis of participants' responses from  
7  
8 the first phase, together with questions grouped into 3 research areas: physical activity,  
9  
10 participation, and health education.  
11  
12

13  
14 The analysis proposed by Giorgi will be used.<sup>91</sup> The researcher's field notes will  
15  
16 complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA  
17  
18 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.  
19  
20  
21

22  
23 Different strategies will be followed before and during the data collection process  
24  
25 to ensure the methodological rigour and quality of this study (i.e., establishing the  
26  
27 positioning of the researchers, triangulation, auditing of the material obtained, and  
28  
29 participant verification).  
30  
31

### 32 33 34 **Monitoring of the methodological quality**

35  
36 Given the multicentric nature of the research study, several mechanisms will be  
37  
38 implemented to avoid inter-observer bias and reduce random errors as much as possible.  
39  
40 Firstly, the assessment protocol is composed of measurement instruments with reliable  
41  
42 inter-observer psychometric characteristics, which allows a standardized data collection.  
43  
44 Secondly, meetings to unify the protocol for administration of the tools and data  
45  
46 collection will be performed, establishing a unification of the evaluation criteria in each  
47  
48 of the items of the tools. Thirdly, training sessions on the procedures and administration  
49  
50 of the evaluation tools will be conducted both face-to-face and virtually. Additionally, all  
51  
52 collaborators will have written manuals that include these standardized and unified  
53  
54 procedures. Finally, the project research team will supervise all procedures and solve any  
55  
56 potential issues, sharing the relevant information with all collaborators participating.  
57  
58  
59  
60

### **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 ( $\rho^2$ ) 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 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  $\alpha$  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.

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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.<sup>87</sup>

### **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.

For peer review only

## **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.

### **Funding**

This work was supported by “Ayudas a Proyectos Internos de Investigación Universidad San Jorge curso 2021-2022” grant number 2122037 and “Ayudas a Proyectos Internos de Investigación Universidad San Jorge curso 2022-2023” grant number 2122037. PB-L is supported by the Grant FPU19/05237 and JB-A by the Grant PIF 2022-2026 from "Gobierno de Aragón". The funders did not have any role in this study.

### **Acknowledgments**

We thank all the collaborating centres involved for the recruitment of study participants: ADACECO (Asociación de Daño Cerebral de A Coruña) in A Coruña, AENO (Asociación de Enfermos Neurológicos Oscense) in Huesca, AGREDACE (Asociación de Daño Cerebral Adquirido de Granada) in Granada. AIDA (Asociación de Ictus de Aragón) in Zaragoza, ASPAYM (Asociación de personas con lesión medular y otras discapacidades física) in Burgos, CEFINE (Rehabilitación Neurológica Cefine) in A Coruña, CEN (Centro Europeo de Neurociencias) in Madrid, CENNER (Centro de NeuroRehabilitación, Nutrición y Fisioterapia) in Pamplona, Centro de neurorrehabilitación (Clínica de Rehabilitación Neurológica Sant Cugat) in San Cugat del Valles, CIRON (Centro Integral de Rehabilitación ON) in Valladolid, Freelance Physiotherapist in Madrid and SanLucar de Barrameda, FUNDACIÓN PITA LÓPEZ (Centro de Neurorehabilitación de Daño Cerebral Adquirido) in Madrid, Grupo 5 CIAN Navarra (Centro Integral de Atención Neurorehabilitadora) in Pamplona, Grupo 5 CIAN

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2 Zaragoza (Centro Integral de Atención Neurorehabilitadora) in Zaragoza, INEURO  
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4 (Neurorrehabilitación y Atención al Neurodesarrollo) in Sevilla, , NEUFIS (Centro de  
5  
6 Fisioterapia y Neurorrehabilitación) in Vitoria, NEURAXIS (Rehabilitación Neurológica  
7  
8 y Desarrollo Infantil) in Ferrol, NEUROESPLUGUES (Centre de Rehabilitació  
9  
10 Neurològica) in Esplugues de Llobregat, Rehabilitación El Carmen in Zaragoza.  
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For peer review only



## **REFERENCES**

1. GBD SC. Global, regional, and national burden of stroke and its risk factors, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet Neurology* 2021;**20**(10):795-820.
2. World Health A. Framework on integrated, people-centred health services: report by the Secretariat. Geneva: World Health Organization, 2016.
3. Cieza A, Causey K, Kamenov K, et al. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2021;**396**(10267):2006-17.
4. Viktorisson A, Reinholdsson M, Danielsson A, et al. Pre-stroke physical activity in relation to post-stroke outcomes - linked to the International Classification of Functioning, Disability and Health (ICF): A scoping review. *Journal of rehabilitation medicine* 2022;**54**:jrm00251.
5. Lee Y, Nicholas ML, Connor LT. Identifying emotional contributors to participation post-stroke. *Topics in stroke rehabilitation* 2021:1-13.
6. Svensson JS, Westerlind E, Persson HC, et al. Occupational gaps 5 years after stroke. *Brain and behavior* 2019;**9**(3):e01234.
7. Singam A, Ytterberg C, Tham K, et al. Participation in Complex and Social Everyday Activities Six Years after Stroke: Predictors for Return to Pre-Stroke Level. *PloS one* 2015;**10**(12):e0144344.
8. Norlander A, Carlstedt E, Jönsson AC, et al. Long-Term Predictors of Social and Leisure Activity 10 Years after Stroke. *PloS one* 2016;**11**(2):e0149395.
9. Kennedy C, Bernhardt J, Churilov L, et al. Factors associated with time to independent walking recovery post-stroke. *Journal of neurology, neurosurgery, and psychiatry* 2021;**92**(7):702-08.

- 1  
2  
3 10. World Health Organization. International Classification of Functioning, Disability  
4  
5 and Health (ICF). *Geneva: World Health Organization, 2001*
- 6  
7 11. Wu Cy, Lin Kc. Defining occupation: A comparative analysis. *Journal of*  
8  
9 *Occupational Science* 1999;**6**(1):5-12.
- 10  
11 12. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
12  
13 domain & process, 4th edition. *The American journal of occupational therapy :*  
14  
15 *official publication of the American Occupational Therapy Association* 2020;**74**
- 16  
17 13. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
18  
19 domain & practice, 2nd edition. *The American journal of occupational therapy :*  
20  
21 *official publication of the American Occupational Therapy Association*  
22  
23 2008;**62**(6):625-83.
- 24  
25 14. English C, Manns PJ, Tucak C, et al. Physical activity and sedentary behaviors in  
26  
27 people with stroke living in the community: a systematic review. *Phys Ther*  
28  
29 2014;**94**(2):185-96.
- 30  
31 15. Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines  
32  
33 on physical activity and sedentary behaviour. *British journal of sports medicine*  
34  
35 2020;**54**(24):1451-62.
- 36  
37 16. Gordon NF, Gulanick M, Costa F, et al. Physical activity and exercise  
38  
39 recommendations for stroke survivors: an American Heart Association scientific  
40  
41 statement from the Council on Clinical Cardiology, Subcommittee on Exercise,  
42  
43 Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing;  
44  
45 the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke  
46  
47 Council. *Circulation* 2004;**109**(16):2031-41.
- 48  
49 17. WHO. Physical activity strategy for the WHO European Region 2016–2025, WHO-  
50  
51 Europe, 2015. 2015
- 52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 18. Letter to the editor: standardized use of the terms "sedentary" and "sedentary  
4  
5 behaviours". *Appl Physiol Nutr Metab* 2012;**37**(3):540-2.  
6
- 7  
8 19. Chastin SF, Granat MH. Methods for objective measure, quantification and analysis  
9  
10 of sedentary behaviour and inactivity. *Gait & posture* 2010;**31**(1):82-6.  
11
- 12  
13 20. Ekelund U, Tarp J, Steene-Johannessen J, et al. Dose-response associations between  
14  
15 accelerometry measured physical activity and sedentary time and all cause  
16  
17 mortality: systematic review and harmonised meta-analysis. *BMJ (Clinical*  
18  
19 *research ed)* 2019;**366**:l4570.  
20
- 21  
22 21. English C, Wondergem R, Hendrickx W, et al. People with Stroke Are Most  
23  
24 Sedentary in the Afternoon and Evening. *Cerebrovasc Dis* 2022:1-6.  
25
- 26  
27 22. Ezeugwu VE, Manns PJ. Sleep Duration, Sedentary Behavior, Physical Activity, and  
28  
29 Quality of Life after Inpatient Stroke Rehabilitation. *Journal of stroke and*  
30  
31 *cerebrovascular diseases : the official journal of National Stroke Association*  
32  
33 2017;**26**(9):2004-12.  
34
- 35  
36 23. Barrett M, Snow JC, Kirkland MC, et al. Excessive sedentary time during in-patient  
37  
38 stroke rehabilitation. *Topics in stroke rehabilitation* 2018;**25**(5):366-74.  
39
- 40  
41 24. Bernhardt J, Dewey H, Thrift A, et al. Inactive and Alone. 2004;**35**(4):1005-09.  
42
- 43  
44 25. Hassett L, Ada L, Hellweg S, et al. Active and sedentary bouts in people after stroke  
45  
46 and healthy controls: An observational study. *Physiother Res Int*  
47  
48 2020;**25**(3):e1845.  
49
- 50  
51 26. Hellström K, Lindmark B, Wahlberg B, et al. Self-efficacy in relation to impairments  
52  
53 and activities of daily living disability in elderly patients with stroke: a prospective  
54  
55 investigation. *Journal of rehabilitation medicine* 2003;**35**(5):202-7.  
56
- 57  
58 27. Salbach NM, Mayo NE, Robichaud-Ekstrand S, et al. Balance self-efficacy and its  
59  
60 relevance to physical function and perceived health status after stroke. *Archives*  
*of physical medicine and rehabilitation* 2006;**87**(3):364-70.

