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Methods to assess Usability and Acceptability of Technologies for Home-based Rehabilitation a Systematic Review

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ABSTRACT: The recent application of Information and Communication Technology (ICT) for stroke and cerebral palsy rehabilitation has permitted the improvement of home-based therapies. Along with the development of new devices, the need to explore the expectations and perceptions of end-users about the use of ICT for rehabilitation at home has emerged. Usability and acceptability of end-user have been identified as the main parameters able to answer to these specific aspects. Standard definition and guidelines of usability and acceptability arose from literature and have been widely applied in different research contexts. A search was conducted on studies in which ICT had been developed for stroke or cerebral palsy home rehabilitation, and either end-users usability and/or acceptability assessment were performed with different tools. The main aim was to identify the common methodology used to assess these items and how different tools were able to investigate the standard requirements. Twenty-one studies met inclusion criteria. We identified standardised and tailored questionnaires as the most common assessment method applied, followed by interviews. The suggestion of this review is to evaluate end-users perception, through a proper tool, considering individual, device and home environment features. Probably, in the context of home rehabilitation, testing the device directly in the home setting could reduce possible bias related to the environment. The appropriate assessment methodology directly respond to specific questions, defined by standard definitions of usability and acceptability. For this purpose, we introduced a reference plan to address outcome measures, allowing quantitative comparison of users' opinion about different kinds of technologies for home-based rehabilitation.

Keywords: Stroke, cerebral palsy, ICT, usability, acceptability.

I. INTRODUCTION

Stroke and Cerebral Palsy (CP) are two of the most common causes of physical disability, respectively in adults, with a various and growing incidence worldwide [1] and in children with a prevalence of 2-3 per 1000 life births [2, 3]. These medical conditions lead to posture and movement disorders due to weakness, spasticity, loss of dexterity and coordination disorders [4] and the overall result is an important chronic limitation in terms of independence and quality of life. People affected by stroke and CP need multidisciplinary care and rehabilitation programs which require many resources, often limited in most areas. In this field, home-based rehabilitation programs are increasing in recent literature and begin to overcome this issue [5]. Healthcare Organizations have to deal with continual rise of post-acute and chronic disabilities, which increases needs, costs and pressure on healthcare budgets [6, 7].

The recent involvement of new technologies (i.e. robotic therapy, virtual reality interfaces and gaming strategies) in neurorehabilitation has offered the possibility to increase delivery, intensity and practice of rehabilitative therapies, and demonstrated to enhance participation and enjoyment of adult and children patients [8]. Several studies on stroke patients have showed that a greater use of Information and Communication Technology (ICT) can improve healthcare quality allowing monitoring, supporting and assisting personal care processes and patient participation, promoting the connection with other people and facilitating the execution of common activities of everyday life. [9, 10]

However, to develop new ICT for home-based rehabilitation, characteristics of end-users, technological devices themselves and environment should be considered. Donald Norman was the first to introduce "The User-Centered Design" (UCD) concept in Norman and Draper (1986) [11], which shifted the focus of the designer on the person who actually uses the product, on his/her needs and on the environment of use. According to this theory, it is essential to involve the end user since the earliest stages of the project and, if possible, in the environment in which the product will be used as also described by Hersh (2010) [12, 13]. The adoption of UCD concept is essential in the design process of any medical devices

and to place the spotlight on end-users is crucial for the success of this kind of product [14]. The requirements and expectations of the user, along with the desired aims of the health care professional, must be taken into account to ensure the success of any ICT for rehabilitation [15].

Studies should firstly investigate end-user usability and acceptability of ICT still in development, to better address rehabilitative therapy and reach their specific goals.

Giving a unique definition of Usability is not easy as this term includes multiple concepts, however one of the best known descriptions of "Usability" is by Nielsen, who stated that "usability is about learnability, efficiency,

memorability, errors, and satisfaction" [16]. However the standard ISO 9241-11 (Guidance on Usability) defines usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [17]. This reference is largely recognised in literature and used in the recent Common Industry Format (CIF) for usability testing [18]. Therefore, in the evaluation process, it is pivotal to identify the users of the system, the goals of users, the environment of use and the measures of outcomes.

