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# Gamification of Orthodontic Treatment with Personalised Facemasks: Enhancing Patient Compliance Through Playful Engagement

**Patrizia Marti [1,*], Giulia Teverini [1], Cecilia Goracci [2] and Lorenzo Franchi [3]**

[1] Department of Social, Political and Cognitive Science, University of Siena, 53100 Siena, Italy; giulia.teverini@student.unisi.it
[2] Department of Medical Biotechnologies, University of Siena, 53100 Siena, Italy; cecilia.goracci@unisi.it
[3] Department of Experimental and Clinical Medicine, University of Florence, 50121 Florence, Italy; lorenzo.franchi@unifi.it
* Correspondence: marti@unisi.it; Tel.: +39-0577232163

**Abstract:** Class III malocclusions, a dentofacial deformity requiring early intervention, pose significant challenges due to the need for prolonged use of facemasks by young patients. The *SuperPowerMe* project aims to improve compliance with the orthodontic treatment by integrating personalised, sensor-equipped facemasks with gamification. Through a design thinking process, the facemasks were custom-fitted using 3D facial scanning and 3D-printed with biocompatible materials to ensure comfort and ergonomic fit. Sensors embedded in the mask monitored wear time, and data collected were used to engage children in a video game allowing children to progress through game challenges as they complied with the treatment. Observational studies were conducted, evaluating patients' adherence and comfort levels. The results indicated a substantial increase in daily wear time and patient satisfaction, with self-reported compliance closely matching sensor data. The personalised design and gamified elements fostered higher patient autonomy over the treatment period, although minor technical issues with the facemasks were noted. In conclusion, the results suggest that gamification paired with custom devices holds promise as a strategy for improving adherence to long-term orthodontic treatments in children. Further refinement of the system and broader trials are promoted to fully validate the efficacy of therapy gamification.

**Keywords:** personalised medical devices; sensor-equipped facemasks; gamification; custom facemasks; 3D facial scanning; wear time monitoring; paediatric orthodontics; Class III malocclusion

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## 1. Introduction

The use of gamification in therapeutic settings has gained significant attention as an innovative approach to increase patient compliance, particularly among children. Gamification refers to the incorporation of game-like elements—such as rewards, challenges, and progress systems—into non-game environments [1]. When applied to therapy, these elements transform routine or challenging medical tasks into engaging and enjoyable experiences, making it easier for young patients to participate actively in their treatment.

The roots of integrating play into therapy can be traced back to the development of play therapy in psychological treatments, where play was used as a medium for children to express emotions and work through psychological challenges [2]. Over time, this approach has been adopted and expanded within healthcare settings, where the goal is to use play and game elements to encourage compliance with medical protocols [3,4]. As children are more receptive to interactive and entertaining formats, gamification presents a unique opportunity to improve compliance with medical treatments.

Key to the success of these methods is the application of core gamification principles, such as positive reinforcement, progress tracking, and immediate feedback. These elements help foster a sense of accomplishment and control, creating a more positive therapeutic experience. When children are rewarded for completing tasks or reaching milestones, they are more likely to stay engaged with their therapy, reducing resistance and increasing their willingness to adhere to treatment protocols.

Recent technological innovations have further propelled the use of gamification in therapeutic settings. Wearable technology, virtual reality (VR)-based therapy, and mobile health games are increasingly being developed to support children's healthcare routines [5]. By incorporating these technologies, healthcare providers have found new ways to increase motivation, reduce anxiety, and improve compliance, especially in long-term or complex treatments where maintaining patient engagement is crucial.

This evolving field holds great promise, offering a bridge between the therapeutic needs of children and their natural affinity for play. As healthcare providers continue to explore the potential of gamification, the focus remains on making therapy not only effective but also enjoyable, transforming compliance from a challenge into a playful experience.

## 2. The Use of Gamification in Therapy for Children

By critically reviewing the literature, two main approaches can be identified to integrate gamification into therapeutic practices: therapeutic games and games for therapy. Therapeutic games are the most used, as they combine therapeutic processes directly into gameplay, where therapy sessions and playtime overlap. This approach transforms repetitive and often tedious tasks into enjoyable game challenges [6]. Adherence to the therapy pairs directly with playing the game, as players follow specific instructions and complete tasks to achieve progress both in the game and in their therapeutic outcomes. By addressing the monotony associated with long-term rehabilitation regimens, therapeutic games provide an innovative solution to improve patient compliance [7,8]. These game-based interventions are commonly associated with cognitive, motor, or social rehabilitation contexts [9–11]. On the other hand, games for therapy are designed as supplemental resources to accompany traditional therapy protocols. While these games are connected to therapeutic objectives, their design often explores broader themes, providing an engaging environment that indirectly supports adherence to therapy. For example, children with chronic disease conditions who must undergo long-term treatment must be stimulated in adopting healthy behaviours that can support them in facing negative side effects of medical treatments. Playful activities have been demonstrated to be effective in this context [12]. Another key example refers to the acceptance of medical devices that can impact the overall outcomes of therapy protocols. In this area, Høiseth et al. [13] transformed games into a means to distract the attention of toddlers with respiratory disorders who were scared by the nebulizer device. The focus of games for therapy, therefore, is on fostering positive conditions that facilitate compliance, such as reducing stress or creating a supportive context for therapy [14], rather than directly incorporating therapeutic tasks into gameplay.

In the field of dentistry and orthodontic treatments, which is the focus of this paper, game-based interventions in therapies for children have evolved along two distinct trajectories. One direction emphasises the use of gamification features to encourage patients in being compliant with maintaining good oral health. Most of the gamified interventions focus on stimulating patients in taking care through frequent and correct oral hygiene [15–17]. By integrating features such as points, badges, rewards, and challenges, these interventions transform routine oral hygiene tasks into engaging playful activities. This approach has shown significant potential in promoting frequent and accurate oral care practices among children, who are typically less inclined to adhere to prescribed recommendations. A second trajectory relates to gamification as a strategy to reduce anxiety in young patients during dental visits. Playful and interactive elements embedded in these interventions create a welcoming and less intimidating environment for dental visits, making treatments more accessible and less distressing for children [18].

## 3. Overcoming Barriers to Facemask-Based Class III Malocclusion Treatment: The Case Study of the *SuperPowerMe* Project

Class III malocclusion, characterised by mandibular prognathism, can lead to an anterior crossbite that negatively impacts on aesthetics and function. Early intervention in paediatric patients, typically between the ages of 5 and 10, is crucial for effective treatment outcomes. Protraction facemasks are often prescribed to stimulate maxillary growth, necessitating a wear time of from 9 to 14 h per day for approximately nine months to achieve optimal results [19]. However, patient compliance remains a critical challenge due to discomfort, aesthetic concerns, and the lengthy duration of treatment. Standardised facemasks, which are only available in two sizes, fail to accommodate the diverse anatomical facial structures of young patients, often resulting in discomfort, skin irritation, and low adherence to treatment protocols. Furthermore, the generic medical appearance of the facemask can evoke feelings of embarrassment or self-consciousness in patients, further impeding compliance [20]. Patient cooperation is essential for the success of the treatment. Some attempts have been made to make the facemask more comfortable, but none of them has been impactful in terms of overall patient experience improvements [21]. Indeed, the literature shows that attempts to improve compliance with therapy primarily focus on the maximisation of the device's performance from an ergonomic perspective. Early attempts experimented with custom protraction headgear [22] by taking an impression of the patient's facial structure to create a precise anatomical model. This ensured the headgear could be customised to the individual's facial contours for a more ergonomic fit. An impression of the child's face was taken using alginate, a widely used material in dentistry for its ability to capture detailed and accurate impressions of anatomical structures. Alginate's quick-setting properties and ease of use make it ideal for creating a precise mould of the patient's facial structure, which was essential for designing the customised protraction headgear. Cacciatore et al. [23] proposed a chin-cup customisation method based on the removal of the felt sticker from the inside of a prefabricated chin cup, filling the chin cup with putty-consistency polyvinyl siloxane (PVS), ensuring the material extends beyond the cup's borders for better retention, and using the chin cup as an impression tray by pressing it against the chin and holding it briefly (hardening of the material is not necessary). With this solution, the impression material can adhere more securely, forming a customised chin cup tailored to the patient's anatomy, improving comfort and compliance. Other attempts to improve the ergonomics of the facemask were proposed by Ieardo et al. [24], who used a silicone chin cup to prevent skin irritations due to the extended use of correction facemasks. Lastly, Almeida et al. [21] experimented with a modified facemask] by moulding the patient's face. All the procedures described above were obviously extremely unpleasant and challenging for both the patient and the clinician, and the proposed solutions were insufficient to address all the issues emerging from the use of facemasks related to a negative patient experience leading to poor compliance with therapy.

Considering this, the *SuperPowerMe* project was initiated as a multidisciplinary effort, combining expertise in orthodontics, product design, software development, and game design to develop child-oriented strategies to facilitate patients' acceptance and improved compliance with the therapy. The project aimed to develop a personalised facemask system that integrates gamification principles to increase patient engagement and compliance, while also allowing precise monitoring of treatment adherence through sensor technology.

The goal of the project is to transform orthodontic therapy by implementing innovative solutions to improve the patient's experience and support the orthodontist with precise and accurate monitoring.