- 1  
2  
3 28. Hanna E, Janssen H, Crowfoot G, et al. Participation, Fear of Falling, and Upper Limb  
4  
5 Impairment are Associated with High Sitting Time in People with Stroke. *Occup*  
6  
7 *Ther Health Care* 2019;**33**(2):181-96.  
8  
9  
10 29. Hebert D, Lindsay MP, McIntyre A, et al. Canadian stroke best practice  
11  
12 recommendations: Stroke rehabilitation practice guidelines, update 2015.  
13  
14 *International journal of stroke : official journal of the International Stroke Society*  
15  
16 2016;**11**(4):459-84.  
17  
18 30. Thilarajah S, Mentiplay BF, Bower KJ, et al. Factors Associated With Post-Stroke  
19  
20 Physical Activity: A Systematic Review and Meta-Analysis. *Archives of physical*  
21  
22 *medicine and rehabilitation* 2018;**99**(9):1876-89.  
23  
24  
25 31. English C, Healy GN, Coates A, et al. Sitting time and physical activity after stroke:  
26  
27 physical ability is only part of the story. *Topics in stroke rehabilitation*  
28  
29 2016;**23**(1):36-42.  
30  
31  
32 32. English C, Healy GN, Coates A, et al. Sitting and Activity Time in People With  
33  
34 Stroke. *Phys Ther* 2016;**96**(2):193-201.  
35  
36  
37 33. Hendrickx W, Riveros C, Askim T, et al. Identifying factors associated with sedentary  
38  
39 time after stroke. Secondary analysis of pooled data from nine primary studies.  
40  
41 *Top Stroke Rehabil* 2019;**26**(5):327-34.  
42  
43  
44 34. Mountain A, Patrice Lindsay M, Teasell R, et al. Canadian Stroke Best Practice  
45  
46 Recommendations: Rehabilitation, Recovery, and Community Participation  
47  
48 following Stroke. Part Two: Transitions and Community Participation Following  
49  
50 Stroke. *International journal of stroke : official journal of the International Stroke*  
51  
52 *Society* 2020;**15**(7):789-806.  
53  
54  
55 35. Fini NA, Bernhardt J, Holland AE. Low gait speed is associated with low physical  
56  
57 activity and high sedentary time following stroke. *Disability and rehabilitation*  
58  
59 2021;**43**(14):2001-08.  
60

- 1  
2  
3 36. Hall J, Morton S, Fitzsimons CF, et al. Factors influencing sedentary behaviours after  
4  
5 stroke: findings from qualitative observations and interviews with stroke  
6  
7 survivors and their caregivers. *BMC public health* 2020;**20**(1):967.  
8  
9  
10 37. Espenberger KR, Fini NA, Peiris CL. Personal and social factors that influence  
11  
12 physical activity levels in community-dwelling stroke survivors: A systematic  
13  
14 review of qualitative literature. *Clinical rehabilitation* 2021;**35**(7):1044-55.  
15  
16  
17 38. Becker I, Maleka MD, Stewart A, et al. Community reintegration post-stroke in New  
18  
19 Zealand: understanding the experiences of stroke survivors in the lower South  
20  
21 Island. *Disability and rehabilitation* 2020:1-8.  
22  
23  
24 39. Wesselhoff S, Hanke TA, Evans CC. Community mobility after stroke: a systematic  
25  
26 review. *Top Stroke Rehabil* 2018;**25**(3):224-38.  
27  
28  
29 40. O'Brien AN, Wolf TJ. Determining work outcomes in mild to moderate stroke  
30  
31 survivors. *Work (Reading, Mass)* 2010;**36**(4):441-7.  
32  
33  
34 41. Kaskutas V. Stroke Rehabilitation. A function-based approach. St. Louis, Missouri.  
35  
36 2016:224-236.  
37  
38  
39 42. Engel-Yeger B, Tse T, Josman N, et al. Scoping Review: The Trajectory of Recovery  
40  
41 of Participation Outcomes following Stroke. *Behavioural neurology*  
42  
43 2018;**2018**:5472018.  
44  
45  
46 43. Kapoor A, Lanctôt KL, Bayley M, et al. "Good Outcome" Isn't Good Enough:  
47  
48 Cognitive Impairment, Depressive Symptoms, and Social Restrictions in  
49  
50 Physically Recovered Stroke Patients. *Stroke* 2017;**48**(6):1688-90.  
51  
52  
53 44. Norlander A, Iwarsson S, Jönsson AC, et al. Participation in social and leisure  
54  
55 activities while re-constructing the self: understanding strategies used by stroke  
56  
57 survivors from a long-term perspective. *Disability and rehabilitation* 2021:1-9.  
58  
59  
60 45. Stern BZJTOJoOT. Critical Reflections on Self-Management Support in Chronic  
Disease: The Value of Occupational Therapy in Health Promotion. 2018

- 1  
2  
3 46. Fini NA, Holland AE, Keating J, et al. How Physically Active Are People Following  
4 Stroke? Systematic Review and Quantitative Synthesis. *Phys Ther*  
5 2017;**97**(7):707-17.  
6  
7  
8  
9 47. Mahendran N, Kuys SS, Brauer SG. Recovery of ambulation activity across the first  
10 six months post-stroke. *Gait Posture* 2016;**49**:271-76.  
11  
12  
13 48. Hendrickx W, Riveros C, Askim T, et al. An Exploration of Sedentary Behavior  
14 Patterns in Community-Dwelling People With Stroke: A Cluster-Based Analysis.  
15 *Journal of neurologic physical therapy : JNPT* 2021;**45**(3):221-27.  
16  
17  
18  
19 49. Tiegens Z, Mead G, Allerhand M, et al. Sedentary behavior in the first year after stroke:  
20 a longitudinal cohort study with objective measures. *Archives of physical*  
21 *medicine and rehabilitation* 2015;**96**(1):15-23.  
22  
23  
24  
25  
26  
27 50. Paul L, Brewster S, Wyke S, et al. Physical activity profiles and sedentary behaviour  
28 in people following stroke: a cross-sectional study. *Disability and rehabilitation*  
29 2016;**38**(4):362-7.  
30  
31  
32  
33  
34 51. Lynch EA, Jones TM, Simpson DB, et al. Activity monitors for increasing physical  
35 activity in adult stroke survivors. *The Cochrane database of systematic reviews*  
36 2018;**7**(7):Cd012543.  
37  
38  
39  
40  
41 52. Kwakkel G, Lannin NA, Borschmann K, et al. Standardized measurement of  
42 sensorimotor recovery in stroke trials: Consensus-based core recommendations  
43 from the Stroke Recovery and Rehabilitation Roundtable. *International journal*  
44 *of stroke : official journal of the International Stroke Society* 2017;**12**(5):451-61.  
45  
46  
47  
48  
49 53. Pohl J, Held JPO, Verheyden G, et al. Consensus-Based Core Set of Outcome  
50 Measures for Clinical Motor Rehabilitation After Stroke-A Delphi Study.  
51 *Frontiers in neurology* 2020;**11**:875.  
52  
53  
54  
55 54. Fini NA, Holland AE, Keating J, et al. How is physical activity monitored in people  
56 following stroke? *Disability and rehabilitation* 2015;**37**(19):1717-31.  
57  
58  
59  
60

- 1  
2  
3 55. Kringle EA, Skidmore ER, Terhorst L, et al. Sedentary behavior patterns over 6 weeks  
4 among ambulatory people with stroke. *Topics in stroke rehabilitation*  
5 2021;**28**(7):537-44.  
6  
7  
8  
9 56. Fini NA, Holland AE, Bernhardt J, et al. How Many Hours of Device Wear Time Are  
10 Required to Accurately Measure Physical Activity Post Stroke? *International*  
11 *journal of environmental research and public health* 2022;**19**(3)  
12  
13  
14  
15 57. Levy T, Laver K, Killington M, et al. A systematic review of measures of adherence  
16 to physical exercise recommendations in people with stroke. *Clinical*  
17 *rehabilitation* 2019;**33**(3):535-45.  
18  
19  
20  
21  
22 58. Kessler D, Egan M. A Review of Measures to Evaluate Participation Outcomes Post-  
23 Stroke. 2012;**75**(9):403-11.  
24  
25  
26  
27 59. Tse T, Douglas J, Lentin P, et al. Measuring participation after stroke: a review of  
28 frequently used tools. *Archives of physical medicine and rehabilitation*  
29 2013;**94**(1):177-92.  
30  
31  
32  
33 60. Fini NA, Bernhardt J, Said CM, et al. How to Address Physical Activity Participation  
34 After Stroke in Research and Clinical Practice. *Stroke* 2021;**52**(6):e274-e77.  
35  
36  
37  
38 61. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational  
39 Studies in Epidemiology (STROBE) statement: guidelines for reporting  
40 observational studies. *BMJ* 2007;**335**(7624):806-8.  
41  
42  
43  
44 62. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the  
45 methodological quality of studies on measurement properties of health status  
46 measurement instruments: an international Delphi study. *Qual Life Res*  
47 2010;**19**(4):539-49.  
48  
49  
50  
51 63. Kottner J, Audigé L, Brorson S, et al. Guidelines for Reporting Reliability and  
52 Agreement Studies (GRRAS) were proposed. *J Clin Epidemiol* 2011;**64**(1):96-  
53 106.  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 64. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research  
4  
5 (COREQ): a 32-item checklist for interviews and focus groups. *International*  
6  
7 *journal for quality in health care : journal of the International Society for Quality*  
8  
9 *in Health Care* 2007;**19**(6):349-57.  
10  
11  
12 65. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative  
13  
14 research: a synthesis of recommendations. *Academic medicine : journal of the*  
15  
16 *Association of American Medical Colleges* 2014;**89**(9):1245-51.  
17  
18  
19 66. Lobo A, Saz P, Marcos G, et al. [Revalidation and standardization of the cognition  
20  
21 mini-exam (first Spanish version of the Mini-Mental Status Examination) in the  
22  
23 general geriatric population]. *Medicina clinica* 1999;**112**(20):767-74.  
24  
25  
26 67. Van Bloemendaal M, Bout W, Bus SA, et al. Validity and reproducibility of the  
27  
28 Functional Gait Assessment in persons after stroke. *Clinical rehabilitation*  
29  
30 2019;**33**(1):94-103.  
31  
32  
33 68. Bellosta-López P, Domenech-Garcia V, Palsson TS, et al. European knowledge  
34  
35 alliance for innovative measures in prevention of work-related musculoskeletal  
36  
37 pain disorders (Prevent4Work Project): protocol for an international mixed-  
38  
39 methods longitudinal study. *BMJ Open* 2021;**11**(9):e052602.  
40  
41  
42 69. Gao Y, Wang Y, Li D, et al. Disability assessment in stroke: Relationship among the  
43  
44 pictorial-based Longshi Scale, the Barthel Index, and the modified Rankin Scale.  
45  
46 *Clinical rehabilitation* 2021;**35**(4):606-13.  
47  
48  
49 70. Lomas-Vega R, Hita-Contreras F, Mendoza N, et al. Cross-cultural adaptation and  
50  
51 validation of the Falls Efficacy Scale International in Spanish postmenopausal  
52  
53 women. *Menopause (New York, NY)* 2012;**19**(8):904-8.  
54  
55  
56 71. Quinn TJ, Dawson J, Walters MR, et al. Reliability of the Modified Rankin Scale.  
57  
58 2009;**40**(10):3393-95.  
59  
60



