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Development of SaraHome: A novel, well-accepted, technology-based assessment tool for patients with ataxia

Susanna Summa[a,*], Tommaso Schirinzi[a,b], Giuseppe Massimo Bernava[c], Alberto Romano[a], Martina Favetta[a], Enza Maria Valente[d,e], Enrico Bertini[f], Enrico Castelli[a], Maurizio Petrarca[a], Giovanni Pioggia[c,1], Gessica Vasco[a,1]

[a] MARlab, Neuroscience and Neurorehabilitation Department, Bambino Gesù Children's Hospital – IRCCS, Rome, Italy
[b] Department of Systems Medicine, University of Roma Tor Vergata, Rome, Italy
[c] Institute for Biomedical Research and Innovation (IRIB-CNR), Via Torre Bianca, Mortelle, Istituto Marino, 98164 Messina, Italy
[d] Department of Molecular Medicine, Unit of Genetics, Università degli studi di Pavia, Pavia, Italy
[e] IRCCS Mondino Foundation, Pavia, Italy
[f] Unit of Neuromuscolar and Neurodegenerative Diseases, Department of Neurosciences, IRCCS Bambino Gesù Children's Hospital, Rome, Italy

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ABSTRACT

Background and objective: Early onset ataxias (EOAs) are a heterogeneous group of neurological conditions, responsible for severe motor disability in paediatric age, which still lack reliable outcome measures. Available scales to assess ataxia, such as the Scale for Assessment and Rating of Ataxia (SARA), are based on subjective assessment of specific motor and language tasks by an examiner, and therefore is age dependent and lacks accuracy in detecting small variations in disease severity.

In last years, novel technologies, including computer interfaces and videogames, have emerged for clinical applications and the advent of Internet of Medical Things and of Information Communication Technology have allowed the remote control of such technologies. This pilot study describes a newly developed tool (SaraHome) for the assessment at home of EOA evaluating its feasibility and acceptability on a small sample of children.

Methods: Ten EOA children and ten caregivers have been enrolled for a preliminary outpatient evaluation. The Microsoft Kinect 2.0 and Leap Motion Controller (LMC) connected to a personal computer with an *ad hoc* software have been set-up, for the acquisition of standardized motor tasks performed by the patients with the caregivers' assistance. Acceptance and practicability have been tested by QUEST 2.0 and IMI questionnaires in caregivers and patients respectively.

Results: The SaraHome software was developed, based on a collection of services provided by a complex architecture that consists of a Restful interface, which enables to access a series of plugins for the execution of different tasks. A graphical user interface allows the acquisition of the patient movements while performing a motor task. A protocol of standard tasks inspired by SARA was established, and a system of video-assisted instruction provided. The set-up for the optimal acquisition of such protocol by Kinect and LMC has been defined. Both patients and caregivers accomplished the SaraHome assessment with good feedback at the technology acceptance questionnaires.

Conclusions: SaraHome represents a newly developed tool for the assessment of ataxia in patients, resulting from the integration of low-cost and easy-accessible technologies. This pilot application highlighted the feasibility and the acceptability of the system, suggesting the potential use in clinical practice.

* Corresponding author.
E-mail addresses: susanna.summa@opbg.net (S. Summa), tommaso.schirinzi@opbg.net (T. Schirinzi), m.bernava@irib.cnr.it (G.M. Bernava), alberto.romano@opbg.net (A. Romano), martina.favetta@opbg.net (M. Favetta), enzamaria.valente@unipv.it (E.M. Valente), enricosilvio.bertini@opbg.net (E. Bertini), enrico.castelli@opbg.net (E. Castelli), maurizio.petrarca@opbg.net (M. Petrarca), g.pioggia@irib.cnr.it (G. Pioggia), gessica.vasco@opbg.net (G. Vasco).
[1] Equally senior authors.

