STUDY PROTOCOL

Psychometric properties of portable devices used in kinematic gait assessment after stroke: a systematic review protocol [version 1; peer review: awaiting peer review]

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Abstract

Background: Kinematic gait assessment is essential to the gait rehabilitation program after stroke. Portable devices composed of inertial sensors are an alternative for this evaluation. However, knowledge regarding the psychometric properties of these devices is needed to understand their accuracy, especially in evaluation of individuals with movement disorders (e.g., people post stroke). This systematic review aims to analyze the psychometric properties of portable devices that use inertial sensors to assess kinematic gait parameters in people post stroke. We will also investigate which portable device assesses alterations in lower limb angular movements during gait.

Methods: We will search for studies in English without publication date restriction, that evaluated psychometric properties of portable devices that use inertial sensors to assess kinematic gait parameters in people after stroke. Searches will be performed in the following electronic databases: Cochrane Central Registry of Controlled Trials (CENTRAL), Medline/PubMed, EMBASE Ovid, CINAHL EBSCO, PsycINFO Ovid, IEEE Xplore Digital Library (IEEE), and Physiotherapy Evidence Database (PEDro). Gray literature will also be searched, including published and unpublished studies (dissertations and theses). The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) risk of bias tool will be used to assess the quality of studies that analyzed reliability and measurement error of devices.

Expected results: This will be the first review assessing the risk of bias in studies that analyzed psychometric properties of portable devices that use inertial sensors to assess kinematic gait parameters.
in people post stroke. Then, we hope to elucidate this topic and help the decision-making of clinicians regarding the feasibility of these devices. Finally, we also hope to provide an overview of the characteristics of portable devices that assessed changes in angular lower limb movements during gait in this population.

Registration: The protocol was registered in Open Science Framework on May 11th 2023 (https://doi.org/10.17605/OSF.IO/7M6DA).

Keywords
stroke, gait, portable devices, inertial sensors, psychometric properties, reliability, measurement error

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Introduction

Background

The World Health Organization defines stroke as a focal (sometimes global) neurological impairment of vascular origin and sudden onset that lasts more than 24 hours and may lead to death.\(^1\) This condition has a global impact: approximately 12.2 million cases and 6.5 million deaths in 2019.\(^2\)

People post stroke commonly present an altered gait, spasticity,\(^3\) and sensory and strength deficits (especially in the paretic lower limb) that are not reversible.\(^4\) Also, more than half of people post stroke will live with permanent gait alterations,\(^5\) hindering function and social interaction.

The sequelae of stroke contribute to changes in lower limb angular movements. For example, excessive knee extension and reduced hip flexion and dorsiflexion (i.e., the most common changes in paretic lower limbs) may alter gait dynamics, including in the contralateral limb. In this sense, spatial (step and stride lengths), temporal (duration of double support and paretic balance), and spatiotemporal (speed and cadence) parameters are commonly altered.\(^6\,7\)

In this context, the quantitative assessment of kinematic gait using accurate systems is essential to the gait rehabilitation program after a stroke. For example, optoelectronic systems (gold standard) allow a three-dimensional gait analysis by capturing light from active (light-emitting diodes, LED) or passive markers (reflect light from infrared sources) using cameras. However, these systems are expensive and require a controlled space, precluding the monitoring of patients in natural environments.

Portable devices are an alternative to optoelectronic systems. They are composed of inertial sensors (accelerometers and gyroscopes) that may be used individually or combined with other sensors (magnetometers) to form inertial measurement units (IMUs). These devices acquire information regarding the movement trajectory of one or several body parts during gait and allow the analysis of intra- and inter-individual variations of kinematic gait parameters.\(^6\) They also have several advantages: portability, low weight, no wires, low energy consumption, easy installation and handling, and low manufacturing cost.\(^6\) For this reason, sensors are widely used for gait analysis because they provide continuous real-time data for clinicians and patients.\(^7\)

Accelerometers and gyroscopes allow different types of analyses. The former consists of a sensor that moves relative to a fixed base and operates based on Newton’s laws of motion. Mass acceleration of the sensing element, opposite to the transducer, produces an electrical signal proportional to the acceleration. Since the mass is constant, the signal is measured, and acceleration is obtained. On the other hand, gyroscopes collect data on angular movement using active sensors that generate an inertial force (Coriolis force) during rotation. The force acts on the mass sensor and generates a movement, measured by electrodes, representing the rotation rate.\(^10\,12\)

Why is this review important?