Since the facemask was identified as the least favoured and least appealing option among ten intra-oral and extra-oral devices [20], the objective of the present study was to design and test solutions to improve the patient experience. To do so, a therapeutic ecosystem composed of a personalised facemask, a monitoring system, and a video game was developed. Personalised facemasks were manufactured and tested in an observational study involving ten patients. Thanks to the positive outcomes of the first study, the personalised facemasks were equipped with electronics to monitor the wear time and connected to a video game. The new system was tested through a clinical study involving two patients over 9 months. The hypothesis of this second study is twofold: first, the implementation of game dynamics serves as an engagement strategy to produce positive effects on the user experience; second, electronic embedding acts as an objective monitoring tool to verify levels of user engagement and adherence to therapy.

## 4. Methodology

The development of the *SuperPowerMe* system followed a two-phase approach. The first phase focused on designing and manufacturing a personalised facemask tailored to the individual anatomical features of each patient. Facial scans are acquired using advanced 3D imaging technologies [25]. The resulting digital models are used to produce custom-fitted facemasks via 3D printing in biocompatible resin. Each facemask is made of several elements, including a forehead pad, a chin cup, and a midline bar, which were ergonomically optimised for comfort and stability.

The manufacturing process consists of eight steps (Figure 1).

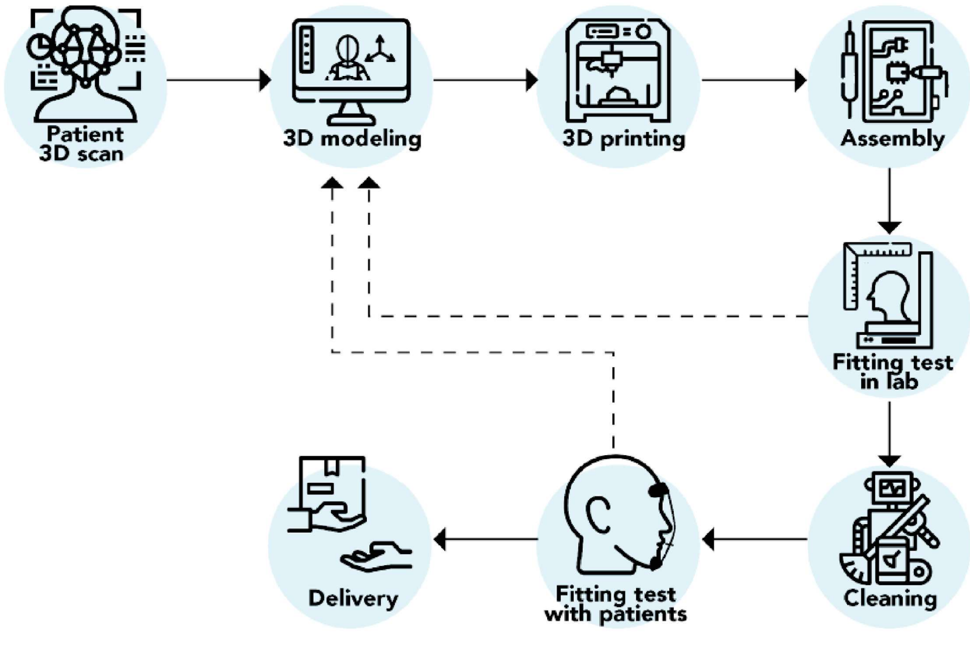


**Figure 1.** Manufacturing process model of a personalised facemask for Class III malocclusion treatment.

The process begins with a 3D scan of the patient's face using either a stationary scanner like the Polishape 3D Faceshape Maxi (Polishape 3D s.r.l., Bari, Italy) or a portable device like an Apple iPhone X or iPad Pro 2018 (Apple, San Diego, CA, USA). Then, the scan file is used to model personalised facemask elements (forehead support, chin cup, midline bar) in Blender software (https://www.blender.org/), integrating and aligning them with a standard central support bar's STL model. Quality is assessed in Autodesk MeshMixer, and the facemask elements are 3D-printed using a FormLabs Form3 SLA printer. At the end, the prints undergo an isopropyl alcohol bath and UV radiation curing. Assembly involves securing the forehead component with a metal fastener and securing the chin support with metal cylinders and nuts that allow adjustment of the position along the bar. At this stage, the process may include some iterations based on tests in the lab and with the patient to finally reach the proper fitting: initial fitting tests are conducted using a 3D polystyrene model of the patient's face. If fitting issues arise, new facemasks are modelled and produced. Once the facemask fits perfectly, it is delivered to the patient to begin treatment.

In the second phase of the process, different sensors are embedded in the forehead pad of the facemask (Figure 2) with a double aim: (1) to develop a monitoring system to be used by the orthodontist to evaluate the progress of treatment, and (2) to create a gamified environment to improve compliance with the therapy by engaging the child in a playful activity. Indeed, the main scope of the project was to enhance the experience of children by making them perceive the mask no longer as an orthodontic appliance but as a special mask. In a gamification perspective, the masks are designed as superhero masks with several fabric adornments (Figure 3).

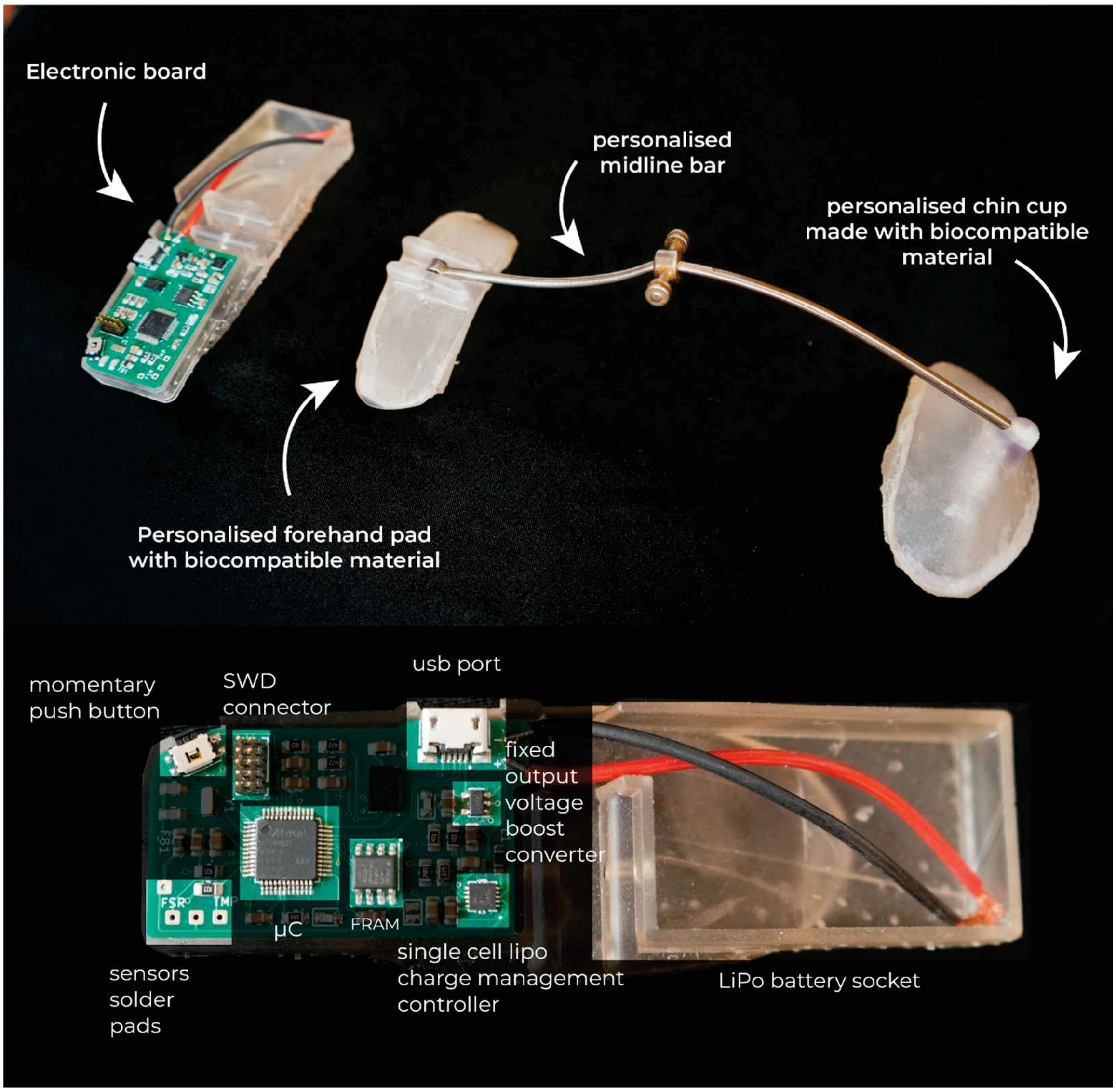


**Figure 2.** Personalised facemask with embedded electronics.

**Figure 3.** Patient wearing the *SuperPowerMe* personalised facemask with fabric adornments.

*Overview of the System*

The monitoring system represents a product–service ecosystem (Figure 4), which aims at making patients' behavioural data available in different forms to the orthodontist and the patients and their family. By behavioural data, we refer to the data generated by the child's behaviour in wearing the facemask, which goes through the data life-cycle journey described below.