- 1  
2  
3 72. Craig CL, Marshall AL, Sjöström M, et al. International physical activity  
4 questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*  
5 2003;**35**(8):1381-95.  
6  
7  
8  
9 73. SC. Mantilla Toloza AG-C. El Cuestionario Internacional de Actividad Física. Un  
10 instrumento adecuado en el seguimiento de la actividad física poblacional. *Revista*  
11 *Iberoamericana de Fisioterapia y Kinesiología* 2007;**10**(1):48-52.  
12  
13  
14 74. Phusuttatam T, Saengsuwan J, Kittipanya-Ngam P. Development and Preliminary  
15 Validation of a Stroke Physical Activity Questionnaire. *Stroke Res Treat*  
16 2019;**2019**:6764834.  
17  
18  
19 75. Rejas J, Ribera MV, Ruiz M, et al. Psychometric properties of the MOS (Medical  
20 Outcomes Study) Sleep Scale in patients with neuropathic pain. *European journal*  
21 *of pain (London, England)* 2007;**11**(3):329-40.  
22  
23  
24 76. Hays RD, Martin SA, Sesti AM, et al. Psychometric properties of the Medical  
25 Outcomes Study Sleep measure. *Sleep medicine* 2005;**6**(1):41-4.  
26  
27  
28 77. Hernandez G, Garin O, Pardo Y, et al. Validity of the EQ-5D-5L and reference norms  
29 for the Spanish population. *Qual Life Res* 2018;**27**(9):2337-48.  
30  
31  
32 78. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta psychiatrica*  
33 *Scandinavica* 1983;**67**(6):361-70.  
34  
35  
36 79. Ayis SA, Ayerbe L, Ashworth M, et al. Evaluation of the Hospital Anxiety and  
37 Depression Scale (HADS) in screening stroke patients for symptoms: Item  
38 Response Theory (IRT) analysis. *Journal of affective disorders* 2018;**228**:33-40.  
39  
40  
41 80. Alegre-Muelas C, Alegre-Ayala J, Huertas-Hoyas E, et al. Spanish Transcultural  
42 Adaptation of the Activity Card Sort. *Occupational therapy international*  
43 2019;**2019**:4175184.  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 81. Hartman-Maeir A, Eliad Y, Kizoni R, et al. Evaluation of a long-term community  
4 based rehabilitation program for adult stroke survivors. *NeuroRehabilitation*  
5 2007;**22**(4):295-301.  
6  
7  
8  
9  
10 82. Vidaña-Moya L, Eklund M, Merchán-Baeza JA, et al. Cross-Cultural Adaptation,  
11 Validation and Reliability of the Spanish Satisfaction with Daily Occupations-  
12 Occupational Balance (SDO-OB): An Evaluation Tool for People with Mental  
13 Disorders. *International journal of environmental research and public health*  
14 2020;**17**(23)  
15  
16  
17  
18  
19  
20  
21 83. Tyson S, Connell L. The psychometric properties and clinical utility of measures of  
22 walking and mobility in neurological conditions: a systematic review. *Clinical*  
23 *rehabilitation* 2009;**23**(11):1018-33.  
24  
25  
26  
27  
28 84. Macchiavelli A, Giffone A, Ferrarello F, et al. Reliability of the six-minute walk test  
29 in individuals with stroke: systematic review and meta-analysis. *Neurological*  
30 *sciences : official journal of the Italian Neurological Society and of the Italian*  
31 *Society of Clinical Neurophysiology* 2021;**42**(1):81-87.  
32  
33  
34  
35  
36  
37 85. Ringeval M, Wagner G, Denford J, et al. Fitbit-Based Interventions for Healthy  
38 Lifestyle Outcomes: Systematic Review and Meta-Analysis. *J Med Internet Res*  
39 2020;**22**(10):e23954.  
40  
41  
42  
43  
44 86. Feehan LM, Geldman J, Sayre EC, et al. Accuracy of Fitbit Devices: Systematic  
45 Review and Narrative Syntheses of Quantitative Data. *JMIR Mhealth Uhealth*  
46 2018;**6**(8):e10527.  
47  
48  
49  
50  
51 87. Klassen TD, Simpson LA, Lim SB, et al. "Stepping Up" Activity Poststroke: Ankle-  
52 Positioned Accelerometer Can Accurately Record Steps During Slow Walking.  
53 *Phys Ther* 2016;**96**(3):355-60.  
54  
55  
56  
57  
58  
59  
60

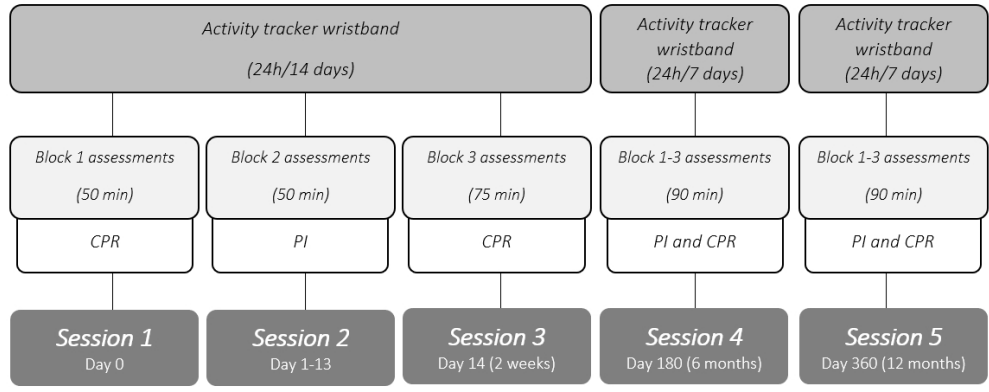
- 1  
2  
3 88. Klassen TD, Semrau JA, Dukelow SP, et al. Consumer-Based Physical Activity  
4  
5 Monitor as a Practical Way to Measure Walking Intensity During Inpatient Stroke  
6  
7 Rehabilitation. *Stroke* 2017;**48**(9):2614-17.  
8
- 9 89. Kim H-K, Jun M, Rhee S, et al. Husserlian phenomenology in Korean nursing  
10  
11 research: analysis, problems, and suggestions. *J Educ Eval Health Prof*  
12  
13 2020;**17**:13-13.  
14  
15
- 16 90. Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3:  
17  
18 Sampling, data collection and analysis. *The European journal of general practice*  
19  
20 2018;**24**(1):9-18.  
21  
22
- 23 91. Giorgi A. The Theory, Practice, and Evaluation of the Phenomenological Method as  
24  
25 a Qualitative Research Procedure. *Journal of Phenomenological Psychology*  
26  
27 1997;**28**(2):235-60.  
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3 **FIGURE LEGEND**  
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5 **Figure 1.** Study timeline design. CPR: Collaborating Professional Researcher; PI:  
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7 Principal Investigator.  
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For peer review only

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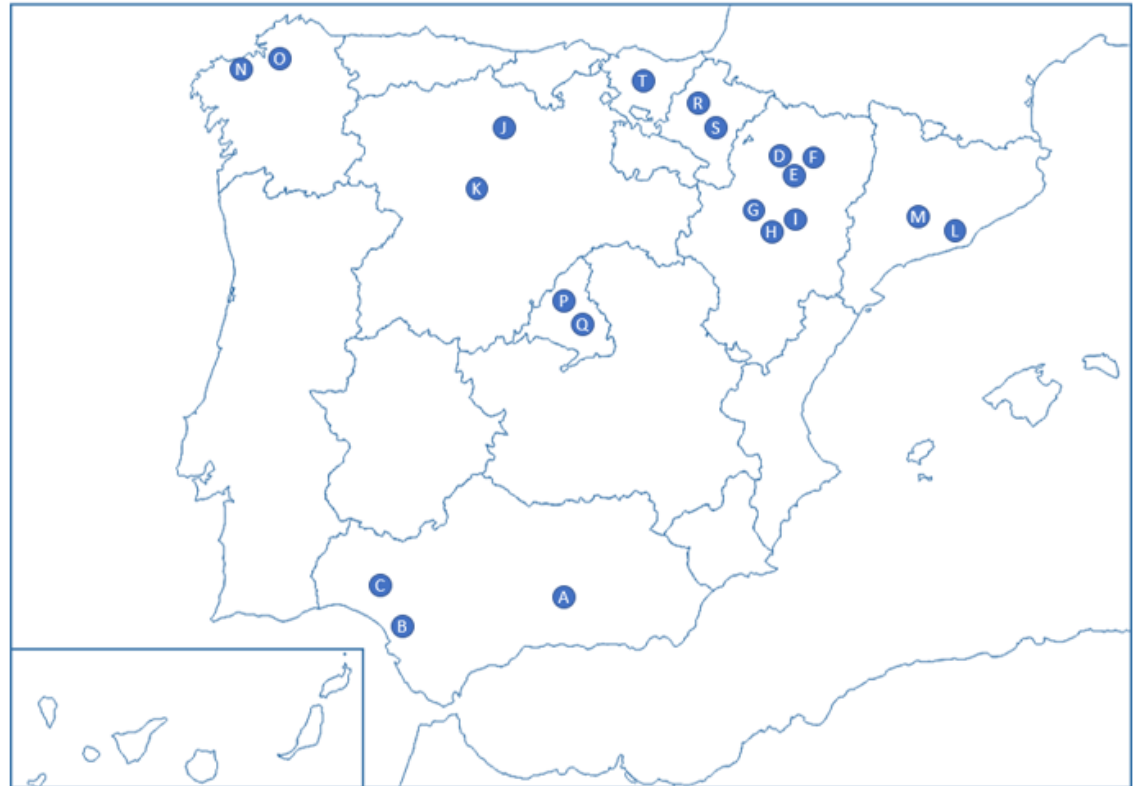


Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

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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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-065628.R2
Article Type:	Protocol
Date Submitted by the Author:	11-Jan-2023
Complete List of Authors:	de Diego-Alonso, Cristina; Universidad San Jorge Alegre-Ayala, Jorge; Centro Europeo de Neurociencias Buesa, Almudena; San Jorge University - University Campus of the Walqa Technology Park, Blasco-Abadía, Julia; Universidad San Jorge, Department of Physiotherapy Lopez-Royo, Maria Pilar; Universidad San Jorge, Roldán-Pérez, Patricia; Universidad San Jorge Giner-Nicolás, Rafael; Universidad San Jorge Collaborators group, Part&Sed-Stroke; Part&Sed Collaborators group Gueita-Rodríguez, Javier; Universidad Rey Juan Carlos, Physiotherapy, Occupational Therapy, Rehabilitation and Physical Medicine. Fini, Natalie; University of Melbourne, School of Health Sciences , Physiotherapy; Alfred Health, Physiotherapy Domenech-García, Victor ; University of San Jorge Faculty of Health Sciences, Department of Physiotherapy Bellosta-López, Pablo; University of San Jorge Faculty of Health Sciences, Department of Physiotherapy
<b>Primary Subject Heading</b>:	Neurology
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, STROKE MEDICINE, NEUROLOGY, Neurological injury < NEUROLOGY

