

Article

A Wearable Device Employing Biomedical Sensors for Advanced Therapeutics: Enhancing Stroke Rehabilitation

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Abstract: Stroke is a leading cause of disability worldwide. The long-term effects of a stroke depend on the location and size of the affected brain area, resulting in diverse disabilities and experiences for survivors. More than 70% of people experiencing stroke suffer upper-limb dysfunction, which can significantly limit independence in daily life. The growing strain on national healthcare resources, coupled with the rising demand for personalised, home-based rehabilitation, along with increased familiarity with digital technologies, has set the stage for developing an advanced therapeutics system consisting of a wearable solution aimed at complementing current stroke rehabilitation to enhance recovery outcomes. Through a user-centred approach, supported by primary and secondary research, this study has developed an advanced prototype integrating electromyography smart sensors, functional electrical stimulation, and virtual reality technologies in a closed-loop system that is capable of supporting personalised recovery journeys. The outcome is a more engaging and accessible rehabilitation experience, designed and evaluated through the participation of stroke survivors. This paper presents the design of the therapeutic platform, feedback from stroke survivors, and considerations regarding the integration of the proposed technology across the stroke pathway, from early days in a hospital to later stage rehabilitation in the community.



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Keywords: stroke; rehabilitation; smart sensors; electromyography; functional electrical stimulation; user-centred design; digital health; med-tech; virtual reality

1. Introduction

Stroke is one of the leading causes of disability, and the second most common cause of death worldwide [1,2]. Depending on the size and location of the stroke, survivors can present with a variety of symptoms. The middle cerebral artery (MCA) is the most commonly affected vessel, which is the major vascular supply to the area of the brain responsible for the upper limbs [3]. According to the Stroke Association [4], 70% of stroke survivors present with lasting symptoms of functional difficulty within the upper limbs. This loss in motor and sensory control of the upper limbs can lead to potential alterations of muscle length and strength and the inability to engage in fine or dextrous hand movement, which is essential for bimanual tasks that affect function and therefore, quality of life [5].

Taub et al. [6] coined the term *learned non-use* to describe the phenomenon whereby people recovering from neurological insult, such as stroke, learn to compensate for the loss

in function of the affected upper limb, and as such, no longer attempt to use it for everyday activities. After a sufficient period without using this limb, the muscles atrophy, and the efficiency of the motor areas of the brain corresponding to this limb will fade [7]. Conversely, the ability of the brain to re-adapt and re-adjust to form new connections in response to local injury and received neural input is known as neuroplasticity [8]. These changes are regulated by the “use it or lose it” principle [9]. In other words, high-repetition movements produce a high level of motor input and output to and from the brain. This elicits the formation of neural pathways in the specific brain areas, i.e., those responsible for upper-limb movements. However, these newly formed pathways require regular motor input; otherwise, they may fade [9]. Therefore, maintaining a rehabilitation plan that reflects this biological need for high repetition exercise is crucial for recovery in stroke survivors until the affected limb has been successfully re-incorporated into daily function/tasks [8,10].

In a systematic review by Serrada, McDonnell, and Hillier [11], it was found that only 21% of inpatient therapy time for people post-stroke was devoted to the upper limbs. More specifically, this equated to 24% of occupational therapy sessions and only 15% of physiotherapy sessions. Likewise, less than 20% of patients in the United Kingdom receive the recommended level of upper-limb rehabilitation [12,13], with the upper limb largely deprioritised in place of balance and walking practise [14]. Other factors limiting upper-limb rehabilitation include organisational drivers such as pressure for quicker discharge times, a shortage of quality research, and the limited resources of the healthcare system [15]. In stroke units, in the average upper-limb-focused rehabilitation session, the number of repetitions for each movement ranges from 23 to 86 [16]. However, animal studies have shown that neuroplastic changes are not seen within the motor cortex until approximately 400 or more repetitions are completed [17]. In the absence of a sufficient rehabilitation programme for the upper limbs, stroke survivors will not be able to meet the number of repetitions required to induce and maintain the neuroplastic changes that bring about recovery [8,10]. This highlights the need to develop and implement effective therapy adjuncts to support functional recovery of the upper limb post-stroke, thereby reducing dependency and improving quality of life post-stroke.

Functional electrical stimulation (FES) is one of the therapy adjuncts recommended to increase functional recovery of the upper limb after stroke [14,18]. Electromyogram-triggered functional electrical stimulation (EMG-FES) has been developed to enable motor activity to synchronise with motor intention [19]. The EMG responds to the nerve signal at the neuromuscular junction, even in patients with severe paresis [20]. EMG-FES triggers a motor response, but also creates a sensory stimulus to the corresponding region of the brain. This motor and sensory stimulation can impact neuroplasticity, thus impacting the formation and maintenance of the neural pathways necessary for targeted function [21].

Another therapy adjunct gaining traction within the field of stroke rehabilitation is virtual reality (VR) devices. With VR technology, users immerse themselves in fully interactive artificial worlds through goggles [22]. VR can deliver engaging and task-specific exercises in a supportive environment by providing multimodal (visual, auditory, and proprioceptive) feedback [23]. This gives clinicians the ability to prescribe a rehabilitation programme that is entertaining for the user and can replicate common therapy exercises, as well as mirroring everyday functional tasks. This makes it possible to personalise rehabilitation sessions by practising a task that is relevant to each person’s goals, while being able to control the sensitivity and difficulty through controlled virtual parameters. A combination of EMG-FES and VR opens the opportunity for stroke survivors with a range of impairments to enjoy the therapeutic effect of VR by reducing the effort required when carrying out activities [23]. Thus, the combination of FES and VR provides patients

with an engaging strategy of attaining the necessary intensity and repetition that their rehabilitation requires.

The paper is structured into six main sections. Section 2, Related Work, provides a critical evaluation of previous research in the field. Section 3, Methods, outlines the research methodology, including the aims and objectives of the developed system, an overview of the interdisciplinary expertise of the team, and participant recruitment details. Section 4, Results, presents key insights derived from interviews with stroke survivors, including design personas, rehabilitation experiences captured through user journeys, and product requirement specifications based on both primary and secondary data. Section 5, System Development and Evaluation, details the iterative design and evaluation of the advanced therapeutics system, covering its key components such as sensors, functional electrical stimulation (FES), virtual reality (VR), wearable technology, and the companion app. Finally, Sections 6 and 7 provide a discussion and the conclusions of the study, including limitations and further work.

2. Related Work

2.1. The Stroke Rehabilitation Pathway

Following a stroke, clinical guidelines [14,24] recommend that rehabilitation be commenced as soon as the person is medically stable. Instigating rehabilitation early after stroke is important, as the first six months post-stroke are characterised by heightened levels of potential for neuroplastic change [25]. Treatments that help to capitalise on this window of optimised recovery involve physical, functional, and cognitive rehabilitation and can be provided on an in-patient, in the home (through day programs), or in the community basis, depending on the needs of the person and the available facilities and resources of the healthcare system [14].

The user journey normally starts at the hyper acute stroke unit (HASU), where the goal is to achieve the medical stability of the patient and to determine the underlying cause of the stroke as soon as possible [26,27]. Stroke survivors typically stay in a HASU for 1–3 days, and those requiring further treatment are transferred to their local acute stroke unit (ASU), where in-patient rehabilitation is provided by the multidisciplinary team. Alternatively, patients are transferred directly home, with treatment from the stroke early supported discharge (ESD) team. Depending on the complexities of the person's needs and/or goals, they can be further transferred to a Level 2 (more complex care) or Level 1 (most complex care) rehabilitation unit for specialist in-patient rehabilitation. Community rehabilitation teams may also see stroke survivors if they have ongoing needs (see Figure 1).