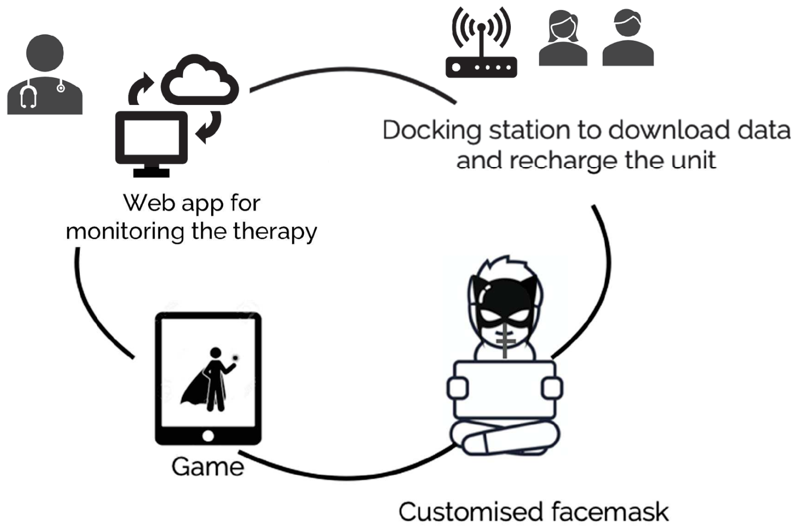


**Figure 4.** The monitoring system of *SuperPowerMe*.

The *SuperPowerMe* system is constituted by four touchpoints, each representing a key component to understand the data journey from gathering to archival.

- The starting point of the system is the phase of data gathering, where the facemask acts as a data generator [26]. To achieve this, a step has been implemented into the manufacturing process to embed electronics in the forehead pad of the personalised facemask to monitor the wear time. The electronic boards and sensors integrated in the facemask enable real-time data communication. To monitor the wear time, the facemask is equipped with an electronic board designed using AutoDesk Eagle and an NTC thermistor to measure the temperature variations, which are useful to record when the facemask is in contact with the child's forehead. The physical manufacturing of the board was outsourced to the company PCB Way, while the component soldering was subsequently performed in-house at the Santa Chiara Fab Lab, University of Siena. Sensor data and time stamps are stored on non-volatile F-RAM memory, which allows low power consumption and high endurance during write/read cycles. The ATSAMD21G18 microcontroller includes a real-time counter circuit that checks the status of the board from the sleep mode every 15 min, optimising energy efficiency. A power subsystem is used to ensure stable power supply to the system, maintaining the 3.3 V required for reliable system operation. The board and lithium battery are enclosed in a housing situated above the forehead pad, while the thermistor sensor is positioned between the protective pad and the inner surface of the pad.

- A docking station serves as both a charging hub for the mask's battery and for receiving data recorded by the mask, which are transmitted to the game server. The shell of the docking station is designed and produced using FDM 3D printing technology. This includes a Raspberry Pi 4 operating on a GNU/Linux® system. When the mask is connected to the docking station via a USB cable, its battery is recharged. This guarantees the frequency of data acquisition. By pressing a designated button located on the mask's shell, the data recorded are downloaded and stored in an SQLite database. The docking station is also connected to the patient's home Wi-Fi network to automatically send the downloaded files to a central server. Every day at 3 pm CET, a cron job starts: a Phyton script checks if an internet connection is available, extracts data that the server has not received yet, and sends these to the central server in the form of a JSON payload, then data are stored in a dedicated table of the MySQL database. If the internet connection is not available, the data are saved in the F-RAM memory and transmitted as soon as the internet connection becomes accessible again. Patients and their parents are instructed on the use of the system, and how to connect the facemask to the docking station and activate a button to ensure that the data are sent to the server. An illustrated user manual describing the system and how to use it is enclosed in the docking station. The manual also highlights that the system does not use a Bluetooth connection directly in the facemask, to avoid any risk associated with the proximity of the radio-frequency device to the child's head.
- Downloaded data are used to feed the dynamics of a video game designed to engage the child in various adventures all along the prescribed therapeutic period. In this way, patients become consumers [26] of their own data, as they can have tangible evidence and reward for the correct wear time of the facemask. The technology infrastructure of the video game is a responsive web app built on the LAMP (Linux, Apache, Mysql, PHP) stack. The PHP Laravel framework was used to develop the game's back- end, while Vanilla JS, Bootstrap, and custom CSS were implemented for the front- end.
- The fourth component of the system is a web app through which data on the wear time are shared with the orthodontist, who can choose different data visualisations, monitor the progress of the treatment, and adjust the therapeutic plan based on reliable and accurate data.

## 5. Game Design of *Save the World of Naturalia!*

### *5.1. A Game for Therapy: Identifying Requirements*

One of the key components of the *SuperPowerMe* monitoring system is the mobile video game *Save the World of Naturalia!*, an instance of games for health (G4H), which are explicitly designed to influence a person's health [27].

To ensure the game's effectiveness in a healthcare context, it is essential that the therapeutic requirements are rigorously considered. First, the game must align with the objectives of healthcare professionals and serve as a supportive tool to facilitate desired therapeutic outcomes [14]. Additionally, the game must adhere to the 'do no harm' principle, ensuring that it does not cause any negative psychological, emotional, or physical effects that could counteract its intended benefits. Therefore, a multidisciplinary approach is necessary to address such design-related challenges [28].

A comprehensive set of therapy requirements and game design considerations was established to guide the development of a therapeutic game aimed at treating Class III malocclusion in children (Table 1).

**Table 1.** Therapy requirements and design considerations.

| Therapy Requirements | Design Considerations |
| --- | --- |
| Therapy duration: 9 months | Gamification supported by a reward strategy |
| At home therapy | Avoid long periods of exposure to the game |
| School-aged children (5–9 years old) as primary therapy target | Educational opportunity beyond therapeutic objectives |

The requirement for a nine-month therapy duration poses a significant constraint on the game's design, as the gameplay must align with the length of the treatment. From a game design perspective, this necessitates that the game is designed to last at least nine months, the expected duration for achieving therapeutic results. Furthermore, patients undergoing Class III malocclusion therapy are required to wear a facemask for at least 9 h daily. Therefore, an engaging reward system is critical to sustain children's motivation and compliance with wearing the facemask consistently.

The second requirement pertains to the context in which playing takes place: the game should be simple enough for children to use it independently at home and should be designed so that children are not overexposed to the game, limiting screen time to maintain a healthy balance [29].

The third requirement relates to the target audience—school-aged children. Research has shown that the therapy is most effective when administered to children between the ages of 5 and 10 [30,31]. This developmental period is crucial for cognitive, social, and moral growth, making it an ideal time to instil values and knowledge that shape future behaviours. For example, lessons about sustainability and environmental impact can inspire a sense of responsibility and purpose [32,33]. Games for health are well suited to integrate such educational elements, extending the game's scope beyond merely achieving therapeutic objectives.

With these considerations in mind, *Save the World of Naturalia!* was devised by the designers in the project team as a therapeutic game specifically for Class III malocclusion treatment. The game is structured to create an engaging, playful experience that encourages compliance with the therapy protocol. Unlike traditional therapeutic games (e.g., exergames), the game's challenges and tasks are not directly tied to the therapeutic regimen. Instead, the game operates independently of the therapy, allowing children to play at any time, following the game's narrative and dynamics.

In the context of orthodontic therapy, patients spend a considerable time passively wearing a facemask, time periods that are perceived as fruitless due to the manifestation of therapy results in the long term. For this reason, the game for therapy of our case study is designed as an idle game. According to Cutting et al. [34], idle games are characterised by four game dynamics:

- Discovery: gradual unveiling of new content and mechanics as players engage with the game;
- Collecting: gathering 'vanity items' or virtual rewards;
- Progression: incremental progress in which both tokens and the effort to obtain them increase over time;

- Waiting: encouraging players to utilise downtime by gathering resources to further their progress in the game.

In addition to these features, self-playing idle games have been recognized as appealing gaming experiences, since the gameplay model provides recurring gratification for players even during their absence from the game [35].

### *5.2. Game Design Methodology*

The design of *Save the World of Naturalia!* was guided by the mechanics, dynamics, aesthetics, and outcomes (MDAO) methodology, as conceptualised by Browning [36]. Built upon the work of Hunicke et al. [37], the methodology is articulated in the following steps.

First, the design team formulated a clear problem statement to be addressed through the game-based intervention, alongside the desired outcomes. This step ensured that all game elements remained consistent with the therapeutic objectives. The next step focused on aesthetics, which refers to the emotional engagement of players and their reactions to the gaming experience. Once the aesthetic strategy was established, the designers considered the game's dynamics.

Dynamics are 'the ways that players play' and refer to the patterns of play that arise when players interact with a game's mechanics over time. Mechanics refers to the rules, goals, and objects governing the game functions. They include the actions players can take, the objects they interact with, and the constraints and limitations within the game world.

Table 2 briefly recaps how the MDAO framework was implemented in the design of *Save the World of Naturalia!*

**Table 2.** MDAO framework as guidelines for the game design process of *Save the World of Naturalia!*

| | |
|---|---|
| **Outcome(s)** | Behaviour change: make patients wear the facemask at least for 9 h per day |
| **Aesthetics** | Narrative, Challenge, Discover |
| **Dynamics** | Reward, Identification, Immersion |
| **Mechanics** | Time, Problem-Solving |

Outcome. The major objective of transforming the therapy into a playful experience is to make patients wear the facemask at least for 9 h per day, which is the minimum amount of time required to obtain results along with the orthodontic therapy. Currently, compliance with the therapy is compromised by the scarce ergonomics and bulkiness of the facemask, the duration of the therapy, the skin irritations that may be provoked by the contact of the plastic material of the facemask pads with the skin, and the poor aesthetics. Therefore, to comply with the orthodontic therapy requirements, gamification strategies were implemented to stimulate a change in behaviour in children under treatment [14].