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Manuscripts

## 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.<sup>1 2</sup> 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.<sup>3</sup> In 2019, Spanish statistics revealed an annual incidence of 61,102 cases and a prevalence of 512,380 people with post-stroke disability.<sup>1</sup> Although the most visible post-stroke consequences are physical, this population also presents long-lasting cognitive and emotional alterations<sup>4</sup>, as well as restrictions in participation in self-care, work, leisure and free time, and social activities.<sup>5-8</sup> Additionally, two-thirds show difficulty in walking independently, which is maintained beyond 3 months post-stroke.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup> Thus, areas of occupation consist of the basic and instrumental activities of daily living, rest and sleep, education, work, playing, leisure, and social participation.<sup>12 13</sup>

Physical inactivity and sedentary behaviour are one of the main lifestyle-related risk factors for stroke recurrence.<sup>14</sup> Physical inactivity is defined as an insufficient physical activity level to meet the current recommendations established by the World Health Organization (WHO)<sup>15</sup> and endorsed by the American Heart Association Council (AHAC)<sup>16</sup>. 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.<sup>17</sup> On the other hand, sedentary behaviour is defined as any waking

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3 behaviour characterized by an energy expenditure  $\leq 1.5$  metabolic equivalents (METs),  
4  
5 while sitting, reclining, or lying.<sup>18</sup> If the sedentary behaviour is maintained throughout  
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7 the day or week while being awake, it can be classified as a Sedentary Behaviour  
8  
9 Pattern.<sup>19</sup> Adult populations who comply with the WHO recommendations for physical  
10  
11 activity show a lower risk of death and developing non-communicable diseases.<sup>20</sup>  
12  
13 However, stroke survivors often report sedentary behaviour most of the day, especially  
14  
15 in the afternoon and evening.<sup>21</sup> Additionally, the average number of sleep hours is much  
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17 higher in stroke survivors than in the healthy population, which is associated with  
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19 cardiovascular morbidity and mortality.<sup>22</sup>  
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23  
24 Regarding the factors that contribute to sedentary lifestyles in the stroke  
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26 population, it has been observed that inpatient stroke survivors in rehabilitation centres  
27  
28 are more sedentary.<sup>23 24</sup> However, those living in the community still do not meet a  
29  
30 healthy level of physical activity.<sup>25</sup> On the other hand, the fear of falling is associated  
31  
32 with sedentary lifestyles,<sup>26 27</sup> to the extent that stroke survivors reduce activities involving  
33  
34 standing or walking by 20% on average.<sup>28</sup> In turn, the intensity and frequency of  
35  
36 rehabilitation treatment,<sup>23 29</sup> the place of residence and characteristics of the community,<sup>25</sup>  
37  
38 social support,<sup>23</sup> years after stroke,<sup>30</sup> initial stroke severity,<sup>31 32</sup> the type of hemiparesis,  
39  
40 greater cognition,<sup>32-34</sup> better endurance and gait speed,<sup>32-35</sup> are further examples of  
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42 contributors to a sedentary lifestyle. Finally, psychosocial factors, such as anxiety,  
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44 depression, and self-efficacy, can play a role.<sup>36 37</sup> This ensemble of factors warrants  
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46 studies analysing multifactorial relationships and establishing a firm consensus on  
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48 policies for the rehabilitation of stroke survivors.  
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54 Systematic reviews show that post-stroke interventions do not impact community  
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56 participation until several years after stroke<sup>38</sup> and that identifying barriers is key.<sup>39</sup>  
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58 However, despite the limited evidence regarding the factors that influence participation<sup>30</sup>,  
59  
60 having an extensive social network and the ability to walk for a few hundred meters or

1  
2 drive are potential facilitators<sup>8</sup>. Additionally, improvements in physical functioning do  
3  
4 not necessarily translate into improved participation in work, domestic, social, and leisure  
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6 activities.<sup>40 41</sup> This could be why stroke survivors feel unsatisfied about not recovering  
7  
8 pre-stroke participation levels in relevant activities, which may be due to their  
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10 environment, age, acceptance of the new situation, or degree of affectation;<sup>42</sup> as well as  
11  
12 due to the presence of comorbidities related to cognitive impairment and depressive  
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14 states.<sup>43</sup>  
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18 Therefore, aiming at emphasizing social reintegration as a long-term goal,<sup>44</sup>  
19  
20 several studies highlight the need to consider other under-investigated factors, such as the  
21  
22 influence of the primary caregiver and the family environment;<sup>36</sup> environmental factors  
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24 such as climate and daylight hours;<sup>33</sup> or the impact of treatments focusing on health  
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26 education<sup>45</sup> and the person-centred model.<sup>2</sup>  
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## 32 **PART&SED-STROKE PROJECT JUSTIFICATION**

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34 The stroke population in Europe, Australia, Canada, and the United States is known to  
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36 have high levels of sedentary lifestyles.<sup>21 25 31 32 46-50</sup> However, there is no solid  
37  
38 information about the Spanish population, which would allow the development, as  
39  
40 recommended by the WHO, of a specific public health plan for the stroke survivors in  
41  
42 Spain. For this reason, longitudinal studies are needed to determine the evolution of the  
43  
44 level of physical activity after stroke.<sup>44 46</sup>  
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49 The assessment tools included in the present protocol have been selected based on  
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51 the 2018 Cochrane review authored by Lynch et al.,<sup>51</sup> and by the recommendations of  
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53 Kwakkel et al.,<sup>52</sup> and its updates in a 2020 Delphi study.<sup>53</sup> Additionally, other reliable  
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55 assessment tools are needed to ascertain the amount of sedentary time, assess its effect on  
56  
57 health, and identify significant predictors of physical activity levels.<sup>14</sup> In this sense,  
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59 devices with high potential have already been identified at the scientific level,<sup>54 55</sup> and it  
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3 is known that 3 or more days, for a minimum of 14 hours per day, are required for accurate  
4  
5 monitoring.<sup>56</sup> However, more studies are needed to analyse the potential of new wearable  
6  
7 devices to record this physical activity and measure adherence or compliance with  
8  
9 physical activity recommendations in the stroke population<sup>57</sup>, as well as to assess their  
10  
11 suitability and ease of use in the clinical setting by professionals and patients.  
12  
13 Consequently, this protocol will evaluate the Fitbit Inspire 2 activity tracker wristband  
14  
15 (*Fitbit, United States, San Francisco, CA*). On the other hand, with the aim of promoting  
16  
17 the recovery of participatory life after stroke, it is relevant that clinicians have validated  
18  
19 assessment tools for the stroke population on occupational satisfaction.  
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24 The current protocol has also included the Activity Card Sort (ACS),  
25  
26 recommended in systematic reviews for the ICF domains of activity and participation in  
27  
28 the stroke population.<sup>58 59</sup> Finally, following the recommendations of other studies, other  
29  
30 factors such as personal, sociodemographic, and psychological factors that may have an  
31  
32 impact on mobility in the community have been considered.<sup>33</sup>  
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35  
36 Considering that the current goal of neurorehabilitation is to design and  
37  
38 personalise physical activity programs according to the ability, goals, and preferences of  
39  
40 the stroke survivor, as well as to encourage long-term lifestyle habits,<sup>60</sup> it is warranted to  
41  
42 conduct longitudinal studies investigating the trajectory and the interrelationship between  
43  
44 sedentary behaviour and participation in stroke survivors.  
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## 48 **Objectives**

- 49  
50 1. To multidimensionally explore the factors associated with participation and  
51  
52 sedentary behaviour in Spanish stroke survivors.  
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- 54  
55 2. To investigate the influence of sedentary behaviour and individual characteristics  
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57 of the primary caregiver on the participation and sedentary lifestyle of Spanish  
58  
59 stroke survivors.  
60

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,<sup>61</sup> the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN),<sup>62</sup> the Guidelines for Reporting Reliability and Agreement Studies (GRRAS),<sup>63</sup> and the COnsolidated criteria for reporting qualitative studies (COREQ),<sup>64</sup> and the Standards for Reporting Qualitative Research (SRQR).<sup>65</sup>

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,

1  
2 including the influence of the primary caregiver. The validation and establishment of the  
3  
4 psychometric properties of the SDO-OB questionnaire in Spanish stroke survivors will  
5  
6 be performed. Additionally, a prospective cohort design will be used to assess the  
7  
8 evolution of sedentary and participation behaviours in stroke survivors over time,  
9  
10 identifying those factors that may contribute to a modification of these behaviours.  
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12 Follow-up assessments will be carried out at 6 and 12 months, to provide a sufficient time  
13  
14 frame in which to appreciate meaningful changes. Finally, the life experience of stroke  
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16 survivors will be investigated through unstructured in-depth interviews and semi-  
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18 structured interviews, which will be analysed by means of a descriptive  
19  
20 phenomenological approach.  
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### 28 **Population**

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30 The study sample will consist of people of both sexes who have suffered a stroke and  
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32 reside in Spain. The inclusion criteria will consist of 1) being over 18 years of age; 2)  
33  
34 having a history of stroke with a medical diagnosis for more than 6-months, regardless of  
35  
36 its aetiology; 3) outpatient living at home; 4) having cognitive and speech ability to  
37  
38 perform and understand the tests to be administered and the purpose of the research  
39  
40 project (i.e., no aphasia and a Mini-Mental Cognitive Test score  $>24$ ,<sup>66</sup>) 5) being able to  
41  
42 ambulate with or without aids, which represent an ambulation ability  $\geq 3$  in the Functional  
43  
44 Ambulatory Category<sup>67</sup> \*[not applicable for SDO-OB validation]; and 6) availability of  
45  
46 a mobile phone with Bluetooth and internet connection. The exclusion criteria will be 1)  
47  
48 non-acceptance of participation in the research project by the primary caregiver; 2) not  
49  
50 tolerating being monitored with an activity tracker wristband; 3) residing in institutions  
51  
52 (e.g., nursing homes); 4) no commitment to continuity; and 5) a history of more than one  
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54 symptomatic stroke. Missing evaluation sessions, existing a personal or family situation  
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3 that interferes with data collection, and willingness to discontinue the study were  
4  
5 considered withdrawal criteria.