The outcomes necessary for the assessment of the usability consist of the following: measuring the effectiveness "How well do the users achieve their goals using the system?"; the efficiency "What resources are consumed in order to achieve their goals?" and the satisfaction "How do the users feel about their use of the system?" [19, 20].

Some standardized scales based on usability model, like the System Usability Scale (SUS), the Post-Study System Usability Questionnaire (PSSUQ) [21], the Computer System Usability Questionnaire (CSUQ) [22] and the After-Scenario Questionnaire (ASQ) [23] have already been developed and administered in different research contexts.

These scales are available and easily accessible on the web and can be used to quickly collect a user subjective rating of the usability of a product or a service.

Despite the existence of these tools, recent studies applied more frequently tailored questionnaires for usability assessment of specific devices, containing Likert [24] or Visual Analogue Scales (VAS) [25] or where users rate their responses to specific questions with yes/no or either/or regarding the intervention [26]. In the healthcare field, the assessment questionnaire can be completed from someone other than the participant, such as a parent, a caregiver or a therapist.

Another critical step for the success of innovative technologies is represented by the lack of user's acceptability, defined as the demonstrable willingness within a user group to employ technology for the task it is designed to support [27]. One of the most highly valued theory about this issue is The Technology Acceptance Model (TAM) [28] which has been widely used outside and inside of health care and has lately become an important tool for health Information Technology research [29]. A recent metanalysis [30] reviewed 88 acceptability studies and reported that the TAM model is highly reliable and may be applied in a variety of contexts. In healthcare field the TAM has been used to investigate the physicians' acceptance of telemedicine technology [31].

The Technology Acceptance Model explores three main items: the perceived usefulness of the system (how the user thinks the system can improve their performance), the perceived ease of use (physical and mental effort) and the attitude towards using the system. Sometimes, other factors like external variables (user training, system characteristics, user participation in design and the implementation process nature) are considered in TAM model. [32].

Even though the importance of acceptability and usability is widely proved, a univocal standard method to assess these outcomes for ICT used in rehabilitation is not present yet. Consequently, the aim of the present review is to analyse the current methodology used to assess how ICT for stroke or cerebral palsy home-based rehabilitation are perceived by end-users. The purpose was to highlight the main usability and acceptability parameters which could be investigated, exploring the end-users' experience with ICT at home. This work also aimed to provide a quick reference tool based on existing guidelines, able to interpret adult and children' opinions and compare different ICT for home-based rehabilitation.

II.MATERIALS AND METHODS

A. Study design and Research questions

This work represents a systematic review and it follows the Preferred Reporting Items for Systematic Reviews (PRISMA) statement [33] and it has been registered at Prospero CRD42018088336. It represents an original work.

The research was conducted aiming to address the following specific questions: (1) How the experience of using a ICT for home-based rehabilitation has been explored for adults and children with stroke and cerebral palsy? (2) What are the most common tools used for assessing the end-users' usability and acceptability parameters? 3) Are these tools able to meet the standards of usability and acceptability definitions?

B. Literature Search

Searches were conducted on literature sources, including PubMed, Web of Science, CINAHL COMPLETE and Scopus databases. The searches were limited to papers in English and included articles published until December 2019. The following terms were used for the research: ((“home” AND “rehabilitation”) AND (“medical device” OR “technology” OR “ICT”) AND (“usability” OR “ease of use” OR “acceptability” OR “acceptance”) AND (“stroke” OR “cerebral palsy”)). The corresponding author (GS) and the two firsts co-authors (GS and MA) defined the terms and performed the literature searches. References were exported into a bibliographic management database and duplicates were removed.

C. Study Selection

Before the literature search, inclusion criteria were established. No limitation regarding study design was applied. Studies were selected if they fulfilled the following criteria: (i) involved patients with stroke and/or with cerebral palsy of any age, (ii) tested ICT or technologies for home rehabilitation like computer-based programs and software, exergames or upper limb robotic devices, and (iii) included usability and/or

acceptability of the used device in the outcome assessment. Moreover, studies were rejected if they met some of the following "exclusion criteria": (i) ICT designed for speech or cognitive rehabilitation; (ii) medical devices for assistive or monitoring purposes; iii) outcome evaluation not directly including the patients themselves. Exclusion criteria were established because the main focus of this work was to investigate the end-users' opinion using devices at home, specifically designed for stroke and CP motor rehabilitation.