Aesthetics. The game *Save the World of Naturalia!* aims to make children interested in playing through a combination of the following taxonomy of aesthetic elements [37]: game as a drama (Narrative), game as an obstacle course (Challenge), and game as exploration (Discovery). The aesthetics of Narrative uses the gradual disclosure of a story as an element to arouse the player's curiosity by drawing players into their stories and making them feel like an integral part of the narrative (i.e., stimulating them in watching how characters grow or in forecasting a plot twist in characters' story or in the general storyline). The aesthetic of Challenge relies on the dissemination of quests [38] which must be solved by the player to progress in the gameplay. Similarly, the aesthetic of Discover leverages the thrill of finding something unexpected or hidden by transforming the gameplay in an uncharted territory that players can uncover by finding new information, secrets, or mechanics.

Dynamics. The first dynamic implemented is *Save the World of Naturalia!* is a well-timed reward to motivate patients to keep wearing the facemask and to sustain their interest in playing. We designed a reward system by assuming the significance of the dynamic of reward as a strategy to provide players with immediate gratification [39] and exclusive access [40] that only patients who are undergoing malocclusion treatment can benefit from. Moreover, opposite to the common way of rewarding players at the end of the task they are asked to perform, the idea was to use the reward as the opening of the game [41]. The second dynamic we focused on to engage patients in being more compliant to the therapy was the identification of players with the game characters [42]. Studies have demonstrated that perceiving a character as being like players' inner selves or personal story fosters intrinsic motivation [43]. Specifically, we addressed the dynamic of identification by creating characters that facilitate the dynamic of 'mirroring', where players see their own traits and emotions reflected in the characters, to facilitate the patient/player immersion in the game. The characters of the story are superheroes wearing the same facemask as the child playing the game.

Mechanics. To enable both the aesthetics and dynamics described above, the game is characterised by two clusters of mechanics: time and problem-solving. Game temporalities are an essential lens to examine the player's experience, as they influence practices within and beyond the game space [44]. This is particularly true when designing a game for therapy, since clinical interventions such as malocclusion treatment involve the whole daily life of the patient (e.g., individual well-being, social interactions). Generally, the time mechanism imposes a temporal constraint on players, often translating into time pressure. Instead, in *Save the World of Naturalia!*, time is considered the gatekeeper of the playtime, as it is connected to the duration of the therapy. As mentioned before, the game aims at making time perceived as a resource, since waiting time has a scope set, i.e., collecting virtual goods. Our aim was to enable this resource collection through the facemask wear time: the more time patients spend wearing the mask, the more they earn coins to help the superheroes of the game in facing the game challenges.

As said above, patients confront themselves with a problem-solving activity during which they develop skills in analysis, resource management, and creative thinking [45].

Considering the above, the game *Save the World of Naturalia!* is a point-and-click idle game [46], focused on solving problems that often involve finding and using specific objects/tools in specific locations/contexts. Players collect objects throughout their journey and manage them in an inventory. These items are crucial for solving problems occurring for the superheroes during an adventure.

### *5.3. A Matrix as Supporting Tool to Design, Understand, and Evaluate the Game Experience Along the Therapy Protocol*

From a design perspective, creating a game for therapy requires a complex balance between elements of the MDAO framework and expected therapy outcomes. To grasp the complexity of the game design process, a journey map [47] was developed representing the duration of the game/therapy and the main elements of the game. Playtime is divided into different segments, each standing for the different sections of the game. The matrix (Figure 5) also includes the mechanics, dynamics, and aesthetics of the MDA framework [37], redefined as follows.

Mechanics includes: the physical evidence, i.e., points of interaction between the player and the game (e.g., levels, maps, and interactive objects), the gameplay rules, i.e., instructions of the game (e.g., winning conditions, scoring), and the actions that the player can make during the game (e.g., navigating the different levels).

Dynamics include: the physical interactions with the game (e.g., swiping or dragging on a screen), the activators (e.g., character, levels, narrative) triggering the player experience, and the outcomes of the game.

Aesthetics are geared towards the desired psychological state of players to improve compliance with the therapy (e.g., possible boredom or enjoyment).

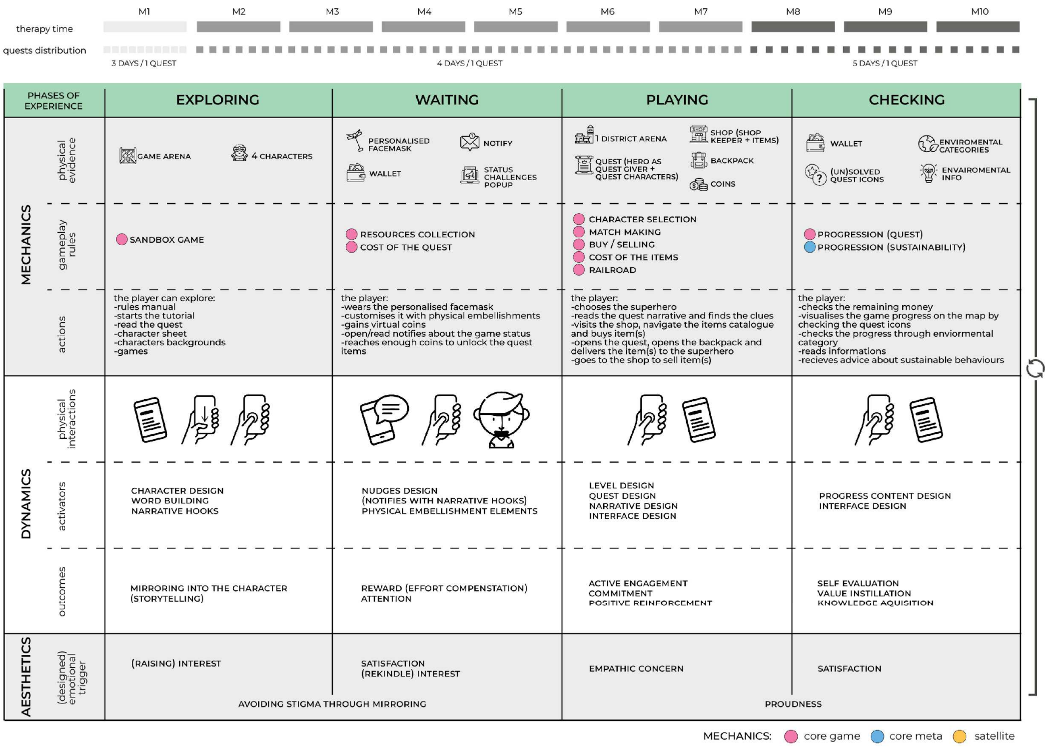


**Figure 5.** Matrix of the gaming experience of *Save the World of Naturalia!*

## 5.4. The Gameplay

The main objective of the game is to improve compliance with the therapy by increasing the wear time. To do so, the core mechanics of the game is based on the bijective relationship between wear time and reward system: by wearing the facemask, patients earn coins necessary to unlock the different challenges of the game. Every 9 h of wear time, the game's back- end credits a variable number of coins to a virtual wallet. Therefore, the game can progress only by wearing the facemask and collecting coins to buy objects/tools necessary to the superheroes to address the challenges.

The superheroes (Figure 6) can be chosen at the beginning of a new challenge from four different characters.

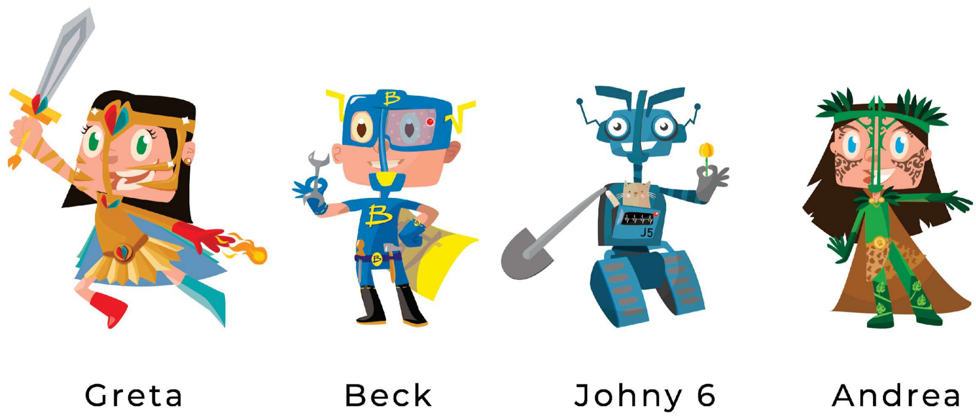


**Figure 6.** The illustrations of the superheroes of *Save the World of Naturalia!*

Greta is a wizard-warrior and strong leader, and lives with her brother Leo at the edge of the Naturalia forest. Skilled with a sword and magic, she decides to stop the Bad Family when they begin cutting down trees. However, Leo is kidnapped, and Greta must rescue him and save Naturalia. For this, she must wear a special mask to hide her identity.

Beck is a young maths and computer genius passionate about technology. The Bad Family company hired him, but he soon discovered their plan to destroy the Naturalia forest to expand their factory. Beck fled and is now being hunted. To save the forest, he plans to stop the factory while hiding his identity with a special mask.

Johnny 6 is a robot who was originally designed by the Bad Family to destroy the forest. After a short circuit changed his programming, he escaped and now protects nature by removing waste, planting trees, and helping animals. The Bad Family has created more robots like him to continue destroying Naturalia. Johnny's mission is to secretly return to the factory and reprogram these robots to be good, while disguising his identity with a special mask.

Andrea is a genderless human shapeshifter living in Naturalia, who loves nature and supports diversity. Andrea can transform into any animal and aims to restore Naturalia's beauty. Eager to defeat the company threatening the forest, Andrea plans to wear a mask and take action to care for animals and plants and restore Naturalia to its former glory.