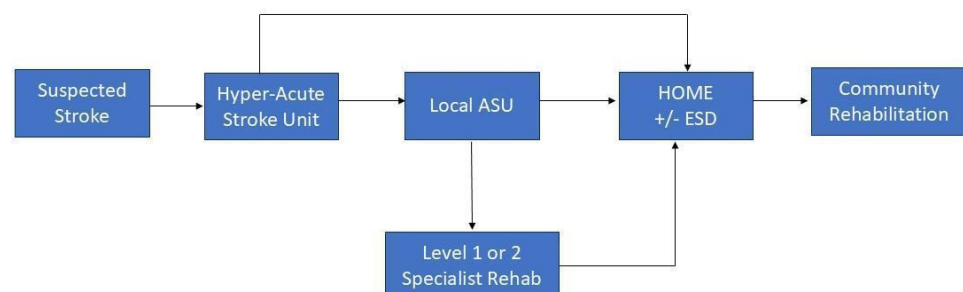


Figure 1. Pathways for rehabilitation following stroke. ESD = early supported discharge; ASU = acute stroke unit.

The National Institute for Health and Care Excellence (NICE) guidelines recommend that stroke survivors in the United Kingdom receive a minimum of three hours of daily rehabilitation at least five days per week [14]. This includes occupational, speech, and physiotherapy services. Sessions are suggested to address strength and functional deficits,

pain, activity limitation, cognition, and overall mental health. FES is further recommended as a therapy-adjunct for those presenting with inferior shoulder subluxation, strength deficits of 3 or less on the Oxford Muscle Scale (OMS), or for strength deficits in the wrist and finger extensors or ankle dorsiflexors (muscles located in the dorsum of the foot) which impact function [14].

There is no definitive evidence on what comprises a high-quality rehabilitation plan or the best therapeutic approach for recovery of the upper limbs post-stroke. However, therapeutic approaches and/or treatment modalities that involve progressive recruitment of motor units, repetitive re-training of motor skills combined with sensory interventions, and practice of functional tasks over weeks or months with high dose (at least 2 h per session) have been associated with better recovery [28–34]. A single-blinded randomised intervention study by Daly et al. [33] examined the effect of long-dose intensive therapy on upper-limb function and any gains retained in moderate and severely impaired chronic stroke survivors ($n = 36$). Results from 300 h of therapy over 12 weeks (5 h per day, 5 days/week) showed a statistically and clinically significant improvement in the Fugl-Meyer score (mean gain = 5.1 points; 95% CI 3 to 6; $p < 0.0001$; effect size(d) 0.59) compared to the results for 150 h of therapy (mean gain = 4.7 points; 95% CI 4 to 6; $p < 0.0001$; effect size(d) 0.54) which was sustained 3 months post-treatment ($n = 31$; mean gain = 9.4 points; 95% CI 5–13; $p < 0.0001$; effect size(d) 0.61). This highlights the need, importance, and potential benefit of increased therapy time.

Intensity is another important theme in post-stroke upper-limb rehabilitation that is rarely or inconsistently defined across studies [29,35] but which forms an important component of neuroplasticity [36] and motor re-learning [37]. Intensity is defined as the perceived level of difficulty of an activity based on a person's ability and/or the conditions under which the task is performed [37–39]. Different techniques have been proposed to determine the appropriate level of intensity for maximising motor learning in stroke survivors [37,39,40]. The consensus is to employ a level of training that maximises performance by identifying current ability and providing progressively difficult, yet achievable functional tasks, without eliciting compensation. This allows for sensorimotor feedback, implicit error detection, and motor strategising [37,39,40]. Technology-based innovation offers the opportunity for users to adjust intensity through detailed guidance provided by the data analysis performed by the device. This is further explored in the article.

2.2. Innovation in Stroke Rehabilitation

An interesting and developing paradigm in stroke rehabilitation is the use of existing and emerging technologies (e.g., robotics, EMG-FES, virtual reality, etc.) to help drive and support neuroplasticity and motor learning in a cost-effective manner [30,34]. Recent studies and guidelines have recommended exploring the synergistic effects of combining these technologies in post-stroke upper-limb rehabilitation [14,30,34,35]. This is important, given that the global burden of stroke is expected to rise, and there are limited resources in healthcare systems, along with an increasing demand for ways to support rehabilitation. This study explored the process of designing a therapeutic device for the upper-limbs post-stroke that combines virtual reality with EMG-FES in a single device using a user-centred design approach.

3. Methods

3.1. User-Centred Design Approach

User-centred design (UCD) is an approach that actively involves end-users throughout the development process to uncover value propositions and create technology devices that directly address user needs. In healthcare, there is a growing emphasis on engaging

end-users—especially patients—in the design of medical devices, a priority reinforced by NHS publications that highlight the value of a user-centred approach for enhancing care quality [41]. Previous research underscores that the successful use of healthcare devices hinges on user acceptance, which is more likely when users are engaged in the design process [42].

This study implemented a UCD approach that prioritised the needs of stroke survivors, followed by those of their carers. Embedding safety, effectiveness, efficiency, and learnability in the wearable rehabilitation device was paramount to this study, as the team aimed to support stroke survivors' rehabilitation, including in unassisted settings. The practical application of a UCD approach is detailed in the following sections. Given the gap identified in design literature regarding the meaningful involvement of users in the development process [43], the following sections provide a detailed description of participant involvement in the study methods. An overview of the research design is reported in Figure 2 below, highlighting the three key components in the approach: desk research, primary research, and iterative design and evaluation with stroke survivors.

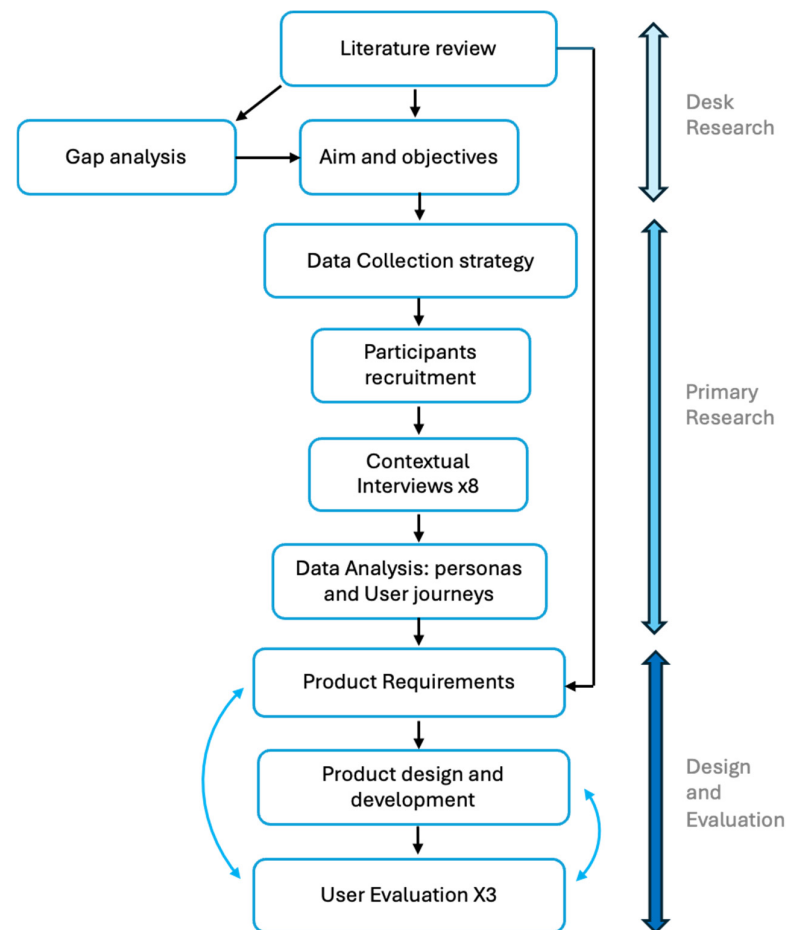


Figure 2. Research design.

