Computational and Structural Biotechnology Journal 24 (2024) 451–463

Contents lists available at ScienceDirect

Computational and Structural Biotechnology Journal

journal homepage: www.elsevier.com/locate/csbj

Innovation report

Unveiling the impact of the SMARTCLAP project on habilitation

Matthew Bonello *, Nathalie Buhagiar, Philip Farrugia, Joseph Mercieca

University of Malta, Msida MSD, 2080, Malta

ARTICLE INFO

Keywords:
Augmented Reality
Habilitation
Product Service System
Smart Wearable
User-Centred Design

ABSTRACT

This report summarises the SMARTCLAP research project, which employs a user-centred design approach to develop a revolutionary smart product service system. The system offers personalised motivation to encourage children with cerebral palsy to actively participate more during their occupational therapy sessions, while providing paediatric occupational therapists with an optimal tool to monitor children's progress from one session to another. The product service system developed includes of a smart wearable device called DigiClap used to interact with a serious game in an Augmented Reality environment. The report highlights the research methodology used to advance the technology readiness level from 4 to 6, acknowledging the contribution of the consortium team and funding source. As part of the technology's maturity process, DigiClap and the respective serious game were evaluated with target users, to identify the system's impact in supporting the children's overall participation and hand function, and to gather feedback from occupational therapists and caregivers on this novel technology. The outcomes of this study are discussed, highlighting limitations and lessons learned. The report also outlines future work and further funding for the sustainability of the project and to reach other individuals who have upper limb limitations. Ultimately, the potential of DigiClap and the overall achievements of this project are discussed.

1. Introduction

Cerebral Palsy (CP) is a life-long condition that affects movement, posture and coordination through the connection of the brain with the body. This condition is the most common motor disability in children, which causes stiff or weak muscles and tremors, with even some cases impacting their cognitive behaviour, vision, hearing, speaking and swallowing [13]. Although there is no cure available for CP, the disorder is not progressive and through occupational therapy, children, as well as adults, can develop the skills they require for daily life. Traditional therapy is increasingly incorporating wearable technology to promote a more effective engagement during the session. Presently, most wearable devices are off-the-shelf with a limited degree of customisation, failing to comply with the requirements of the users.

Within this context, the project reported herein regards to the development and evaluation of 'A Smart User-Centred Product Service System (PSS) for Evaluating and Developing Functional Hand Skills in Children with Cerebral Palsy' (SMARTCLAP). A User-Centred Design (UCD) approach was taken by placing these children with CP at the centre of the design process, with the scope to develop a revolutionary smart PSS. Through this PSS, SMARTCLAP seeks to enhance the motivation of these children, who have dexterity and hand mobility challenges due to CP, to stay engaged in more therapy through an unprecedented, personalised experience, incorporating their functional goals and emotional response as part of the development of the PSS.

This PSS is presented in Fig. 1. The product layer, consists of the smart wearable device, called DigiClap, produced via additive manufacturing. This device is worn on the hand of the user and is used to capture the movements of the hand. Compared to state-of-the-art upper limb rehabilitation devices, such as the Rapael-Smart Glove [16] and YouGrabber [17], DigiClap is targeted to meet the expectations of children. DigiClap presents a less intrusive and child-friendly wearable device that is able to capture with high accuracy the individual phalanges to interact with a serious game in an Augmented Reality (AR) environment, which provides an immersive experience. Fig. 2 depicts a computer-aided design model of DigiClap and its innovations.

Since the device is additive-manufactured, it can be personalised according to the user's liking. It also allows the user to attach a splint to the device, via 3D scanning and reverse engineering, to provide support and correct positioning of the hand during the intervention. In addition, the device offers modularity, allowing finger modules to be added or removed according to the goals of the user and OT.

* Correspondence to: Engineering Research and Innovation Laboratories, University of Malta, Msida MSD, Room 518, 2080, Malta.
E-mail address: matthew.bonello@um.edu.mt (M. Bonello).

https://doi.org/10.1016/j.csbj.2024.06.001
Received 31 May 2024; Accepted 1 June 2024
Available online 3 June 2024

The modularity and personalisation of the wearable, aims to prompt children to participate during their habilitation exercises, instigating a more positive attitude towards therapy. By motivating the child to participate, this PSS can help address children's dexterity challenges and strengthen their hand mobility. Aside from being motivating for the child, SMARTCLAP seeks to provide a high-added value to paediatric Occupational Therapists (OTs), by remotely monitoring the child's movements and in-game achievements. This is attained by transferring the motion recorded by the device into data accessible through a cloud-based system, permitting the therapist to monitor the child's progress whilst allowing the child to use the device more regularly in the comfort of their own home.

In this regard, existing patented systems exhibit only limited similarities when compared to SMARTCLAP. Taking a UCD approach, SMARTCLAP considers an array of user factors, including behaviour, characteristics, needs, functional goals and skills to curate a PSS which not only satisfies the user but generates a positive emotional response. This gives SMARTCLAP significant international market potential and economic impact. This potential was confirmed by the business plan developed by KPMG, which projected the net income within the first 5 years of production [12]. Furthermore, the personalisation outlook does not stop at the appearance and sizing of the device. The serious game can be remotely configured by the OT according to the child's capabilities, preferences and progress made.

Through this PSS the SMARTCLAP team intends to improve the quality of life of its users, for both the active users, the children with CP who have limitations with their upper limb, as well as the passive users, including the paediatric OTs and the children's caregiver/s. Due to its benefits and therapeutic nature, this project prospects to add value to the (re)habilitation sector. Through the various multidisciplinary activities conducted, SMARTCLAP draws together various specialisation areas towards a shared goal, cross-cutting specialisations including paediatric occupational therapy, product design and additive manufacturing, and information and communication technology.

Further details on the scope of the project and details about the consortium on board will be provided in Section 2. Section 3 presents the impact of the project, highlighting the results and outcomes following a set of evaluation studies with the primary users and other stakeholders. Subsequently, Section 4 provides a brief breakdown of the results, focusing on the main findings and achievements made throughout the course of the project. Ultimately an extended explanation of the prospective actions will be discussed in Section 5, indicating the main outcomes from this project in the conclusion.

2. Project description

SMARTCLAP focused on the development of the technology, to feasibly assess the concept and its potential into a useful technology. In this section, the objectives of the project and an overview of the methodology followed will be provided, acknowledging the consortium and funding source behind the development of this innovation.