The characters have been designed with distinctive features and abilities (e.g., magical powers, physical appearance, clothing). They all wear a superhero facemask. This design choice aims at stimulating patients in identifying with the superheroes of the game and developing a deep engagement with them and the game.

Children can explore the superheroes by entering a personal page where they introduce themselves and describe their abilities and superpowers (Figure 7B,C). Children can also explore the different areas of the game (Figure 7D) by scrolling through the map (exploring phase).

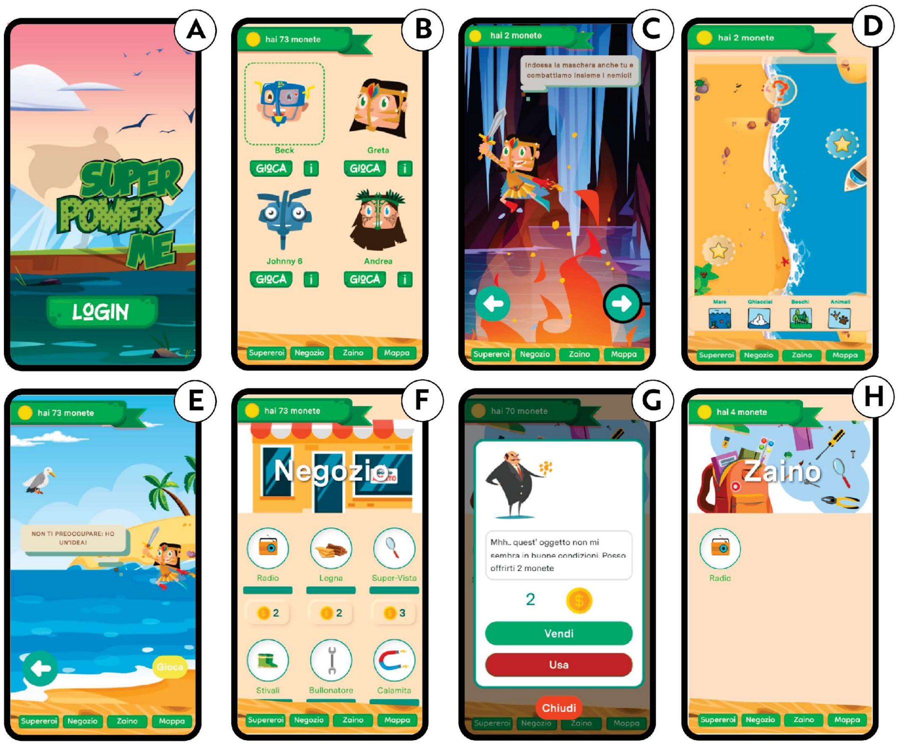


**Figure 7.** Screenshots of general gameplay in *Save the World of Naturalia!* (**A**) The homepage of the video game. (**B**) Choosing the superhero to play the quest. (**C**) Discovering the personal storyline of the superhero. (**D**) The mission map with the environmental categories. (**E**) Revealing the quest. (**F**) The item shop. (**G**) Trading. (**H**) The player back-pack.

Once the hero has been selected, the quest begins with a short description of the challenge the hero must face (Figure 7E). To overcome it, the player has to buy an item displayed in a virtual shop (Figure 7F,G): only one of the 73 items in the shop will be the right one to solve the challenge. There are several clues to guide the player to buy the right object; however, if the choice is not correct, it is still possible to buy more objects (playing time).

Once the challenge has been solved, the player must wear the facemask again to unlock the next quest. In the meantime, it will be possible to monitor the progress of the game by clicking on the completed challenges on the map (checking phase).

### *5.5. Time Design*

The video game is intrinsically linked to the mechanics of time. Besides the fact that the reward system is time-bound, the duration of the game must be designed according to the duration of the therapy. This requires a well-thought-out timeline of the various challenges that patients will face. For this reason, the timeline of the quest release was divided into three main periods, as follows.

- During the 1st month of the therapy, the quest is playable every 3 days, which corresponds to 10 challenges in the month.
- Between the 2nd and the 7th month of the therapy, 1 quest is playable every 4 days, which corresponds to 7 challenges per month and thus to 42 challenges in the 6 months.
- In the 8th and 9th months, 1 quest is playable every 4 days, which corresponds to 6 challenges per month and thus to 18 challenges in the last 3 months.

To monitor treatment compliance, the game server processes data from the embedded sensors in the facemask and compares readings against predefined thresholds. The system calculates the cumulative daily wear time, and when the usage exceeds 540 min (9 h) within a 24 h period, it awards the patient with a virtual gold coin. Moreover, the mechanism controlling the quest drop is linked to the number of coins the player has to spend for buying the objects necessary to progress in the game. Indeed, each object is incrementally priced, calculating the hours of the facemask wear time necessary to earn the coins (e.g., in the first month, each object costs 2 coins and patients can earn a maximum of 1 coin per day, while in the fifth month, an object costs 4 coins, and consequently, patients must wear the facemask for at least 4 days before collecting the needed amount).

This time design stems from the idea that the more time players spend in the game, the more exciting, complex, and demanding the challenges must be in order to keep a high level of engagement. Secondly, the frequency of challenges is higher in the game's initial phases, since players have to become familiar with game mechanics and dynamics. Lastly, delaying the time between challenges as the therapy progresses has a therapeutic goal: to make playing *Save the World of Naturalia!* a special occasion and not a daily ritual.

### *5.6. Narrative Design: Character Design and World Building*

An essential aspect of the design process is the creation of a good narrative. A significant effort was devoted in crafting a storyline that is not only engaging but also educational, specifically aimed at instilling values of sustainability in young players. The narrative is intricately woven to integrate themes of environmental stewardship, resource conservation, and ecological awareness, making these concepts accessible to children. By embedding these values within the storyline, the game seeks to foster an early appreciation and understanding of sustainable practices, encouraging players to adopt eco-friendly habits both in the game and in their daily lives.

Considering this, the plot of the video game *Save the World of Naturalia!* is based on the story of a magical world of Naturalia where peace reigns. People, animals, and plants live in a perfect balance based on mutual respect. One day, a company of villains, the Bad Family, arrives in Naturalia. They are ruthless and greedy, and their scope is to expand their factory to produce and earn more money. To do this, the Bad Family villains have started to raze the forest, capturing animals to imprison them, constructing big buildings and parking lots, polluting the atmosphere, and scaring the inhabitants.

Intimately interwoven with the main storyline are the personal storylines of the four superheroes.

Both the main and the personal storylines are contextualised in the magical world of Naturalia. Visually, Naturalia is made up of four areas: the forest (2), the seaside, (3) the city, and (4) the industrial area (Figure 8). Each area represents part of the background of the game arena and corresponds to different levels of difficulty for players.

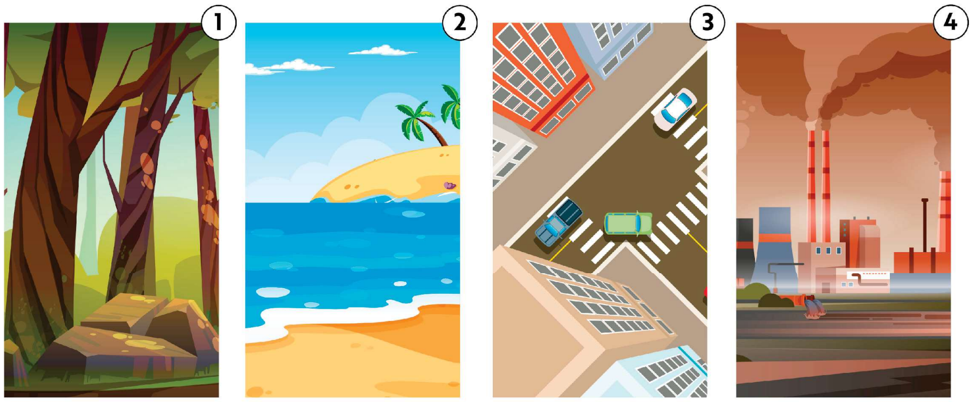


**Figure 8.** The game arena of Naturalia: (**1**) the forest, (**2**) the seaside, (**3**) the city, and (**4**) the industrial area.

## 6. Field Experiments

The therapeutic game associated with the custom facemasks developed in the project was evaluated through two distinct observational studies: a preliminary case series feasibility study and a case report.

### *6.1. Preliminary Case Series Feasibility Study*

The study sought to explore whether a personalised Petit facemask, tailored to the patient's facial anatomy with customised pads and a midline bar in stainless steel, could provide comfort and be well received by patients undergoing early treatment for Class III malocclusion. Additionally, it aimed to identify any potential complications that might occur during the therapy with the customised facemask. This preliminary study investigated the efficacy of the *SuperPowerMe* system without the gamification strategy.

A prospective two-centre case series was conducted in accordance with the Declaration of Helsinki and approved by the Regional Paediatric Ethics Committee at the University of Florence (protocol number 236/2020; chairperson of the Ethic Committee: Professor Alessandro Mugelli). The study involved a sample of 10 patients (aged 5 to 9 years). Five patients (three males and two females) were treated at the Orthodontic Clinic of the University Hospital of Careggi in Florence (Italy), and five patients (three females and two males) were treated at the Orthodontic Clinic of the University of Belgrade (Serbia) [48].

