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ESCOLA SUPERIOR
POLITÉCNICO SETÚBAL

INÊS CATARINA RODRIGUES OLIVEIRA

RECOMMENDATIONS FOR COMBINING BRAIN-COMPUTER INTERFACE, MOTOR IMAGERY AND VIRTUAL REALITY IN UPPER LIMB STROKE REHABILITATION: A QUALITATIVE PERSON - CENTERED CODESIGN STUDY

Relatório de Dissertação do Mestrado de Prática Avançada de Fisioterapia em Neurologia

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Dezembro 2024

Relatório de Investigação apresentado para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Fisioterapia em Neurologia, realizado sob a orientação científica de Professora Doutora Carla Mendes Pereira e coorientação de Professora Ana Isabel Almeida e Professor Doutor Athanasios Vourvopoulos.

DECLARAÇÕES

Declaro que este Relatório de Projeto de Investigação é o resultado da minha investigação pessoal e independente. O seu conteúdo é original e todas as fontes consultadas estão devidamente mencionadas no texto, nas notas e na bibliografia.

O/A candidato/a, ____________________ Local, 19 de Novembro de 2024

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Reconhecermos a sorte que temos na vida deve ser um exercício constante, não permitindo que os agradecimentos sejam opcionais. Assim, aqui ficam:

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À vida, que assegura que nos rodeiam todos os que necessitamos para continuar a dar resposta e procurar uma vida plena e significativa.

Índice

Original Paper

Recommendations for combining Brain-Computer Interface, Motor Imagery, and Virtual Reality in Upper Limb Stroke Rehabilitation: A qualitative person-centered codesign study

Abstract

Background: The high incidence and prevalence of upper limb impairment post-stroke highlights the need for the development of rehabilitation in this field. Brain-Computer Interfaces (BCIs) can directly train the central nervous system providing promising technology in this area and the use of associated motor imagery (MI) and virtual reality (VR) can provide valuable rehabilitative opportunities. However, the diversity in interventions designs demonstrates the lack of guiding recommendations integrating neurorehabilitation principles for BCI.

Objective: This study aims to develop recommendations for BCI interventions using task specificity and ecological validity through simulated VR tasks for upper limb stroke survivors, by gathering tacit knowledge from neurorehabilitation experts, patients' experiences, and engineers' expertise to ensure a comprehensive approach.

Methods: a multi-perspective qualitative study was conducted through collaborative design workshops involving stroke survivors (N=17), rehabilitation experts (N=13) and biomedical engineers (N=3), totaling 33 participants. This innovative approach aimed to actively engage stakeholders in developing multifaceted solutions for complex health interventions.

Results: Six themes emerged from the thematic analysis: i) Importance of patient centred approach; ii) Clinical evaluation and patient selection; iii) Recommendations for task design; iv) Guidelines for structuring BCI intervention; v) Key factors influencing motivation; and vi) Technology features. From these themes, the following recommendations (R) are established: R1 - BCI-MI-VR interventions must be conducted through a Patient Centered Approach, based on individualized preferences, needs and goals of the user, by an interdisciplinary team; R2 - Selection criteria must include upper limb impairment, cognitive and communication assessment and clinical traits like motor imagery capacity, neglect and depression must be assessed once it might influence intervention outcomes; R3 - Tasks to perform should preferably be based on daily living activities including unilateral and bilateral tasks and a variety of tasks must be available for selection to ensure significance for the user and adequation to clinical traits; R4 - Intervention must be structured by different progressing levels starting with simple, gross movements and adding complexity through movement features, cognitive demand and motor imagery difficulty; R5 - Optimal levels of motivation must be sustained through task variability, gamification elements and task demand adequacy; R6 - Multisensorial potential of BCI-MI-VR must be effectively harnessed through the adequate adjustment of visual, haptic and proprioceptive feedback modalities to the patient.

Conclusions: These results contribute to establishing clear guidelines on patient selection, task design, intervention structuring, motivation factors and tailoring of sensory feedback. This framework presents a foundation for optimal implementation of BCI-MI-VR based interventions, optimizing cortical activity during the intervention, patients' engagement and clinical outcomes. Future research should explore the application of these guidelines for validation and investigate BCI's efficacy according to different combinations of patients' profiles, task characteristics and technology features.