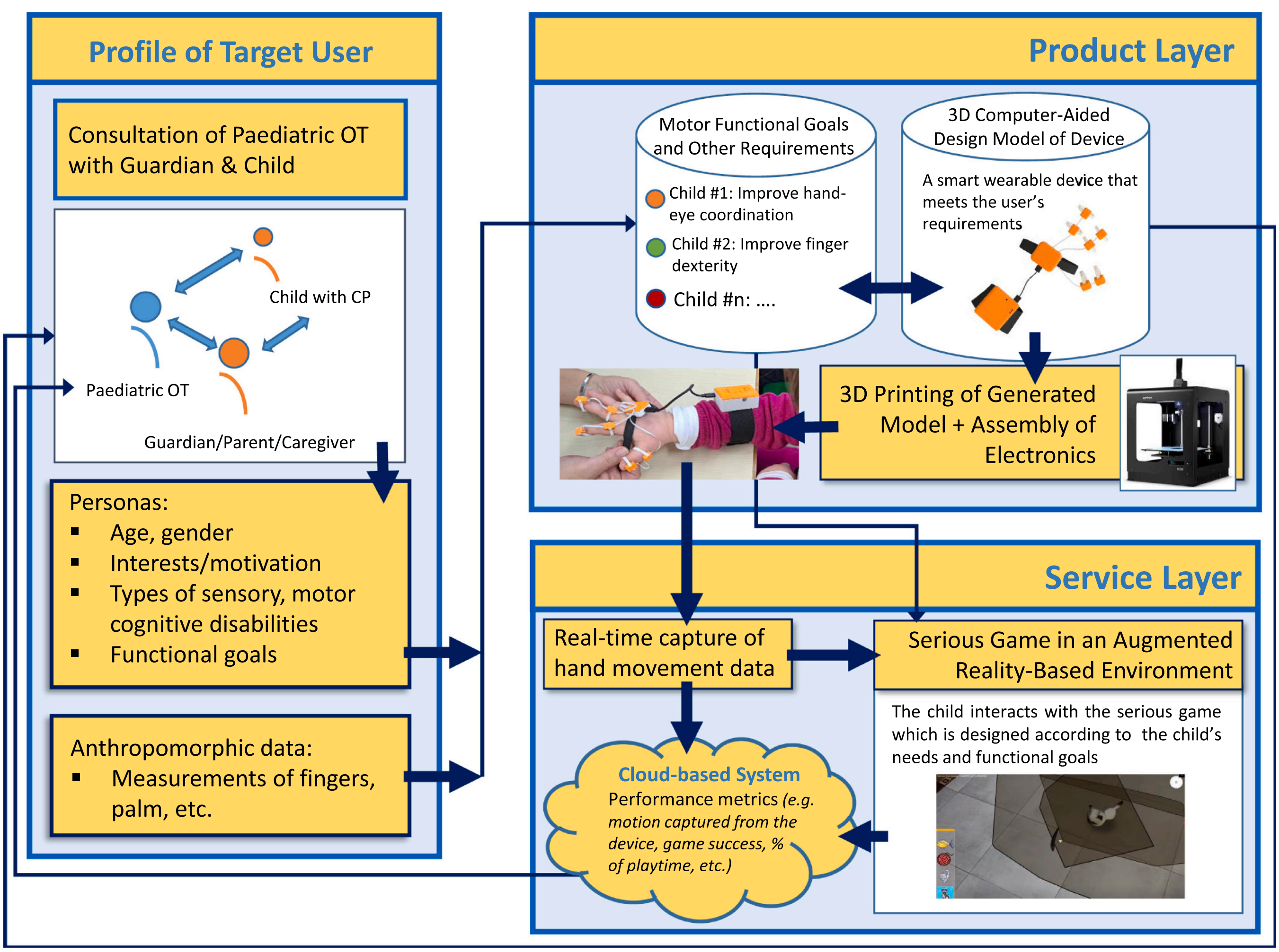

Fig. 1. PSS proposed in the SMARTCLAP project.

2.1. Project's objectives

To achieve the innovation highlighted, the following objectives were set:

- Generate several customised smart wearables depending on the children's motivations/likings and anthropomorphic data;
- Generate a modular structure of the 3D-printed wearables, such the necessary electronics can be assembled;
- Develop the motion sensing hardware and software backend necessary to be able to capture hand movements and transmit them to the cloud in real-time;
- Develop a platform which can monitor the progress of the child in real-time and remotely configure the serious game based on the progress being made;
- Develop, test and implement at least one AR-based serious game;
- Develop a prototype of a computer-based tool based on the SMARTCLAP framework;
- Evaluate the PSS of SMARTCLAP with paediatric OTs, children and product development stakeholders;
- Disseminate the project results on scientific and public forums;
- Develop a business plan and an IP management strategy.

By addressing these objectives, SMARTCLAP will contribute a prototyped PSS which will be used to enhance the experience of children with CP during therapy, motivating them to interact more during their sessions to prospectively undergo a more effective habilitation process. Habilitation differs from rehabilitation as it is aimed at helping children with limitations learn new functional skills they have never been able to perform. Rehabilitation, on the other hand, focuses more on regaining a previously held functional skill, targeting more adults.

2.2. Methodology overview

This project took off at the Technology Readiness Level (TRL) 4. At this level, the product was still under development and the focus was to determine whether the individual elements, making up SMARTCLAP, would work cohesively. To systematically address this multi-faceted task, the methodology presented in Fig. 3 was developed. This was the original research methodology of SMARTCLAP, and it mainly consists of six phases under this project proposal, marking the project impact as well as further phases after the project.

The initial phase focused on the generation of profiles of children with CP who can potentially benefit from such a PSS. The profiles encompass what motivates each child, background on their abilities and limitations, functional goals, and hand measurements. These profiles were built by the paediatric OT during clinical observations and consultations with the caregivers. This data was supported by conducting focus groups with external paediatric OTs and other caregivers who have children with CP to determine overall requirements concerning the PSS. Subsequently, in *Phase 2* different working principles of the smart wearable device were generated based on these requirements and user profiles, establishing the geometric form of the device and product properties (including surface finish and colour) to attain a motivating product for habilitation purposes.

Phase 3 consisted of the development of the backend hardware and software, which was being executed concurrently with *Phase 2*. The main goal of this phase was the functionality of the device, identifying all the electronic components, designing the circuit boards and coding the motion capture algorithm capable of recording the movements of the child's hand and translating these numbers into meaningful data for the serious game. Related to this, *Phase 3* also involved the development of the frontend software comprising a serious game in an AR environment. The scope of the frontend software is to provide an artistic and interactive game that as a by-product has functional goals to improve the hand function skills of the child. Additionally, a preliminary prototype of the dashboard was developed to allow the OT to alter the difficulty of the game, while also being able to monitor the child's progress.

Phases 4 and *5* focused on the testing and evaluation of the device, motion capture algorithm and game, to deduce their functionality, user experience and potential benefits to the users. Meanwhile, the aim of Phase 6 was the dissemination of the developments and results of the project through relevant events and conferences to promote DigiClap and its respective service-system. By adhering to the main points of this methodology, the TRL of SMARTCLAP advanced from 4 to 6.

2.3. SMARTCLAP's consortium

The team members forming the consortium are distributed over interprofessional fields, from mechanical and electrical engineering to computer information systems to occupational therapy, all of which practising at the University of Malta. Aside from academics, the project achieved synergy between academia and industry through collaboration with two small-medium enterprises, Invent3D ltd. and HumAIn ltd. The

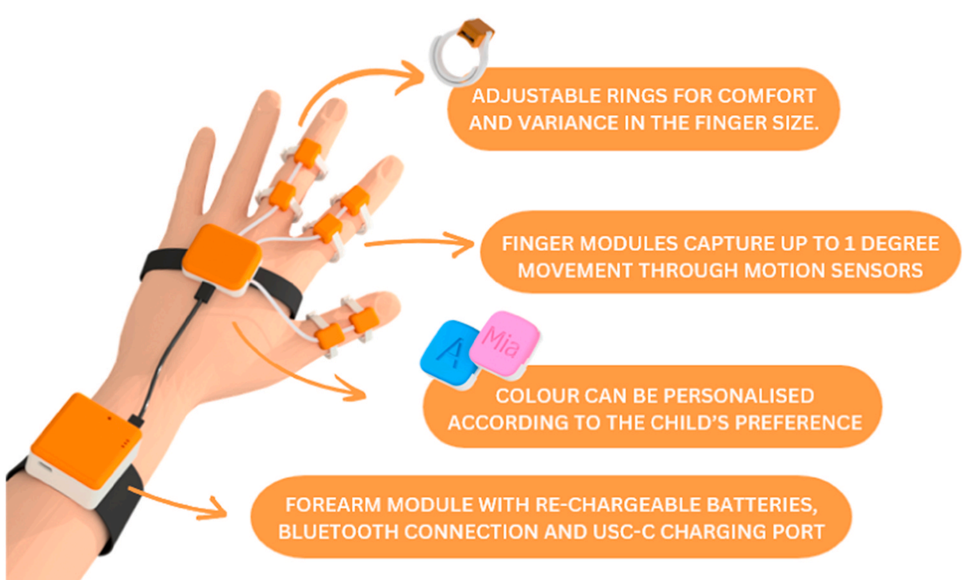

Fig. 2. The main features of DigiClap.