During the therapy, the patients were instructed to wear the facemask for at least 9 h a day. To monitor the experience with the personalised facemask, a questionnaire was administered at intervals of 1 week, 3 months, 6 months, and 9 months. The questionnaire, completed by the patients with assistance of their parents or guardians, was structured in two parts, each containing two different visual analogue scales (VAS): the first one aimed at evaluating the pain levels ranging from 0 (no pain) to 10 (worst imaginable pain), while the second one served to monitor patient satisfaction with the therapy, ranging from 0 (no satisfaction) to 10 (maximum satisfaction). The questionnaire also explored therapy adherence using a qualitative approach, focusing on aspects such as patient autonomy regarding the use of the facemask, parental involvement, skin irritations, sleep disruptions, and general discomfort.

At the end of the study period, 9 out of 10 patients had completed the treatment successfully. One male patient, who underwent treatment at the University of Belgrade, interrupted the therapy before the final survey at 9 months due to personal reasons.

The results showed that the levels of pain reported by the patients generally decreased over time. Patient Z.D. noticed an increase in pain at month three. This was mainly due to discomfort in some lower teeth and a slight skin irritation. However, the sense of discomfort disappeared in the following months, and the child declared that they were highly satisfied with the new facemask. Indeed, the already high level of satisfaction increased after 6 and 9 months, and the child wore the mask continuously for 9 h a day as prescribed (Table 3). Patient Mi.Mi. noticed a pain at month 6 due to an instability of the facemask during the night causing pain in the canines and commissures of the mouth (Table 4). However, this problem had disappeared completely by month 9.

At the end of the observational study, all nine patients declared that wearing the personalised facemask was painless (Figure 9).

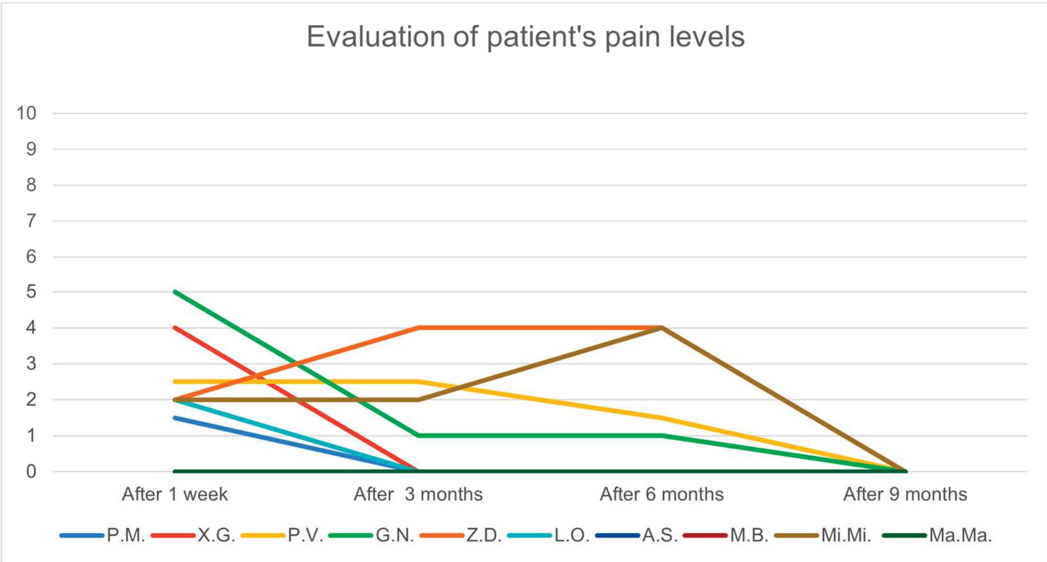


**Figure 9.** Results of VAS of reported pain levels.

**Table 3.** Answers to observational study questionnaire—patient Z.D.

| Questions | After 1 Week | After 3 Months | After 6 Months | After 9 Months |
|---|---|---|---|---|
| Do you feel pain? | upper-left gum | right and left gum | where underwires are placed | |
| Are you happy with the new facemask? | 8 | 9 | 10 | 10 |
| Daily weartime | 9 h | 9 h | 9 h | 9 h |
| Do you wear the facemask without parental reminders? | yes | yes | yes | yes |
| Do you often ask to remove the mask? | no | no | no | no |
| Do your parents explain the importance of wearing the facemask when you do not want to? | yes | yes | yes | yes |
| Any skin irritations? | no | forehead and chin | forehead and chin | forehead and chin |
| Did you sleep badly with the mask on? | no | yes | no | no |
| Have you had any other ailments due to the mask? | no | discomfort in some lower teeth | no | no |
| Any other occurrences? | no | no | no | no |

**Table 4.** Answers to observational study questionnaire—patient Mi.Mi.

| Questions | After 1 Week | After 3 Months | After 6 Months | After 9 Months |
|---|---|---|---|---|
| Do you feel pain? | 2 | 2 | 4 (canines and commissure of the mouth) | |
| Are you happy with the new facemask? | 8 | 9 | 9 | 8 |
| Daily weartime | 12 h | 8/10 h | 8 h | 8 h |
| Do you wear the facemask without parental reminders? | yes | yes | yes | yes |
| Do you often ask to remove the mask? | no | yes | no | no |
| Do your parents explain the importance of wearing the facemask when you do not want to? | no | yes | no | no |
| Any skin irritations? | forehead, chin, and mouth edges | chin and mouth edges | no | chin |
| Did you sleep badly with the mask on? | yes | no | no | no |
| Have you had any other ailments due to the mask? | no | no | no | no |
| Any other occurrences? | no | no | no | no |

Overall, the patients declared being satisfied with the therapy: patient satisfaction throughout the treatment consistently averaged above 7.8 on a VAS ranging from 0 to 10, with a maximum value of 8.7 recorded at the end of therapy (Figure 10).

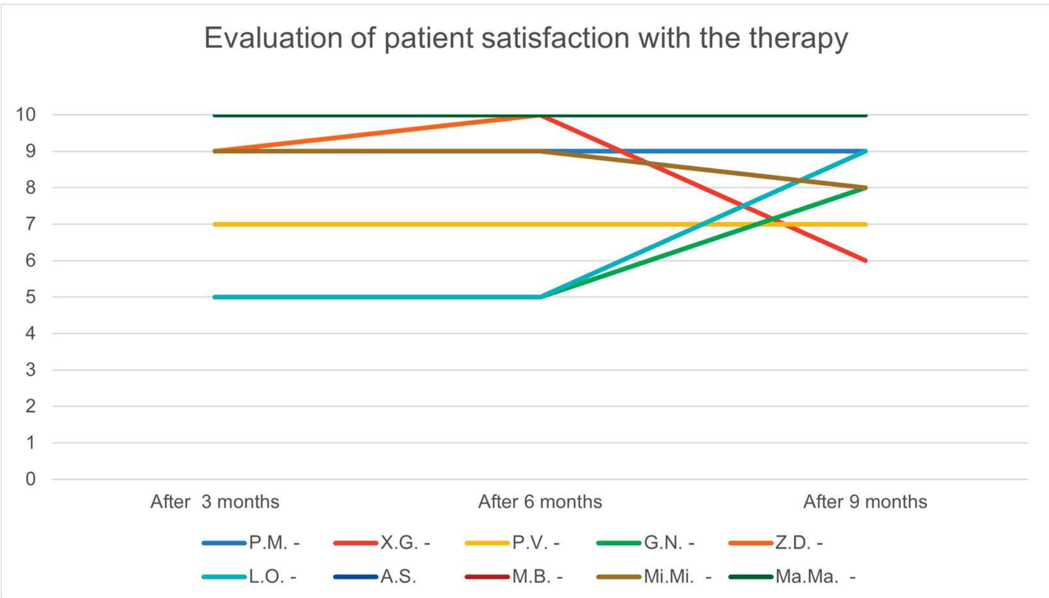


**Figure 10.** Results of VAS of patient satisfaction with the therapy.

Patient X.G. reported a drop in satisfaction from month 6 to month 9. However, this was due to tooth decay. Despite this problem, the patient maintained a high facemask wear time even in the presence of pain due to tooth decay (Table 5).

**Table 5.** Answers to observational study questionnaire—patient X.G.

| Questions | After 1 Week | After 3 Months | After 6 Months | After 9 Months |
|---|---|---|---|---|
| Do you feel pain? | 4 (tooth) | 0 | 0 | 0 |
| Are you happy with the new facemask? | - | 10 | 10 | 6 |
| Daily weartime | 9 h | 9 h | 10 h | 9 h |
| Do you wear the facemask without parental reminders? | no | no | yes | yes |
| Do you often ask to remove the mask? | yes | no | no | no |
| Do your parents explain the importance of wearing the facemask when you do not want to? | yes | yes | yes | yes |
| Any skin irritations? | forehead and chin | chin | no | chin |
| Did you sleep badly with the mask on? | no | no | no | yes |
| Have you had any other ailments due to the mask? | no | lacerations due to hooks moving outwards | no | no |
| Any other occurrences? | no | no | no | tooth decay |

### *6.2. Two Case Reports: Materials and Methods*

In accordance with the Declaration of Helsinki, the clinical study was approved by the Regional Paediatric Ethics Committee at the University of Florence (protocol number 124/2022; chairperson of the Ethics Committee: Dr. Roberto Satolli). The approval was based on the results of the preliminary observational study described above, which consolidated the effectiveness and safety of the innovative manufacturing process adopted in the project.

The aim of the study was to monitor the effective patient wear time by comparing the reported wear time in questionnaires with objective data obtained by sensors integrated into the forehead pad of the facemask. Patients were included or excluded from the study according to two eligibility criteria [49]:

- Display of indications for early treatment of Class III malocclusion;
- Absence of dental abnormalities in the upper arch, cleft lip and/or palate, any congenital craniofacial syndrome.