6  
7 If the stroke survivor has a primary caregiver, the primary caregiver will be invited  
8  
9 to participate in the study. A primary caregiver is defined as a person, either a family  
10  
11 member or an employee, who spends more than half of their daily time supporting or  
12  
13 caring for the stroke survivor.  
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15

### 16 17 18 **Patient and public involvement**

19  
20 Patients or the public were not involved in the design, conduct, reporting, or  
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22 dissemination plans of this research.  
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### 25 26 27 **Contact and recruitment**

#### 28 29 *Centres and Health professionals*

30  
31 The collaborators will be composed of health professionals (physiotherapists and  
32  
33 occupational therapists) working in institutions, centres, and associations, as well as self-  
34  
35 employed professionals, whose field of action is focused on the neurological  
36  
37 rehabilitation of stroke survivors. Specifically, in the first phase, contact will be  
38  
39 established via email or telephone with professionals who form part of the research team's  
40  
41 network. While in the second phase, general information about the research study will be  
42  
43 disseminated through social networks (i.e., Twitter and LinkedIn) to increase the number  
44  
45 of potential organizations and professionals collaborating. These collaborators will meet  
46  
47 the conditions of residing in different parts of Spain, having extensive experience in  
48  
49 neurological rehabilitation, and currently providing care to stroke survivors.  
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52  
53 All those who will show interest in the study will receive a document that includes  
54  
55 information on the objective of the study, criteria for the selection of the sample, functions  
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57 to be carried out that would imply their commitment to participate, and a timetable for  
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1  
2 data collection. If there is continued interest in participating, a first meeting will be held  
3  
4 to provide further information and resolve doubts. After this meeting, the centres and  
5  
6 professionals will express their willingness to participate. Each participating centre must  
7  
8 sign the collaboration agreement, and each professional belonging to these centres must  
9  
10 accept the commitment document to participate in the research. These documents will  
11  
12 regulate the transfer of the anonymized data collected for research use, as well as the  
13  
14 commitments and functions of the institutions and professionals involved.  
15  
16

17  
18 Participating centres will be instructed in homogenizing data collection through  
19  
20 videoconference meetings and training sessions. With the aim of facilitating access to  
21  
22 information on the study, a secure shared folder has been created in a virtual space  
23  
24 containing documents on the study, information sheets for participants, consents,  
25  
26 collaboration documents, and manuals of procedures to be followed. In addition, the  
27  
28 research team will provide and send a minimum of 2 Fitbit Inspire-2 monitoring  
29  
30 wristbands to each collaborating centre.  
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### 37 *Stroke survivor participants and primary caregivers*

38  
39 The recruitment process of participants (stroke survivors and their respective caregivers)  
40  
41 will be carried out in two phases. Firstly, each of the collaborating centres will be  
42  
43 responsible for promoting the existence of the study through their usual internal channels  
44  
45 of communication with their users, such as posters, information circulars, and posts on  
46  
47 social networks. Each potential participant will be given an information sheet about the  
48  
49 research project, and any questions they may have regarding the development of the  
50  
51 research project and their participation in it will be answered.  
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55  
56 Secondly, those users who voluntarily agree to participate in the study will be  
57  
58 assessed by healthcare professionals (occupational therapists and physiotherapists) with  
59  
60 training and clinical experience in neurorehabilitation to corroborate compliance with the

1  
2  
3 eligibility criteria. Those who meet the selection criteria will be selected as potential  
4  
5 participants and will be asked to sign the informed consent for inclusion in the study.  
6  
7 Once the informed consent is signed, they will be assigned an appointment for the first  
8  
9 assessment session within approximately one week. The same assessors will conduct the  
10  
11 assessment sessions at each centre.  
12  
13

### 14 15 16 **Data collection and security measures**

17  
18 Each collaborator will be responsible for collecting part of the data for participants from  
19  
20 their centres. The collection of all the data will be supervised and coordinated by the  
21  
22 research team, and the principal investigator will be in direct contact with each  
23  
24 collaborator to assist with solving any problems that may arise.  
25  
26

27  
28 In order to maintain security in the process of collecting data from each  
29  
30 participant: 1) each collaborator will be assigned an account and password to access the  
31  
32 P4Work application where the data collected from each participant in the study is  
33  
34 recorded;<sup>68</sup> and 2) each collaborator will be provided with accounts and passwords that  
35  
36 must be assigned to each participant (stroke survivor and their main caregiver) to use the  
37  
38 Fitbit application.  
39  
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41  
42 Only the collaborators at each centre will know the identity of each participant  
43  
44 recruited at their centre. In such a way, the research team will have access to anonymized  
45  
46 data in both the Fitbit and P4Work applications.  
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### 50 51 **Outcome measures**

#### 52 53 *Sociodemographic data*

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55 Sociodemographic data will include age, sex, smoking, educational level, economic level,  
56  
57 employment status, height and weight, municipality, type of housing, presence of  
58  
59 architectural barriers, and home cohabitation.  
60

### 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,<sup>69</sup> the Fall Efficacy Scale (FES-I),<sup>70</sup> and the modified Rankin scale.<sup>71</sup>

### 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<sup>72 73</sup> and has been used in previous studies with stroke population.<sup>74</sup>

### 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<sup>75</sup>. 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.

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3 It is a sensitive assessment tool for detecting the impact of an illness or medication on the  
4  
5 different dimensions of sleep <sup>76</sup>.  
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### 9 10 Current health status

11 Current health status will be evaluated with the self-assessed, health-related, quality of  
12  
13 life questionnaire EQ-5D-5L. The EQ-5D-5L measures quality of life on a 5-component  
14  
15 scale, including mobility, self-care, usual activities, pain/discomfort, and  
16  
17 anxiety/depression. Each of these dimensions has five possible answers or levels of  
18  
19 severity. In the second part of the questionnaire, respondents are asked to rate their current  
20  
21 health status on a scale, where 100 corresponds to "the best health status you can imagine"  
22  
23 and 0 to "the worst health status you can imagine". The EQ-5D-5L is a valid and reliable  
24  
25 tool for assessing the quality of life <sup>77</sup>.  
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### 32 33 State of anxiety and depression

34 The state of anxiety and depression will be evaluated with the Hospital Anxiety and  
35  
36 Depression Scale (HADS). The HADS is a 14-item questionnaire consisting of a  
37  
38 depression and anxiety subscale with interspersed items. The items are scored on a 4-  
39  
40 point Likert scale (0-3) with a total score ranging from 0 to 21 for each subscale, where a  
41  
42 higher score indicates greater symptom severity. The HADS is a reliable and valid tool  
43  
44 for assessing levels of depression and anxiety <sup>78</sup> and has been used with stroke survivors  
45  
46 in previous studies <sup>79</sup>.  
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### 53 54 Degree of community participation

55 The degree of community participation will be assessed using the Activity Card Sort for  
56  
57 the Spanish population (ACS). The ACS is a scale that measures self-perceived  
58  
59 participation using photographs reflecting everyday activities. The activities are  
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3 categorised into four domains, instrumental activities, leisure activities with low physical  
4 demand, leisure activities with high physical demand, and socio-educational activities. It  
5 covers eight of the nine domains of participation as defined by the ICF.<sup>10</sup> The final score  
6 is the percentage of activities maintained after an illness, which is developed as a quotient  
7 between the number of activities carried out before the illness and those carried out at  
8 present. The ACS is a reliable and validated tool for measuring the perceived level of  
9 participation.<sup>80 81</sup>

### 20 21 Degree of occupational satisfaction and balance

22  
23 The degree of occupational satisfaction and balance will be assessed with the Satisfaction  
24 with Daily Occupation-Occupational Balance (SDO-OB). The SDO-OB is an interview-  
25 based instrument that assesses 13 different occupational items organised into 4 domains:  
26 productivity, leisure or free time, housework, and self-care. The SDO-OB assesses the  
27 level of participation in an activity, the occupational satisfaction derived from  
28 participating in this activity, and the perceived occupational balance within each domain.  
29 For each item, the interviewer will determine whether there is participation by the person  
30 and then indicate the degree of satisfaction from 1 to 7 (1 being extremely dissatisfied  
31 and 7 being extremely satisfied). The SDO-OB has good reliability and validity <sup>82</sup>.

### 46 47 Physical mobility tests

48  
49 The 10 Meter Walk Test (10MWT) will be used to assess walking speed in m/s. The  
50 person will be asked to walk for 10 meters while being timed. The comfortable speed for  
51 walking over 10 meters will be taken 3 times. The average of the 3 recordings will be the  
52 value of the assessment. The 10MWT is a reliable and validated tool for measuring  
53 walking speed.<sup>83</sup>

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3 The 6 Six-Minute Walk Test (6MWT) will be used to assess the distance walked  
4 by the participant in 6 minutes. Standardized guidelines will be followed during the test  
5 to give verbal indications concerning the time elapsed and positive reinforcement without  
6 any other indications not allowed by the test. The 6MWT is a reliable and valid tool for  
7 measuring distance run, endurance, and aerobic capacity.<sup>84</sup>  
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14 Additionally, walking aids and a modified Borg Index (0-10) will be collected  
15 after each test.  
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19 Furthermore, physical mobility tests will be performed in all centres under similar  
20 standardized conditions. Before signing the collaborating agreement, each centre will  
21 ensure sufficient space on its premises to carry out the tests.  
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#### 28 Activity tracker wristband

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30 The Fitbit Inspire 2 activity tracker will be used to assess the level of activity throughout  
31 14-days continuously. The device is based on a 3-axis accelerometry system that  
32 monitors physical activity, number of steps, heart rate, sleep duration, and sleep score.  
33  
34 The Fitbit wristbands are considered a valid and reliable tool for monitoring physical  
35 activity and sleep hours,<sup>85 86</sup> which are considered a valid procedure in stroke survivors.<sup>87</sup>  
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#### 46 Evaluation of caregivers

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

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3 The evaluations will be carried out similarly at 3 points in time over a 12-month period  
4 (i.e., baseline, 6- and 12-months). Each evaluation will be composed of different tests and  
5 questionnaires grouped by blocks, to avoid saturation of the participants. Specifically,  
6  
7 block 1 will be assessed by the collaborators approximately one week after recruitment,  
8  
9 consisting of sociodemographic data, IPAQ-SF, FES-I, Barthel Index, HADS, and EQ-  
10  
11 5D-5L. After completing the assessment of block 1, the Fitbit Inspire 2 activity tracker  
12  
13 wristband will be linked to the mobile device for 14 days of 24-hour monitoring. Block 2  
14  
15 will be assessed in the settings of collaborator centres approximately two weeks after  
16  
17 completing block 1, coinciding with the return of the activity tracker wristband, and will  
18  
19 consist of the ACS, the 6MWT, and the 10MWT. Block 3 will be assessed homogeneously  
20  
21 in all participants by the principal investigator via teleconference within the period  
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23 between the blocks 1 and 2, and will consist of clinical data, MOS-Sleep, and SDO-OB  
24  
25 (figure 1).  
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32 One to two weeks after completing the baseline evaluation, a minimum of 50  
33  
34 participants will complete the IPAQ-SF, MOS-sleep, and SDO-OB again. Additionally,  
35  
36 during the follow-up period after baseline, a random sample of around 30 participants  
37  
38 will participate in unstructured and semi-structured interviews as part of the qualitative  
39  
40 design.  
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### 46 **Qualitative design**