3.2. Aim and Objective for the Advanced Therapeutics Platform

The wrist is an important focus in post-stroke rehabilitation, as it plays a critical role in functional hand and arm movements, including gripping, lifting, and manipulating objects. Stroke survivors often experience spasticity, weakness, or reduced motor control in the wrist and hand, which can significantly affect their ability to perform daily activities independently [44]. For these reasons, the aim of the project became to design and develop

advanced therapeutics for the support of upper-limb rehabilitation, specifically for the following three muscle groups: wrist extensors, ulnar deviators, and radial deviators.

In considering the upper-limb rehabilitative aim of the project that the device was required to support, the team also took into account the latest guidelines for stroke rehabilitation issued by the Intercollegiate Stroke Working Party [14]. The instrumental objectives of the project, selected on the basis of the latest guidelines were as follows:

- Significantly increasing rehabilitation time offered to stroke survivors from 45 min per day to three hours per day, five days a week (4.2A).
- Supporting those unable to exercise against gravity independently through additional support (such as neuromuscular or functional electrical stimulation) to enhance their participation in exercise training (4.17G).
- Integrating repetition of functional tasks and targeted exercise in the therapeutic platform, since it leverages neuroplasticity (4.18).

3.3. *The Interdisciplinary Research and Development Team*

The interdisciplinary development team for the project comprised five key skill areas:

- Stroke rehabilitation and physiotherapy: Experts in post-stroke care and rehabilitation were included to ensure that the solution aligned with clinical best practices and effectively addressed the needs of stroke survivors.
- Design and product development: Specialists in creating and refining the physical and digital aspects of the solution ensured that functionality, usability, and experience were included in bringing the concepts to market.
- Technology and engineering: Team members with technical expertise in advancing designs from concept to implementation were involved to integrate innovation and ensure reliability in the final product.
- Innovation and commercialisation knowledge: Professionals with expertise in understanding market trends, consumer needs, and the competitive landscape were included, ensuring that the product was viable and met real-world demands.
- Expert users (stroke survivors): Involving individuals with lived experiences provided invaluable insights into user needs, preferences, and challenges. Stroke survivor carers took part in the study to provide their perspective on the system's requirements.
- Stroke survivors advocate: a charity in North West London supported the recruitment of participants to the study and advised on optimising the design of data collection tools to provide an educational, yet comfortable, experience to stroke survivors.

3.4. *Recruiting Representative End Users*

The study recruited 11 participants through convenience and snowball sampling from a single stroke charity (Different Strokes West London Group). Two of the primary researchers were randomly allocated to interview four participants each, analyse the data, and extract insights for the design and development stage. The third researcher undertook a thematic analysis of the interviews and engaged with three additional stroke survivors in the usability testing of the prototypes. The research team travelled to a venue provided by the charity to undertake the interviews, thus ensuring a familiar and comfortable setting for the participants. Participants were also offered the opportunity to have a 'communication buddy', often their carer, if they felt unsure about their ability to communicate in the study. Participants were not paid for their participation in the research, but received a GBP 20 voucher as a token of thanks.

The study received ethics approval by the University Research Ethics Committee prior to the engagement with the participants. Inclusion criteria for the selection of study participants were as follows:

- Adults (18 years or over) who have had a stroke;
- Individuals capable of providing informed consent;
- Stroke survivors who have experienced and/or currently experience problems with moving their upper limbs;
- Adults with sufficient communication skills to take part in the interview.

Exclusion criteria comprised significant dysphasia, lack of capacity to give consent to participate in the study, and the presence of significant cognitive problems. Table 1 captured some of the key attributes of the study participants.

Table 1. Participant characteristics.

	Pseudonyms	Gender	Time from Stroke	Length of Stay in Hospital (Total Time Spent In-Patient)	Most Affected Upper-Limb Joint(s)
User Research Phase					
Participant 1	Cate	Female	151 months (13 years)	16 weeks	Left elbow
Participant 2	Arthur	Male	14 months	1 week (self-discharged)	Right hand
Participant 3	Lace	Female	20 months	8 weeks	Right elbow, wrist, and hand
Participant 4	Maya	Female	18 months	12 weeks	Right wrist and hand
Participant 5	Jan	Female	113 months (9.5 years)	22 weeks	Right hand
Participant 6	Michael	Male	66 months (5.5 years)	1 week	Left shoulder
Participant 7	Kelly	Female	16 months (1.5 years)	5 weeks	Left wrist and hand
Participant 8	Angela	Female	17 months (1.5 years)	1 week	Right arm; all joints equally affected
Evaluation Phase					
Participant 1	Theo	Male	54 months (4.5 years)	13 weeks	Left arm and hand
Participant 2	Adam	Male	120 months (10 years)	17 weeks	Right arm and hand
Participant 3	Jan	Female	113 months (9.5 years)	22 weeks	Right hand

4. Results

4.1. Identifying Intended Users (Persona)

Personas are fictitious, archetypal representations of users. They are created based on real observations and insights from actual users [45]. The creation of persona in design is a process that aids the designers in contextualising their initial user research and in better understanding their audience's goals, behaviours, needs, and pain points, creating a user-centred approach to product or service development [46]. Two personas were identified based on the profile information of the 11 study participants:

Alison, a 64-year-old woman, suffered a severe stroke eight months ago. She spent two months in an acute stroke unit (ASU), where she received limited rehabilitation, primarily in group settings, due to constrained clinical resources. During her inpatient care, functional electrical stimulation (FES), a therapy known to support motor function recovery, was not implemented. This was attributed to the perceived complexity and the time required for accurate electrode placement. Now at home, Alison has begun FES-based rehabilitation. However, she struggles to place the FES electrodes correctly, a task made difficult by her reduced dexterity in the affected arm. Her partner, although willing to assist, lacks proper guidance and training, adding to the challenges of correctly setting up the device for effective therapy.

Benjamin, a 53-year-old man, suffered a mild stroke two years ago. His hospital stay was brief, lasting only a week due to the less severe nature of the stroke. However, in the years since, Benjamin has struggled to manage his recovery independently at home. He faces challenges in maintaining motivation and engagement with his rehabilitation exercises. Lacking consistent support, he finds it difficult to stay on track with his recovery regimen, which has led to a gradual decline in the use of his affected arm. The absence of engaging rehabilitation tools further compounds his struggle, as the exercises feel monotonous and lack the stimulation needed to keep him motivated. Despite his initial progress, Benjamin now finds himself at risk of losing further function in the affected arm due to a lack of sustained effort and guidance.

4.2. Patients Experience with Post-Stroke Rehabilitation

The rehabilitation experiences of the user personas, Allison and Benjamin, expose significant gaps in post-stroke recovery systems and pathways like those shown in Figure 3. Allison benefits from structured hospital support within the hyper acute stroke unit (HASU) and in the acute stroke unit (ASU), where she notices improvements in her symptoms. Upon discharge, she transitions home without early supported discharge (ESD) and struggles with unclear exercise guidance. Over time, she joins a community rehabilitation programme, aiding long-term recovery, although she ultimately misses the optimal neuroplasticity window.