D. Validity assessment

The methodological quality of selected studies was evaluated with the modified version of the Downs and Black (D & B) quality assessment scale for randomized [34] and non-randomised trials, by Eng *et al.*, 2007 [35]. The D & B checklist consists of 27 questions divided in five domains: Reporting, External Validity, Internal Validity (Bias), Internal Validity (Confounding) and Power. Questions from 1 to 26 can be answered 0 or 1, except for the fifth question with a range from 0 to 2 and the last from 0 to 5. In the revised version, used in this review, the final question has only a yes/no (0-(1) answer, resulting in a total score of 28 points [35]. All studies have been separately assessed with the modified Downs and Black (D & B) quality assessment scale by three review authors, GS, MA and EB disagreements were resolved by discussion. Finally, quality judgment, as suggested by Benjamin et al. 2014 and Hooper et al. 2007, has been integrated aiming to characterise obtained scores (26-28 excellent, 20-25 good, 15-19 fair, below 14 poor).

For each ICT developed, the Technological Readiness Level (TRL) were determined, using the US Department of Energy, Technology readiness assessment guide, that led to classify the technological product on different 9 levels [36].

We also carried out, for each study, a tailored assessment for primary outcomes' methodology evaluations. The "standard ISO 9241-11 Guidance for Usability" has been taken into account as a baseline for Usability assessment, considering three main domains: Effectiveness, Efficiency and Satisfaction [17]. In particular, we considered if authors gave an answer (directly or indirectly) or not to the following specific questions: (1) Effectiveness "How well do the user achieve their goals using the system?" (2) Efficiency "What resources are consumed in order to achieve the goals?" (3) Satisfaction "How do the users feel about their use of the system?" [19, 20]. The Acceptability was assessed considering the Technology Acceptance Model (TAM) parameters: (1) Perceived usefulness defined as "the degree to which a person believes that using a particular system would enhance his/her performance" (2) Perceived ease of use defined as "the degree to which a person believes that using a particular system would be free from effort" and (3) Attitude towards the system defined as "the user's desirability of employing a particular information system application" [37]. Each study was screened to evaluate if the outcome measures answered to the items of selected criteria, judging "yes" if the item was respected, "no" if the item was not reported and "indirect" if the item was explored but not clearly researched or found out from the individual interviews. "Indirect" judgment was mostly given in case of individual open interviews, in which the users talking about their own device's use experience, reporting some information related to the selected outcomes. Another situation considered "indirect" was related to studies in which authors reported device data suitable for infer for example users' "Perceived ease of use" and "Attitude towards the system".

Even for this assessment, GS MA and EB separately assessed each study and all disagreements were resolved by discussion.

III. RESULTS AND DISCUSSION

The PRISMA Flow Diagram of the review process is reported below.

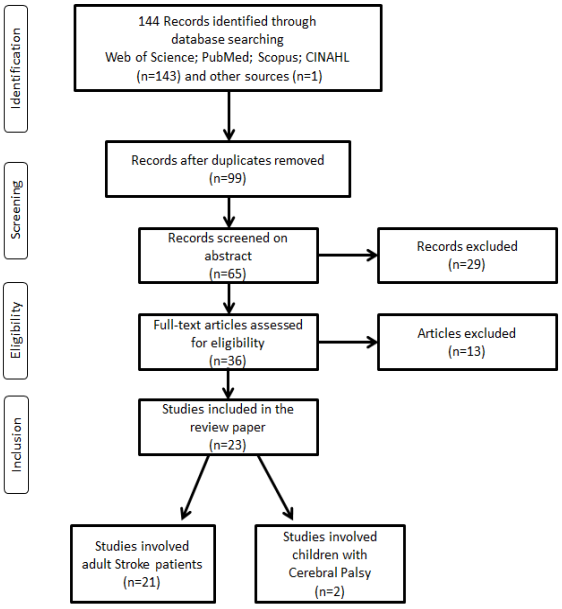

Fig. 1. Prisma Flow Diagram.