Currently, portable devices are used to analyze several kinematic gait parameters, such as speed, cadence, balance, asymmetry, and stance times (single and double).\(^13\) However, knowledge regarding the psychometric properties of these devices is needed to understand their accuracy, especially in individuals with movement disorders (e.g., people post stroke).

In this sense, two studies performed recently – Ferraris et al. (2021) and Cimolin et al. (2022) analyzed the agreement between a gold standard system (instrumented 3D- Gait analysis) and a test system (single RGB-D-camera) in the evaluation of gait parameters of patients with stroke and Parkinson’s disease. For this, the authors used tests such as Spearman correlation, intra-class correlation coefficient (ICC) and Bland–Altman plot analysis.\(^14,15\) However, studies along these lines are still scarce.

A systematic review by Peters et al. (2021) analyzed studies performed with wireless devices to assess the gait and mobility of people after stroke and few studies on psychometric properties were found.\(^16\) However, terms related to psychometrics were not included in the review search strategy. Furthermore, the review did not assess the psychometric properties of these devices.

The psychometric properties “reliability” and “measurement” error are defined respectively as “the proportion of the total variance in the measurements which is due to “true” differences between patients” and “the systematic and random error of a patient’s score that is not attributed to true changes in the construct to be measured”.\(^17\) Although this taxonomy was initially developed for studies with patient-reported outcome measures (PROMs), it is possible to analyze these properties referring to other types of measurement instruments, such as portable devices. Moreover, it is possible to verify the quality
of studies that perform this analysis using the “COSMIN Risk of Bias tool to assess the quality of studies on reliability or measurement error of outcome measurement instruments”.

Therefore, we believe that a review that investigates the psychometric properties of portable devices based on inertial sensors, especially “reliability” and “measurement error”, may allow a more specific analysis of this technology. Another important aspect concerns the altered angular movements of the lower limbs of people after stroke, since the most recent reviews that included inertial sensors did not assess this result.

Objective
This systematic review protocol aims to analyze the psychometric properties of portable devices that use inertial sensors to assess kinetic gait parameters in people post stroke. We will also investigate which portable device assesses alterations in lower limb angular movements during gait in people post stroke and observe their main characteristics (e.g., number and type of inertial components, sensor positioning, and sampling rate of data collection).

Methods
Study design
This systematic review protocol was developed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P). Our study question was structured based on the recommendation by Munn et al. (2018) for reviews of psychometric properties, which covers the following: 1) construct of interest or name of measurement instruments (kinematic gait parameters); 2) population (people post stroke); 3) type of instrument (portable devices that use inertial sensors); and 4) measurement properties (validity, reliability, responsiveness and measurement error).

Study registration
This protocol has been registered in Open Science Framework on May 11th 2023 (Registration DOI: http://doi.org/10.17605/OSF.IO/7M6DA).

Inclusion criteria
Types of studies
We will include studies that assessed psychometric properties (validity, reliability, responsiveness and measurement error) of portable devices that use inertial sensors to assess kinematic gait parameters in people post stroke. Only full-text studies, published or not (e.g., theses and dissertations), will be included.

Participants
We will include studies conducted with people post stroke of both sexes at the acute, subacute, or chronic stages and aged > 18 years.

Instrument types
Studies that assessed kinematic gait parameters of people post stroke through portable devices that use inertial sensors.

Primary outcomes
Psychometric properties (validity, reliability, responsiveness and measurement error) related to outcomes obtained by portable devices will be considered the primary outcome.

Secondary outcomes
Angular changes in the sagittal plane of lower limb joints (hip, knee, and ankle) during gait will be considered secondary outcomes.

Search strategy
We will search for studies in English without publication date restriction.
**Data sources**

Searches will be performed in the following electronic databases: Cochrane Central Registry of Controlled Trials (CENTRAL), Medline/PubMed, EMBASE Ovid, CINAHL EBSCO, PsychINFO Ovid, IEEE Xplore Digital Library (IEEE), and Physiotherapy Evidence Database (PEDro).

A strategy was developed based on descriptors indexed in the Medical Subject Headings Database (MeSH terms) related to: condition (e.g., ‘stroke’ and ‘cerebrovascular accident’), inertial sensors (e.g., ‘inertial sensors’, ‘inertial measurement unit’, and ‘wearable devices’), and psychometric properties (e.g., ‘psychometric properties’, ‘validity’, and ‘reliability’). The terms regarding condition were combined with those for portable devices and psychometric properties using the boolean operator AND. The initial strategy was developed for the MEDLINE/PubMed database and will be translated and adapted to other databases according to codes and syntaxes. Details of the search strategy are shown in the Extended data.22

**Searching other resources**

We will search the reference lists of primary studies included in the review to identify relevant studies. The gray literature will also be searched, including published and unpublished studies (dissertations and theses). Moreover, we will contact authors to obtain information from relevant articles and search for additional information regarding the device on the websites of manufacturers.