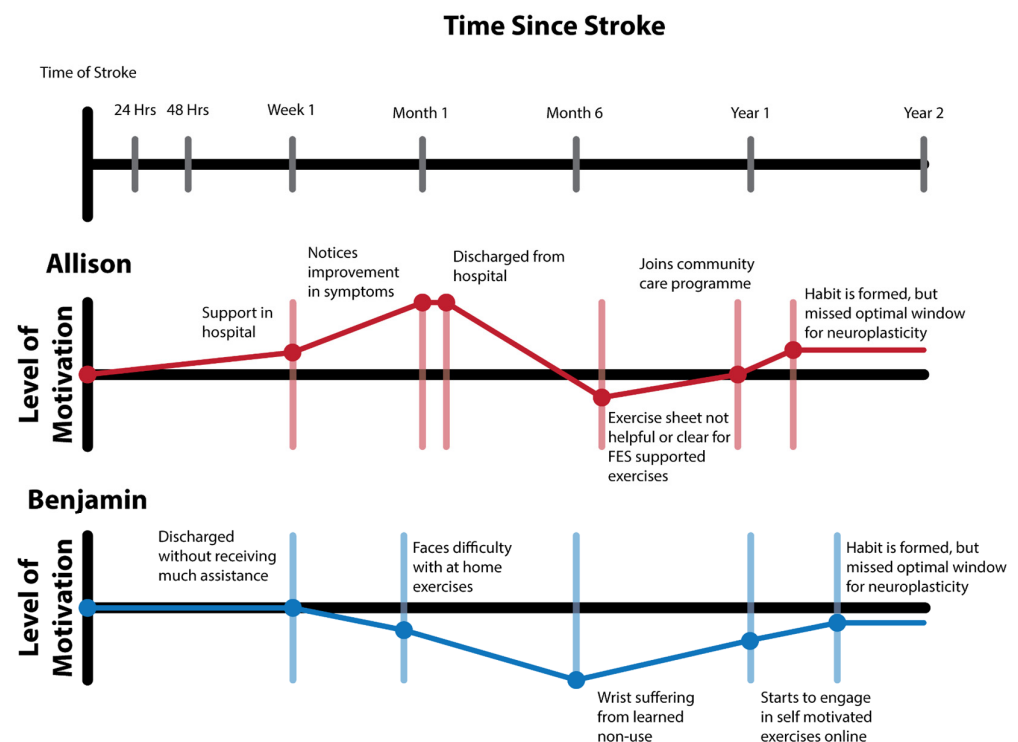


Figure 3. User journeys of the two design personas identified in the study. Cate (participant 1), a female stroke survivor, described her inpatient journey below.

In contrast, Benjamin, who had a mild stroke, was discharged without receiving much structured assistance. Without adequate support, he faces challenges in adhering and progressing with his home exercises, leading to learned non-use of his hand. Eventually, Benjamin engages in self-directed online exercises, gradually improving, although like Allison, he also misses the optimal neuroplasticity window. Both cases emphasise the critical need for clear, accessible, and timely rehabilitation support to sustain motivation and optimise recovery trajectories, particularly through structured interventions during

and after the patients' time in hospital. Figure 3 displays the user journeys of the two design personas identified in the study. The level of motivation and the timeline of stroke survivors pathway represent, respectively, the vertical and the horizontal dimensions in the figure. Declines in the motivation level are characterised as user pain points.

"... I went to the hyper acute stroke unit after my stroke and I was there for about three or four days. And then I went to the stroke ward back to the local hospital... they decided I would benefit from rehabilitation. So, I went to a regional rehabilitation unit... All together, my experience was four months in a hospital."

4.3. Product Specifications

The product requirements for a solution supporting post-stroke rehabilitation were defined based on the personas' needs and findings from primary and secondary research. The identified essential and desirable requirements include the following.

Essential:

- Increase the number of repetitions performed by users to enhance rehabilitation outcomes, promoting muscle strengthening and motor learning [8,10,16,17].
- Initiate and support wrist extension, as well as ulnar and radial deviation, through cyclic FES, targeting key muscle groups essential for daily activities and functional independence [44].
- Utilise FES to facilitate muscle movement in the upper limb, enabling users to regain control and strength in their affected limb [19–21].
- Serve as an adjunct to existing rehabilitation programs, seamlessly integrating into current clinical practices and home-based exercises [14].
- Enable independent use and compatibility with supervised therapy sessions, providing flexibility and accommodating diverse user needs and preferences [47,48].
- Take into account existing comorbidities of user group, potential adverse effects, and contraindications
- Promote neuroplasticity to achieve functional improvements by stimulating the brain and encouraging the formation of new neural pathways [8,10,19,21].

Desirable:

- Incorporate goal-oriented tasks and/or gamification elements through integration with the existing VR system, enhancing user engagement and motivation during rehabilitation [48,49].
- Track progress and provide data accessible to medical professionals for monitoring and evaluation, allowing for personalised feedback and adjustments to the rehabilitation plan [48,50].

5. Development and Iterative Evaluation

To ensure that the proposed solution was beneficial and effective, the development process, from concept design to advanced prototypes, revolved around an iterative evaluation with primary (stroke survivors) and secondary stakeholders (carers, occupational therapists, and physiotherapists). The initial evaluation, at the stage of concept generation, consisted of less structured conversation considering the wearability, intuitiveness, and usability of the potential device. Such evaluation sessions became more structured as the form and functions of the device became more precise.

In addition to the ongoing support of clinicians actively involved in the design team, the final round of evaluation included three stroke survivors with varying levels of upper-limb impairment. The evaluation sessions were video recorded for accuracy of analysis.

A task-based protocol [51] was implemented, followed by the development of task analysis trees for each executed task. This approach was applied because it effectively addresses the identification of usage errors and performance malfunctions [52].

Task 1 consisted of the use of testing traditional FES pads. Participants were asked to set up the hydrogel pads of a traditional FES device. This task was timed and used as a control to evaluate the usability of the smart sensor concept in tasks 2 and 3.

Task 2 required participants to put the prototyped sleeve on their affected arm. Following a demonstration from the researcher, the participants put on the wearable prototypes twice to also identify optimization strategies used in donning. This task was timed.

The participants were asked to put on two variations of the wearable prototype; the first prototype utilised a two-strap fastening to ensure that there was constant contact of the fabric electrodes on the skin, whilst the second prototype was fashioned on a compression sleeve, where the user would slide the device onto their forearm, rather than fasten it. Table 2 presents the time taken by users to apply wearing existing FES hydrogel pads compared to two prototype designs.

Table 2. Participants' timings for applying wearable traditional hydrogel FES pads (control), wearable devices with straps (sleeve 1), and slip-on wearable devices (sleeve 2).

Participants	Control Test (s)	Sleeve 1 (s)	Sleeve 2 (s)
Theo	78	73	43
Adam	56	52	40
Jan	58	51.5	14

The final task aimed at understanding the participants' understanding of the device control unit, the puck. Following a brief explanation on how to turn on the device and how to switch between function modes, the participants engaged in a 'thinking aloud' task [53], verbalising the thought process guiding their decisions when interacting with the device.

The analysis of the qualitative comments from the Think Aloud task suggest a desire for the users to feel in control of the device and of its functions. This was evidenced by the unanimous preference for the puck, which had manual override controls of the muscle location feature and FES intensity on the device itself. In addition, high contrast controls buttons were preferred, as they could be easily spotted by participants with limited or impaired vision. Fabric electrodes embedded in the sleeve were preferred, as they did not press or irritate the skin.