A. Description of studies

A total of 143 papers were collected from different databases and a single study was extracted from references of the recent review by Klaassen *et al.* (2016) [38]. After the duplicates were removed, a total of 99 papers were screened. Upon reviewing the titles, 34 papers were removed. Following this, three authors independently reviewed the remaining sixty-five abstract papers and based on the inclusion criteria 29 papers were removed. The remaining 36 full-texts of the selected articles were analysed by the reviewers and the eligibility of the study inclusion was assessed independently; in case of mismatched opinion, consensus was reached after discussion. Twenty-three of the 36 papers were included based on clear fulfilment of our inclusion criteria. The thirteen articles were excluded for the following reasons: two of them tested different samples (no stroke or CP patients), two of them only analysed professionals' or stroke caregivers' device usability, three are preliminary study protocol without patients' involvement, two studies included only clinical effectiveness or feasibility outcomes, two of them explored usability of technologies for cognitive or speech therapies and two tested devices not designed to home use.

The majority of the studies enrolled adult or elder stroke survivors (21) while only two studies included children with cerebral palsy. Most of the studies enrolled small samples of about 13 patients (min 3; max 61). Studies characteristics are set out in Table 1.

The methodological quality results reported 3 papers as “poor”, 11 as “fair” and 7 as “good” (Table 2). In case of mismatched opinion, a consensus was reached between the three first reviewers, in particular answers of questions number 5, 16 and 20 were widely discussed for five papers. [24, 26, 39-41]

Regarding the primary outcomes quality assessment, three categories of outcomes with relative subitems were identified: (i) Usability (Effectiveness, efficiency and satisfaction), (ii) Acceptability (perceived usefulness, perceived ease of use and attitude towards the system), (iii) Motivation/Perception. Only two studies respected all subitems of the three mentioned outcomes. Five studies showed to directly answer to at least two of the three main outcomes (usability and acceptability/ motivation or acceptability and motivation). Seven papers completely addressed only items relative to one primary outcome measures (acceptability or usability). The remaining seven studies directly answered only to motivation/perception outcome or to one/two subitems belonged to one of the primary outcome (Table 3).

ICT for home rehabilitation. In the 23 studies collected, different kinds of ICT for home use had been described, mostly designed for upper limb rehabilitation therapies. Ten studies evaluated the usability/acceptability of Game Systems (Kinect, Nintendo Wii, EXERGAMES) both in adults and children. [4, 15, 24, 25, 41, 47] Four authors presented results of Virtual Reality interventions. [26, 45, 48, 49] In three studies usability of using the SCRIPT, a hand-wrist exoskeleton, had been tested in stroke patients [44, 50, 51].

Rodriguez de Pablo and colleagues also evaluated end-user usability and motivation using the Arm Assist System for stroke upper limb rehabilitation [39]. Another robotic device for the upper limb treatment had been tested by Sivan *et. al.*, in 2016, who explored the users’ opinion about the use of home-based Computer Assisted Arm Rehabilitation (hCAAR) [52]. A combined strategy with interactive Computers based interfaces and wearable wrist sensors had been used in patients with stroke by Mountain *et al.*, 2010 [40]. The users’ opinion about the rehabilitative use of off-the-shelf applications had been tested in three studies. [15, 53, 54] In a single case the use of Sensorised Garments for home rehabilitation has been tested [55].

The number values of the readiness level of each ICT developed, were reported in the Table 1.

Table 1: Studies Characteristic Summary of the included studies. (TRL: The Technological Readiness Level; SUS: System Usability Scale; IMI: Intrinsic Motivation Inventory; TAM: Technology Acceptance Model; RCT Randomised controlled trial).