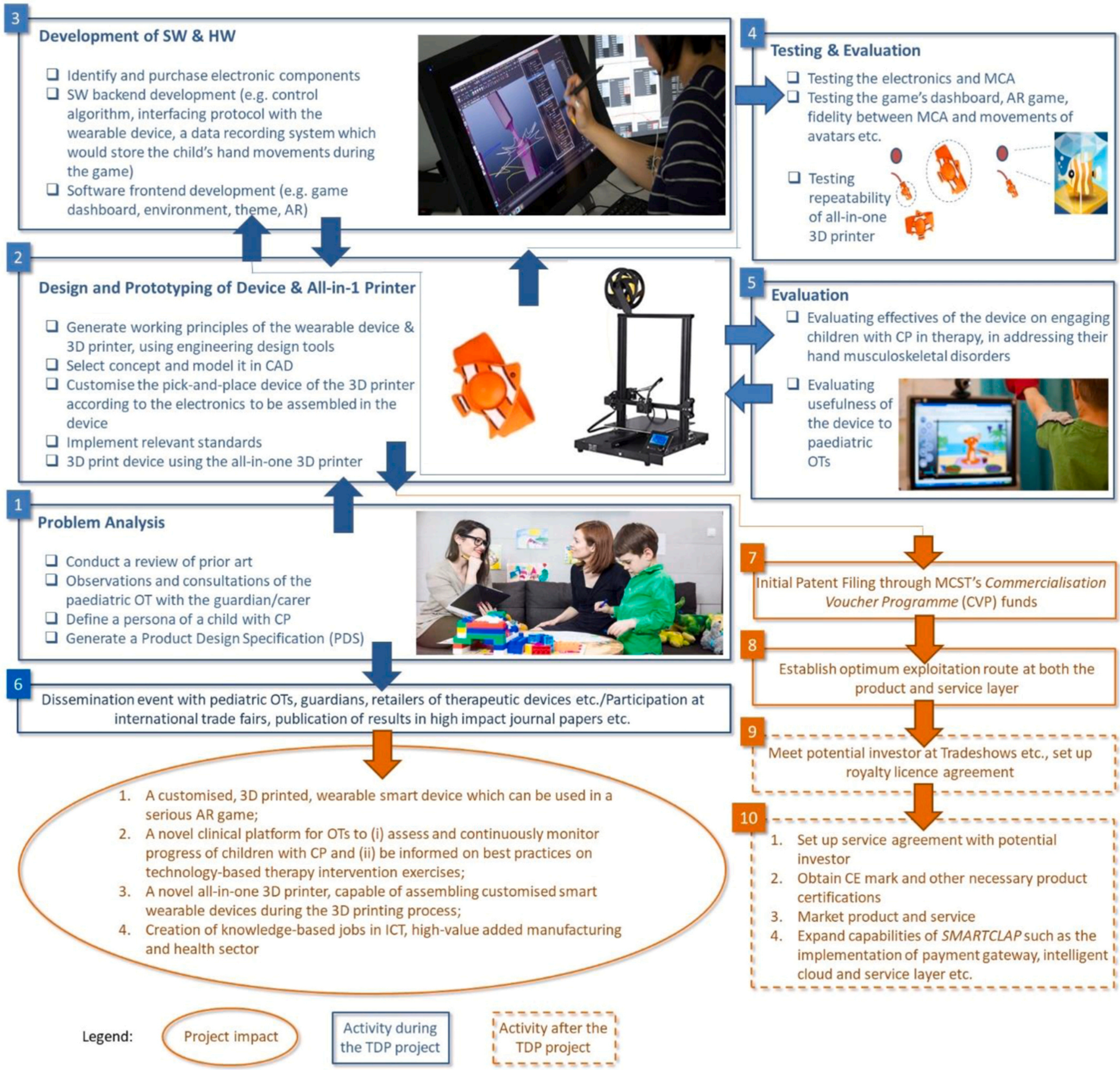

Fig. 3. Original methodology of SMARTCLAP.

former put forward its expertise in 3D printing, catering to industrial clients through design and additive manufacture of components. The academics and enterprises on board the SMARTCLAP team are all responsible for various roles and responsibilities, contributing to the goal of SMARTCLAP. The responsibility of Invent3D ltd. in this project was to design the form geometry of the device and its configuration utilising the necessary engineering design tools throughout the design process, manufacturing the device according to the primary users. On the other hand, HumAIn ltd., provided its expertise in the application of artificial intelligence in AR serious games, creating educational systems which promote learning in schools. HumAIn is responsible for the development of the frontend software as part of the SMARTCLAP framework. This includes the development of the game and the respective testing, the design of the dashboard, based on the requirements of the OTs, as well as the artistic outlook of the game for a positive user interaction.

Aside from the academics and industrial partners, SMARTCLAP recruited two full-time Master of Science by Research students, one focusing in the area of paediatric occupational therapy and the other in the area of control systems, with a focus on the development of motion capture algorithms. In addition, full-time Research Support Officer was recruited who enrolled on a Ph.D. in the area of design for Additive Manufacturing.

The team members forming the SMARTCLAP consortium can be found on the project website: https://www.um.edu.mt/projects/smartclap/ [19].

2.4. Funding sources

The SMARTCLAP project was funded through the Technology Development Programme (TDP) within Fusion, by the Malta Council for Science and Technology (MCST). This programme aims to financially

support research, development and innovation encompassing science and technology, progressing the TRL from 4 to 6. This was obtained through the validation of the technology through prototyping and relevant testing of the system from a laboratory setting to an operational environment. Further details on the evaluation of the system, in a clinical setting, are provided in the following section.

The financial support was provided in the form of grants and was applied through the submission of a proposal. The proposal was a result of collaboration between the Department of Industrial and Manufacturing Engineering, the Department of Occupational Therapy, the Department of Control Systems Engineering and the Department of Microelectronics & Nanoelectronics, at the University of Malta. To emulate the proposal significant research efforts were invested including various discussions and the necessary literature search to identify the gaps in current technology used in paediatric occupational therapy.

3. Impact – results and outcomes

Throughout this section, the main findings and outcomes of the different stages of the project are presented. The evaluation phase was the final step as part of the SMARTCLAP project to assess the impact of this novel smart wearable technology for paediatric habilitation. Various steps took place to obtain a fully-fledged prototype which could be assessed by the users.

Initially, studies with the potential users of this novel technology were conducted. Users were categorised, into two categories: active users and passive users, as showcased in Fig. 4. The primary users refer to the individuals who will be interacting directly with the device, by wearing it on their hand and utilising it to interact with the serious game. In this case, these active users are mainly children with CP who have upper limb limitations due to the condition. The passive users are the ones who interact with the device indirectly, by providing input and/or benefit from its output. In the case of DigiClap, the passive users are the paediatric OTs and the caregivers of the primary users. As these users generate different requirements three studies were conducted, including one-to-one sessions with potential primary users who could benefit from utilising such a technology, and two separate focus groups, with paediatric OTs and the caregivers of the children participants. Further details on these studies and their outcomes can be found in the journal paper by Bonello et al. [5]. These studies helped to shape the requirements of these user groups.

Based on these requirements, various design tools were used e.g. Quality Function Deployment, Design for Assembly and Design Failure Mode and Effect Analysis, developing various design concepts and taking the necessary design iterations to ensure the final product is safe and does not pose any risks to the users. The necessary design iterations were conducted including manufacturing of physical prototypes, risk assessments and preliminary assessments with child participants. The prototypes, as well as the final versions of DigiClap were additive manufactured utilising a multi-material fused filament fabrication printer. This was achieved by utilising a multi-head printer that permits the fabrication of up to four materials and/or colours during one print. A depiction of the printer and the multi-material parts is visualised in Fig. 5. These parts were designed of two materials; Polylactic acid (PLA), which is a rigid material to house the sensor board, and Thermoplastic polyurethane (TPU) used for the flexible part of the rings to secure the housing onto the user's fingers in a more comfortable manner. The end-user version of DigiClap is presented in Fig. 6.

Subsequently, the motion capture algorithm was developed to meet the functional requirements of the device. The model was based on dual quaternions, which consist of four-by-four ordered numbers to represent both the translation and rotations of the hand in 3D space. This modelling approach provided the best compromise between

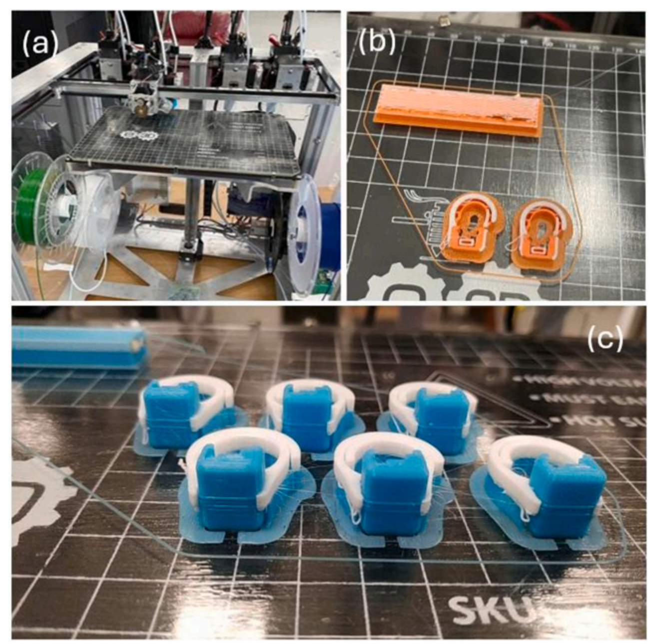

Fig. 5. a) The four-head fused filament fabrication printer (b): During print (c): Post completion of print.