5.1. Technical Specifications

The wearability and comfort of the device presented significant challenges during its development. Similarly, the identification, development, and integration of the technical elements required for the advanced rehabilitation proved to be equally complex. The design process considered how the device would fit comfortably on the user's arm, while also ensuring that the electronic components and sensors would function effectively. The resulting design is a sophisticated piece of technology that utilizes key electronic and sensor technologies to achieve its functionality.

The sleeve incorporates FES to stimulate muscle contractions, EMG sensors to detect muscle activity, and a microcontroller for real-time data processing and control. These components are coupled with a VR platform or a companion app, creating a comprehensive rehabilitation system. The stroke survivor can use Nura, the name given to the system, alone, guided by clinical staff during in-person sessions, or can access the Reneural platform, the gamified rehabilitation system, through the use of the VR and companion app, as displayed in Figure 4.

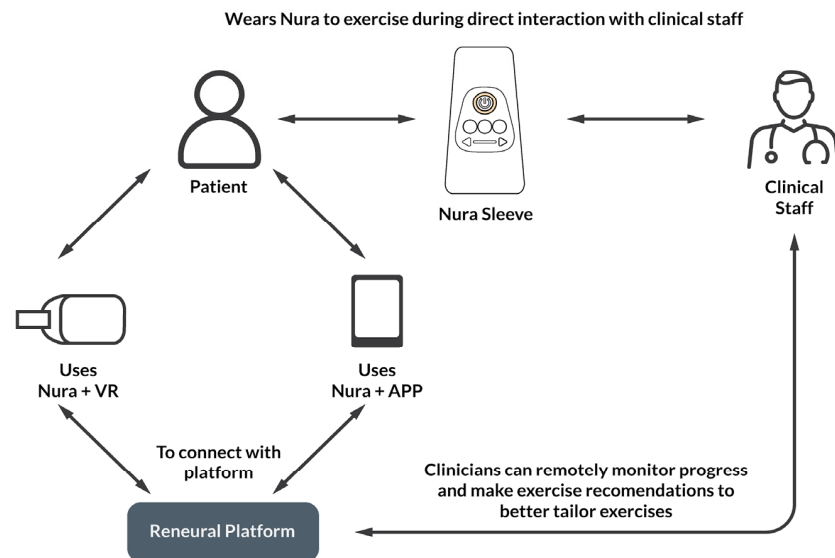


Figure 4. Configuration of the entire stroke rehabilitation system.

The following sections will describe the technological components in detail, explaining how Nura has integrated them into a cohesive and effective rehabilitation tool.

5.2. Microcontroller

The Nura puck was developed using a system-on-chip (SoC). The ESP32 was selected for its high processing power, reliable connectivity, and scalability, making it suitable for integration in rehabilitation technologies where precision control is required. The dual-core processor of the ESP32 allows for efficient multitasking, which is crucial for real-time data processing from the VR to which Nura connects to engage in gamified rehabilitation and the EMG sensors required to detect existing skeletal muscle signals. The microcontroller's integrated WiFi and Bluetooth capabilities enable connectivity across various platforms, such as Android, iOS, Windows, and VR systems. Figure 5 shows the Nura puck, where the function controls are visible on the user product interface.

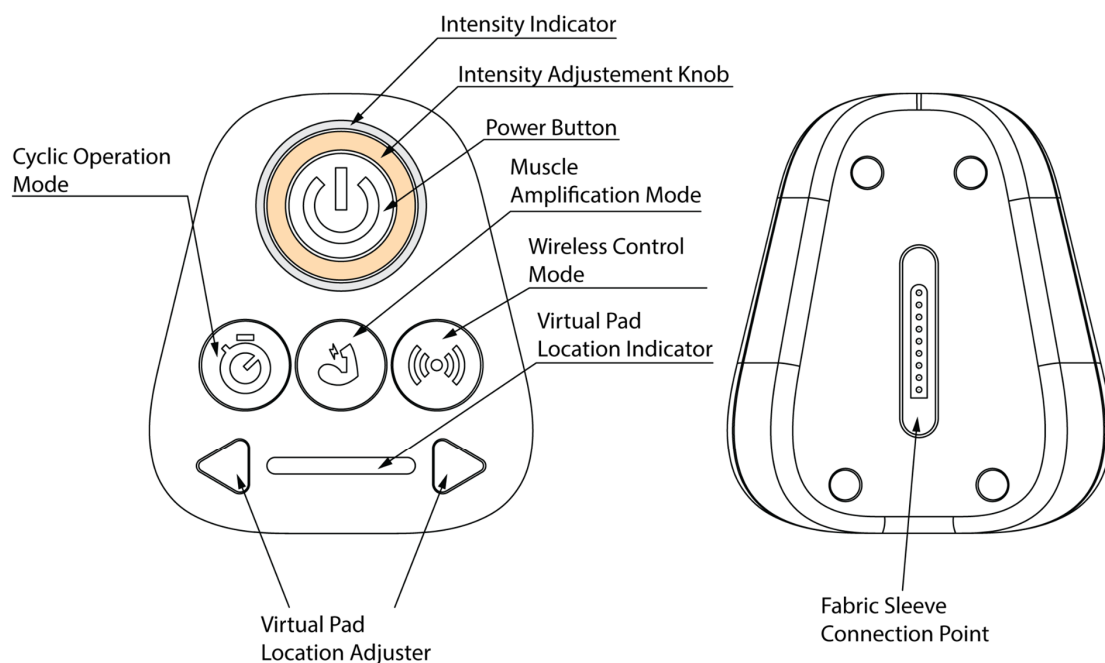


Figure 5. Nura puck's interface.

The ESP32 also supports Edge AI, allowing for the execution of lightweight machine learning models directly on the device. This functionality enables on-device analytics and adaptive responses, which are essential for processing data from VR and EMG sensors in real time. Real-time processing is not feasible with cloud-based solutions due to inherent latency issues, making on-device processing crucial for effective rehabilitation applications. Figure 6 demonstrates the integration of the puck with the wearable sleeve.

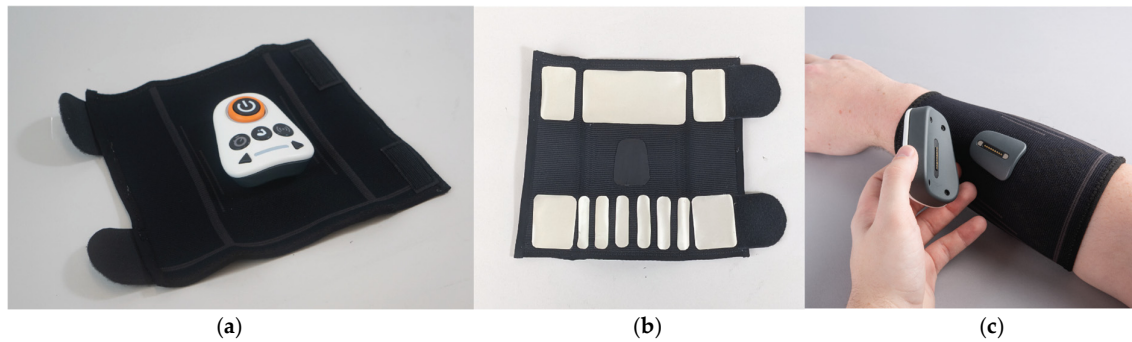


Figure 6. Nura sleeve with attached puck (a); current FES electrode array on underside of sleeve (b); Nura puck being placed onto fabric sleeve on arm (c).