Each patient went through the following step-by-step process.

1. Active expansion: patients received treatment using a Hyrax-type rapid maxillary expander (RME). This appliance was activated only when a transverse discrepancy between the dental arches was identified. The RME was adjusted incrementally, at a rate of one-quarter turn per day, which corresponds to an expansion of 0.2 mm per turn.
2. Face scanning at the Orthodontic Clinic: patients' anatomies were digitally acquired through a facial scanning by using either an iPad Pro 2018 (Apple Inc., Cupertino, CA, USA) with the Bellus3D DentalPro app (Bellus3D, Campbell, CA, USA), or the Face Scanner Maxi 6 (Polishape 3D, Bari, Italy) with Agisoft Photoscan Professional Edition software V1.4 (Agisoft LLC, St. Petersburg, Russia). This process took place in a well-lit environment, and patients wore disposable caps to keep their hair from obstructing the scan. Patients were asked to sit calmly with their teeth in occlusion and their lips relaxed.

3. Digital design and manufacturing of the personalised facemasks: after receiving patients' face scans, the production of the personalised facemask followed the eight steps of the manufacturing process described in paragraph 2.
4. Delivery of the personalised facemask to the patient: upon completion of facemask production, the orthodontist received the personalised facemasks and distributed them to the patients. During the fitting session, the orthodontist performed three essential steps: first, the orthodontist attached the sliding crossbar, then applied 500 g extraoral elastics, and finally instructed patients and caregivers on proper facemask use and daily wear time.
5. Monitoring and evaluation of the therapy: therapy progress was monitored through regular questionnaires at one week, three months, six months, and nine months from the beginning of the therapy. Patients, with the help of their parents, rated pain and satisfaction using visual analogue scales. The questionnaire also assessed issues related to therapy adherence through a qualitative approach by investigating patient autonomy in terms of mask wearing, parental support, skin irritations, sleep disturbances, and overall discomfort. In addition, the last part of the questionnaire was designed to evaluate the playful experience that patients went through. Patients were asked to express their preferences on a scale from 0 to 10 with respect to the game characters, game storyline, and game world, and finally to rate their feelings arising from the interaction with the game *Save the World of Naturalia!*

### *6.3. Case Report: Results of Clinical Case 1*

From a clinical perspective, the malocclusion was corrected in both patients. Figures 11 and 12 presents the comparison of wear time recorded by the *SuperPowerMe* system over a period of approximately nine months. The horizontal axis represents the time frame, marked from 1 week to 9 months, while the vertical axis represents the daily hours of wear time, ranging from 0 to 14 h, which corresponds to the prescribed wear time [18–50].

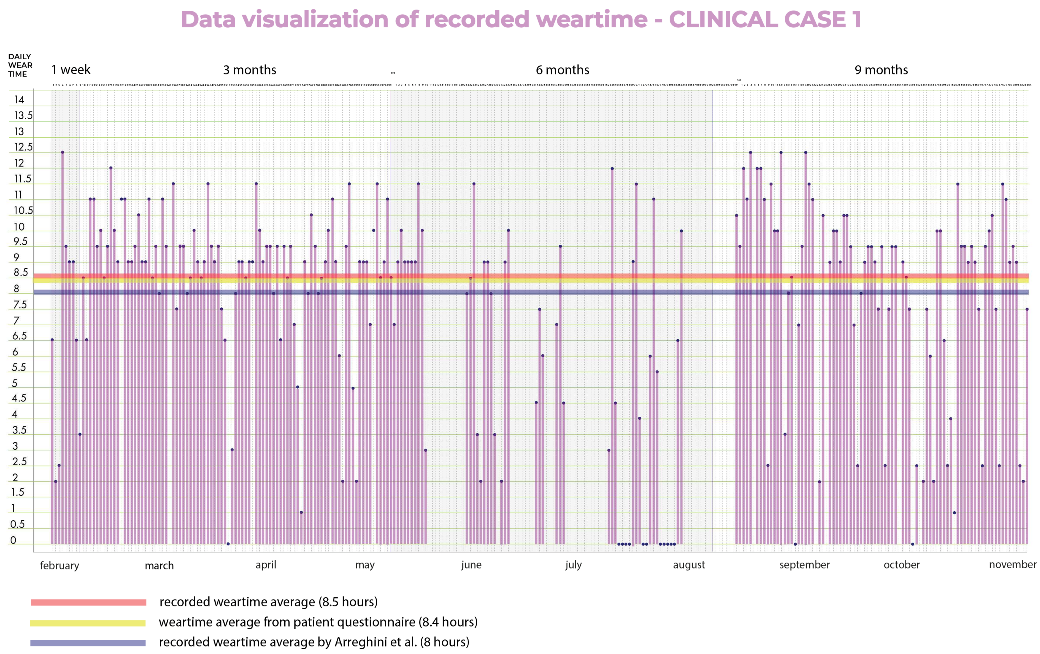


**Figure 11.** Data visualisation of wear time in the first clinical trial reporting the hours of wear time (y-axis) and the month of treatment (x-axis) [30].

To fully understand the data visualisation, key components of the graph include: purple vertical bars, which represent daily recorded wear times, indicating variations in the usage of the facemask throughout the therapy period, and coloured horizontal lines, which denote the recorded wear time average detected by the sensors integrated in the facemasks (yellow line), the wear time declared in the patient questionnaire (red line), and the benchmark set by the previous study of Arreghini et al. [30] (blue line).

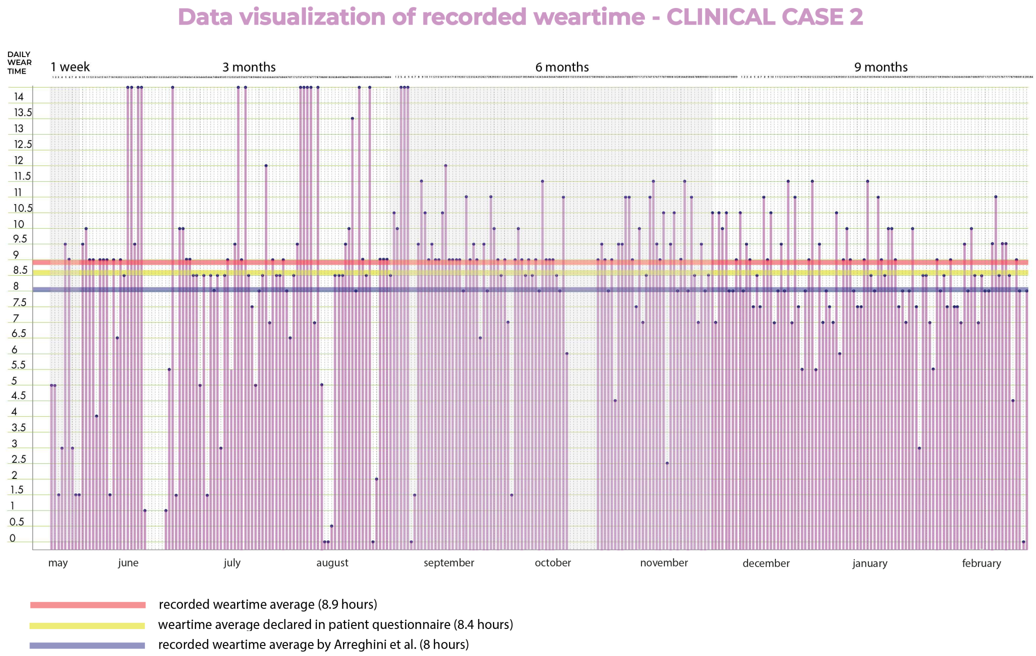


**Figure 12.** Data visualisation of the second clinical case in terms of wear time reporting the hours of wear time (y-axis) and the month of treatment (x-axis) [30].

The first clinical case refers to a 7-year-old female patient, who presented with a Class I dental relationship in the primary mixed dentition and 0 overjet and overbite. Treatments with the personalised facemask spanned from February 2022 to November 2022, totalling 284 days of treatment. Throughout this period, the sensor-embedded personalised facemask successfully recorded 83% of the therapy days. However, missing data were noticeable due to some technical issues orthodontists reported during June and July, particularly with the forehead pads and midline bar, which led to incomplete data capture during those months. These mechanical problems with the facemask contributed to brief interruptions in continuous data collection, highlighting a need for further refinement in the device's durability and fit.

When comparing the patient's self-reported wear time with the data collected by the sensors, the results are highly consistent. The patient reported wearing the facemask for an average of 8.5 h per day, while the sensor recorded an average of 8.4 h. The near-identical lines suggest a high degree of reliability in the patient's self-reporting, with any minor discrepancies likely attributable to occasional delays in putting on or removing the mask, or perhaps brief technical lapses in the sensor's ability to capture data. These results offer promising evidence that the facemask, when functioning optimally, provides reliable data on patient adherence, closely mirroring self-reported usage.

Regarding the patient's engagement with the game, their behaviour revealed an interesting pattern. The child adopted a strategic approach to gameplay, stockpiling coins and resources to solve multiple quests in a single session rather than spreading her efforts evenly across the therapeutic period. This behaviour suggests a deep engagement with the game mechanics, possibly indicating that the game provided a meaningful distraction or even motivation for wearing the facemask. The patient rated her overall game experience as positive, with particular emphasis on the appeal of the game characters. The design of these characters appeared to be a key factor in maintaining her interest, suggesting that the visual and narrative elements of the game contributed to her adherence to therapy (Table 6).