47  
48 A qualitative phenomenological design will be followed based on Husserl's framework.<sup>89</sup>  
49  
50 Data collection will be completed when the information obtained in the interviews  
51  
52 becomes repetitive.<sup>90</sup> First-person data collection instruments (unstructured and semi-  
53  
54 structured interviews) and the researcher's field notes will be used simultaneously.<sup>90</sup> Data  
55  
56 collection will be conducted in two phases. The first phase of data collection will be  
57  
58 conducted through unstructured in-depth interviews. The second phase will be conducted  
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1  
2 through semi-structured interviews based on the analysis of participants' responses from  
3  
4 the first phase, together with questions grouped into 3 research areas: physical activity,  
5  
6 participation, and health education.  
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10 The analysis proposed by Giorgi will be used.<sup>91</sup> The researcher's field notes will  
11  
12 complement the analysis of the interviews recorded and transcribed verbatim. MAXQDA  
13  
14 2022 software (Verbi Software, Berlin, Germany) will be used for data analysis.  
15  
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17 Different strategies will be followed before and during the data collection process  
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19 to ensure the methodological rigour and quality of this study (i.e., establishing the  
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21 positioning of the researchers, triangulation, auditing of the material obtained, and  
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23 participant verification).  
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### 30 **Monitoring of the methodological quality**

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32 Given the multicentric nature of the research study, several mechanisms will be  
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34 implemented to avoid inter-observer bias and reduce random errors as much as possible.  
35  
36 Firstly, the assessment protocol comprises measurement instruments with reliable inter-  
37  
38 observer psychometric characteristics, allowing a standardized data collection. Secondly,  
39  
40 meetings will be held to unify the protocol for the administration of the tools and data  
41  
42 collection, establishing a unification of the evaluation criteria for each tool. Thirdly,  
43  
44 training sessions on the procedures and administration of the evaluation tools will be  
45  
46 conducted both face-to-face and virtually. Additionally, all collaborators will have written  
47  
48 manuals that include these standardized and unified procedures. Finally, the project  
49  
50 research team will supervise all procedures and solve any potential issues, sharing the  
51  
52 relevant information with all collaborators participating.  
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### 60 **Sample size**

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3 The sample size has been calculated with G\*Power (v3.1.9.4; *Heinrich-Heine-University,*  
4 *Dusseldorf, Germany*) based on the requirements of the most demanding research  
5 objective in terms of the number of participants (i.e., objective 1). Specifically, after  
6 running a priori analysis with an alpha value of 0.05, a power of 80%, and expecting a  
7 coefficient of multiple determination ( $\rho^2$ ) between 0.30 and 0.50, a minimum of 130  
8 participants will be required to perform a random-effects multiple regression model with  
9 up to 15 variables. Furthermore, a sample size higher than 73 participants during follow-  
10 ups will be sufficient to perform a mixed model for repeated measures with a power of  
11 80% and an alpha error of 0.05 to detect a small to medium standardized mean difference  
12 (i.e.,  $f = 0.15$ ) and expecting at least a moderate correlation among repeated measures  
13 (i.e.,  $r = 0.5$ ).

### 30 **Statistical analysis**

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

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

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

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51 In the validation process of the SDO-BO in the Spanish stroke survivors,  
52 Cronbach's  $\alpha$  statistic will be used to test internal consistency and intraclass correlation  
53 coefficients to assess test-retest reliability. In addition, Spearman's rank correlation will  
54 be used to assess the construct validity of the SDO-BO compared to EQ-5D-5L and ACS.  
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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.<sup>87</sup>

### **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.

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## **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.

### **Funding**

This work was supported by "Ayudas a Proyectos Internos de Investigación Universidad San Jorge curso 2021-2022" grant number 2122037 and "Ayudas a Proyectos Internos de Investigación Universidad San Jorge curso 2022-2023" grant number 2122037. PB-L is supported by the Grant FPU19/05237 and JB-A by the Grant PIF 2022-2026 from "Gobierno de Aragón". The funders did not have any role in this study.

### **Acknowledgments**

We thank all the collaborating centres involved for the recruitment of study participants: ADACECO (Asociación de Daño Cerebral de A Coruña) in A Coruña, AENO (Asociación de Enfermos Neurológicos Oscense) in Huesca, AGREDACE (Asociación de Daño Cerebral Adquirido de Granada) in Granada, AIDA (Asociación de Ictus de Aragón) in Zaragoza, ASPAYM (Asociación de personas con lesión medular y otras discapacidades física) in Burgos, CENNER (Centro de NeuroRehabilitación, Nutrición y Fisioterapia) in Pamplona, Centro de neurorrehabilitación (Clínica de Rehabilitación Neurológica Sant Cugat) in San Cugat del Valles, CIRON (Centro Integral de Rehabilitación ON) in Valladolid, Freelance Physiotherapist in Madrid and SanLucar de Barrameda, FUNDACIÓN PITA LÓPEZ (Centro de Neurorehabilitación de Daño Cerebral Adquirido) in Madrid, Grupo 5 CIAN Navarra (Centro Integral de Atención Neurorehabilitadora) in Pamplona, Grupo 5 CIAN Zaragoza (Centro Integral de Atención Neurorehabilitadora) in Zaragoza, HOSPITAL PROVINCIAL SAGRADO CORAZÓN

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10 Neurològica) in Esplugues de Llobregat, Rehabilitación El Carmen in Zaragoza.  
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## REFERENCES

1. GBD SC. Global, regional, and national burden of stroke and its risk factors, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet Neurology* 2021;**20**(10):795-820.
2. World Health A. Framework on integrated, people-centred health services: report by the Secretariat. Geneva: World Health Organization, 2016.
3. Cieza A, Causey K, Kamenov K, et al. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2021;**396**(10267):2006-17.
4. Viktorisson A, Reinholdsson M, Danielsson A, et al. Pre-stroke physical activity in relation to post-stroke outcomes - linked to the International Classification of Functioning, Disability and Health (ICF): A scoping review. *Journal of rehabilitation medicine* 2022;**54**:jrm00251.
5. Lee Y, Nicholas ML, Connor LT. Identifying emotional contributors to participation post-stroke. *Topics in stroke rehabilitation* 2021:1-13.
6. Svensson JS, Westerlind E, Persson HC, et al. Occupational gaps 5 years after stroke. *Brain and behavior* 2019;**9**(3):e01234.
7. Singam A, Ytterberg C, Tham K, et al. Participation in Complex and Social Everyday Activities Six Years after Stroke: Predictors for Return to Pre-Stroke Level. *PloS one* 2015;**10**(12):e0144344.
8. Norlander A, Carlstedt E, Jönsson AC, et al. Long-Term Predictors of Social and Leisure Activity 10 Years after Stroke. *PloS one* 2016;**11**(2):e0149395.
9. Kennedy C, Bernhardt J, Churilov L, et al. Factors associated with time to independent walking recovery post-stroke. *Journal of neurology, neurosurgery, and psychiatry* 2021;**92**(7):702-08.



- 1  
2  
3 10. World Health Organization. International Classification of Functioning, Disability  
4  
5 and Health (ICF). *Geneva: World Health Organization, 2001*  
6
- 7 11. Wu Cy, Lin Kc. Defining occupation: A comparative analysis. *Journal of*  
8  
9 *Occupational Science* 1999;**6**(1):5-12.  
10
- 11 12. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
12  
13 domain & process, 4th edition. *The American journal of occupational therapy :*  
14  
15 *official publication of the American Occupational Therapy Association* 2020;**74**  
16  
17
- 18 13. Roley SS, DeLany JV, Barrows CJ, et al. Occupational therapy practice framework:  
19  
20 domain & practice, 2nd edition. *The American journal of occupational therapy :*  
21  
22 *official publication of the American Occupational Therapy Association*  
23  
24  
25 2008;**62**(6):625-83.  
26
- 27 14. English C, Manns PJ, Tucak C, et al. Physical activity and sedentary behaviors in  
28  
29 people with stroke living in the community: a systematic review. *Phys Ther*  
30  
31 2014;**94**(2):185-96.  
32  
33
- 34 15. Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines  
35  
36 on physical activity and sedentary behaviour. *British journal of sports medicine*  
37  
38 2020;**54**(24):1451-62.  
39  
40
- 41 16. Gordon NF, Gulanick M, Costa F, et al. Physical activity and exercise  
42  
43 recommendations for stroke survivors: an American Heart Association scientific  
44  
45 statement from the Council on Clinical Cardiology, Subcommittee on Exercise,  
46  
47 Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing;  
48  
49 the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke  
50  
51 Council. *Circulation* 2004;**109**(16):2031-41.  
52  
53
- 54 17. WHO. Physical activity strategy for the WHO European Region 2016–2025, WHO-  
55  
56 Europe, 2015. 2015  
57  
58  
59  
60

- 1  
2  
3 18. Letter to the editor: standardized use of the terms "sedentary" and "sedentary  
4  
5 behaviours". *Appl Physiol Nutr Metab* 2012;**37**(3):540-2.  
6
- 7  
8 19. Chastin SF, Granat MH. Methods for objective measure, quantification and analysis  
9  
10 of sedentary behaviour and inactivity. *Gait & posture* 2010;**31**(1):82-6.  
11
- 12  
13 20. Ekelund U, Tarp J, Steene-Johannessen J, et al. Dose-response associations between  
14  
15 accelerometry measured physical activity and sedentary time and all cause  
16  
17 mortality: systematic review and harmonised meta-analysis. *BMJ (Clinical*  
18  
19 *research ed)* 2019;**366**:l4570.  
20
- 21  
22 21. English C, Wondergem R, Hendrickx W, et al. People with Stroke Are Most  
23  
24 Sedentary in the Afternoon and Evening. *Cerebrovasc Dis* 2022:1-6.  
25
- 26  
27 22. Ezeugwu VE, Manns PJ. Sleep Duration, Sedentary Behavior, Physical Activity, and  
28  
29 Quality of Life after Inpatient Stroke Rehabilitation. *Journal of stroke and*  
30  
31 *cerebrovascular diseases : the official journal of National Stroke Association*  
32  
33 2017;**26**(9):2004-12.  
34
- 35  
36 23. Barrett M, Snow JC, Kirkland MC, et al. Excessive sedentary time during in-patient  
37  
38 stroke rehabilitation. *Topics in stroke rehabilitation* 2018;**25**(5):366-74.  
39
- 40  
41 24. Bernhardt J, Dewey H, Thrift A, et al. Inactive and Alone. 2004;**35**(4):1005-09.  
42
- 43  
44 25. Hassett L, Ada L, Hellweg S, et al. Active and sedentary bouts in people after stroke  
45  
46 and healthy controls: An observational study. *Physiother Res Int*  
47  
48 2020;**25**(3):e1845.  
49
- 50  
51 26. Hellström K, Lindmark B, Wahlberg B, et al. Self-efficacy in relation to impairments  
52  
53 and activities of daily living disability in elderly patients with stroke: a prospective  
54  
55 investigation. *Journal of rehabilitation medicine* 2003;**35**(5):202-7.  
56
- 57  
58 27. Salbach NM, Mayo NE, Robichaud-Ekstrand S, et al. Balance self-efficacy and its  
59  
60 relevance to physical function and perceived health status after stroke. *Archives*  
*of physical medicine and rehabilitation* 2006;**87**(3):364-70.