5.3. FES

Functional electrical stimulation was chosen over other technologies, such as pneumatic systems, due to its ability to prevent muscle wastage, reduce device complexity, and integrate with electromyography. The recent development of multi-pad fabric electrodes [54,55] have improved selectivity in muscle activation, allowing for more precise targeting of specific muscles [56]. They also offer enhanced user comfort, as the system is fabric-based and acts more like a traditional garment [57]. Most importantly here, however, is the ability to simplify the pad application process, saving time, in order to enable easier donning, especially for those with limited dexterity.

The innovation integrated in Nura aims to stimulate the wrist extensors, as well as the radial and ulnar deviator muscle groups, which together control the movement of the wrist. The use of a multi-pad electrode has enabled one of the core advancements in the Nura sleeve: the creation of virtual electrodes. A virtual electrode is a location between the physical electrodes where stimulation is experienced. By superimposing electrical stimulation from multiple electrodes and adjusting stimulation intensities, the virtual electrode position can be dynamically altered to target specific motor units or muscle fibres. This allows for customisable and precise muscle activation without the need for exact physical placement of the electrodes. The FES system compensates for minor misalignments of the pads by leveraging the virtual electrode, ensuring effective stimulation, even under suboptimal conditions. This approach enhances usability and adaptability, providing a more user-friendly and efficient method for wrist movement rehabilitation. Figure 7 demonstrates the location of the FES pad around the user's upper arm when Nura is worn.

5.4. Electromyography Sensors

Electromyography (EMG) is a technique for evaluating and recording the electrical activity produced by skeletal muscle in the body [58]. As stroke rehabilitation focuses on redeveloping the voluntary control and functionality of the weak arm, EMG offers a unique way of enhancing existing forms of rehabilitation. According to recent research [59], EMG must be coupled with other forms of therapy, such as robots, VR, FES devices, or mirror therapy, in order to improve neuroplasticity and motor function.

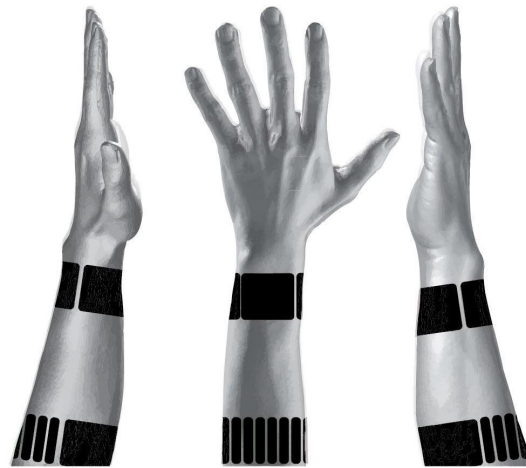


Figure 7. Visualisation of exact location of FES pads when Nura is worn.

When combined with EMG, FES systems can operate in a responsive, closed-loop manner, where electrical stimulation is triggered based on the patient's voluntary muscle activity [60,61]. This feedback loop and synchronization facilitate personalised rehabilitation based on individual muscle electrical activity detection and consequent cognitive response. This means that neuroplasticity is further supported, enabling the brain to reorganize and strengthen neural pathways essential for recovering more efficiently [62].

The system operates by detecting muscle activity through EMG sensors, which measure the amplitude and duration of muscle signals. If the EMG signal is insufficient to achieve the desired movement, functional electrical stimulation (FES) is triggered to stimulate the appropriate muscles; a visualisation showing the relationship between voluntary muscle activity and FES can be seen in Figure 8. The stimulation signal is generated based on the EMG activity, the target muscles, and the required movement, ensuring that the user receives the necessary assistance. Throughout this process, virtual reality (VR) sensors continuously monitor whether the desired action has been successfully performed. Once VR confirms that the movement is complete, the FES stimulation automatically stops, preventing unnecessary activation. This closed-loop system ensures that electrical stimulation is applied only when needed, making it an adaptive and responsive rehabilitation tool. The equation below captures the closed-loop system implemented in the designed system.

$$S(t) = \begin{cases} K(A_e + T_e + M_r + M_s + D_a) & \text{if } V_{fb} = 0 \\ 0 & \text{if } V_{fb} = 1 \end{cases}$$

S = electrical stimulation signal (activation level)

K = scaling factor (adjusts the strength of the stimulation)

A_e = EMG signal amplitude (mV)

T_e = EMG signal duration (s)

M_r = muscle activation level from the EMG source (normalised from 0 to 1)

M_s = muscle activation needed for the stimulation (normalised from 0 to 1)

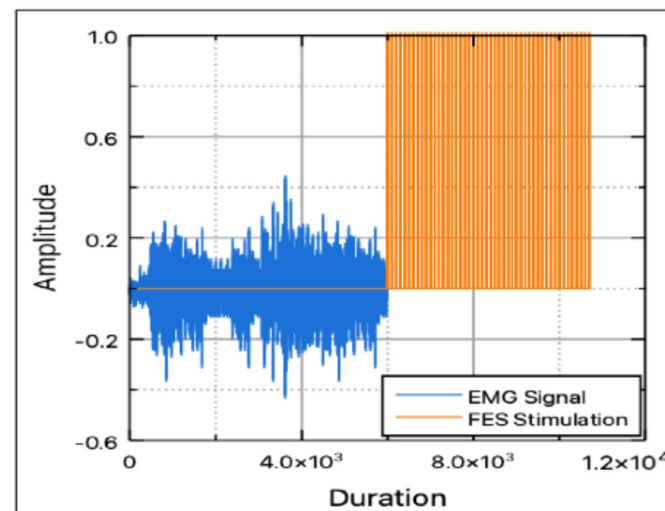
D_a = action difficulty level (scaled from 0 to 1)

V_{fb} = VR feedback (1 = action complete; 0 = action not complete)

In Table 3, the procedure employed by the system in order to achieve a closed-loop EMG-FES system is explained.

Table 3. Procedural steps to achieve closed-loop EMG-FES.

Step	Condition	Action Taken
1. Detect EMG activity	A_e is detected but weak	Wait for strong enough EMG signal
2. Check VR feedback	$V_{fb} = 0$ (movement not achieved)	Prepare to trigger FES
3. Apply FES	A_e is too low and M_s needs activation	Stimulate target muscle
4. VR confirms movement	$V_{fb} = 1$	Stop FES

**Figure 8.** Electromyographic (EMG) activity of a muscle during functional electrical stimulation (FES).

For example, when a patient attempts wrist extension, EMG sensors detect initial muscle activity, even if the movement is weak. As this signal can vary daily based on the user's voluntary control or the progression of her rehabilitation, additional data are required to effectively adapt the therapy. Whilst previous research [63] has integrated angle sensors to track wrist position data, the proposed system can integrate the hand tracking capabilities using modern VR headsets [64], as described above. Based on the combined input from the EMG sensors and the VR headset, the Nura sleeve triggers FES at the onset of the user's effort, stopping the FES stimulation when the VR headset confirms movement. This real-time adjustment of the FES ensures that the user receives the appropriate amount of stimulation based on their specific needs. The system synchronizes visual feedback from the VR with the electrical stimulation, creating a cohesive and immersive experience designed to aid the brain in relearning the neural pathways required to control movement. By combining these technologies, Nura delivers a personalised FES therapy that is highly responsive to the user's specific needs and intentions, offering a significant advancement over the results of less adaptable solutions.