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1. Introduction

The term early onset ataxia (EOA) comprises a heterogeneous group of neurological disorders, with inherited or acquired aetiology, characterized by balance, gait and coordination disturbances, whit onset before 25 years [1]. EAOs are rare conditions (estimated European prevalence 26/100,000) [2], moreover they represent severe heterogeneous diseases that are responsible for relevant disability and high costs, which still lack effective therapies and specific outcome measures [3–5]. The most used clinical score for ataxic disorders is the Scale for Assessment and Rating of Ataxia (SARA) [6]. The scale is made up of 8 items related to gait, stance, sitting, speech, coordination (finger-chase test, nose-finger test, hands fast alternating movements and heel-shin test). Usually clinical scales are based on the subjective assessment and grading of specific tasks by an external examiner. Therefore, floor and ceiling effects or the inter-rater variability limit the reliability, as well as the presence of concurrent neurological disturbances (e.g. movement disorders) [7]. Moreover, SARA is age dependent, in fact it loses its accuracy in patients younger than 11 and lacks accuracy especially in detecting small variations in disease severity [1,8,9].

In the last years, novel technologies, including computer interfaces, videogames or “serious games”, and wearable sensors, have emerged for clinical and experimental applications in neurology and neurorehabilitation [10–14]. The advent of “Internet of Medical Things” (IoMT) and of the Information Communication Technology (ICT) which allow the remote control of such devices and the real-time communication with clinicians has further revolutionized the traditional healthcare systems [15,16]. One of the major objectives of such technologies is to identify new and reliable outcomes, which may improve the assessment of diseases course or the response to therapeutic interventions, overtaking the limitations of clinical-based instruments [17]. In recent years, promising results have been reported with two devices, the Microsoft Kinect and the Leap motion controller (LMC), which were originally produced for entertainment but have later been used for rehabilitation [11,12,18,19] and for clinical assessment [20,21].

While the potential of such technologies is undoubtedly high, their practical application in the medical field is subordinate to the acceptance by its prospective users. Indeed, despite the issue of technology acceptance is highly discussed and modelled in job-related contexts [22–26], this remains largely unaddressed into clinical frameworks. For instance, to date, only one specific questionnaire has been developed to evaluate the degree of technology acceptance in older and disabled people [27,28].

Here, we employed novel, low-cost technologies to develop a tool for the automatic assessment of patients with ataxia, shaping the SARA’s structure to explore for increased accuracy than those obtained by conventionally administered clinical scores, and to improve feasibility without needing a highly trained rater. In particular, for the first time, we combined Kinect, LMC and IoMT paradigm to produce an innovative system (that we called “SaraHome”) for the standardized and objective quantification of ataxic features in patients, even in non-hospital settings. Then, we conducted a pilot study to test its feasibility and acceptability by *ad hoc* questionnaires, in order to evaluate its future translation in clinical practice.

2. Methods

2.1. Study population and experimental protocol

The study was conducted at the Neurorehabilitation Unit of IRCCS Bambino Gesù Children’s Hospital – Rome, Italy in collaboration with CNR-ISASI Messina, Italy, from 2017 to 2018, and involved a total of 20 voluntary subjects (10 with EOA and 10 caregivers, here respectively children and parents).

In this study, the EOA group included five patients with Friedreich Ataxia, and five patients with other genetic ataxias. Sex distribution was 60% female, 40% male. Mean age was 11.9 ± 2.8 years (mean±SD). Patients underwent demographic and medical history recording, full neurological examination and conventional SARA scoring. The averaged value of the total SARA score was 11.8 ± 7.2 (mean±SD) while the sum of the 6 over 8 items that were executed in the SaraHome was 8.9 ± 5.9 (mean±SD), see Table 1.

One parent for patient was enrolled and trained by experienced personnel to the correct use of SaraHome (instructions on principles and methods of operation were provided). Then, patients were invited to perform SaraHome assessment under the guide of caregivers (as it would have been at home). At the end, both patients and parents underwent satisfaction questionnaires.

The research conformed to the ethical standards of Helsinki Declaration on human rights and was approved by the Ethical Committee of the “Bambino Gesù” Children’s Hospital. All the participants and their parents signed an informed consent.