**Table 6.** Mean of the answers to the game experience questionnaire over 9 months on a scale from 0 to 10 (clinical case 1).

| Evaluation | Overall Game Experience | Game Characters | Game Arena and Storyline | Overall Feeling When Playing |
|---|---|---|---|---|
| Scale ranging from 1 to 10 | 8.5 | 9.5 | 9.25 | 8.25 |

One significant aspect of this case was the gradual increase in the patient's autonomy in wearing the facemask. Initially, during the first week of therapy, the patient required regular parental prompting to wear the device, as she had not yet fully adapted to the routine. However, over time, the need for parental involvement steadily decreased, and by the end of the treatment period, the patient was wearing the facemask independently. This shift toward autonomy can be attributed not only to the gamified nature of the therapy, which helped sustain her engagement, but also to the fact that skin irritations decreased over time. After the first week and at the three-month follow up, the patient reported experiencing irritation on her forehead and chin. However, these issues eventually subsided, and no further skin irritation was noted for the remainder of the therapy. Notably, irritation around the mouth or its angles was never reported, which likely made the facemask more comfortable and contributed to the patient's growing willingness to wear it without external encouragement. The reduction in physical discomfort, combined with the motivational elements of the game, played a key role in fostering greater self-motivation and adherence to the treatment.

### *6.4. Case Report: Results of Clinical Case 2*

The second clinical case refers to an 8-year-old male patient, who presented unilateral posterior crossbite on the left side and anterior crossbite. First permanent molars and deciduous canines were in Class III relationships bilaterally. Treatment began in May 2022 and extended to March 2023, lasting a total of 306 days. Unlike the first case, this patient required an additional month of treatment due to the orthodontist's assessment of the therapy's progress. Throughout this period, the monitoring system captured data for 95% of the total therapy days, reflecting a high degree of reliability in sensor performance (Figure 12).

However, some issues were noted in October, when the bolts securing the midline bar began to loosen, causing discomfort, particularly at night. The patient occasionally woke to find that the facemask had shifted during sleep, and in some cases had completely fallen off by morning, leading to gaps in data collection for those specific days. This condition is reflected in terms of physical comfort. Indeed, from an overall point of view, the patient did not report any skin irritation on the forehead, mouth, or its angles. However, after three months of therapy, he did experience discomfort in the chin area. This contrasts with the first case, where skin irritations on the forehead and chin were reported early, but disappeared over time.

Interestingly, the recorded wear time from the sensors was slightly higher than the patient's self-reported hours. While the patient reported wearing the facemask for an average of 8.5 h per day, the sensor data indicated an average of 8.9 h. Furthermore, the patient consistently wore the facemask for at least six hours on 80% of the total therapy days. This small, but notable discrepancy might be explained by the fact that the patient may have underestimated his wear time or failed to account for periods when the facemask remained on for longer than anticipated, particularly during the night when he might not have been fully aware of the facemask's presence.

In terms of game engagement, this patient demonstrated a similar tendency to the first case by stockpiling coins to solve multiple quests in a single day. However, unlike the previous patient, this child encountered challenges within the game, particularly when trying to find the correct items to complete quests. Part of the quest narrative design (e.g., clues in texts or item descriptions) seemed to pose some difficulties for him, which may have affected his overall satisfaction with the game. In fact, after six months, the patient's gaming experience averaged consistently above 5.5 on a VAS ranging from 0 to 10. It was only by the end of therapy that he rated the game more favourably. This suggests that his initial frustrations with the game mechanics gradually gave way to a greater sense of achievement as he adapted to the dynamics of puzzle games. In addition, while the patient appreciated the design of the game characters, he was less impressed by the overall game arena and narrative, indicating that these elements could benefit from further enhancement to boost engagement (Table 7).

**Table 7.** Mean of the answers to the game experience questionnaire over 9 months on a scale from 0 to 10 (clinical case 2).

| Evaluation | Overall Game Experience | Game Characters | Game Arena and Storyline | Overall Feeling When Playing |
|---|---|---|---|---|
| Scale ranging from 1 to 10 | 6 | 8 | 7 | 7.5 |

In contrast to the first case, this patient demonstrated a high degree of autonomy throughout the entire therapy period, wearing the facemask independently from the outset. He reported never asking to take the facemask off, which shows a strong personal commitment to the treatment. However, parental involvement persisted throughout the therapy, providing consistent encouragement and reinforcing the importance of the treatment for his health.

## 7. Discussion and Limitations of the Study

Through the setup of the clinical study, patients engaged with the gamified elements of the *SuperPowerMe* system, and the positive outcomes observed in patient adherence—supported by both self-reported and sensor-derived data—suggest that when children perceive their therapy as a game rather than a duty, their willingness to engage increases. This shift in perception is particularly critical given the lengthy duration required for effective treatment, which can often lead to frustration and non-compliance. This statement is supported by evidence, as our study found that, except during the summer season, compliance remained largely stable during the first 9 months of treatment, while the mean wear time was 8.6 h. This aligns with the existing literature, which consistently shows that compliance realistically ranges from 7 to 9 h [30], even when 8 to 15 h of daily wear is recommended [31–50]

In addition, different studies have reported that patients tend to overestimate perceived wear time [30,31]. Our study reveals a consistent correspondence between self-reported wear time and sensor-derived data. This highlights the importance of objective monitoring in capturing wear time accurately to grasp misconceptions related to therapy protocol.

In conclusion, the two analysed cases during the clinical trial showed that the *SuperPowerMe* system facilitated a sense of autonomy and achievement, as the gradual decrease in parental prompts required for facemask use reflects a growing independence in patients. However, parental guidance persisted throughout the therapeutic period. Indeed, patients reported that parents' interventions were in the form of verbal incentives and explanations, rather than physical rewards. This underscores the importance of embedding motivational strategies within the therapeutic framework to support and maintain patients' compliance.

The gamification strategy was effective, particularly thanks to the superheroes' design, which facilitated patients' mirroring process with them. Tables 6 and 7 show the appreciation of the patients of the game characters. Superheroes and their mythologies hold a unique appeal for children, offering relatable figures who solve problems, overcome challenges, and achieve success in ways that children often aspire to, but cannot yet achieve themselves. These characters capture children's imaginations effortlessly. Studies demonstrated that children engage more in playing with superhero characters rather than with non-superhero toys [50].

This flexible and imaginative approach opens countless possibilities for therapeutic engagement, leveraging the endless potential of both superheroes and the human imagination.

Patient engagement with the game was generally positive, although more trials are necessary to fully assess the effectiveness of the game.

## 8. Conclusions

Through the setup of the clinical study, patients engaged with the gamified elements of the *SuperPowerMe* system, and the positive outcomes observed in patient adherence—supported by both self-reported (Tables 6 and 7) and sensor-derived data (Figures 11 and 12)—suggest that when children perceive their therapy as a game rather than a duty, their willingness to engage increases. This shift in perception is particularly critical given the lengthy duration required for effective treatment, which can often lead to frustration and non-compliance. This statement is supported by evidence, as our study found that, except during the summer season, compliance remained largely stable during 9 months of treatment, while the mean compliance wear time was 8.6 h. This aligns with the existing literature, which consistently shows that compliance realistically ranges from 7 to 9 h [31–51], even when 8 to 15 h of daily wear is recommended [32–52].

In addition, different studies have reported that patients tend to overestimate perceived wear time [31,32]. Our study reveals a consistent correspondence between self-reported wear time and sensor-derived data. This highlights the importance of objective monitoring in accurately capturing wear time to grasp misconceptions related to therapy protocol.

In conclusion, the two cases analysed in the clinical trial demonstrated that the *SuperPowerMe* system fostered a sense of autonomy and accomplishment, as evidenced by the gradual reduction in parental prompts needed for facemask use, indicating increased patient independence over time. Nonetheless, parental guidance remained necessary throughout the therapeutic period. Patients indicated that parental involvement primarily took the form of verbal encouragement and explanations, rather than physical rewards. This highlights the importance of incorporating motivational strategies into the therapeutic framework to effectively support and sustain patient compliance.

The gamification strategy proved effective, largely due to the design of the superheroes, which facilitated a mirroring process between patients and the game characters. Up to now, the project has aimed to test the functional and experiential effects of both the customised mask with 10 patients and the customised mask associated with the use of the game with 2 patients. Although the results obtained are positive and encouraging in both cases, it is difficult to assert how much of these results are due to the customised mask and how much to the association with the game. However, the results of the questionnaire relating to the gaming experience, the design of the superheroes, and the setting and storytelling show that the use of the game has contributed positively to maintaining a constant level of compliance with the therapy. Since this is a therapy that lasts a rather long time, it is important to try to stimulate and maintain the collaboration of the patients, making them feel 'special' during this journey that can be painful and stigmatising.

## 9. Patents

The project is covered by patent number 102018000002713; inventors: Professor Cecilia Goracci, Professor Patrizia Marti, Professor Lorenzo Franchi, Ing. Matteo Sirizzotti, Professor Alessandro Vichi.

**Author Contributions:** Conceptualisation: P.M.; game design: P.M. and G.T.; methodology for the clinical trials: C.G. and L.F.; analysis and discussion of results: C.G. and L.F.; writing—original draft preparation: G.T. and P.M.; writing—review and editing: P.M., G.T., C.G. and L.F.; visualisation:

G.T.; project administration: P.M.; funding acquisition: P.M. All authors have read and agreed to the published version of the manuscript.

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**Data Availability Statement:** The raw data supporting the conclusions of this article will be made available by the authors on request.

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