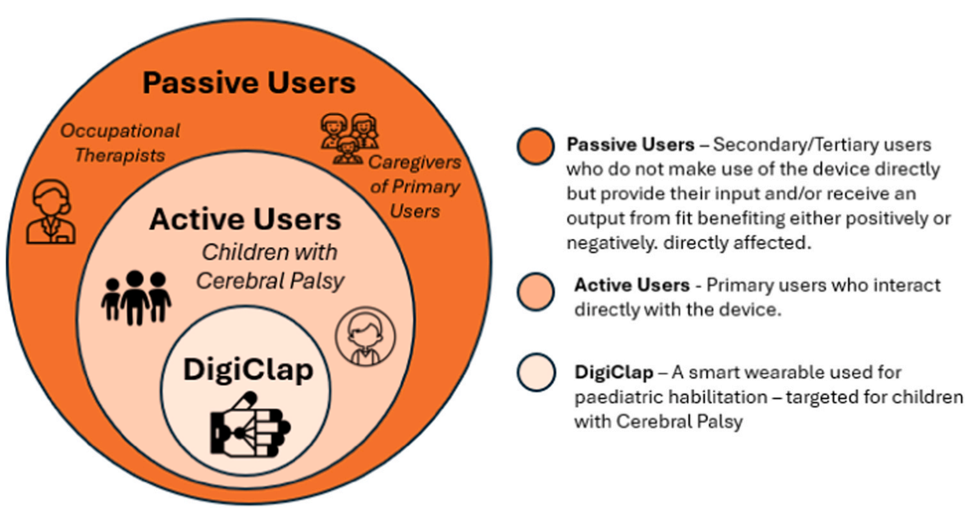

Fig. 4. User classification of DigiClap [5].

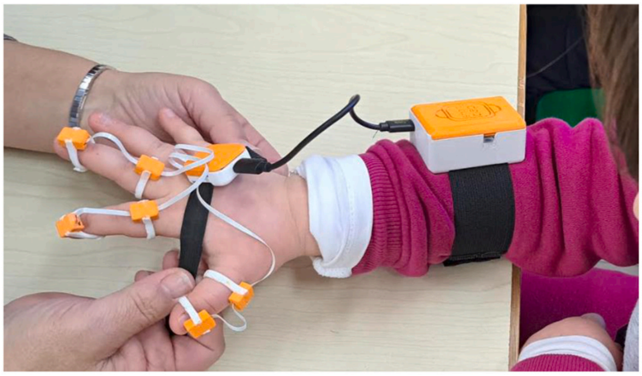

Fig. 6. DigiClap being put on a typically developing child.

computation efficiency and memory usage. The necessary testing was conducted to ensure the mathematical model is able to capture the movement of the hand. Fig. 7 illustrates the testing set-up employed to assess the motion capture algorithm. The VICON Motion Capture system includes a network of 8 cameras set up around a room, which can track the motion of a subject through InfraRed signals reflected off special reflectors attached to the device. To ensure as much similarity of the measurement as possible between the VICON system and the DigiClap, a VICON reflector was attached to each sensor enclosure of the device, as well as on the distal phalanges of the index and middle finger, as shown in Fig. 7. The offsets between the centre of the reflectors and the sensor boards, and the fingertip were noted for each distal reflector (including the thumb) so that both the rotation angle and the positioning of the finger phalanges can be calculated. Further detail on the use of dual quaternions and the development and testing of the motion capture algorithm can be found in Farrugia [9].

In the meantime, the backend hardware was designed to capture the hand and finger movements of the users. Screening exercises were conducted to select the most suitable sensors, controller boards and batteries. This included the breakdown of similar current systems and the technology used in them was conducted and reviewed [9]. From this review, a list of motion capture sensors used and available in research was also generated, highlighting the pros and cons of each technology. For simplification and space on the controller board purposes, it was decided to use only one type of sensor in the wearable device. Three sensing technologies which showed the most promising options were filtered through a decision matrix, where all options were scored according to several criteria (e.g. sensitivity, modularity, wearability, weight, etc.). The exercise was conducted by the consortium team. The most suitable sensors were Inertial Measurement Units (IMUs), as they incorporate a 3-axis accelerometer, gyroscope, and a magnetometer, which can be used to measure the positioning and movement of the hand. Additionally, they come with a small footprint and are easily available on the market. Meanwhile, the development of the backend hardware included the coding of the Bluetooth adapter to be able to send data to the peripheral device connected.

Aside from developing the backend software and hardware, this project involved the development of the frontend software. This primarily involves the design and testing of one Augmented Reality (AR) serious game, including its artistic aspects and its respective bi-product activities to reflect the therapeutic goals, as well as the integrated dashboard. The serious game was split into two parts, including calibration and an object-throwing game, based on the notion of virtual pets. The calibration game involved the user opening and closing the respective finger, to grasp different ball sizes, with the ball getting small after each round to make it more challenging for the user to grasp it. The visualisation of the calibration game is shown in Fig. 8.

The latter game involved, an interactive Augmented Reality game, where a 3D model of a cat is displayed onto the physical environment as seen through the screen, and the user is asked to either play with the cat by throwing a ball or feed it by throwing a fish utilizing grasping movements. The actions associated with grabbing the item and throwing it will help the user explore different forms of motion. When the user succeeds in feeding the virtual cat, they are rewarded a star for their efforts. The display of the AR game on the tablet is illustrated in Fig. 9.

Following these developments, the final phase of the SMARTCLAP project was to evaluate the product-service system holistically through an intervention-based study. Further details are provided in the following sub-sections.

3.1. Introduction to evaluation study

This evaluation study took place in June and July 2023. During this period, the device was tried with children with CP, as the primary users, at the Occupational Therapy Clinical Skills lab at the Faculty of Health Sciences, Mater Dei Hospital, Malta. The research methodology and results will be discussed further in the following section, highlighting the impact on the participants.

More specifically, the main objectives of this evaluation with DigiClap were:

1. To identify any changes in hand function following the use of the device by children with CP, when used during therapy as well as outside a therapy setting such as at the home.
2. To gather the perspective and perception of the OTs, parents/ caregivers, and significant others on the use of such device and its contribution to the functional hand skills.
3. To identify the significance of the device in supporting the child's overall participation at home, in school and in the community.

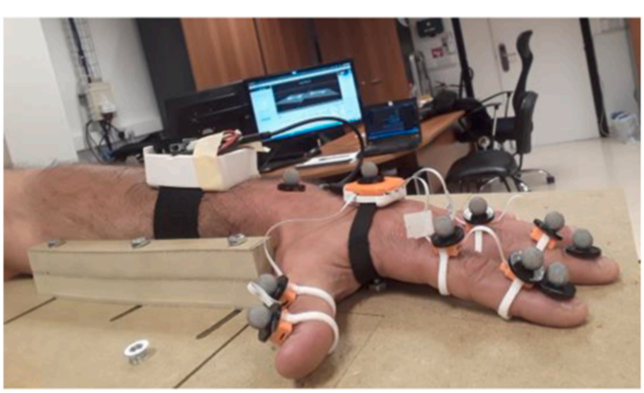

Fig. 7. The motion capture algorithm being tested with the Vicon Motion System.

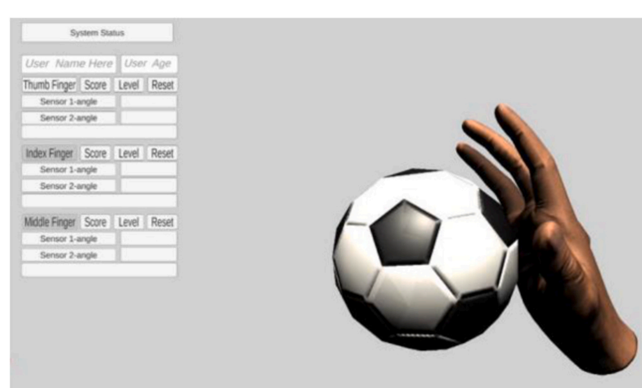

Fig. 8. Calibration part of the serious game.

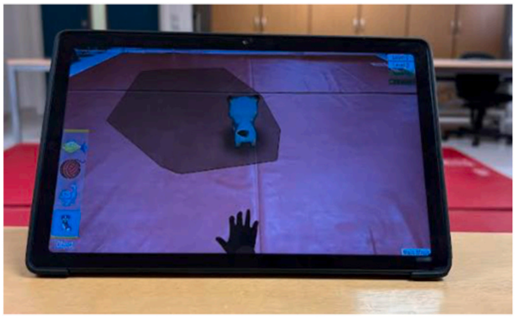

Fig. 9. AR serious game as displayed on a tablet.