2.2. Hardware equipment and set-up

We used the markerless motion capture devices Microsoft Kinect 2.0 and LMC, based on the infrared technology (IR) and connected to a personal computer to acquire biometric data of SARA tasks.

The **Kinect 2.0** is a motion sensing input device by Microsoft Windows. It comes integrated with proprietary software for application development and it is useful in applications that require user interaction. The Kinect offers an attractive processing platform due to its low-cost build, non-intrusive acquisition, available software. Besides the color (resolution: 1920 × 1080) and IR (resolution: 512 × 424) cameras, the Kinect provides depth images (resolution: 512 × 424), body index images and the skeleton information for every tracked person recognizing 25 joints from the human shape at a frequency of 30 Hz. In fact, it allows a coherent extraction of a skeleton structure from the depth frames, connecting a set of joints by rigid segments in time. The sensor tracking volume is defined by the field of view (FOV, 70 horizontally, 60 vertically) and the range of depth sensing (0:5–4:5 m). These data streams can be accessed using Microsofts software development kit (v2.0).

The **LCM** is a USB device that has been developed with the specific purpose of hand gesture recogniser. Technically it has two IR cameras and three IR leds, the device observes a roughly hemispherical area, to a distance of about 1 m. Its frame rate is 200 fps. The depth-pattern is analysed by the Leap Motion software that synthesizes 3D position data creating, similarly to Kinect, a skeleton structure of the hand. The overall average accuracy of the controller was shown to be 0.7 mm [29].

Acquisitions with the Kinect were conducted in a space of 4.15 m length x 1.80 m width x 2 m height. Online data storage was used to collect the acquisitions. Each task requires a particular set-up and devices locations (see Fig. 2) as described in the next section. Our hardware architecture consists of a single LCM and a single Microsoft Kinect v2 sensor mounted on a tripod positioned in a normally lighted room. Both the devices are plugged into a computer (SO Windows 10 Pro).

2.3. User satisfaction assessment

As SaraHome was performed by participants’ parents, we administered the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0). It is a widely used instrument for evaluating a person’s satisfaction with a wide range of assistive

Table 1
Demographic and clinical parameters of the study population.

	Age	Age of onset	Gait status	SARA score	Gait	Stance	Sitting	Finger chase	Speech	Fast alternating hand movements
Subj1	14	5	Ambulant	16.5/40	4	2	1	1	2	3
Subj2	9	7	Ambulant	13.5/40	2	3	1	1	1	1.5
Subj3	12	5	Non-ambulant	29.5/40	8	6	4	1	2	3
Subj4	9	5	Ambulant	3.5/40	1	0	0	0	0	1.5
Subj5	8	6	Ambulant	10/40	2	0	0	1	1	3
Subj6	8	4	Ambulant	11/40	2	2	0	1	1	1
Subj7	12	6	Ambulant	7.5/40	1	2	0	0.5	1	0.5
Subj8	16	12	Ambulant	8/40	2	2	0	0.5	2	0
Subj9	10	3	Ambulant	8/40	3	1	0	1	1	1
Subj10	10	5	Ambulant	10/40	2	2	1	1	0	1
mean±SD	10.8 ± 2.7	5.8 ± 2.4	–	11.8 ± 7.2	2.7 ± 2.1	2 ± 1.7	0.7 ± 1.3	0.8 ± 0.3	1.1 ± 0.7	1.6 ± 1.1

technologies [30,31]. Satisfaction is considered as a multidimensional concept with two underlying dimensions related to assistive technology: Device and Services [30]. The Device dimension embraces 8 items related to salient characteristics of the assistive technology whereas the Services dimension encompasses 4 intercorrelated items. Each item was scored on a 5-points Likert scale between 1 (not satisfied at all) and 5 (very satisfied). The QUEST requests to the compiler to choose the three most important items of the questionnaire for him/her. The 12 items to choose were: a) Dimension; b) Weight; c) Adjustments; d) Safety; e) Durability; f) Easy to use; g) Comfort; h) Effectiveness; i) Service delivery; j) Repairs/servicing; k) Professional service; and l) Follow-up services. From these items we excluded items j) Repairs/servicing and l) Follow-up services; because they were not applicable.