Keywords: Neurological Rehabilitation; Cerebrovascular Disorders; Upper Extremity; Brain-computer interfaces; Health Planning Guidelines; Qualitative Research; User-Centered Design

Introduction

Stroke is among the most common causes of disability worldwide and is the chronic neurological disease with the greatest impact at this level [1,2]. Among the multiple consequences of stroke, upper limb (UL) impairments are one of the most prevalent presentations, with around 70% of stroke survivors showing residual disability at this level, 40 % maintaining persistent functional disability [3] and only 5 to 20 % showing complete dexterity six months after stroke [4]. Motor control impairments result in altered movement dynamics, characterized by muscle synergies that reduce optimal motor performance and induce movement compensations [5,6].

Upper limb rehabilitation (ULR) after stroke is recognized as a complex challenge due to different factors, namely the multifactorial nature of the condition (e.g. spasticity, decreased muscle strength, changes in sensitivity and perception) [7–9] and the nonlinear progression of disability over time. In addition, the complexity underlying intervention is also related to the multiplicity of intervention parameters that need to be defined, such as the type of intervention, dose (duration and difficulty/intensity), application format, and the underlying factorial paradigm, which involves different degrees of parameter interaction [10].

Multiple types of motor rehabilitation interventions have been studied throughout be years with the goal of reducing motor impairments and improving functioning in activities making use of learning- and use-dependent mechanisms [11] to promote motor learning.

Considering upper limb intervention, traditional or modified constraint-induced movement therapy, mental practice, robot-assisted movement therapy and Neuromuscular Electrical Stimulation are among the most recommended strategies currently [11–13]. Neuroplasticity is the structural or functional changes (or both) within neurons affecting its connectivity with each other that occur during learning after injury, being a key element of motor rehabilitation and motor acquisition [14]. During motor rehabilitation patients learn to optimize and adapt their motor, sensory and cognitive functioning through appropriately dosed repetitive, goal-oriented, progressive, task- and context-specific training [11]. The combination of traditional therapy methods with technologies that enable the use of enriched environments, sensory stimulation and task-specific training is a neuroplasticity promoter, enhancing functional recovery for stroke survivors [15].

Brain-computer interfaces (BCI) have been increasingly studied over the last 20 years as a way of enhancing upper limb rehabilitation being a facilitator of intensive and repetitive practice [16]. BCI is a technology that allows the collection, analysis and decoding of brain activity, translating it into communication and control commands for an interface [17]. Measuring and analyzing brain activity data is often done using electroencephalography (EEG), which makes it possible to measure the cortical sensorimotor rhythm during the performance or imagination of motor tasks, commonly referred as motor imagery (MI)[18]. This is the most widely used recording technique in BCI because it is non-invasive, portable, low-cost and has a high temporal resolution [19], making it possible to capture sensorimotor activity (e.g. Event-Related Synchronisation and Desynchronisation) during MI [20]. Three paradigms can be identified as the basis for intervention using BCI: motor imagery, motor observation and motor intention [7]. Kruse et al. [21] conducted a systematic review and meta-analysis of the addition of MI-based BCI (MI-BCI) to conventional therapy for the improvement of upper limb function, the efficacy of the intervention on motor function recovery and brain function recovery. Although meta-analysis on different design characteristics of BCI interventions favor motor execution over mental practice [17,22], MI offers a unique opportunity for stroke survivors, who are unable to move their extremities by attempting to stimulate the brain regions responsible for motor movement [21,23].

MI, also referred to as mental practice, is described as training movements or tasks in an imagined way and without producing movement, with the specific aim of improving performance [24]. Its application is extensively recommended as an adjunct to conventional therapy [25–29]. Neuroimaging findings provided evidence that MI and physical practice are functionally equivalent, i.e., recruits overlapping brain regions within the brain motor networks underlying motor preparation and execution, including pre-motor, parietal, primary somatosensory and motor cortices [30]. The neurophysiological principles underlying the relevance of this practice for improving motor performance are the fact that imagining a movement or carrying it out have in common the activation of those same brain areas [30]. Either MI and planning and execution of movement involve the activation of the cerebellum, putamen, inferior frontal gyrus and supplementary motor area [31]. Thus, the utility of motor imagery practice lies in reinforcing the motor schemas involved in actual movement through the mental visualization of motor actions [24]. MI can involve explicit or implicit tasks where the first involves active and conscious imagination of a particular movement, and the second subconsciously induced processes for task-imagery problem solving, such as mental rotation of an image [28].

