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Telehealth intervention involving the HEARTS Technical Package and the use of an activity monitor to increase physical activity level post-stroke: protocol for a feasibility randomized controlled trial

Paula da Cruz Peniche*[1], Olive Lennon[2], Jordana de Paula Magalhães[1], Jéssica Melo dos Santos[1], Janaine Cunha Polese[1], Christina Danielli Coelho de Morais Faria[1]

1 Department of Physiotherapy, Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil
2 School of Public Health, Physiotherapy and Sports Science, University College Dublin, Belfield, Dublin 4, Dublin, Ireland
*penichepaula@yahoo.com.br

INTRODUCTION & AIM

Insufficient physical activity is a common risk factor for recurrent stroke in individuals post-stroke. The HEARTS Technical Package, developed by organizations like the World Health Organization, is a potential resource for promoting physical activity post-stroke. It aligns with secondary stroke prevention recommendations, addresses barriers/facilitators for physical activity post-stroke, and can be implemented remotely. However, evidence about its use to promote physical activity post-stroke by telehealth is absent. Furthermore, while activity monitors are used in physical activity interventions, their effectiveness post-stroke is primarily studied in-person.

Therefore, this study aims to investigate whether the telehealth intervention involving the HEARTS Technical Package and the use of an activity monitor to increase physical activity level post-stroke is feasible, and to estimate parameters for conducting a fully powered randomized controlled trial (RCT).

METHOD

- **This phase 1 feasibility RCT study, with concealed allocation and blinded assessments, that will adhere to the CONSORT extension for pilot or feasibility trials will be carried out in Belo Horizonte (MG, Brazil). This study was prospectively registered at the ClinicalTrials.gov (NCT06068036) and received approval (CAAE: 66980723.2.0000.5149) from the institutional ethical review board.**
- **24 individuals post-stroke (diagnosed ≥6 months), who were aged ≥18 years, inactive, able to walk 10 meters independently, and with medical approval to participate in physical activity, will be recruited and randomly assigned to experimental (n=12) or control group (n=12) (Figure 1). Both groups will carry out a theoretically-informed telehealth intervention, for 12 weeks, based on the HEARTS Technical Package. The experimental group will have the additional use of an activity monitor.**
- **Descriptive statistics will be calculated for all outcomes. The mean difference between groups and the standard deviation for the Adjusted Activity Score (AAS) outcome from the Human Activity Profile (HAP) will be identified. The effect sizes for this outcome will be calculated to determine the magnitude of within-groups and between-groups comparisons (α=5%).**

RESULTS & DISCUSSION

- **The outcomes will include the feasibility of recruitment, intervention, and measurement, as well as clinical outcomes.**
- **Feasibility of recruitment will be determined by the ratio between the total number of eligible individuals (EI) and the total number of screened individuals (SI) (measure= EI/IS), and by the ratio between the total number of eligible individuals (EI) and the total number of recruited individuals (RI) (measure=EI/RI).**

RESULTS & DISCUSSION (CONTINUATION)