The subjective experience of patients with EOA was tested with the Intrinsic Motivation Inventory (IMI) [32]. This is a 33-items multidimensional measurement tool, which assesses participants' interest/enjoyment, perceived competence, effort/importance, and felt pressure and tension while performing a given activity, thus yielding six subscale scores. Each item is given a score between 1 (not true at all) and 7 (very true) on a Likert scale. We defined a positive response when the score was higher than 4, negative when it was lower than 4 and neuter when it was equal to 4.

3. Results

3.1. SaraHome: the concept

The SaraHome tracks and assesses SARA-derived motor tasks through a virtual skeleton of the whole body produced by the Kinect sensor and another virtual skeleton only of the hands produced by LCM. *Ad hoc* software was written to acquire the digitalised tasks. A graphical user interface (GUI) allows an easy acquisition of the movements while performing the motor task.

3.2. SaraHome: the software architecture

The SaraHome software is based on a collection of services provided by a complex architecture, see Fig. 1. This consists of a Restful interface called Bifrost through which it is possible to access a series of plugins (present on physical or virtual servers created with Xen Server) that allow the execution of different services.

Since the infrastructure has been designed with particular attention to the need for privacy, security, reusability and ease of use, when the user logs in an authorization is assigned in the form of token which allows to access only to certain services. A

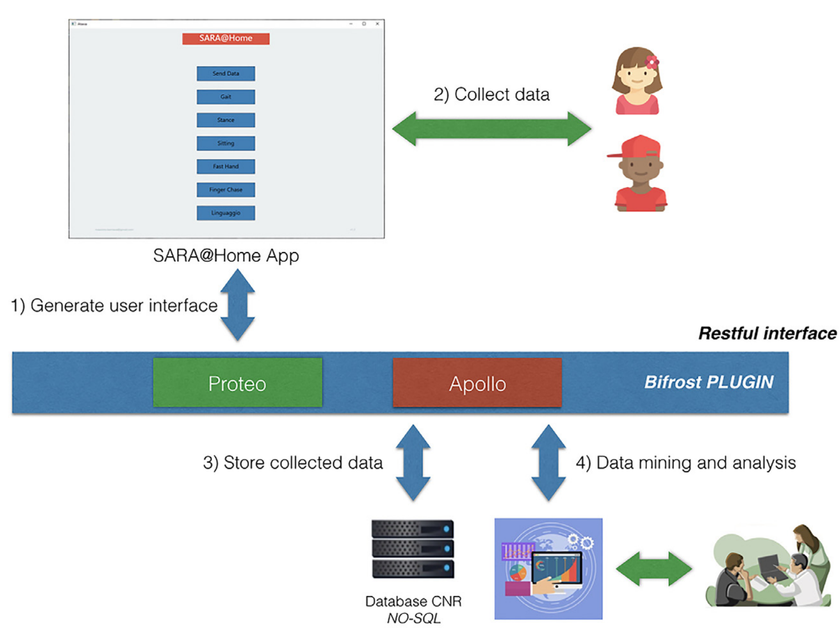

Fig. 1. SaraHome software architecture. The Restful interface Bifrost allows the access to a series of plugins that executes services: 1) Generation of the user interface; 2) Data collection of the patients; 3) Sending data on the server database; 4) Data mining and analysis.

computer script generates anonymous id with alphanumeric coding as access information that was provided to each patient. At the patient's registration these codes where archived on a separate MySQL server database, this is not part of the SaraHome system.

During the tasks the acquisition of data is done through a client software for Windows made in C# that uses a specific service. This service uses two plugins, the first (Proteo) for managing the user interface using the Lua script language, the second (Apollo) for saving the data collected by the client. Data storage is on a NoSQL server database, named CouchDB, document based which ensures less impedance mismatch between the data structures stored and those used by the application. Indeed, data storage has been prearranged to allow the usage of quantitative data for novel algorithms of data science. The SaraHome client application is composed of Proteo service and an API that manages the graphical user interface (GUI), the communication with the devices (Kinect and LMC) and the transmission of data to the server database.