The use of neurofeedback associated with BCI seems to promote changes not only at the neurophysiological level but also at the clinical level [32]. This can be provided through different modalities, such as visual, auditory, and tactile feedback [33].

Virtual reality (VR) is one of the feedback possibilities to combine with BCI [7,32] which allows users to experience being part of a virtual body rendered through a 3D environment and interact with it in a realistic way [34]. Multiple meta-analysis have described the positive effects of using VR in upper limb rehabilitation, not only in terms of motor function but also in activities of daily living [35,36] and practice guidelines recommend it's usage to improve stroke rehabilitation outcomes [27]. Immersive virtual reality, when used as a complement to conventional therapy, can provide a suitable environment for practicing the repetitive and specific tasks needed to improve motor skills after stroke [37].

Considering the principles of motor learning, which are closely related to the mechanisms of neuroplasticity, the specificity of the task, intensity and repetition are necessary factors for the development and strengthening of synapses and, consequently, for motor recovery [38]. The multisensory stimulation potential associated with VR and its association with BCI have the potential to enhance hand function by delivering targeted sensory feedback across different systems, such as somatosensory, visual, and auditory pathways, thereby promoting neuroplasticity [39]. In addition to intensity and repetition, the relevance of the task performed by users is of high importance for optimizing motor learning. Therefore, the multiplicity of tasks allowed by VR supports its use [40].

Although the individual approaches that underpin an intervention paradigm based on BCI-MI-VR present robust scientific evidence for their effectiveness in improving upper limb rehabilitation outcomes, this paradigm is quite recent and innovative, raising various questions regarding design and implementational aspects. BCI based technologies have a broad range of applications and are growingly being researched, but there remains a gap between the technology and the end-user [41]. The development of BCI systems for rehabilitation must consider patients' needs while encompassing clinical applicability and technical feasibility [42]. Research states that practitioners and researchers need to involve users in creating solutions that consider factors such as convenience, ease-of-use, privacy, security, safety and quality standards, prioritizing users and ergonomics [43]. Given these considerations, it is necessary to establish recommendations for the use of BCI-MI-VR and adjust the technology to meet the real needs of users and clinical practice [44]. To address the gaps in existing evidence, this study aimed to explore the insights of: i) rehabilitation experts about the most effective factors and the principles of neurorehabilitation and neurophysiology that may be relevant to adapt for BCI intervention; ii) stroke survivors to inform recommendations concerning their needs, preferences and motivation; iii) biomedical engineers on the technical knowledge of the technology. With this collaborative methodology, the aim of this study was to contribute to the development of a set of realistic recommendations for designing more effective interventions for the rehabilitation of the UL in stroke survivors using BCI-based interventions associated with VR and MI.

Methods

Study Design

A qualitative study was selected to draw from the tacit knowledge of experts and experience from stroke survivors through a reflexive thematic analysis. Thus, a multi-perspective collaborative design process was used, including clinical rehabilitation experts, stroke survivors and biomedical engineers, who participated in various workshops [45]. For this study, both online and in-person workshops were planned. The first allowed the participation of geographically dispersed participants [46] and the second helped fully leverage interpersonal dynamics for enhanced collaboration and permitted an experimentation with the MI-VR paradigm. Logistical and time constraints, particularly the extensive preparation and calibration required of the EEG, limited opportunities for technology experimentation including the BCI, only allowing MI-VR. The consolidated criteria for reporting qualitative research (COREQ) checklist was followed for this study [47].