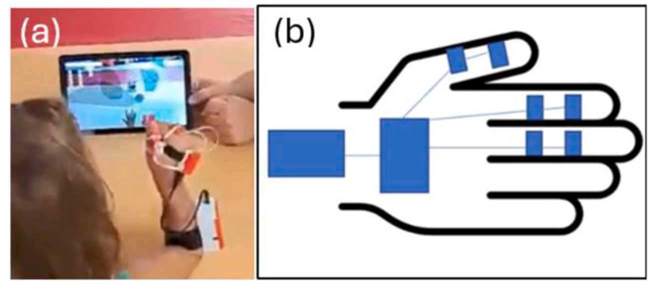

Fig. 10. (a): Set up used during the session; (b): A simplified presentation of how DIGICLAP is worn on the user's hand.

3.2. 3.2 Methodology of study

In order to meet the objectives a mixed-method design of data collection was used, yielding both quantitative and qualitative data. A mixed methodology serves to triangulate data and support the findings thus increasing the validity of the study [6]. Every child with CP that was enrolled was considered as an individual "case" and a detailed analysis of each case was done. This was necessary since every child with CP has unique needs which need to be addressed in the context of their individual situation.

The evaluation study followed the following sequence:

1. Recruitment of the participants;
2. Provision of intervention sessions with the device;
3. Distributing a questionnaire for the participants'/caregivers to complete;
4. Conducting a one-to-one interview with the caregivers;
5. Conducting a focus group discussion with OT.

From October 2021 till June 2023 the evaluation of the device included monthly meetings of the team members where the final prototype was confirmed. Meanwhile, the necessary permissions from the University of Malta Research Ethics Committee (UREC form reference number: FHS-2022–00041) were obtained. Once all the permissions from the intermediaries, hospital chief of staff, head of departments, and data protection officers were acquired, the participants' caregivers were contacted through the intermediary person. Following this, the details of their children with CP were obtained. The children were accompanied by their parents and attended a total of eight sessions. On average one session per child was missed due to sickness or other personal reasons. The sessions included having an introduction, donning the device on their hand and interacting with the serious game. During the sessions the researcher, an academic with expertise in paediatric occupational therapy, other team members of SMARTCLAP, and the caregivers were present. The sessions took around 30 min and all the participants except one attended the sessions in a clinical setting. During the sessions, the researcher observed and filled out a progress form for each child. The progress form included the game scores, the observations during the sessions, and comments on the child's upper limb.

(b).

(a).

The sessions involved a simple set-up, including a table, an adjustable chair, a tablet, and the device (worn as shown in Fig. 10a). During the sessions, the device was donned on the affected hand of the child and connected to the tablet via Bluetooth. The layout of the device was fixed on the user's hand as presented in Fig. 10b, secured on the wrist and attached to the middle of the metacarpal area, extending dorsally to the thumb, index finger and middle finger. After putting on the device, the user was asked to interact with the serious game aforementioned, under the observation of the OT.

Following the intervention sessions, the caregivers participated in an interview and filled in a questionnaire. Their responses helped to analyse the outcomes and perceptions of the device on children with CP and their caregivers. Verbal feedback, in the form of semi-structured in-depth interviews with the caregivers, was recorded and transcribed. This provided evidence that use of the device yielded various benefits.

To maximize the validity of the evaluation all data collection tools were reviewed by an advisor who was also a participant observer on the SMARTCLAP project team. The questionnaires were then circulated with members of the SMARTCLAP project to be further critiqued and submitted to UREC who provided some further suggestions for fine-tuning. Once the approval was obtained the questions were piloted with the first participant and some final adjustments were made prior to being used with all the other participants.

Three experienced paediatric OTs were recruited through an intermediary to observe the evaluation sessions conducted with the children. During these sessions they were asked to document any significant observations and insights on the sessions. At the end of the data collection period, a focus group was held with these therapists. It was recorded and transcribed. The transcript was analysed using thematic analysis, where common and important phrases were highlighted and coded. The codes helped to develop the common themes.

3.3. Participants

The children with CP were regarded as the main participants and the scope of these sessions was to interact with the device and respective game. Each participant had at least one caregiver who attended all the sessions, filled in the questionnaire and participated in an online one-to-one interview. A total of 7 children were enrolled. Four of the children were male ($n = 4$, 57 %), while three children were female ($n = 3$, 43 %). Their age ranged from 4 years to 12 years ($M = 7.71$ years, $SD = 2.43$ years).

Three external OTs attended one set of sessions each, where they observed the sessions, took notes, and subsequently, participated in a focus group. The OTs have worked with children for more than ten years, and have worked with clients who were diagnosed with CP. The three OTs attended three sessions each, and observed the device being used with the participants. They also were in a position to ask members of the research team any questions. They took notes and after the data collection phase ended, they participated in an online focus group.

3.4. Results

To meet the evaluations' objectives the results were analysed in three parts. The first part involved the analysis of the observations during the sessions, and the analysis of responses from the caregivers' questionnaire and the game scores. The primary part involved the analysis of the one-to-one interviews with the caregivers of the children. The third part involved the analysis of the focus group data gathered from the OTs.

3.4.1. Outcomes from studies with primary users and their caregivers

This set of results helped to provide a generalised overview of how the children performed and how their caregivers perceived the device. Table 1 shows the mean scores of each child participant (pseudonymised with letters) and the mean rating their caregivers gave to the device. The mean scores of the calibration part and the object-throwing game were calculated by adding the scores obtained by the child and dividing them by the number of sessions attended. The caregiver's mean rating was achieved by taking the average of 24 5-point Likert scale questions concerning the experience with the device and game from their perspective. The caregivers' comments are provided in Table 1.

3.4.2. Outcomes from the focus group with the occupational therapists

The transcripts were analysed using thematic analysis, where common and important phrases were highlighted and coded. The codes helped to develop the common themes. A total of five themes emerged which were:

- The benefits of DigiClap
- The shortcomings of DigiClap
- DigiClap as a useful tool for Occupational Therapy Intervention
- OTs' presence in DigiClap usage- necessary or not?
- Using Augmented Reality in a therapeutic environment: Participants' and Therapists' perspective.

The inter-rate reliability using the percentage of agreement score was 78.94 %. Which according to Graham, Milanowski and Westat [10] is sufficient reliability since the minimum percentage score is 75 %.

Data obtained from the focus group yielded insights on the benefits of the device, suggesting its potential utility during occupational therapy sessions. It appears that the device can be a useful tool to enhance therapy sessions, however, its effective use may still depend on the way the therapist facilitates the session. Further refinements can maximise the potential of this novel technology. Table 2 includes the main themes and quotes extracted from the focus group data.

This section outlined the main actions conducted to achieve an in-depth evaluation of DigiClap and the respective serious game. The data presented will be used to refine DigiClap and upgrade the serious game in line with the expectations, needs and suitability of the children with CP, their caregivers and the OTs. In the following section, a summary of the overall outcomes achieved will be discussed.

4. Discussion

Following the completion of the evaluation study, the project was completed. The impact of the project in occupational therapy, and on a technology level, is discussed in the following sub-sections. Furthermore, the limitations encountered in this project, along with other challenges, are outlined, while also highlighting the value of additional funding and potential future work to push DigiClap to infiltrate the market.

4.1. Impact of SMARTCLAP in occupational therapy intervention

The benefits for children and their families in using a device such as DigiClap is evident from testimonials provided by these stakeholders. As remarked by caregivers A, B, D and G, with further modifications DigiClap has good potential benefits in the rehabilitation of the upper limbs in children with CP. Similarly, all the occupational therapy professionals unanimously remarked that such a device is also a useful tool to complement occupational therapy intervention.

Features of the device such as its portability, adaptability, weight and ease of wearing make it more attractive to the user. Table 1 presented earlier gave a summary of the data collected and presented by the eight participants, namely the children and their parents. Whilst overall the feedback was positive, some challenges were also highlighted.

During engagement, it could be observed that the interaction with the device and the gamification of therapy elicited a positive emotional response from the children. This was the result, of the device being easy to wear, aesthetically pleasing and comfortable for the user. The caregivers of the children with CP remarked that the device was indeed a great tool to increase the children's self-esteem potentially, as it allowed them to play without the support of an adult. It is documented that self-actualisation and self-esteem are impacted by being able to participate independently in one's occupation [22]. In this case, the occupation of play and leisure were considered.

From the OTs' perspectives, "A fun approach to therapy that can be beneficial if personalised to the child's needs" was paramount. The device was perceived as an important addition to the routine of a regular therapy session allowing an element of independent engagement with a tool that can also support the development of more functional hand use as well as empower the child to feel in control [20].