Depending on the user account the GUI changes in order to modify the interface functions. When the user account is a clinician it is possible to insert the SARA score at the end of each task of the SARA scale.

3.3. SaraHome: tasks development

The SARA includes eight separate items (gait, stance, sitting, and speech; finger chase, nose-finger, fast alternating hands movements, and heel-shin slide for both sides), to which a discrete score is assigned on the bases of clinical observation. Six of these tasks were adapted to be recorded by Kinect and Leap Motion.

Gait, Stance and Sitting: during these tasks, the patient was placed in front of the Kinect sensor, at a distance of 4.15 m, which resulted the most adequate for an accurate data collection. The Kinect sensor was positioned 1 m from the ground, with the lens perpendicular to the floor and pointing towards the participant. The gait task was composed of two sub-tasks: the normal gait and the tandem gait (heels to toes). The patient had to walk barefoot at its self-selected speed (Fig. 2A). The Stance task was composed of three sub-tasks: the normal stance (natural position), parallel stance (big toes touching each other) and tandem stance (both feet on one line, no space between heel and toe). In all sub-tasks, patient had to stand in front of the Kinect for a total time of 20 s (Fig. 2B). In the sitting task, the patient had to sit on a stool without backrest and without feet support, eyes open and arms outstretched in front, for 20 s (Fig. 2C).

Finger chase: this task was modified in a pointing task of a squared target (side 1 cm). The patient, seated in front of a screen, distant the 50% of the patient's arm length, had to perform five consecutive, sudden, fast, and precise pointing movements in unpredictable directions with the index finger, following the target (one side at a time). The target moved with an amplitude of 30 cm and a frequency of 1 movement every 2 s. Movements were acquired by the LMC that was placed under the screen (Fig. 2D).

Speech: this task essentially replicated the paraspeech "PATA" test. The patient (in the same position of finger chase task) had to repeat continuously the word PATA for a total of 10 s. The voice was recorded by the microphones array of the Kinect (Fig. 2E).

Fast alternating hand movements: the patient, seated, had to perform repetitive alternation of pro- and supinations of the hand (one side at a time). Movements were acquired by the LMC that was placed on a flat tablet placed on the patient's legs (Fig. 2F).

Nose-finger and heel-shin items were not possible to be adapted to SaraHome because of technical limitations of the devices.

Table 2
Quest results of the two factors expressed in percent.

QUEST	Subscales		Total score
	Assistive device	Services	
very positive feedback	6	9	9
positive feedback	4	1	1
negative feedback	0	0	0
very negative feedback	0	0	0

Patients accomplished the tasks following either the oral instructions or a video movie (included in the software), to improve the comprehension and the participation of very young patients.

The time to complete the whole protocol of SaraHome ranged 15 to 20 min (5–10 min more than SARA scale), an interval that could be considered as acceptable.

3.4. Questionnaires

At the QUEST questionnaire (see Table 2), 60% of the interviewed parents gave scores between 4 (quite satisfied) and 5 (very satisfied) at the Device subscale. The remaining 40% reported scores between 3 (more or less satisfied) and 4. At the Services subscale, all but one parents (90%) gave scores between 4 and 5, while only one gave a score between 3 and 4. General QUEST score was between 4 and 5 for nine out of ten parents, and between 3 and 4 for one. The interviewed parents considered that the most important aspects of the device were: h) Efficacy (90%); f) Easy to use (90%); k) Professional service (40%); d) Safety (30%); and g) Service delivery (10%).

Information collected through IMI questionnaire (see Table 3) showed that 60% of the participants feel the performance of the task quite enjoyable (score higher than 4). While 30% answered with a negative feedback and the 10% was neutral. All involved subjects reported that they felt to be very involved in this activity (score higher than 4) and that they did not feel anxious performing the tasks (score lower than 4). Moreover, all but one patient (90%) perceived SaraHome to be very useful, reporting that the proposed activities could be suitable for them.