Workshop planning was based on the literature review conducted to familiarize the topic and identify the gaps of evidence. This search focused on meta-analysis in the stroke population, including the MeSH terms "stroke" AND "rehabilitation OR intervention OR therapy" and "upper extremity", published in the last 5 years and guidelines for rehabilitation and in meta-analysis on "Brain Computer Interface", "Virtual Reality", "Motor Imagery".

Sample and Recruitment

The recruitment took place between January 2023 and July 2024, using a purposive sample, with participants being selected based on the researcher's judgement about their contribution to the study [48] and based on the professional network of the researchers. Considering the study goals, the priority in participant selection were the richness of contributions and good communication skills.

Experts were included if they had experience with stroke rehabilitation at least in the last 10 years. Stroke survivors were included if they had a stroke-caused impairment of the UL movement, were over 18 years old at the time of stroke and had participated in at least 20 post-stroke rehabilitation sessions with preferential previous technological experience either in therapy or daily life. Potential stroke participants were excluded if they had a diagnosis of cognitive impairment or diagnosis of impaired communication (for example, aphasia), that limited their ability to understand complex instructions and to report their experience with stroke rehabilitation. The inclusion criteria for engineers were based on the experience with BCI-based interventions and knowledge on the technical details.

After an initial informal contact to gauge the willingness to participate, the invitation letter, demographic characterization questionnaire, consent form and scheduling options were sent to potential participants. Stroke survivors' recruitment was assisted by a national stroke survivors association (literally: "Portugal AVC - União de

Sobreviventes, Familiares e Amigos") by disseminating the study through their network contacts.

From the 25 rehabilitation experts that were contacted, 21 showed interest in participating, however, eight where not able to participate due to scheduling difficulties. From the 23 eligible stroke survivors interested to take part, six could not also for scheduling issues. From the four engineers who accepted to participate, one could not be present due to illness. A total of 33 participants were recruited, including 13 rehabilitation experts, 17 stroke survivors; and three biomedical engineers and sociodemographic information collected (Tables 1-3).

Table 1. Description of Participants – Rehabilitation Experts (N=13)

Gender N (%)	**Field of rehabilitation** N (%)	**Clinical Experience w/ Stroke** (Mean ± SD)	**Previous experience with VR** N (%)	**Familiarity with technology for rehabilitation** N (%)
Female (38%) Male (62%)	OT (23%) Physicians (8%) PT (53%) SLT (8%) Psychologist (8%)	16, 1 years ± 6,55 years	None (8%) Slight contact (61%) Some experience (23%) Frequent use (8%)	None (8%) Slight contact (54%) Some experience (15%) Frequent use (23%)

OT = Occupational Therapists; PT = Physiotherapists; SD= Standard Deviation; SLT = Speech and Language Therapists; VR=Virtual Reality

Table 2. Description of Participants – Stroke survivors (N=17)

Age (Mean ± SD)	**Gender** N (%)	**Time Post Stroke** (Mean ± SD)	**Perceived Dependency** N (%)	**Movement Capacity** N (%)	**Previous VR Experience** N (%)
54,8 ± 8,32 years	Female (59%) Male (41%)	5,2 years±4,58 years	Completely independent (12%) Slightly dependent (29%) Moderately dependent (35%) Highly dependent (24%)	Movement moderately useful for ADL's (18%) Some movement although not useful for ADL's (64%) Unable to move (18%)	Yes, before the stroke (29%) Yes, after the stroke (18%) No (53%)

ADL = Activities of daily living; SD= Standard Deviation; VR=Virtual Reality

Table 3. Description of Participants – Biomedical Engineers (N=3)

Gender N (%)	**Academic Degree** N (%)	**Experience w/ BCI Systems Development** N (%)	**Experience w/ Technology for Rehabilitation Development** N (%)	**Experience w/ VR in Stroke Rehabilitation** N (%)
Female (67%) Male (33%)	Doctorate (67%) Bachelor (33%)	Some Experience (33%) Moderate (33%) Moderate to High (34%)	Some Experience (67%) Moderate to High (33%)	None (33%) Moderate (33%) Moderate to High (34%)

BCI=Brain-Computer Interface; VR= Virtual Reality

Data Collection

Three workshops with rehabilitation experts, two workshops with stroke survivors and one workshop with rehabilitation experts, stroke survivors and biomedical engineers were conducted (6 in total). For each workshop goals were established and, accordingly, selected the methodologies that best suited the given goals. The workshops were planned through an iterative process, with the outcomes of each session informing the next to address any gaps, clarify inconclusive points, or address disagreements. To ensure that the planned workshop would achieve the defined objectives, a test workshop was held previously. A detailed description of the workshops' development and implementation process is provided at the end of data analysis section (Figure 1).