The common themes which emerged from qualitative analysis of interviews with the OTs revealed that DigiClap had shortcomings that were mostly related to the efficiency and accuracy of the device as well as the limited variety in the game. However, it also had benefits and was ultimately perceived as a useful tool during Occupational Therapy Intervention because as one therapist said, "It speaks the children's language".

Motivation to move the hand was a key benefit of using DigiClap. It

Table 1
Summary of children's game scores and rating means, supported by caregiver's mean ratings and comments.

Participant	Attendance	Calibration Game Mean Score	Throwing Game Mean Score	Caregiver's Mean Rating	Comments
A	100 %	11.75	17.63	4.5	The device caused functional benefits to the child. The current device was fragile and the game can get boring if used for a long time. AR was not affecting the child.
B	100 %	11	21	4.2	The device increased the participant's self-esteem. The device is therapeutic and can be an asset to occupational therapy. Modifications in the game and device are needed for more benefits.
C	75 %	7.33	14	3.8	The device had a positive effect on the child. Simplicity, vibrancy, and technology are ideal for children with CP.
D	75 %	12.33	24.67	2.8	The games presented were not ideal for the child, personalisation, rewards, colourful and functional games are more adequate. The child enjoyed the sessions but mostly the AR and technology involved.
E	62.5 %	12.8	24.4	4.1	DigiClap encouraged function, but auditory and more visual stimuli could have facilitated engagement more.
F	25 %	9.5	16.5	3.3	A fun approach to therapy that can be beneficial if personalised to the child's needs.
G	100 %	3.75	22.88	4.4	The device is highly recommended for occupational therapy since it helped in making function easier for the child. Better graphics and small device rings increase the child's engagement.

Table 2
Interview themes and supporting direct quotes.

Themes	Quotes
The benefits of the DigiClap	"a very interesting experience moving away from the traditional media like blocks, puzzles and having more technology. It was very much interesting, and it applies more for the age group we as OTs deal with" "with the few sessions that the children had with the study so many benefits came out of these sessions, that it showed that it could be a really good tool" "can help motivate the child and improve function" "speaks the children's language".
The shortcomings of the DigiClap	"there should be more auditory feedback for example more claps, and when it throws the ball for the cat to catch it, there should be some sort of auditory stimulation so that the child understands that the movement needs to be now" "having the cat catching the ball it is not that exciting. Kids are "used to fantastic graphics on their games" "it was measuring more the flexion and ignores the extension and in most cases I was happier when seeing them extending their hand, and this was not being recorded". The device should "encourage more extension."
DigiClap as a useful tool for Occupational Therapy Intervention	"they are coming for dressing and the device is part of the session, where the big movements, that can be included in the games (gross patterns) can help and can be a motivating factor to come to therapy. Because they find dressing very boring. It can be really good for motivation." "For therapy it can be encouraging for the initiation of movements, even movements that the child might think that he could never manage. They are calibrated, and you can improve from one session to another and having different levels". "This device could be also used as a home program because if you use it during the session and the parent is seeing the therapist how you are placing the hand, how the child is seated, how you are putting the device on then it can be easily used as a home program which could be motivating. Especially if it has more levels since the child needs to be motivated to work more. And win more trophies."
Occupational Therapists' presence in DigiClap usage- necessary or not?	"with the aid of the OT certain children would have lost interest and with the help of the OT that did tweaking and adaptations during the session the child was able to manage, so it has to be in guidance of a professional. because on their own the child will have adverse reactions like increased tone and associated tone." "it is important that the OT will guide and be present when it is being used" "The OT looks at all the holistic aspects like the ergonomics, poor head control, deciding to put the device at an angle, the sensory aspect, the sitting positioning, or the positioning of the arms."
Using Augmented Reality in a therapeutic environment: Participants' and Therapists' perspective.	"for the children it did not make much of a difference" "the children were not realising that it was using AR" "the AR, it was a bit confusing, especially with these children sometimes they also have visual difficulties"

was noted that even the children who had severe challenges in the upper limb movements engaged with the device and the activity. A study carried out by Abela et al. (2022) identified motivation as a key component when using rehabilitation medical devices in therapy [1].

The challenges underlined included connectivity problems due to loose ribbon cables caused during wearing the device or by sudden movements by the user, as well as limited variations in the gaming aspect of the device, which may have influenced the perception of the device, and game. Thus, further refinements to the device and modifications to the game can reap more benefits. As one parent said, *"Simplicity, vibrancy, and technology are ideal for children with CP"*. However, this is not enough to engage the user. Another parent said, "*personalisation, rewards, colourful and functional games are important for the child*". If the game is not meaningful and does not pose the just right challenge then the child will not be engaged [18]. In addition, if the device stops working several times during game playing then the child stands the chance of losing interest. DigiClap encouraged function, but the elicitation of more multisensory involvement [7] from the characteristics of the game such as auditory and visual stimuli could have facilitated more engagement.

One question that arises is whether the presence of an OT is necessary when interacting with DigiClap, as this device could potentially enable independent use by the service user, allowing them to utilise it without therapist supervision or outside the therapeutic environment. Such an approach would prioritize child-centeredness and could potentially be integrated into the child's specific educational plan within a school setting.

Other strategies similarly evaluated in previous literature include Gloreha and Hand of Hope [11,21]. Feasibility studies were conducted for both technologies and their outcomes were quite positive. However, the primary purpose of these technologies is to assist in accomplishing specific movements such as grasping, pinching and other hand motions, targeting post-stroke patients.

Literature more aligned with the scope of DigiClap includes the work by Munroe et al. [15], who used a MYO armband to capture electromyographic signals from the arm along with AR glasses to provide an interactive experience for children with CP. Similarly, Dunne et al. [8] developed a platform for upper extremity rehabilitation for children with CP, which included a wearable accelerometer on the user's trunk to sense movement and a multitouch display. However, these systems lacked evaluation with the target users and did not integrate a comprehensive assessment of the benefits and limitations of the system.

The outcomes of the evaluation study helped to disclose the benefits and shortcomings of DigiClap. Despite its limitations, according to the study participants, DigiClap was deemed an important tool and resource in occupational therapy intervention as well as an innovative tool that can motivate children with CP to engage in therapy and play/leisure occupations. It appears that the therapists' input may be instrumental in reaping benefits but potentially this can be done under long-arm supervision. DigiClap has the potential to support clinicians in a therapy setting and could also prove beneficial in a home and community setting.

4.2. Dissemination and exploitation of SMARTCLAP results

Aside from influencing the occupational therapy field, SMARTCLAP has made discoveries, externalising to the research community on an international level. Following the development of the technical solution of DigiClap, a patent application was filed in the beginning of 2023 at the UK Patent Office. This application was reviewed, and no objections were raised against the patentability of nine of the claims made, it appears that the invention defined in these claims is considered both novel and inventive. These claims were then rebutted a year later in the beginning of 2024. Some of the claims that had no objections include the splint attachment, multi-material ring design and the modularity that allows finger modules to be added or removed. These aspects are depicted in Fig. 11.

Throughout the course of this project, various studies were conducted as part of the development and implementation of this novel technology. Some of the outcomes obtained from these studies were published in peer-reviewed journals and conferences [5,2,3,4].

These publications helped to collect feedback from fellow individuals in the field through peer-reviewed papers and presentations during conferences. Additionally, a wider audience is reached through these comprehensive publications to increase visibility and potentially attract investors.

DigiClap was also showcased at the prestigious Med-Tech World Summit, where individuals from across the world indulge in the latest advancements in the field of medical devices and e-health platforms. This was a great opportunity to present the device and the developments made, to various experts in the field. Several individuals, coming from America, Europe and Eastern countries visited the booth and showed interest in the device and its development. A number of these attendees approached the SMARTCLAP team to discuss potential commercialisation opportunities. This was also a great chance to collect feedback from professionals in the medical field. The booth set up during the Med-Tech World Summit is shown in Fig. 12.

Fig. 12. DigiClap showcased at the Med-Tech World Summit, 2023.

4.3. Limitations and lessons learned

As with any other novel innovation, this project had its limitations. One of the main limitations met was recruiting participants who met the user criteria of these devices. This was mainly challenging due to the small population of Malta and the limited number of children with cerebral palsy. This restricted expanding the studies to a bigger sample group to collect further feedback and reach data saturation. This was also a limitation when conducting the initial set of focus groups to collect the design requirements of the smart wearable and serious game [5].