- 1  
2  
3 28. Hanna E, Janssen H, Crowfoot G, et al. Participation, Fear of Falling, and Upper Limb  
4  
5 Impairment are Associated with High Sitting Time in People with Stroke. *Occup*  
6  
7 *Ther Health Care* 2019;**33**(2):181-96.  
8  
9  
10 29. Hebert D, Lindsay MP, McIntyre A, et al. Canadian stroke best practice  
11  
12 recommendations: Stroke rehabilitation practice guidelines, update 2015.  
13  
14 *International journal of stroke : official journal of the International Stroke Society*  
15  
16 2016;**11**(4):459-84.  
17  
18  
19 30. Thilarajah S, Mentiplay BF, Bower KJ, et al. Factors Associated With Post-Stroke  
20  
21 Physical Activity: A Systematic Review and Meta-Analysis. *Archives of physical*  
22  
23 *medicine and rehabilitation* 2018;**99**(9):1876-89.  
24  
25  
26 31. English C, Healy GN, Coates A, et al. Sitting time and physical activity after stroke:  
27  
28 physical ability is only part of the story. *Topics in stroke rehabilitation*  
29  
30 2016;**23**(1):36-42.  
31  
32  
33 32. English C, Healy GN, Coates A, et al. Sitting and Activity Time in People With  
34  
35 Stroke. *Phys Ther* 2016;**96**(2):193-201.  
36  
37  
38 33. Hendrickx W, Riveros C, Askim T, et al. Identifying factors associated with sedentary  
39  
40 time after stroke. Secondary analysis of pooled data from nine primary studies.  
41  
42 *Top Stroke Rehabil* 2019;**26**(5):327-34.  
43  
44  
45 34. Mountain A, Patrice Lindsay M, Teasell R, et al. Canadian Stroke Best Practice  
46  
47 Recommendations: Rehabilitation, Recovery, and Community Participation  
48  
49 following Stroke. Part Two: Transitions and Community Participation Following  
50  
51 Stroke. *International journal of stroke : official journal of the International Stroke*  
52  
53 *Society* 2020;**15**(7):789-806.  
54  
55  
56 35. Fini NA, Bernhardt J, Holland AE. Low gait speed is associated with low physical  
57  
58 activity and high sedentary time following stroke. *Disability and rehabilitation*  
59  
60 2021;**43**(14):2001-08.

- 1  
2  
3 36. Hall J, Morton S, Fitzsimons CF, et al. Factors influencing sedentary behaviours after  
4  
5 stroke: findings from qualitative observations and interviews with stroke  
6  
7 survivors and their caregivers. *BMC public health* 2020;**20**(1):967.  
8  
9  
10 37. Espenberger KR, Fini NA, Peiris CL. Personal and social factors that influence  
11  
12 physical activity levels in community-dwelling stroke survivors: A systematic  
13  
14 review of qualitative literature. *Clinical rehabilitation* 2021;**35**(7):1044-55.  
15  
16  
17 38. Becker I, Maleka MD, Stewart A, et al. Community reintegration post-stroke in New  
18  
19 Zealand: understanding the experiences of stroke survivors in the lower South  
20  
21 Island. *Disability and rehabilitation* 2020:1-8.  
22  
23  
24 39. Wesselhoff S, Hanke TA, Evans CC. Community mobility after stroke: a systematic  
25  
26 review. *Top Stroke Rehabil* 2018;**25**(3):224-38.  
27  
28  
29 40. O'Brien AN, Wolf TJ. Determining work outcomes in mild to moderate stroke  
30  
31 survivors. *Work (Reading, Mass)* 2010;**36**(4):441-7.  
32  
33  
34 41. Kaskutas V. Stroke Rehabilitation. A function-based approach. St. Louis, Missouri.  
35  
36 2016:224-236.  
37  
38  
39 42. Engel-Yeger B, Tse T, Josman N, et al. Scoping Review: The Trajectory of Recovery  
40  
41 of Participation Outcomes following Stroke. *Behavioural neurology*  
42  
43 2018;**2018**:5472018.  
44  
45  
46 43. Kapoor A, Lanctôt KL, Bayley M, et al. "Good Outcome" Isn't Good Enough:  
47  
48 Cognitive Impairment, Depressive Symptoms, and Social Restrictions in  
49  
50 Physically Recovered Stroke Patients. *Stroke* 2017;**48**(6):1688-90.  
51  
52  
53 44. Norlander A, Iwarsson S, Jönsson AC, et al. Participation in social and leisure  
54  
55 activities while re-constructing the self: understanding strategies used by stroke  
56  
57 survivors from a long-term perspective. *Disability and rehabilitation* 2021:1-9.  
58  
59  
60 45. Stern BZJTOJoOT. Critical Reflections on Self-Management Support in Chronic  
Disease: The Value of Occupational Therapy in Health Promotion. 2018

- 1  
2  
3 46. Fini NA, Holland AE, Keating J, et al. How Physically Active Are People Following  
4 Stroke? Systematic Review and Quantitative Synthesis. *Phys Ther*  
5 2017;**97**(7):707-17.  
6  
7  
8  
9 47. Mahendran N, Kuys SS, Brauer SG. Recovery of ambulation activity across the first  
10 six months post-stroke. *Gait Posture* 2016;**49**:271-76.  
11  
12  
13 48. Hendrickx W, Riveros C, Askim T, et al. An Exploration of Sedentary Behavior  
14 Patterns in Community-Dwelling People With Stroke: A Cluster-Based Analysis.  
15 *Journal of neurologic physical therapy : JNPT* 2021;**45**(3):221-27.  
16  
17  
18 49. Tieges Z, Mead G, Allerhand M, et al. Sedentary behavior in the first year after stroke:  
19 a longitudinal cohort study with objective measures. *Archives of physical*  
20 *medicine and rehabilitation* 2015;**96**(1):15-23.  
21  
22  
23 50. Paul L, Brewster S, Wyke S, et al. Physical activity profiles and sedentary behaviour  
24 in people following stroke: a cross-sectional study. *Disability and rehabilitation*  
25 2016;**38**(4):362-7.  
26  
27  
28 51. Lynch EA, Jones TM, Simpson DB, et al. Activity monitors for increasing physical  
29 activity in adult stroke survivors. *The Cochrane database of systematic reviews*  
30 2018;**7**(7):Cd012543.  
31  
32  
33 52. Kwakkel G, Lannin NA, Borschmann K, et al. Standardized measurement of  
34 sensorimotor recovery in stroke trials: Consensus-based core recommendations  
35 from the Stroke Recovery and Rehabilitation Roundtable. *International journal*  
36 *of stroke : official journal of the International Stroke Society* 2017;**12**(5):451-61.  
37  
38  
39 53. Pohl J, Held JPO, Verheyden G, et al. Consensus-Based Core Set of Outcome  
40 Measures for Clinical Motor Rehabilitation After Stroke-A Delphi Study.  
41 *Frontiers in neurology* 2020;**11**:875.  
42  
43  
44 54. Fini NA, Holland AE, Keating J, et al. How is physical activity monitored in people  
45 following stroke? *Disability and rehabilitation* 2015;**37**(19):1717-31.  
46  
47  
48  
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55  
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60

- 1  
2  
3 55. Kringle EA, Skidmore ER, Terhorst L, et al. Sedentary behavior patterns over 6 weeks  
4 among ambulatory people with stroke. *Topics in stroke rehabilitation*  
5 2021;**28**(7):537-44.  
6  
7  
8  
9 56. Fini NA, Holland AE, Bernhardt J, et al. How Many Hours of Device Wear Time Are  
10 Required to Accurately Measure Physical Activity Post Stroke? *International*  
11 *journal of environmental research and public health* 2022;**19**(3)  
12  
13  
14  
15 57. Levy T, Laver K, Killington M, et al. A systematic review of measures of adherence  
16 to physical exercise recommendations in people with stroke. *Clinical*  
17 *rehabilitation* 2019;**33**(3):535-45.  
18  
19  
20  
21  
22 58. Kessler D, Egan M. A Review of Measures to Evaluate Participation Outcomes Post-  
23 Stroke. 2012;**75**(9):403-11.  
24  
25  
26  
27 59. Tse T, Douglas J, Lentin P, et al. Measuring participation after stroke: a review of  
28 frequently used tools. *Archives of physical medicine and rehabilitation*  
29 2013;**94**(1):177-92.  
30  
31  
32  
33 60. Fini NA, Bernhardt J, Said CM, et al. How to Address Physical Activity Participation  
34 After Stroke in Research and Clinical Practice. *Stroke* 2021;**52**(6):e274-e77.  
35  
36  
37  
38 61. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational  
39 Studies in Epidemiology (STROBE) statement: guidelines for reporting  
40 observational studies. *BMJ* 2007;**335**(7624):806-8.  
41  
42  
43  
44 62. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the  
45 methodological quality of studies on measurement properties of health status  
46 measurement instruments: an international Delphi study. *Qual Life Res*  
47 2010;**19**(4):539-49.  
48  
49  
50  
51 63. Kottner J, Audigé L, Brorson S, et al. Guidelines for Reporting Reliability and  
52 Agreement Studies (GRRAS) were proposed. *J Clin Epidemiol* 2011;**64**(1):96-  
53 106.  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 64. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research  
4  
5 (COREQ): a 32-item checklist for interviews and focus groups. *International*  
6  
7 *journal for quality in health care : journal of the International Society for Quality*  
8  
9 *in Health Care* 2007;**19**(6):349-57.  
10  
11  
12 65. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative  
13  
14 research: a synthesis of recommendations. *Academic medicine : journal of the*  
15  
16 *Association of American Medical Colleges* 2014;**89**(9):1245-51.  
17  
18  
19 66. Lobo A, Saz P, Marcos G, et al. [Revalidation and standardization of the cognition  
20  
21 mini-exam (first Spanish version of the Mini-Mental Status Examination) in the  
22  
23 general geriatric population]. *Medicina clinica* 1999;**112**(20):767-74.  
24  
25  
26 67. Van Bloemendaal M, Bout W, Bus SA, et al. Validity and reproducibility of the  
27  
28 Functional Gait Assessment in persons after stroke. *Clinical rehabilitation*  
29  
30 2019;**33**(1):94-103.  
31  
32  
33 68. Bellosta-López P, Domenech-Garcia V, Palsson TS, et al. European knowledge  
34  
35 alliance for innovative measures in prevention of work-related musculoskeletal  
36  
37 pain disorders (Prevent4Work Project): protocol for an international mixed-  
38  
39 methods longitudinal study. *BMJ Open* 2021;**11**(9):e052602.  
40  
41  
42 69. Gao Y, Wang Y, Li D, et al. Disability assessment in stroke: Relationship among the  
43  
44 pictorial-based Longshi Scale, the Barthel Index, and the modified Rankin Scale.  
45  
46 *Clinical rehabilitation* 2021;**35**(4):606-13.  
47  
48  
49 70. Lomas-Vega R, Hita-Contreras F, Mendoza N, et al. Cross-cultural adaptation and  
50  
51 validation of the Falls Efficacy Scale International in Spanish postmenopausal  
52  
53 women. *Menopause (New York, NY)* 2012;**19**(8):904-8.  
54  
55  
56 71. Quinn TJ, Dawson J, Walters MR, et al. Reliability of the Modified Rankin Scale.  
57  
58 2009;**40**(10):3393-95.  
59  
60