This cohesive and immersive experience also provides valuable biofeedback for the patients, allowing them to visualize their muscle activity in real time, providing motivation to continue the rehabilitation. Figure 7 illustrates the layout of the electrode arrangement. The central electrode is strategically positioned to detect muscle activity associated with wrist extension by targeting the extensor muscles (extensor digitorum, extensor ulnaris, and extensor radialis), while the side electrodes capture activity from the flexor muscles and monitor radial/ulnar deviations (flexor ulnaris or flexor radialis). The reduction in the number of sensors, yielding a more compact wearable device design, is possible because the system only targets a wrist movement at a given time, in addition to targeting main the

muscle groups rather than individual muscles in the arm, requiring only three extra EMG sensing electrodes [65]. Another feature of the layout of the sleeve is its symmetry. As the sleeve only targets larger muscle groups, the side electrodes can be mirrored, leading to a fully ambidextrous design.

Wrist extension is detected solely by the central sensing electrode; radial/ulnar deviation involves both the central and one of the side electrodes; and flexion is detected only by the side muscle groups, potentially reducing false sensor readings from flexion movement. Figure 9 displays the position of all type of electrodes in the sleeve. The existing research posits that EMG sensors can function simultaneously with FES electrodes, as the EMG sensor may start to detect the FES pulses rather than actual muscle activity, which can lead to a positive feedback loop [63]. When linked with the virtual pad concept described previously, the Nura sleeve can detect initial voluntary control from the whole muscle group using the sensing electrodes, accurately stimulating the correct muscle group for the intended movement.

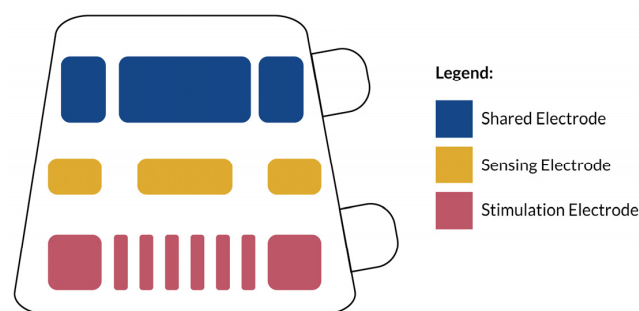


Figure 9. Visualisation of electrode arrangement for combined FES and EMG sleeve.

The combination of EMG sensors and FES in Nura is also implemented for more precise remote monitoring. In addition to specific data on exercise performance, such as repetitions and exercise intensity, additional non-tangible data, including voluntary control and quality of movement (collected with hand and finger tracking through a VR headset), help to provide recommendations for targeted improvements. Moreover, the use of EMG with a VR platform enhances the rehabilitation experience. Synchronising muscle activity with virtual tasks or games fosters an engaging therapy experience, helping patients practice functional tasks in simulated scenarios. One such scenario may be the water pouring exercise seen in existing exercise sheets, such as the GRASP training manual [66]. This approach aids motor recovery and builds confidence in daily activities. Although this task may be performed solely with a VR headset, the incorporation of EMG and FES reduces the need for significant voluntary muscle control, allowing patients to begin engaging with it earlier in their recovery journey.

5.5. Integration with VR

VR systems, such as Meta Quest, leverage advanced, affordably priced sensors to deliver effective, self-directed therapy options for stroke rehabilitation. Their compact, portable design makes them easy to use at home. The Oculus Quest 2, in particular, was chosen for its exceptional technical performance, robust developer support, and advanced capabilities at the time.

Within the Nura system, VR technology was incorporated to enable hand tracking, pose recognition, and when paired with EMG sensors, to monitor hand movements and muscle activation.

The Nura FES sleeve integrates with the NeuroVive VR rehabilitation platform to allow users to perform VR-based exercises while receiving FES. This combination enhances the effectiveness of rehabilitation by creating an engaging experience that encourages user

participation and improves therapeutic outcomes. By merging VR and FES, the system supports neuroplasticity and aids stroke recovery.

The Meta Quest device uses hand-tracking technology to monitor 21 points on the user's hands. It processes this data and sends wireless commands to the Nura FES sleeve, which stimulates specific muscles to facilitate desired movements. Through the Neuro-Vive VR platform, users perform gamified physical activities that combine movement, stimulation, and VR for a more effective rehabilitation process.

5.6. Companion App

Given that the average age of stroke survivors is between 68 and 78 years [67], and that strokes often impact cognitive function, the application is designed to provide gamified exercises without the extra complexity of the VR platform, along with intuitive control of the sleeve. This includes incorporating user-friendly interfaces, simplified navigation, and adaptive features to accommodate potential cognitive and physical impairments, ensuring effective engagement and usability across the target population. Figure 10 shows key wireframe of the companion app.



Figure 10. Nura's app: selection of limb for exercise (a); control of virtual electrodes (b); exercise guidance (c); power detected by the sensors in simulated daily task exercise (d); summary of rehabilitation session (e); progress chart (f).

The app was designed to control the sleeve and to provide additional functionality that the puck alone could not implement, such as gamified rehabilitation exercises, employing interactive games to increase user engagement and mitigate the monotony of repetitive upper arm movements. The application was also designed to incorporate user feedback through progress-tracking systems, encouraging adherence to rehabilitation routines, and was designed to provide real-time visual feedback regarding muscle activity. A key design decision of the app is its ability to monitor user progress, allowing medical professionals to access rehabilitation data remotely in both clinical and home settings, while also transmitting data wirelessly to hospital staff. This functionality supports clinical monitoring by offering insights into subjective difficulty and adherence, enabling tailored adjustments to exercises for optimal rehabilitation outcomes. Users are also able to view post-workout summaries to track improvement over time. A storyboard capturing key functions enabled by the app is shown in Figure 11. As the current system requires the hand tracking of a VR headset, further research is required in order to develop a cost-effective solution.

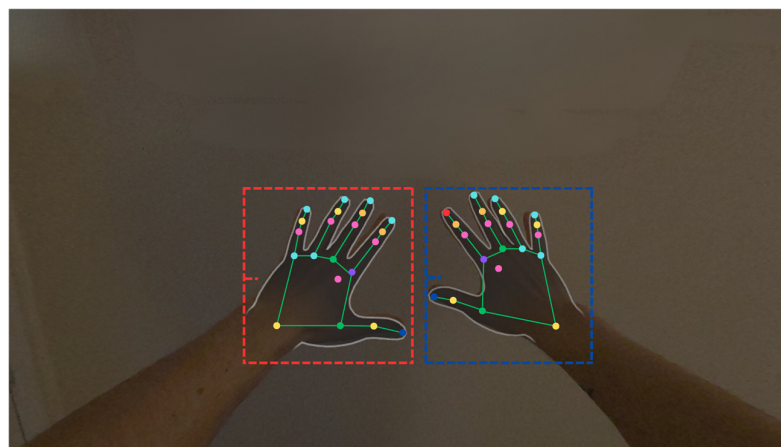


Figure 11. Hand tracking points for VR development.

6. Discussion

Having observed the considerable potential held by sensors from their application in gaming—where they enable more immersive, interactive, and responsive gameplay—the healthcare sector is rapidly adopting similar technologies for advanced medical and rehabilitation applications [68]. While the implementation of sensors in diagnostic devices, such as electronic medical thermometers and electrocardiograms (ECG), is well-established and widespread, the movement towards digital health is creating opportunities to integrate sensors into cost-effective, digital, and sustainable solutions that are simultaneously safe and adaptable to diverse population needs. This paper highlights one such case of integrating sensors in personalised rehabilitation therapy and in maximising their functionalities by linking it with other technologies, namely FES and VR.