4. Discussion

The technology-based assessments represent a rapidly growing opportunity to support clinical practice either in standardized environments, such as hospital, outpatient settings, or in the familial context of everyday life [33–35]. In particular, they can be a viable tool to facilitate reliable detection of functional outcome measures from children suffering of EOA.

Here we present a new tool that we define SaraHome, conducting a pilot study to test feasibility of a newly developed system, which integrates Kinect, LMC and IoMT technologies with the aim to obtain an objective and standardized rating of ataxia applicable also in young patients, suitable at home. Such a system relies on markerless motion capture devices, both easily accessible and low-cost [12,18,19], which were used to record a series of guided tasks reproducing the main items of the SARA scale (apart heel-shin task assessing lower limbs coordination), performed by young EOA patients, under the assistance of the caregiver (one parent).

Specifically, we equipped a set-up with established supports, distances, positions, and time, in which the devices could acquire motion optimally, even into a non-hospital setting, such as home. Then, we defined standardized motor tasks, inspired by SARA scale and other clinical tests, exploring gait, balance, coordination and language of patients, suitable for Kinect and LMC recordings. In this way, we arranged a complete and standardized protocol of

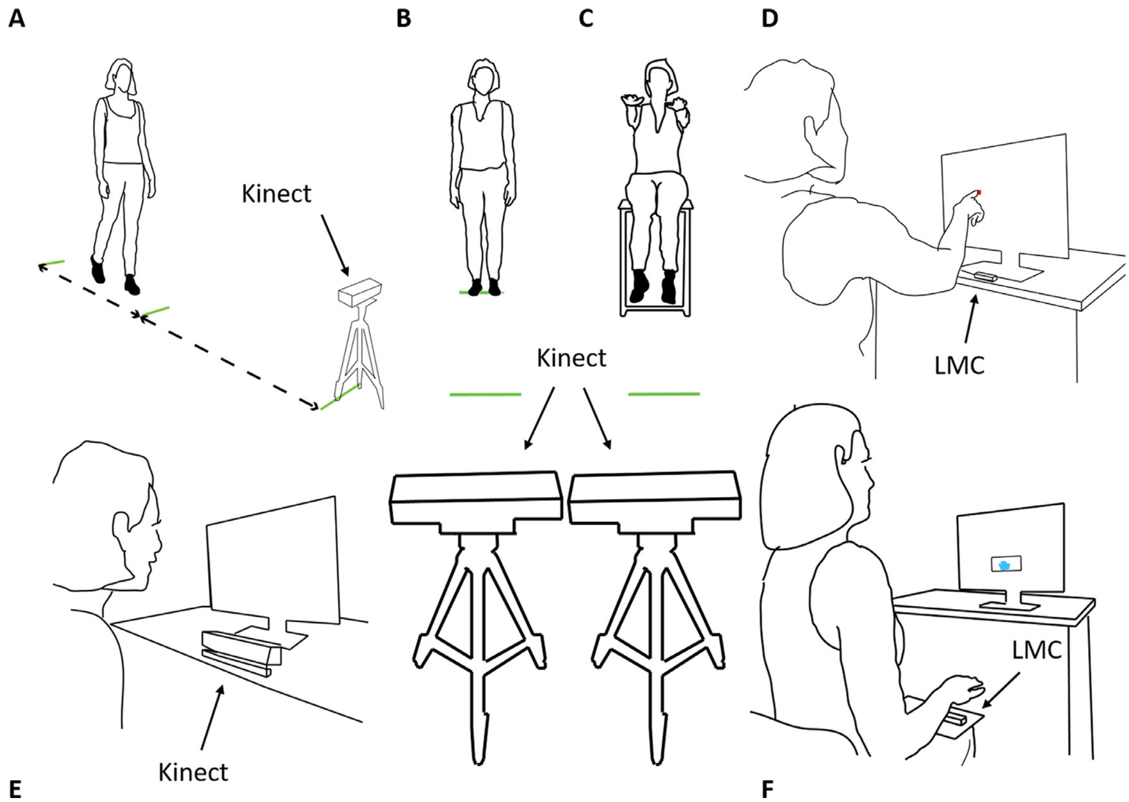

Fig. 2. SARA tasks replicated in SaraHome system. A: Gait task is acquired by the Kinect cameras. B: Stance task is acquired by the Kinect. C: Sitting task is acquired by the Kinect. D: Finger chase task is acquired by the Leap Motion Controller (LMC). E: Speech task acquired by the microphone array of the Kinect. F: Fast alternating hand movement task acquired by the LMC.

Table 3
IMI results of the six sub-scales expressed in percent.

IMI	Subscales					
	Interest/Enjoyment	Perceived Competence	Effort/Importance	Pressure/Tension	Perceived Choice	Value/Usefulness
positive feedback	6	7	10	10	6	9
negative feedback	3	3	0	0	4	1
neutral feedback	1	0	0	0	0	0

clinical examination that the devices could acquire and transmit to a specific software, running on a web-connected personal computer and transforming the motor tasks in objective, accurate and continuous numerical variables. Since SaraHome can be also applied to a paediatric population, we provided video-assisted instructions to guide the execution of motor tasks, in order to improve collaboration and participation of young patients more than simple verbal orders usually do.

The SaraHome set-up was able to obtain a systematic clinical examination of ataxic patients and translate performances into a series of data, ready for sharing and analysis by dedicated algorithms, thus representing a tool, which potentially may overtake the well-known limitations of current clinical-based assessments for EOA.