Authors	Country	Study Design	Device	TRL	Total Sample size	Users	Outcomes Measures	Research field	Publication Type
Amirabdollahian F. *et al.*, 2014	UK, Netherlands and Italy	Multicenter Feasibility study Quantitative	Supervised Care and Rehabilitation Involving Personal Tele-robotics (SCRIPT)	7	10	Stroke patients	Usability/SUS	Engineering and Rehabilitation Medicine	Journal Article
Brokaw E.B. *et al.*, 2015	USA	Pilot study Quantitative	Home Arm Movement Stroke Training Environment (HAMSTER)	6	10	Stroke patients	Usability/ individual interviews	Rehabilitation Medicine	Journal Article
Brown E. *et al.*, 2015	USA	Observational study Qualitative	NeuroGame Therapy (NGT) + surface electromyography (sEMG) biofeedback + computer game.	6	10	Stroke patients	Acceptability/semi-structured interviews	Rehabilitation Medicine	Journal Article
Cameirao M.S. *et al.*, 2016	USA	Case control study Quantitative	Computer assisted task with Kinect Sensor	5	25	Healthy subjects and Stroke patients	Usability/SUS; Acceptability/Customised self-report questionnaire	Rehabilitation Medicine and Engineering	Journal Article
Chen *et al.*, 2019	USA	Clinical Trial Quantitative	Home based Telerehabilitation System	8	13	Stroke patients	Acceptability/semistructuredinteviews based on UTAUT model	Rehabilitation Medicine	Journal Article
Crotty M. *et al.*, 2014	Australia	Feasibility study Qualitative	Computer assisted telerehabilitation	8	78	Patients needed rehabilitative treatment including Stroke	Usability/ SUS Perception/ qualitative individual interviews	Rehabilitation Medicine	Journal Article
Gerber C.N. *et al.*, 2016	Switzerland	Clinical Trial Quantitative	New portable version of the YouGrabber® system (YouRehab AG, Zurich, Switzerland)	7	27	13 Cerebral Palsy Children and 14 Caregivers	Usability and Motivation/qualitative interviews using a Visual Analogue Scale (VAS) score	Rehabilitation Medicine and Engineering	Journal Article
Giorgino T. *et al.*, 2009	Italy	Pilot Experimental Trial Qualitative	A Portable Remote rehabilitation system with sensorised garments	6	13	Stroke patients	Usability and Acceptability/ qualitative questionnaire	Rehabilitation Medicine and Engineering	Journal Article
Held J.P. *et al.*, 2017	Switzerland and Spain	Pilot cohort study Quantitative	REWIRE platform-Autonomous telerehabilitation system for balance and gait	8	15	Stroke patients	Acceptability/ TAM	Rehabilitation Medicine	Journal Article

To be continued…

Authors	Country	Study Design	Device	TRL	Total Sample size	Users	Outcomes Measures	Research field	Publication Type
Kizony R. *et al.*, 2014	Israel	Clinical effectiveness study Quantitative	Gertner Tele-Motion-Rehab system	7	8	Stroke patients	Usability/Customised Questionnaire	Rehabilitation Medicine	Conference paper
Llorens R. *et al.*, 2015	Spain	RCT Quantitative	Computer and Kinect rehabilitation system	6	30	Stroke patients	Usability/SUS; Motivation/ IMI	Rehabilitation Medicine	Journal Article
Mahmood *et al.*, 2019	India	Cross sectional study Quantitative	m-Health system	7	102	Stroke patients and Caregivers	Acceptability	Rehabilitation Medicine	Journal Article
Mountain G. *et al.*, 2010	UK	Observational study Qualitative	Computer assisted telerehabilitation with sensors	5	16	8 Stroke patients and 8 Healthcare Professional	Usability and Acceptability/ Semi-structured Interviews.	Rehabilitation Medicine and Engineering	Journal Article
Nijenhuis S.M. *et al.*, 2015	Netherlands Italy and UK	Multicentric Longitudinal Clinical Trial Quantitative	(SCRIPT) Dynamic Orthotic Device with games and remote monitoring	7	21	Stroke patients	Usability/SUS Motivation/ IMI	Rehabilitation Medicine and Engineering	Journal Article
Nijenhuis S.M. *et al.*, 2017	Netherlands	RCT Quantitative	(SCRIPT) Dynamic Orthotic Device + the SaeboMAS + gaming exercises on computer with touchscreen	8	20	Stroke patients	Acceptability/indirect measures; Motivation/IMI	Rehabilitation Medicine and Engineering	Journal Article
PlajaroBlazquez M. *et al.*, 2014	Spain	Pilot study Qualitative	REWIRE platform-Autonomous telerehabilitation system for balance and gait	8	3	Stroke patients	Acceptability/TAM	Rehabilitation Medicine and Engineering	Conference paper
Prange G.B. *et al.*, 2014	Netherlands Italy and UK	Multicentric Longitudinal experimental trial Quantitative	Hand wrist orthosis with Telerehabilitation system (SCRIPT1)	7	20	Stroke patients	Usability/ SUS	Rehabilitation Medicine and Engineering	Conference paper
Rodriguez-de-Pablo C. *et al.*, 2016	Spain	Clinical Trial Quantitative	Robot-assisted rehabilitation based on serious games	7	12	10 Stroke patients and 2 Healthcare Professionals	Usability/ customised scale Motivation/ IMI	Rehabilitation Medicine and Engineering	Book Section
Sivan M. *et al.*, 2014	UK	Observational study Qualitative	Various Home-based arm rehabilitation systems.	6	15	9 Stroke patients and 6 Healthcare Professionals	Usability and Acceptability/ Semi-structured Interviews.	Rehabilitation Medicine and Engineering	Journal Article
Sivan M. *et al.*, 2016	UK	Observational study Qualitative	A home-based rehabilitation device (hCAAR, home-based Computer Assisted Arm Rehabilitation).	7	24	17 Stroke patients and 7 Healthcare Professionals	Users' experience: semi-structured interviews and extraction of meaningful concept	Rehabilitation Medicine and Engineering	Journal Article
Verma S. *et al.*, 2017	India	Experimental Trial Quantitative	VBaT-VR-based balance training platform.	5	7	Stroke patients	Usability/questionnaire	Engineering	Journal Article
Weightman A.P.H. *et al.*, 2010	UK	Experimental Trial Qualitative	A computer game and a force feedback interface	5	88	37 Healthy and 33 Cerebral Palsy children; 18 Caregivers	End-users and parent perception and acceptability/questionnaire and interviews.	Engineering	Journal Article
Wingham J. *et al.*, 2015	UK	Qualitative study within Randomised Clinical Trial Mixed method	Nintendo Wii Sports games (Wii (TM))	7	28	18 Stroke and 10 Healthcare Professionals	Acceptability/ semi-structured interviews	Rehabilitation Medicine	Journal Article