After each workshop, participants had the opportunity to provide feedback on their experience, through a form with closed and open questions. The analysis of the feedback questionnaires was used to plan the subsequent workshop. A summary of each workshop was presented at the beginning of the next one. Specifically, for workshops five and six a written summary was sent to the participants for validation (Appendix 1 and 2, respectively).

Data Analysis

An inductive thematic analysis was conducted using data from the verbatim transcripts [49]. The six-phase process of thematic analysis was followed: data familiarization, systematic data coding, generating initial themes, developing themes, refining, and naming themes and producing the report [50].

The workshops were transcribed initially using the Microsoft Office Word transcribe feature, followed by manual reviewed. Each transcript was scanned for relevant quotes, which were lifted into a codebook to group them into preliminary themes according to the study's goals.

The preliminary themes were combined and reassembled into different themes and subthemes, until achieving the final thematic map. The analysis made was validated by a second author and discussed with the investigation team, with frequent debriefing sessions between the researchers and supervisors of the project.

Figure 1. Workshop Development and Implementation Process

Researcher characteristics and reflexivity

The research team was comprised of four physiotherapists and one biomedical engineer, with clinical experience and/or research experience in the field of stroke rehabilitation. They believe in stroke survivors' potential to improve, the importance of the stroke survivors' active role in their rehabilitation, and of neurorehabilitation principles knowledge to support intervention.

Throughout the study, there was an introspective concern, to keep the attention on the research question and relevant framework and maintaining a balance between promoting an environment of free participation by the participants while not losing the focus on the study's goals. For the first four workshops there was none or very limited previous contact and no personal relationship with the participants. In the fifth and sixth workshops, a professional association was present between the researcher conducting the sessions and six patient participants, as well as three health professionals, due to their shared involvement at the same rehabilitation center. Of the patient participants, five had previously received treatment from the researcher in group classes (N= 3) or individual sessions (N=2). These pre-existing professional relationships did not influence the design, methodology, or conduct of the workshops.

To ensure the quality of the study, meetings were held for discussion of the methodology, supervision of the analysis and review of the text. This step reduced possible bias from the researchers and increased the scientific rigor.

Results

The findings from the workshops revealed six themes regarding recommendations for planning and implementing BCI-MI-VR interventions. The conceptual map of the thematic analysis is provided at the end of the initial summary presentation of the results (Figure 2). A compilation of the most representative quotes can be found at Appendix 3.

Participants highlighted the importance of planning all intervention stages (from task selection to feedback output and intervention structure) according to the individual user, suggesting the creation of a User Profile. The importance of a Patient Centered Approach (theme 1) was highlighted, focusing on the individualization of care (subtheme 1.1), and ii) working as a team (subtheme 1.2), reflecting the need for multidisciplinary collaboration, communication and shared decision-making.

The clinical evaluation and patient selection (theme 2) were recognized as important for customizing intervention, monitoring progress, preventing adverse effects, assessing effectiveness and allowing stratification. Participants identified: i) selection criteria (subtheme 2.1), and the ii) assessment of influencing factors (subtheme 2.2), as important for planning BCI interventions.

These considerations influence intervention planning (themes 3 and 4) and technological development (themes 5 and 6), which are closely intertwined.

Recommendations for task Design (theme 3) to enhance intervention significance and usefulness include task characteristics (sub-theme 3.1) and personalized task selection (sub-theme 3.2).