**Data collection and analysis**

**Study selection**

Two independent researchers (SS and KR) will use Rayyan software23 to examine the titles and abstracts of studies and exclude irrelevant articles. Full texts of all potentially eligible articles will be retrieved. The same researchers will read the texts, identify studies, record reasons for excluding ineligible studies, and discuss disagreements. A third researcher (RS) will be consulted in case of disagreements. Duplicates will be removed, and the authors of studies will be contacted if more information is needed. The selection process will be recorded following the PRISMA flowchart.24

**Data extraction**

Two researchers will independently extract (SS and KR) the following data regarding methods, participants, and characteristics of inertial sensors using a predefined form (see the Extended data):25

- **Methods**: objectives, year of publication, study duration, number of study centers and location, assessment environments, psychometric properties assessed, time between repeated measurements, results, and withdrawals.

- **Participants**: age, sex, anthropometric data (body weight, height, and body mass index), stroke duration and etiology (acute or hemorrhagic), most affected side (right or left), stroke stage (acute, subacute, or chronic), and use of assistive devices.

- **Inertial sensors**: technology type, sensor components, reports of discomfort and inadequacy, kinematic parameters, location of sensors on the body, angular data (hip, knee, and ankle joints), cost of equipment, and feasibility of implementation.

**Quality assessment**

The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) risk of bias tool18 will be used to assess the quality of studies that analyzed reliability and measurement error. The reliability box contains six items referring to study design and three regarding statistical methods. The measurement error box contains six items referring to study design and four regarding statistical methods. The checklists of the COSMIN risk of bias tool18 classify items as very good, adequate, doubtful, inadequate, or not applicable. The final score of each checklist is based on the worst score counts.

To assess the quality of the evidence we will use the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. According to the COSMIN methodology for systematic reviews of PROMs,26 some factors must be considered for studies of measurement properties: 1) risk of bias, 2) inconsistency, 3) indirectness and...
4) imprecision (wide confidence intervals). The tool also has four levels of evidence quality: “high”, “moderate”, “low” and “very low”. In the evaluation, we will start from the highest level of evidence quality (high), which may be downgraded depending on the factors: risk of bias, inconsistency, indirectness and imprecision.

**Data synthesis**
Results will be presented and explained in a narrative synthesis, while tables will summarize the information. The extracted data will be explained using descriptive statistics and presented in graphs.

Measures of central tendency, such as mean and standard deviation, will describe continuous parametric data (sample size and anthropometric characteristics). For non-parametric data, we will use median and interquartile ranges.

**Dissemination plans**
A systematic review will be performed according to this protocol and published in a relevant journal in the health area. We also intend to present the results at conferences and academic events.

**Study status**
Currently, the review is in the phase of “study selection”.

**Discussion**
This will be the first review assessing the risk of bias in studies that analyzed psychometric properties of outcomes obtained by portable devices that use inertial sensors to assess kinematic gait parameters in people post stroke. As the low number of studies that analyzed measurement properties may have neglected this topic, we believe our initiative will foster interest in these issues.

In addition, the characteristics of portable devices that assessed changes in angular lower limb movements during gait will help provide an overview of how this outcome has been assessed since few studies with portable devices addressed this question.

Last, we believe that recent reviews involving the assessment of gait aspects of people post stroke using portable devices may restrict the scope of this review and be a potential limitation of the study.

**Conclusion**
This study aims to provide evidence regarding measurement properties of portable devices for gait analysis in people post stroke. We hope to elucidate this topic and help the decision-making of clinicians regarding the feasibility of these devices.

**Authors’ contributions**
R.S.S., T.S.R., and K.M.O.B.R, conceived the idea of the study and contributed to the design of the research. R.S.S. wrote the initial draft. All authors contributed to the writing, editing, and approval of the final protocol.

**Data availability**
**Underlying data**
No underlying data are associated with this article.

**Extended data**

This project contains the following extended data:

- Search strategy.pdf

This project contains the following extended data:

- Data extraction form.pdf

**Reporting guidelines**


Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

### References


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