B. Users Evaluation

The evaluation of End-users' opinion was the main focus of this work and 16 studies focused the outcomes assessment only on the direct user of the rehabilitative device, also including some healthy participants. Seven studies included in the evaluation setting, also people who helped or were in close contact with the end-user. These subjects were generally health care professionals or therapists, caregivers and children's family members.

Table 2: Studies quality assessment, scores on the subscale of the modified Downs and Black checklist.

Study, year	Reporting	External validity	Bias	Confounding	Total	Quality categories*
Amirabdollahian,2014	8/11	3/3	4/7	3/6	18/28	fair
Brokaw, 2015	7/11	2/3	3/7	4/6	16/28	fair
Brown, 2015	7/11	3/3	3/7	3/6	16/28	fair
Cameirao, 2016	10/11	3/3	5/7	3/6	21/28	good
Chen, 2019	9/11	3/3	5/7	4/6	21/28	good
Crotty, 2014	9/11	3/3	5/7	4/6	21/28	
Gerber, 2016	9/11	3/3	4/7	2/6	18/28	fair
Giorgino, 2009	8/11	2/3	3/7	2/6	15/28	fair
Held, 2017	11/11	3/3	5/7	3/6	22/28	good
Kizony, 2014	9/11	3/3	4/7	2/6	18/28	fair
Llorens, 2015	10/11	3/3	6/7	5/6	24/28	Good fair
Mahmood, 2019	8/11	2/3	5/7	4/6	19/28	Poor
Mountain, 2010	6/11	2/3	3/7	2/6	13/28	
Nijenhuis,2015	9/11	3/3	5/7	5/6	22/28	good
Nijenhuis,2017	8/11	3/3	5/7	4/6	20/28	good
Plajaro-Blazquez, 2014	7/11	2/3	4/7	2/6	15/28	fair
Prange, 2014	11/11	3/3	5/7	3/6	22/28	good
Rodriguez-de-Pablo,2016	5/11	3/3	4/7	2/6	14/28	poor
Sivan, 2014	7/11	2/3	3/7	3/6	15/28	fair
Sivan, 2016	6/11	2/3	3/7	3/6	14/28	poor
Verma, 2017	8/11	2/3	5/7	3/6	18/28	fair
Weightman,2010	5/11	3/3	4/7	3/6	15/28	fair
Wingham, 2015	9/11	2/3	4/7	3/6	18/28	fair