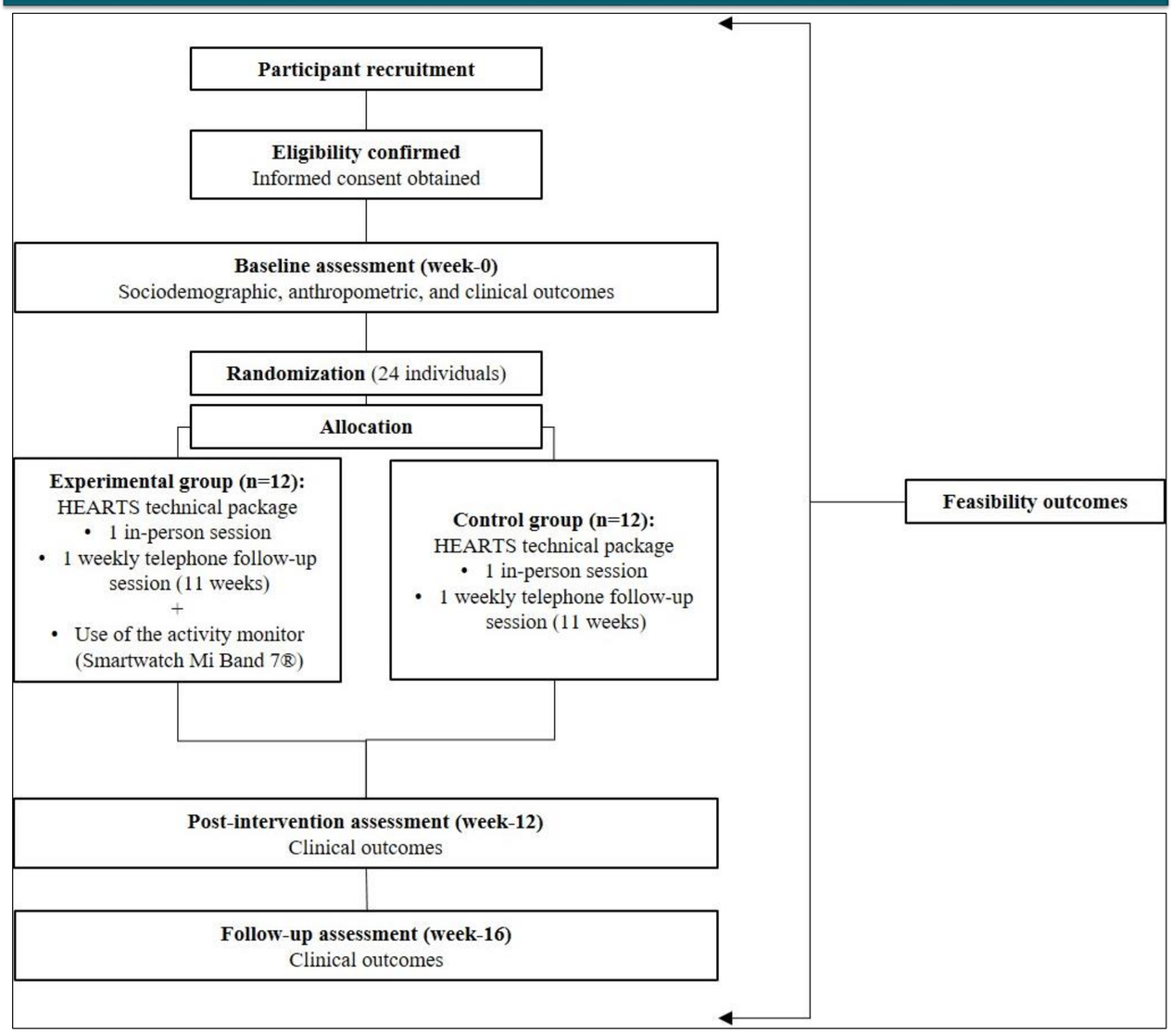

Figure 1. Study conduction flowchart

- **Feasibility of intervention will be determined by examining retention, follow-up of individuals, attendance, safety, and perceived effectiveness.**
- **Feasibility of measurement will be determined by the percentage of clinical outcomes measured and the percentage of participants who filled-out the diary.**
- **Clinical outcomes will include physical activity levels and the number of individuals post-stroke who met the threshold to be considered physically active, systolic blood pressure (SBP) and diastolic blood pressure (DBP), cardiorespiratory fitness, self-efficacy for physical activity and health-related quality of life.**

CONCLUSION

The proposed intervention meets secondary stroke prevention recommendations and will be implemented via telehealth, aiming to overcome barriers to in-person interventions. This study will inform future phases of conducting an RCT.

FUTURE WORK / REFERENCES

A limitation of the present study is that the results will not be able to be generalized for individuals post-stroke who are not able to walk independently. Therefore, future studies aiming to promote participation in physical activity using the proposed intervention should address this topic.