Moreover, the first stage of the project was conducted during the COVID-19 pandemic, which faced additional hurdles in reaching a bigger number of participants. Despite these challenges, the focus groups were shifted to online sessions and the study could proceed. Conducting the study online, however, may have restricted engagement from the participants to comfortably share their thoughts. The pandemic also delayed the subsequent stages of the project due to electronics shortages, differing the development of prototypes and end-user version of the wearable device, leading to further delays in the evaluation studies.

Despite these challenges, the adaptability and communication among the consortium members helped to overcome them and adjust accordingly. This allowed the team to still meet the project deliverables and achieve impactful technology outcomes.

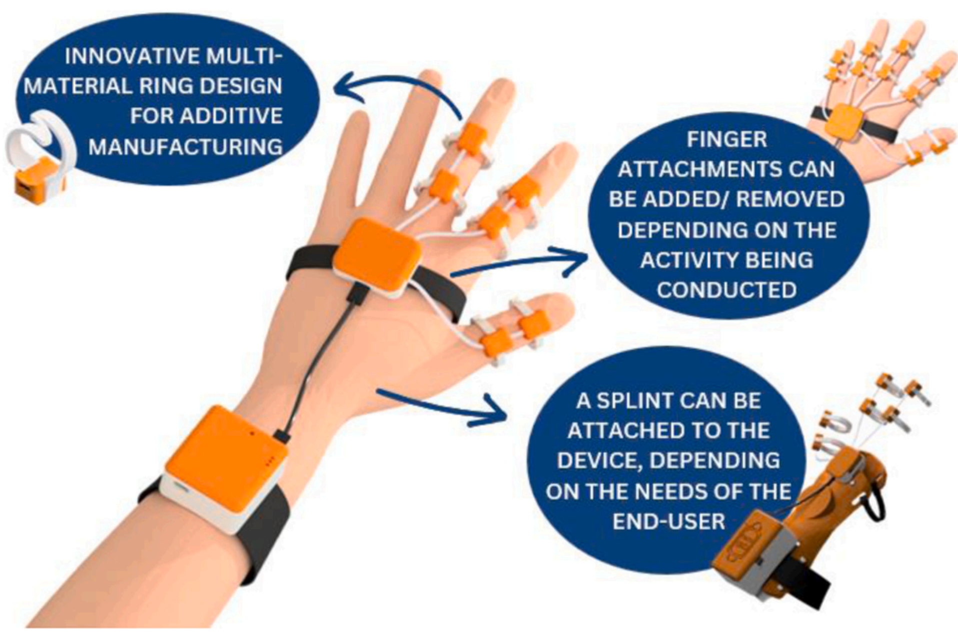

Fig. 11. Claims not objected to in the patent application filed.

4.4. Future work and further funding

Following the successful completion of the SMARTCLAP project, further fundings were acquired for its sustainability and to continue refining DigiClap. Further funds were secured through the Go to Market programme within Fusion, by MCST, with the scope to lead DigiClap to the final commercial release. To date, the device has already been enhanced by making it more compact and robust. Subsequently, a new game has been created to better align with the functional goals of these children. This new serious game offers a selection of cooking recipes with varying levels of difficulty depending on the abilities of the user. A representation of the serious game is visualised in Fig. 13. Further work will focus on developing the dashboard for the OTs to monitor the child’s progress and adjust the difficulty and other parameters of the game accordingly. In addition, the use of AR will be further exploited as a medium in connotation with the use of habilitation technology to support the user’s engagement in the activity. The experience can also be enhanced further with the involvement of multisensory feedback through additional visual stimuli and the use of auditory stimuli to facilitate engagement by the user.

Following these modifications, the device was shipped to a rehabilitation centre in Cyprus and will be evaluated there through a set of usability studies. Through this centre a wider audience will be reached, considering the limitation highlighted due to the small population of children with cerebral palsy in Malta. The scope of this is to demonstrate the modified version of DigiClap in a more operational environment with more concrete evidence. This progression will indicate the maturity of the system advancing the TRL from 6 to 7 and bringing it closer to full-scale deployment.

Additionally, aside from children with cerebral palsy, other individuals who have upper limb limitations will also be considered in these studies to exploit the capabilities of the device and determine if it can be used by users of all ages and varying conditions, including Down Syndrome and post-stroke.

Aside from usability studies, the necessary safety assessments were conducted with potential users of this novel technology to affirm that the latest version of the device meets its intended purpose and is overall safe. This assessment was also conducted to ensure the product meets the general safety measures outlined in Medical Device Regulation 2017/745/EU [14]. As the device is classified as a Class I medical device according to the aforementioned regulation, after completing this safety assessment, an application was filed to obtain the CE mark. The

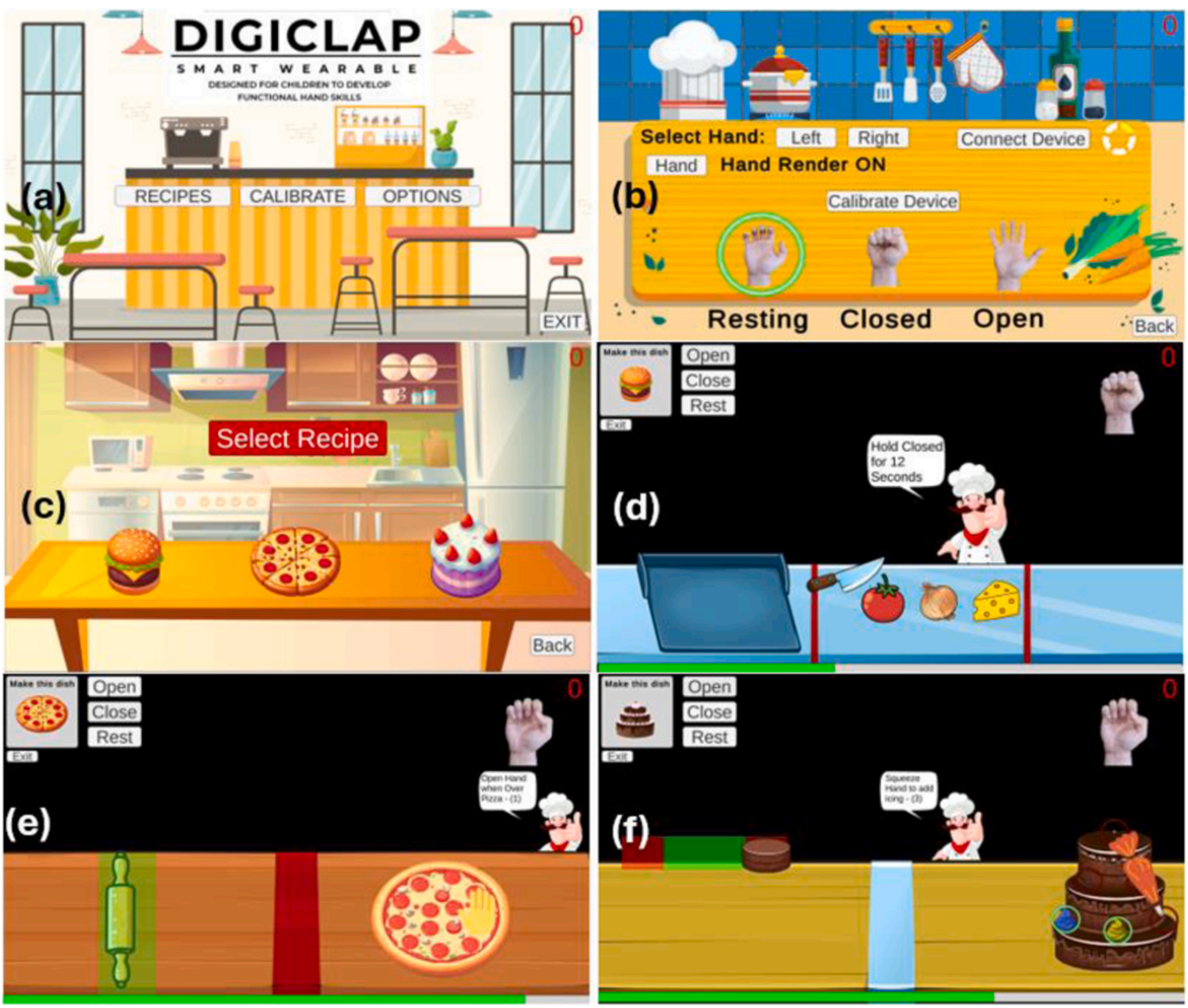

Fig. 13. New serious game developed under the CURACLAP project (a): Main Menu; (b): Calibration screen; (c) Recipe selection; (d): Burger Game; (e): Pizza Game; (f): Cake Game.

submission was successfully accepted, and the EC Declaration of Conformity was received. As the device is classified as an active medical device accompanied by software, future steps will involve certifying the software to ensure compliance with necessary regulations. This conformity will help to bring DigiClap one step closer to the market.

