PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	MULTIDIMENSIONAL ANALYSIS OF SEDENTARY BEHAVIOUR AND PARTICIPATION IN SPANISH STROKE SURVIVORS (PART&SED-STROKE): A PROTOCOL FOR A LONGITUDINAL MULTICENTRE STUDY
AUTHORS	de Diego-Alonso, Cristina; Alegre-Ayala, Jorge; Buesa, Almudena; Blasco-Abadía, Julia; Lopez-Royo, Maria Pilar; Roldán-Pérez, Patricia; Giner-Nicolás, Rafael; Collaborators group, Part&Sed-Stroke; Gueita-Rodriguez, Javier; Fini, Natalie; Domenech-Garcia, Victor; Bellosta-López, Pablo

VERSION 1 – REVIEW

REVIEWER	Cabanas-Valdés, Rosa Universitat Internacional de Catalunya Facultat de Medicina i Ciencies de la Salut, Physiotherapy
REVIEW RETURNED	25-Jul-2022

GENERAL COMMENTS	Thank you for allowing me to review this interesting project. Is this study registered on any platform? Is this study followed the Helsinki statement? Limitations are not considered. Page 4 line 56, it is necessary to write "minutes". Page 9 line line 33 regarding inclusion criteria, Both sex?, it is necessary let it be the first stroke? "6) minimum knowledge and availability of a mobile phone" How it will be assess? ;line 49 "7) accept informed consent" it is not a inclusion criteria, it is a requirement. Page 12. Outcome measures. How many strokes has the patient suffered? Page 14. The EQ-5D-5L, In my opinion the reference is incorrect, There is a Spanish version. Page 15. Concerning the Physical mobility tests 10 meter walk test it is necessary 14 meter path walker , What happens if you don't have this space? Page 18 Sample size. The author took into account possible drops outs as it is a long-term study?

REVIEWER	Izawa, Kazuhiro Graduate School of Health Sciences, Kobe University
REVIEW RETURNED	10-Nov-2022

GENERAL COMMENTS	This manuscript is very interesting, so I recommend to publish this asap.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer #1:

Thank you for allowing me to review this interesting project.

We are pleased to read your feedback and thank you for your comments and suggestions for improving our manuscript.

Specific comments:

- **Is this study registered on any platform?**

We thank the reviewer for raising this question. Due to the observational nature of the project, we have not registered the project in any platform. The main reason we are publishing this protocol is to increase transparency of the methodological procedure, which, if finally accepted, will be open-access and freely available.

- **Is this study followed the Helsinki statement?**

We thank the reviewer for this comment as we consider is a relevant point. We have included a sentence in the "Ethics and confidentiality" section stating that it was designed following the Helsinki statement.

> *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).*

- **Limitations are not considered.**

We thank the reviewer for pointing out this relevant comment. Accordingly, we have created a new section under the subheading "Limitations". Now it reads on page 20 as follows:

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

- **Page 4 line 56, it is necessary to write "minutes".**

We thank the reviewer for this comment. We have fully written the word.

- **Page 9 line 33 regarding inclusion criteria, Both sex?, it is necessary let it be the first stroke? "6) minimum knowledge and availability of a mobile phone" How it will be assess? ;line 49 "7) accept informed consent" it is not a inclusion criteria, it is a requirement.**

We thank the reviewer for these comments that clearly help us to improve the description of the selection criteria of the sample.

> *The study sample will consist of people **of both sexes** who have suffered a stroke and reside in Spain. The inclusion criteria will consist of 1) be over 18 years of age; 2) have a history of stroke with a medical diagnosis for more than 6-months, regardless of its aetiology; 3) outpatient living at home; 4) have cognitive and speech ability to perform and understand the tests to be administered and the purpose of the research project (i.e., no aphasia and a Mini-Mental Cognitive Test score >24;66) 5) be able to ambulate with or without aids, which represent an ambulation ability ≥ 3 in the Functional Ambulatory Category67 *[not applicable for SDO-OB validation]; and 6) **availability of a mobile phone with Bluetooth and internet connection**. The exclusion criteria will be 1) non-acceptance of participation in the research project by the primary caregiver; 2) not tolerating being monitored with an activity tracker wristband; 3) residing in institutions (e.g., nursing homes); 4) no commitment to continuity**; and 5) a history of more than one symptomatic stroke**. …*

- **Page 12. Outcome measures. How many strokes has the patient suffered?**

We thank the reviewer for this comment and the opportunity to explain this relevant aspect. According to our answer to the previous comment, having a history of more than one stroke associated to clinical symptoms was considered an exclusion criterion. However, we have detailed in the "Clinical data" subheading that we have registered the number of silent/subclinical strokes suffered by the patient:

> *Clinical data will include information such as age at the time of stroke, type of stroke, damaged cerebral hemisphere, time of evolution, pain experience, other pathologies **(including number of silent or subclinical strokes)**, current medication, current rehabilitation and hours per week, number of falls in the last six months, use of assistive devices, …*

- **Page 14. The EQ-5D-5L, In my opinion the reference is incorrect, There is a Spanish version.**

We thank the reviewer for this comment, and we completely agree that referencing the Spanish version is appropriate. Now, we have updated the reference:

> ***Hernandez G, Garin O, Pardo Y, et al. Validity of the EQ-5D-5L and reference norms for the Spanish population. Qual Life Res 2018;27(9):2337-48.***

- **Page 15. Concerning the Physical mobility tests 10 meter walk test it is necessary 14 meter path walker, What happens if you don't have this space?**

We thank the reviewer for this comment, which we consider a very relevant point. Because it applies both to the 10-meter walk test as to the 6-minute walking test, we have included an explanatory sentence at the end of the section. Now it reads on page 16 as follows:

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

- **Page 18 Sample size. The author took into account possible drops outs as it is a long-term study?**

We thank the reviewer for pointing-out this relevant point. Due to the sample size was calculated for the most exigent hypothesis contrast, we only presented the requirement for the regression model which correspond to the objective 1 (which follows a cross-sectional design, and no follow-up is required for that aim). However, to make it clearer for readers, we have expanded that section showing the minimum sample that will be required for the hypothesis contrast with follow-ups (which is quite bellow 130 participants and potential lost during follow-up seem to be covered). Now it reads:

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

Reviewer #2:

This manuscript is very interesting, so I recommend to publish this asap.

Thank you very much for your comment.