When a novel technology device as SaraHome has be used successfully to measure coordination disability in ataxia, a preliminary evaluation of technology's acceptance is necessary [36]. Technology acceptance is a highly discussed issue that must be taken in consideration in this era where technology innovation is providing new instruments to clinicians. Actually, the acceptability of a new technology is a field of study whose analysis started in 1989, measuring either the perceived usefulness or the perceived ease of use [22]. Because this kind of measures did not consider other factors, such as the complexity of the technology and user's characteristics, the Unified Theory of Acceptance and Use of Technology was developed later, which included other parameters (e.g. performance expectancy, effort expectancy, social influence and facilitating conditions) [26], resulting suitable for tests in clinical frameworks [28].

According to this, here we specifically evaluated acceptance and practicability of SaraHome in both caregivers and patients. Following previous similar studies [11,37], we used the QUEST 2.0 and the IMI questionnaires to estimate respectively the level of caregivers' satisfaction and the patient's intrinsic motivation during SaraHome assessment. However, as it has been done previously [28], we had to adapt the QUEST 2.0 questionnaire, excluding two inapplicable items. We observed high interest and participation from patients and, likewise, a substantial satisfaction and a perception of ease of use from the parents involved in the assessment, which indeed reassures on the time needed and possible technical problems due to inexperience.

Moreover, since the overall procedure was fully tolerated and patients reported no anxiety and tension, the proposed technology can now be tested on larger cohorts of patients, even in remote settings, to verify its usefulness and accuracy compared to traditionally delivered ataxia scoring systems.

5. Conclusion

In this study, we provided a description of SaraHome, a novel, low-cost technology-based tool for remote assessment of specific items related to ataxia in young patients with EOA. The pilot application of SaraHome in a small group of ataxic children and the subsequent measurement of technology acceptance by specific questionnaires highlighted its feasibility, tolerability and ease-of-use supporting its potential applicability in clinical practice, even in non-hospital settings.

The next mandatory step is now intended to elaborate algorithms for data processing, able to generate indexes and values from SaraHome acquisitions, to be compared with traditional SARA scores, in order to validate this tool and define new, accurate and objective outcomes for people with ataxia disease, that could be immediately transferable in clinics. Moreover, further effort will be dedicated to develop specific tasks evaluating either the lower limbs coordination or non-ambulant patients.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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