5. Conclusion

The main actions conducted in evaluating the device's prototype through the mixed methodology adopted and qualitative/quantitative data gathered have been presented. The results of this evaluation will aid the manufacturers of DigiClap in upgrading the device in line with expectations, needs and suitability for children, caregivers, and OTs. With further development and creation of novel games the element of motivation can be further enhanced for these children and bring about a more positive behaviour towards therapy. Furthermore, with additional personalisation of the device, such as its aesthetics, form and texture for each child's specific requirements and preferences, the engagement can improve, ultimately impacting the effectiveness of the intervention.

Through the final study conducted as part of the SMARTCLAP project, it was shown that DigiClap is an innovative device that:

- has potential to support play/leisure participation in children that have limited upper limb function.
- provides a medium for play for children with CP who otherwise have limited opportunities to play because of their mobility challenges.
- can support and encourage even minimal movement patterns.
- is another important and innovative tool in an OT's clinic,
- can increase the child's self-esteem by making them aware of their capabilities no matter how small they may seem.
- contributes to developing the functional use of the affected hand in children with certain tonal problems such as hemiplegia.
- is unique in providing upper limb habilitation since it uses innovative technologies and child friendly concepts.
- is attractive to children and therefore it can motivate a child to engage more in therapy sessions
- has the potential to be used effectively as a home therapy tool.
- can be used in school setting with further exploration on how to yield positive child participation in school occupations.
- has potential to be more attractive for the user with more refinement on the graphics, levels, rewards, and stimuli in the game.

In conclusion, the investment of the SMARTCLAP project, resulted in an impactful novel habilitation technology that elicited feelings of contentment, eagerness and happiness in children with upper limb limitations. This underlines DigiClap's capacity to enhance children's overall well-being and quality of life. Apart from this, DigiClap has made contributions to the research community through publications submitted under SMARTCLAP, and via further studies it has the potentially to enter the market in the near future.

CRediT authorship contribution statement

Philip Farrugia: Funding acquisition, Supervision, Writing – review & editing. **Nathalie Buhagiar:** Supervision, Writing – original draft. **Matthew Bonello:** Writing – original draft. **Joseph Mercieca:** Data curation.

Declaration of Competing Interest

This statement is to disclose that there are no conflicts of interest in connection with the submitted manuscript entitled "Innovation Report: Unveiling the Impact of the SMARTCLAP Project on Habilitation." All authors have contributed to the development of the manuscript and are aware of its submission to the Innovation Report section under CSBJ Smart Hospital. The research was funded by the Malta Council for Science and Technology through the Fusion R&I Technology Development Programme 2020 (R&I-2019–003-T) and Fusion R&I Go To Market Accelerator Programme 2022 (R&I-2019–003-A).

Acknowledgements

The project discussed in this report was supported by the Malta Council for Science and Technology (MCST) through the FUSION R&I Technology Development Programme 2020 (R&I-2019–003-T). The consortium members would like to extend their gratitude to all the participants who took part in the studies, especially the children and their caregivers who contributed to the evaluation study, offering valuable throughout the intervention. Additional funding has been received from MCST to exploit further the novelty of DigiClap and improve its technology readiness level, through the Fusion R&I Go To Market Accelerator Programme 2022 (R&I-2019–003-A).

References

[1] Abela E, Farrugia P, Gauci MV, Balzan E, Vella P, Cassar G. The perspectives of clinicians on enriching patient experiences in a clinical context: a qualitative study. Proc Des Soc 2021;1:3061–70. https://doi.org/10.1017/pds.2021.567.
[2] Bonello M, Farrugia P. A designers' perspective on additive manufactured smart wearables for paediatric habilitation. Proc Des Soc 2022;2:1243–52. https://doi.org/10.1017/pds.2022.126.
[3] Bonello M, Farrugia P. Towards a multi-perspective based ontology to develop smart wearables for paediatric habilitation. J Comput Aided Des Appl 2022;20:170–81. https://doi.org/10.14733/cadaps.2023.S6.170-181.
[4] Bonello, M., Farrugia, P., & Buhagiar, N. (2023). Investigating Children's Experiences for Smart Wearables: Implications on Design for Additive Manufacturing. Proceedings of the ASME 2023 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference. Volume 5: 28th Design for Manufacturing and the Life Cycle Conference (DFMLC). Boston, Massachusetts, USA. https://doi.org/10.1115/DETC2023–110629.
[5] Bonello M, Farrugia P, Buhagiar N, Mercieca J. Towards a multi-user experience approach to exploring key requirements to design smart habilitation devices for children with cerebral palsy. J Rehabil Assist Technol Eng 2022;9:2022. https://doi.org/10.1177/20556683221103164.
[6] Bryman, A. (2012). Social research methods 4th edition (4th ed.). New York: Oxford University Press Inc.
[7] Bundy AC, Lane SJ. Sensory integration: Theory and practice. F.A. Davis Company; 2019.
[8] Dunne, A., Son Do-Lenh, Laighin, G. O., Chia Shen, & Bonato, P. (2010). Upper extremity rehabilitation of children with cerebral palsy using accelerometer feedback on a multitouch display. 2010 Annual International Conference of the IEEE Engineering in Medicine and Biology. https://doi.org/10.1109/iembs.2010.5626724.
[9] Farrugia, M. (2023). A Real Time Hand-Movement Motion Capture System for Rehabilitation of Children with Cerebral Palsy. University of Malta.
[10] Graham, M., Milanowski, A. & Westat, J. (2014). Measuring and Promoting Inter-Rater Agreement of Teacher and Principal Performance Ratings.
[11] Hu XL, Tong KY, Wei XJ, Rong W, Susanto EA, Ho SK. The effects of post-stroke upper-limb training with an electromyography (EMG)-driven hand robot. J Electro Kinesiol 2013;(5):1065–74. https://doi.org/10.1016/j.jelekin.2013.07.007.
[12] KPMG. Bus Plan Proj - *SMARTCLAP* 2023.
[13] McGuire DO, Tian LH, Yeargin-Allsopp M, Dowling NF, Christensen DL. Prevalence of cerebral palsy, intellectual disability, hearing loss, and blindness, National Health Interview Survey, 2009-2016. Disabil Health J 2019;12(3):443–51. https://doi.org/10.1016/j.dhjo.2019.01.005.
[14] Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (2017). Official Journal, L 117, 1–175. http://data.europa.eu/eli/reg/2017/745/oj.
[15] Munroe C, Meng Y, Yanco H, Begum M. Augmented reality eyeglasses for promoting home-based rehabilitation for children with cerebral palsy. 11th ACM/IEEE Int Conf Hum-Robot Interact (HRI) 2016;2016. https://doi.org/10.1109/HRI.2016.7451858.
[16] Neofect. (n.d). Rapael-Smart Glove. Retrieved 15 April 2024, from: https://www.neofect.com/us/smart-glove.
[17] Neurorehab Directory. (n.d.). YouGrabber. Neurorehab Directory. Retrieved 15 April 2024, from https://www.neurorehabdirectory.com/rehab-products/yougrabber.
[18] Poulsen AA, Rodger S, Ziviani JM. Understanding children's motivation from a self-determination theoretical perspective: implications for practice. Aust Station Ther J 2006;53(2):78–86. https://doi.org/10.1111/j.1440-1630.2006.00569.x.
[19] SMARTCLAP. (n.d) Retrieved 3 May 2024, from: https://www.um.edu.mt/projects/smartclap/.

[20] Townsend EA, Polatajko HJ. Enabling occupation II: advancing an occupational therapy vision for health, well-being, and justice through occupation. Can Assoc Occup Ther 2013.
[21] Vanoglio F, Bernocchi P, Mulè C, Garofali F, Mora C, Taveggia G, Scalvini S, Lusica A. Feasibility and efficacy of a robotic device for hand rehabilitation in hemiplegic stroke patients: a randomized pilot controlled study. 2017 Clin Rehabil 2017;31(3):351–60. https://doi.org/10.1177/0269215516642606.
[22] Ziviani, J., Poulsen, A.A., & Cuskelly, M. (2012). The art and science of motivation: A therapist's guide to working with children. Jessica Kingsley Publishers.