

Identify the prosthesis users' necessities concerning their devices.

VITÓRIA, BRASIL

6 DE NOVEMBRO 2023

Original	
Original Primary Outcome Measures ICMJE	Number of patients that have an unconformity with the weight of the device and which functional characteristics they would improve their devices s concerning their devices.
Current Secondary Outcome Measures ICMJE	-
Brief Summary (5000 Ch)	Despite many advances in prosthesis development, there are still some areas that need to be improved. One of them is the weight of the devices which could cause muscular fatigue in long-term use of the prosthesis and even abandonment. This study aims to identify the desired improvements in prosthetic devices from the perspective of the users, therapists, and relatives. That would be done through two kinds of questionnaires about technology acceptance.
Detailed Description (32000 Ch)	<p>The World Health Organization (WHO) estimates that around 1.3 billion people experience significant disability. One of the actual challenges is facilitating and breaking the barriers of persons with disabilities. Assistance technology supports inclusion and participation, principally for people with disabilities.</p> <p>In Brazil, the DATASUS estimated that around 57802 amputations (one kind of disability) were performed in 2022. Prostheses are assistive devices that aim to mitigate the psychological impact of missing a member and help in activities of daily life (ADL). One kind of prosthesis is electrically powered, which uses electrical components to actuate the device and is commonly controlled by body signals such as surface electromyography (sEMG). Despite many advances in prosthesis development, some areas need to be improved such as weight, size, ergonomic design, etc. of the devices which could cause muscular fatigue in long-term use of the prosthesis and even abandonment.</p> <p>This study aims to identify the aspects that cause major discomfort in upper limb prosthesis users. Also, recognize in which activities of daily life, the prosthesis is involved. That information will be used to improve the design of an upper limb prosthesis.</p>
Study Type ICMJE	Observational, qualitative-quantitative study
Study Phase ICMJE	Waiting for the approval to contact the prosthesis users
Study Design ICMJE	The study is grounded on a non-invasive protocol, which investigates the necessities in the design of the upper limb prosthesis from the users', relatives', and therapist's perspectives.
Condition ICMJE	Upper limb amputees
Intervention ICMJE	For the execution, three kinds of questionnaires about technology acceptance will be used. In the first questionnaire, which is for prosthesis users, there will be 15 questions to identify what kind of activities the person uses the prosthesis, how much is the use time and what is the main problem with the device. In the second and third questionnaires,

	<p>which are for the therapist and relatives respectively, there will be between 8 and 9 questions to analyze which device characteristics, they think that cause major discomfort during the use and could be improved.</p>								
<p>Study Arms ICMJE</p>	<table border="1"> <thead> <tr> <th data-bbox="663 421 817 450">Arm</th> <th data-bbox="817 421 1331 450">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="663 450 817 562">Prosthesis Users</td> <td data-bbox="817 450 1331 562">30 participants, aged between 18 and 60, will be part of the study. It is necessary that the users have at least 6 months of experience using upper limb prostheses.</td> </tr> <tr> <td data-bbox="663 562 817 618">Therapists</td> <td data-bbox="817 562 1331 618">10 therapists that have experience working with prostheses.</td> </tr> <tr> <td data-bbox="663 618 817 701">Relatives</td> <td data-bbox="817 618 1331 701">30 of the prosthesis users' relatives who live with the person and see the daily difficulties of using the device,</td> </tr> </tbody> </table>	Arm	Description	Prosthesis Users	30 participants, aged between 18 and 60, will be part of the study. It is necessary that the users have at least 6 months of experience using upper limb prostheses.	Therapists	10 therapists that have experience working with prostheses.	Relatives	30 of the prosthesis users' relatives who live with the person and see the daily difficulties of using the device,
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Publications *

Recruitment Information	
Recruitment Status ICMJE	Enrolling by invitation
Actual Enrollment ICMJE	Participants will be selected from a predetermined population
Original Actual Enrollment ICMJE	
Actual Study Completion Date ICMJE	September 2024
Actual Primary Completion Date	September 2024
Eligibility Criteria ICMJE	Prosthesis users with at least 6 months of device use. A therapist with experience in working with amputees. Relatives of the prosthesis users.
Sex/Gender ICMJE	Mixed
Ages ICMJE	18 to 60 years
Accepts Healthy Volunteers ICMJE	-
Contacts ICMJE	Laura Vanesa De Arco Barraza