Current FES devices rely on fixed stimulation patterns that do not dynamically adjust to a patient's needs or recovery trajectory. In the proposed system, the integration of a modest number of EMG sensors has amplified the impact of functional electrical stimulation FES, marking significant progress in its application. This is achieved through a closed-loop system, consisting of muscle electrical signal detection, real-time calibration of FES support, and improved muscle movement range, as detected by the VR technologies. Additionally, existing FES devices work on isolated muscle stimulation, which fails to replicate the coordinated movements essential for daily life. The proposed location and use of sensors overcome these limitations by focusing on coordinated muscle groups that control the wrist joint, enhancing functional independence. The seamless integration with

VR provides feedback to the advanced therapeutics platform regarding the movements achieved by the patients; this reduces the need for operational supervision, making Nura an effective solution for therapists and stroke survivors. This feedback loop represents a key mechanism for delivering personalised rehabilitation, tailored to the specific needs of each stroke survivor and supporting their long-term rehabilitation trajectory.

Through a user-centred design approach that identified a clear desire by stroke survivors to independently lead their rehabilitation journey, Nura has been designed to eliminate the need for gel pads, offering a more comfortable and user-friendly experience. This prevents skin irritation, eliminates the challenge of electrode repositioning, and enables independent use.

The opportunities offered by advanced therapeutics such as the one presented here are several, including: (i) increasing repetition in rehabilitation which without VR, may become tedious and demotivate the users; (ii) reducing staff workload in monitoring patients' progression and adjusting therapy accordingly; (iii) providing real-time personalised therapy support, thanks to the closed-loop feedback between sensor, stimulation, and detection of movements; (iv) offering a therapeutic device that stroke survivors can use independently.

Interconnected with a companion app, Nura enhances rehabilitation by creating engaging settings where repetition, a central tenet for neuroplasticity, is less tedious and can be embedded in gamified or functional daily tasks, thus providing users with a tangible sense of improvement [69].

Theo, the first participant in the evaluation tests, had previously used a VR rehabilitation prototype developed by Reneural and provided the following comments on how Nura, when linked with VR, could be utilized for rehabilitation:

"I can see this [Nura when linked with a VR headset] being used in rehabilitation, where one nurse takes care of something like 12 patients at once".

"I can definitely see myself using VR in my rehabilitation journey".

Participants in this study expressed enthusiasm for adopting technology-enhanced rehabilitation, particularly for systems that are easy to wear and use without requiring third-party intervention, factors that significantly contribute to patient adherence.

Jan, the third participant in the evaluation, emphasised the importance of ease of use, noting that setup time presents a significant barrier, as reflected in the following quotes from her.

[Referring to the virtual electrode innovation introduced by the Nura sleeve] "You can do that? I don't have to keep changing it when it's on?"

"With that one [gesturing to a standard FES device with hydrogel electrode pads] I have to constantly shift it around. I like how with this one [Nura Sleeve] can just press that [muscle adjustment feature] and it'll do it".

The literature highlights three key priorities for advancing healthcare delivery:

1. Enhanced rehabilitation pathways that improve patient outcomes, supported by data analytics capabilities [70].
2. Efficiency gains achieved via clinical remote monitoring, which alleviates pressure on healthcare providers [71].
3. Cost savings and environmental benefits of digital health solutions through reduced hospital visits and lower CO₂ emissions [72].

In response to these needs, smart sensor-integrated medtech like Nura is driving a shift towards decentralised care, bringing both diagnostic and therapeutic interventions closer to primary care settings and directly into patients' communities.

A key limitation of this research is the lack of testing of the closed-loop system with patients to demonstrate its ability to provide detect-calibrate-deliver functionalities. This was not possible due to the absence of CE marking, which makes its use on study participants both unlawful and unethical. Consequently, the study relies on desk research [69], market device appraisal, mathematical modelling, and empirical results obtained outside of direct patient trials. Another limitation is the relatively limited engagement with therapists during this phase of the research. This was, in part, due to the study's focus on stroke survivors and the patient-facing elements of the project. However, research funding has since been secured to develop the clinical dashboard module, which will enhance clinician involvement and ensure appropriate supervision in future iterations of the system.

Despite their potential, sensor-based medical technologies face several barriers to wider adoption. Traditional rehabilitation methods are often preferred due to the high cost of smart, personalised rehabilitation systems. In addition, the limited clinical evidence supporting their efficacy and the lack of standardisation in protocols and sensor technologies hinders comparability across studies. Concerns also persist regarding the perceived replacement of human expertise, highlighting the need for sensor-based systems to enhance rather than replace clinical care. Further research is essential to assess whether remote clinical monitoring of advanced therapeutics like Nura can provide both patients and clinicians with confidence, ensuring safe and effective integration into rehabilitation pathways.

7. Conclusions

The growing market of personal lifestyle devices, including privately purchased medical technologies, is shifting the landscape of rehabilitation solutions. Consumers are increasingly investing their personal finances in medical technologies that promise longer, healthier lives. This trend has led to rising demands for devices that are intuitive, effective, and aesthetically pleasing.

This research addresses the need for an advanced therapeutic solution that facilitates repetitive movement, a critical factor in promoting neuroplasticity after a stroke. The proof of concept presented distinguishes itself from existing functional electrical stimulation (FES) technology for muscle stimulation. Through the integration of EMG sensors, FES, and virtual reality (VR), a closed-loop system has been developed to detect, calibrate, and deliver personalised rehabilitation therapy. The technical complexities of the device have been minimised through an intuitive design that eliminates the need for elaborate FES pad adjustments. Designed using a user-centred approach, the wearable sleeve—housing both sensors and pads—has been positively received by stroke survivors.

The research and innovative rehabilitation system presented in this paper pave the way for rehabilitation solutions that can be seamlessly integrated into home settings and primary care, without compromising the clinical supervision necessary to strategically guide patients' progress. By ensuring that rehabilitation decisions remain under the oversight of qualified clinical staff, this approach offers both effectiveness and confidence in patient care. However, significant development is still required before the system can reach the market, as several limitations must be addressed to fully validate and implement the proof of concept outlined in this study.

8. Patents

A Patent Cooperation Treaty (PCT) application was submitted to secure intellectual property protection for the innovative aspects of the system. The patent application, registered under the number PCT/GB2024/051520, encompasses the unique technologies and methods developed previously and within the project.

Author Contributions: The manuscript was proposed, initiated and structured by G.S. She was responsible for the Section 3, Section 6, and Section 7. C.K. and G.S. designed the data collection methods. C.K. was also responsible for maintaining the relationship with the charity that enabled the recruitment of participants. K.P.E. was the lead researcher applying for research ethics approval and was responsible for the design of Nura. He provided the technical description of the system, with support from V.H., who contributed the VR section of the paper. L.C. was the key author in the clinical sections of the paper, supported by M.J., L.C., and K.P.E. developed the tables and figures. Collectively, we also acknowledge that this paper is the outcome of independent and academically supervised research conducted by K.P.E., L.C., and M.J. as part of their respective undergraduate and postgraduate dissertations. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: All subjects provided their informed consent for inclusion before they participated in the study. The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the University Research Ethics Committee, with reference number 46533-MHR-Mar/2024-50321-2 on the 25 March 2024.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: For privacy and confidentiality, the data collected through qualitative interviews and usability evaluation cannot be made publicly available.

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Conflicts of Interest: Author Victor Harabari was employed by the company Reneural Technologies limited. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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