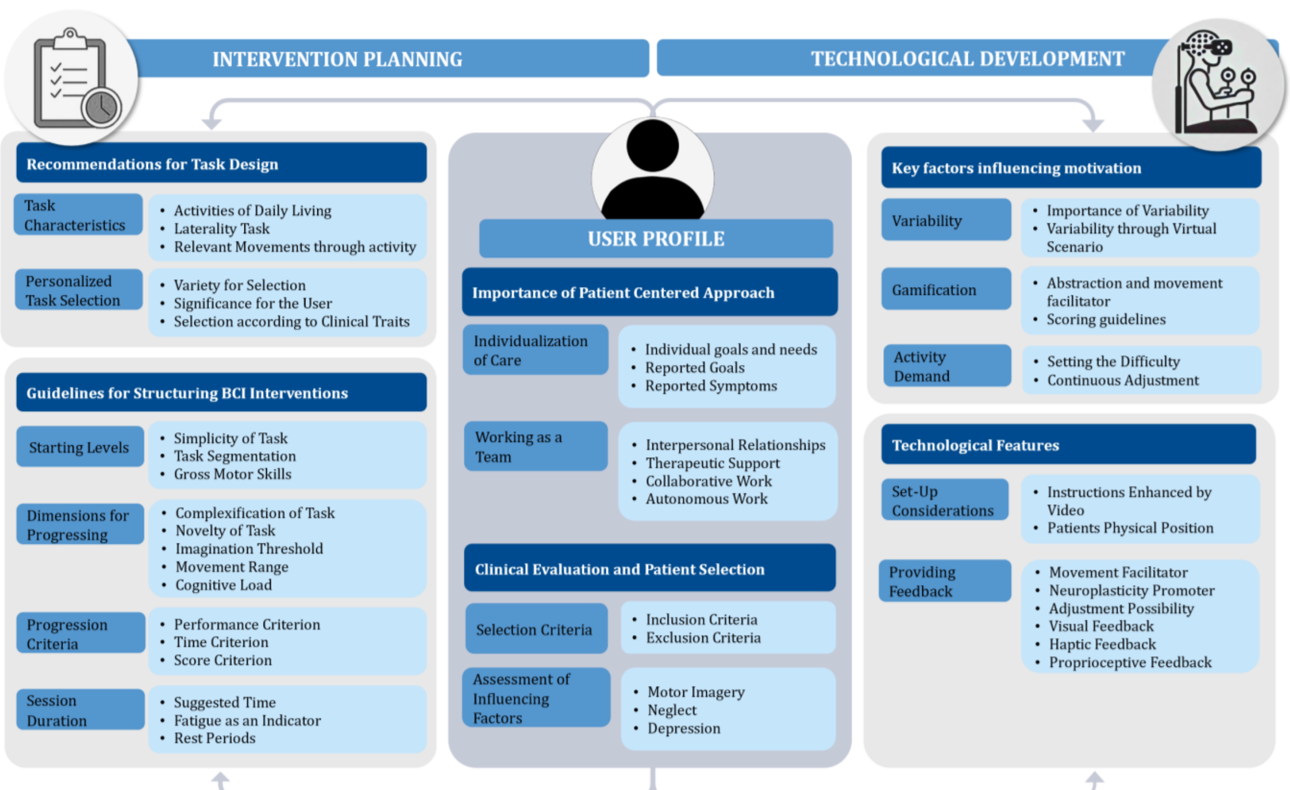
Guidelines for structuring BCI interventions (theme 4) address the progression of sessions over time defining i) characteristics of staring levels (subtheme 4.1) ii) dimensions for progressing (Subtheme 4.2); iii) progression criteria (subtheme 4.3) and iv) aspects influencing session duration (subtheme 4.4) to maintain optimal levels of engagement and therapeutic benefit.

Motivation was highlighted as essential to promote engagement and adherence to the intervention and as key factors influencing motivation (theme 5) for UL BCI-MI-VR-based rehabilitation participants identified: i) task variability (subtheme 5.1) ii) gamification (subtheme 5.2) iii) adequation of activity demand (subtheme 5.3).

Considering technology features (theme 6), namely the interaction of the user with the technology and the multisensorial potential of BCI-MI-VR, participants discussed: i) set-up considerations (subtheme 6.1) and ii) the guidelines for providing feedback (subtheme 6.2) to enhance the recruitment of motor areas in the brain, thereby improving movement.