	USABILITY			ACCEPTABILITY			
	Effectiveness	Efficiency	Satisfaction	Perceived Usefulness	Perceived easy of Use	Attitude towards using the system	Motivation/ Perception
Amirabdollahian,2014	●	●	●	o	o	o	o
Brokaw, 2015	●	●	●	●	x	x	x
Brown, 2015	●	o	●	●	o	●	o
Cameirao, 2016	●	●	●	●	●	●	o
Chen, 2019	o	o	o	●	●	●	o
Crotty, 2014	●	●	●	o	x	x	●
Gerber, 2016	o	●	●	o	●	●	o
Giorgino, 2009	x	●	●	●	●	●	o
Held, 2017	o	o	o	●	●	●	o
Kizony, 2014	●	●	●	o	o	o	o
Llorens, 2015	●	●	●	o	o	o	●
Mahmood, 2019	o	o	o	●	●	●	o
Mountain, 2010	o	●	x	o	●	●	●
Nijenhuis,2015	●	●	●	o	o	o	●
Nijenhuis,2017	o	o	o	o	x	o	●
Plajaro-Blasquez, 2014	o	x	o	●	●	●	o
Prange, 2014	●	●	●	o	o	o	o
Rodriguez-de-Pablo,2016	●	●	●	●	●	●	●
Sivan, 2014	o	●	o	●	x	●	●
Sivan, 2016	o	●	●	●	x	o	o
Verma, 2017	●	o	x	●	●	●	x
Weightman,2010	o	o	●	●	●	●	●
Wingham, 2015	●	●	●	●	●	●	●

● = yes; o = no; x = unclear

Fig. 2. Evaluation of primary outcome quality assessment.

C. Types of assessment

Even if the described rehabilitative devices were designed and/or developed for home use, in certain cases the outcome assessment was not carried out in the home environment [15, 24, 25, 40, 41, 43-45, 50, 52, 56] but in clinical settings (8 studies) [26, 39, 42, 48, 51, 53, 55]. Only Weightman *et al*., 2010 performed outcome assessments both in clinical and home settings [4, 46, 49].

Studies were first classified based on the applied assessment features; we distinguished qualitative (e.g. open questions) versus quantitative outcome assessments (e.g. Likert scale): seven studies used quantitative assessment for the three outcomes measures [39, 42, 44, 45, 47-50, 54], eight studies used qualitative measures [15, 24, 26, 40, 41, 43, 52] and the remaining six used both types of assessments [4, 25, 52, 55].

Usability. Fifteen studies declared to explore usability as a primary outcome of specific devices for home rehabilitation. Most of these used a quantitative scale: five studies used the "SUS" [42, 44, 48-50, 52], three studies used evaluation questionnaires with a score [24, 47, 53] or yes/no answers [26] and in a single case authors produced a suited evaluation test the "Arm Assist Usability Evaluation Test". [39]In the remaining cases usability was directly assessed with individual interviews or through technical issue measurements (e.g. number of adverse events, number of assistant requests). However, only in nine of the fifteen studies, methods permitted to answer to each of the three items previously identified in the usability definition. In two cases [45, 46], even if the authors had declared to investigate the usability, they reported data unable to address usability items rather than the safety and acceptability of the system used. In the remaining cases usability assessment resulted incomplete, with only one or two items directly answered. Moreover, Wingham *et al.* 2014, despite having declared to assess acceptability as major outcome, conformed to all the usability items as well [43].

Acceptability. Acceptability evaluation for home-based rehabilitative devices was performed in 13 studies. Most of these used direct semi-structured interviews [15, 40, 41, 43, 47, 52, 55, Chen] and customized self-reported questionnaires. [4, 42, 52, 54]

Only in two cases users' acceptability was assessed through the TAM [45].

In seven studies all the three acceptability items were completely investigated. In the remaining six cases the evaluation set was not complete, respecting only one or two items or they resulted indirectly answered [4, 42, 43, 45, 47, 54, 55]. Otherwise, in three studies where different kind of questionnaires and/or individual interviews addressed to usability issues, emerged information about some of the three items of acceptability [24-26, 39].

Other Outcomes. Beside primary outcomes assessments some studies considered users' perception and experience through individual interviews, [4, 40, 41, 52, 53] and motivation through the Intrinsic Motivation Inventory scale [57], [39, 44, 49, 55]. Only in one study [52] authors previous applied a specific scale to analysed users' familiarity with technology in general.