- 1  
2  
3 72. Craig CL, Marshall AL, Sjöström M, et al. International physical activity  
4 questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*  
5 2003;**35**(8):1381-95.  
6  
7  
8  
9 73. SC. Mantilla Toloza AG-C. El Cuestionario Internacional de Actividad Física. Un  
10 instrumento adecuado en el seguimiento de la actividad física poblacional. *Revista*  
11 *Iberoamericana de Fisioterapia y Kinesiología* 2007;**10**(1):48-52.  
12  
13  
14  
15 74. Phusuttatam T, Saengsuwan J, Kittipanya-Ngam P. Development and Preliminary  
16 Validation of a Stroke Physical Activity Questionnaire. *Stroke Res Treat*  
17 2019;**2019**:6764834.  
18  
19  
20  
21  
22 75. Rejas J, Ribera MV, Ruiz M, et al. Psychometric properties of the MOS (Medical  
23 Outcomes Study) Sleep Scale in patients with neuropathic pain. *European journal*  
24 *of pain (London, England)* 2007;**11**(3):329-40.  
25  
26  
27  
28 76. Hays RD, Martin SA, Sesti AM, et al. Psychometric properties of the Medical  
29 Outcomes Study Sleep measure. *Sleep medicine* 2005;**6**(1):41-4.  
30  
31  
32  
33 77. Hernandez G, Garin O, Pardo Y, et al. Validity of the EQ-5D-5L and reference norms  
34 for the Spanish population. *Qual Life Res* 2018;**27**(9):2337-48.  
35  
36  
37  
38 78. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta psychiatrica*  
39 *Scandinavica* 1983;**67**(6):361-70.  
40  
41  
42  
43 79. Ayis SA, Ayerbe L, Ashworth M, et al. Evaluation of the Hospital Anxiety and  
44 Depression Scale (HADS) in screening stroke patients for symptoms: Item  
45 Response Theory (IRT) analysis. *Journal of affective disorders* 2018;**228**:33-40.  
46  
47  
48  
49 80. Alegre-Muelas C, Alegre-Ayala J, Huertas-Hoyas E, et al. Spanish Transcultural  
50 Adaptation of the Activity Card Sort. *Occupational therapy international*  
51 2019;**2019**:4175184.  
52  
53  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 81. Hartman-Maeir A, Eliad Y, Kizoni R, et al. Evaluation of a long-term community  
4 based rehabilitation program for adult stroke survivors. *NeuroRehabilitation*  
5 2007;**22**(4):295-301.  
6  
7  
8  
9  
10 82. Vidaña-Moya L, Eklund M, Merchán-Baeza JA, et al. Cross-Cultural Adaptation,  
11 Validation and Reliability of the Spanish Satisfaction with Daily Occupations-  
12 Occupational Balance (SDO-OB): An Evaluation Tool for People with Mental  
13 Disorders. *International journal of environmental research and public health*  
14 2020;**17**(23)  
15  
16  
17  
18  
19  
20  
21 83. Tyson S, Connell L. The psychometric properties and clinical utility of measures of  
22 walking and mobility in neurological conditions: a systematic review. *Clinical*  
23 *rehabilitation* 2009;**23**(11):1018-33.  
24  
25  
26  
27  
28 84. Macchiavelli A, Giffone A, Ferrarello F, et al. Reliability of the six-minute walk test  
29 in individuals with stroke: systematic review and meta-analysis. *Neurological*  
30 *sciences : official journal of the Italian Neurological Society and of the Italian*  
31 *Society of Clinical Neurophysiology* 2021;**42**(1):81-87.  
32  
33  
34  
35  
36  
37 85. Ringeval M, Wagner G, Denford J, et al. Fitbit-Based Interventions for Healthy  
38 Lifestyle Outcomes: Systematic Review and Meta-Analysis. *J Med Internet Res*  
39 2020;**22**(10):e23954.  
40  
41  
42  
43  
44 86. Feehan LM, Geldman J, Sayre EC, et al. Accuracy of Fitbit Devices: Systematic  
45 Review and Narrative Syntheses of Quantitative Data. *JMIR Mhealth Uhealth*  
46 2018;**6**(8):e10527.  
47  
48  
49  
50  
51 87. Klassen TD, Simpson LA, Lim SB, et al. "Stepping Up" Activity Poststroke: Ankle-  
52 Positioned Accelerometer Can Accurately Record Steps During Slow Walking.  
53 *Phys Ther* 2016;**96**(3):355-60.  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 88. Klassen TD, Semrau JA, Dukelow SP, et al. Consumer-Based Physical Activity  
4  
5 Monitor as a Practical Way to Measure Walking Intensity During Inpatient Stroke  
6  
7 Rehabilitation. *Stroke* 2017;**48**(9):2614-17.  
8  
9  
10 89. Kim H-K, Jun M, Rhee S, et al. Husserlian phenomenology in Korean nursing  
11  
12 research: analysis, problems, and suggestions. *J Educ Eval Health Prof*  
13  
14 2020;**17**:13-13.  
15  
16 90. Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3:  
17  
18 Sampling, data collection and analysis. *The European journal of general practice*  
19  
20 2018;**24**(1):9-18.  
21  
22  
23 91. Giorgi A. The Theory, Practice, and Evaluation of the Phenomenological Method as  
24  
25 a Qualitative Research Procedure. *Journal of Phenomenological Psychology*  
26  
27 1997;**28**(2):235-60.  
28  
29  
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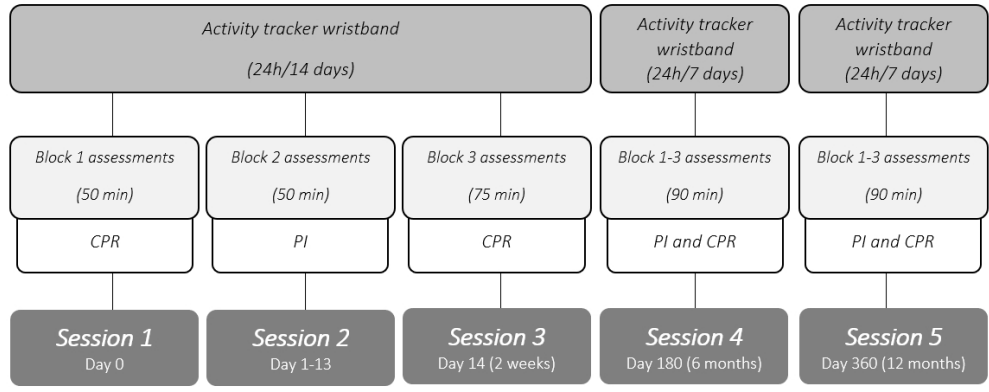
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3 **FIGURE LEGEND**  
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5 **Figure 1.** Study timeline design. CPR: Collaborating Professional Researcher; PI:

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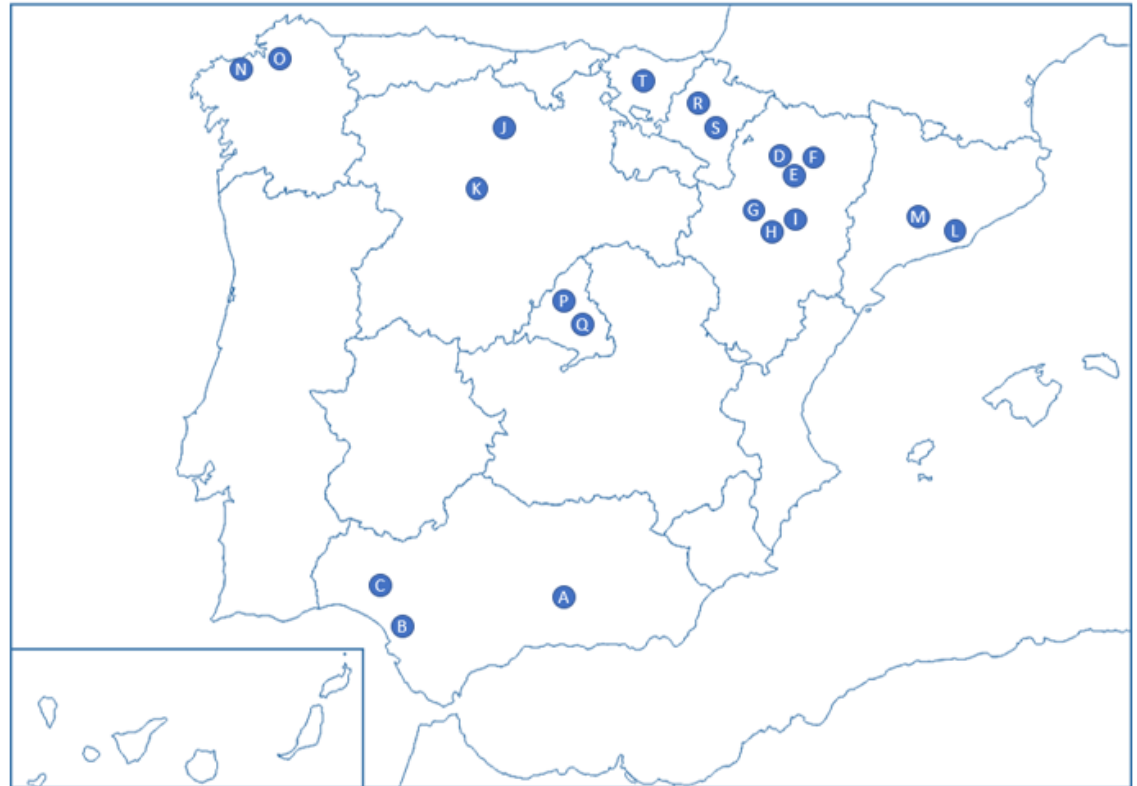


Study timeline design. CPR: Collaborating Professional Researcher; PI: Principal Investigator.

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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.