D. Discussion

Recent literature states that perspectives of both end-users and healthcare professionals should be primarily considered to ensure the success of any developed ICT. The success strongly depends on the users' decision to use the technology, which implies the acceptance of it [58]. It has been demonstrated that the inclusion of end-user usability perception leads to improvement of efficiency and safety and greater marketability of the device [59]. Our data on rehabilitative devices for home use were consistent with this statement, showing that both adults and children were directly asked about their opinion on the device's use. However, in the improving field of stroke and cerebral palsy home rehabilitation, it is important to add to the end-user evaluation, also the point of view of the healthcare professionals and, in case of children, of their families.

We found that nowadays there are, unfortunately, few studies focused on children rehabilitation (two in our search) [4, 25] and this could be a result of the lack of technology aimed at children's rehabilitation and of the complex application of specific acceptability and usability assessments.

From our search, it emerged that even though different kinds of ICT focused on different rehabilitative goals, were developed and adapted for the home environment, not all of them had been already tested in the home setting [26, 39, 47, 49, 55]. Exploring user's opinion about ICT addressed for home use but not already completed for home delivery, could be incomplete and could led to possible bias in the interpretation of results. User's perception about technological rehabilitation could be different in clinical context and at home, considering that the home environment is full of potential bias (individual characteristics, home spaces, family compliance, daily routine).

From our literature survey, usability and acceptability assessment guidelines emerged; the ISO 9241-11 "Guidance on Usability" and the Technology Acceptance Model (TAM) for acceptability. However, the majority of studies in this review, even if declaring to assess users' usability and/or acceptability as primary outcomes, not always conformed to the standard items and/or the guidelines. The most used evaluation method encountered in this systematic review was represented by questionnaires, either standardised such as the SUS, as seen in all types of telemedicine systems [38], or particularly designed for the study. This is probably linked to the simple application of the tool, that can be suitable for different contexts and quickly delivered face-to-face or via e-mail.

Also in other non-clinical fields, the assessment of acceptability is very important and often made using questionnaires, as in Mahanta *et al*., (2019) and Ismagilov *et al.,* (2019) [60, 61].

The second most used assessment method was represented by individual interviews, with high variability in the structure and administration processes, between different studies. Interviews had been conducted with open questions and self-reported opinion [4, 24, 26, 42, 53, 55] or through semi-structured questions with quantitative data [15, 40, 41, 43, 52]; however in some cases, data collected have been reconducted to specific items of the above mentioned guidelines.

The quality analysis of outcome measures, proposed in this review and schematically reported in Table 3, could be a useful guide for authors to verify if their users' assessment models respect standard requirements of usability and acceptability. Directly answering to the simple usability/acceptability sub-items described above, could provide a wide, clear picture of users' opinion and perception about technological rehabilitation at home.

Moreover, the method used should be able to offer a comparable inter-subjects and inter-studies measurement in different contexts (type of device, time available, kind of end users, resources disposable), allowing to achieve the goals [38]. For this purpose, quantitative methods including Likert scales or numerical scores could be more appropriate.

IV. CONCLUSION

Possibility to bring technology at home has led to many advantages in stroke and CP rehabilitation programs, due to the chronicity, complexity and heterogeneity of clinical pictures of these patients. In order to meet users' needs, usability and acceptability of any rehabilitative ICT for home use should be assessed in the home environment, considering that home setting differs from clinical context. The use of technology could appear easy for the experts who prescribe it it but could be harder for the end users. A complete usability/acceptability assessment should involve the adult or children patient (end-user), the caregivers and children families' opinion, but also the healthcare professionals' point of view. Questionnaires, structured interviews and other different methods can be used to successfully assess these outcome measures, being able to directly respond to the standard items described in this review. Obtaining quantitative and reliable outcomes data should lead to an easy comparison of different devices and different users' opinion about technological home rehabilitation. In particular, for the studies conducted on children, their opinions could help to design new intervention and to improve the quantity and quality of home treatments, proposed in a highly modifiable phase of life.

V. FUTURE SCOPE

This paper aimed to provide useful tools and general guidelines to analyse the end-users' usability and acceptability for technological based neuro-rehabilitation at home. Standard approaches in the development of new ICTs in rehabilitation field could be fundamental to acknowledge patients perception but also to compare different kind of products and their usability and marketability.

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Conflict of Interest. None

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