BCI-MI-VR rehabilitation strategy was well received and the collaboration multi-perspective design implemented for this was highly acclaimed.

Figure 2. Conceptual Map of the Thematic Analysis



Importance of Patient Centered Approach

Individualization of Care

Participants emphasized that, although stroke is a common diagnosis, each case presents uniquely, with distinct needs and preferences. Therefore, from their perspective, it is essential to consider the stroke survivor's unique characteristics and goals, placing them at the center of the rehabilitation process and intervention planning.

The most relevant goals identified by stroke survivors included a focus on enhancing functionality and independence. Specifically, functionality was defined as the ability to perform daily tasks, and the term "functional hand" used to highlight the importance of hand movements to achieve goals. From participants' viewpoint, functionality is closely linked to autonomy and the desire to engage in activities that users can no longer perform, being a significant motivator for their rehabilitation efforts. The ability to participate in family life and social interaction, manifested through gestures such as hugging, handshaking, or clapping, was also highlighted as important by various participants. These gestures underscore the connection between the impaired motor skills and the ability to engage socially, illustrating the significant role these interactions play in enhancing the quality of life after stroke. Such gestures were identified as critical targets for rehabilitation efforts.

Participants also identified several structural impairments that must be addressed to facilitate the recovery of motor skills following a stroke. These included the improvement of manual dexterity, the enhancement of sensitivity associated with movement, and pain management. Some stroke survivors reported that neglect affected their daily activities, making it difficult to interact with their surroundings, such as bumping into walls or missing objects in front of them. This led to frustration and reduced functionality, especially impacting their ability to drive. Moreover, changes in perception were also noted as detrimental to the rehabilitation process, as they disrupt body schema, reduce understanding of exercises and the ability to execute movements.

The wide range of symptoms and goals described indicates that each stroke survivor's priorities and therapeutic needs may vary, with different combinations of impairments leading to distinct life challenges and rehabilitation objectives. This notion should guide the design of tasks and technological features of BCI-MI-VR solutions and ensure that different dimensions—such as dexterity, perception, or motor planning—are addressed through specific, targeted activities. For example, stroke survivors with dexterity issues might require tasks focused on fine motor control, while those with perceptual difficulties would benefit from activities that engage different sensory modalities. By systematically assessing stroke survivor-specific symptoms and goals, the rehabilitation process is effectively individualized, tailoring the approach to the unique needs of the stroke survivor and optimizing intervention outcomes and relevance.

> "We have to put the patient here at the centre. Not here near me... but in the centre." (RE 13, Wk 6)

> "(When asked to write down what is more important for arm recovery, stroke survivors wrote:)
> - Participate with agility in our grandchildren's games
> - Hugging and shaking hands
> - Functional hand (for daily tasks like eating, dressing, and hygiene)
> - Regaining functional autonomy;" (Group written conclusion, Wk 5)

Working as a Team

During the workshops, participants emphasized the importance of involving an interdisciplinary team in the intervention process. This collaboration enables specialists from different fields to support stroke survivors based on their expertise and guide decision-making throughout the intervention. Collaboration was particularly valued during the assessment phase, ensuring that stroke survivors receive optimal benefits, and all possible influential factors are identified. Additionally, it is essential for stroke survivors to be active members of the team, participating equally in decisions. This collaborative approach plays a positive role in participant selection, clinical profiles establishment, intervention outcomes optimization and avoidance of adverse effects. Given that BCI represents a cutting-edge intervention with extensive research exploration, participants also highlighted the importance of collaboration not only within the clinical team but also between clinical and research teams.

Regarding interpersonal relationships, stroke survivors identified being understood by the therapist as a positive contribution to their rehabilitation. This understanding, along with receiving positive feedback from health professionals, enhances their overall satisfaction with each session, fostering a sense of contentment. Participants also stressed the importance of health professionals being adequately prepared to address the stroke survivor's feelings of frustration and discomfort.

Stroke survivors highlighted the importance of having therapeutic guidance and specialized attention from health professionals during their rehabilitation, but also shared the need to be empowered to develop and perform their own work autonomously. Correspondingly, the end of each session or the time constraints associated with it were identified as demotivating factors in the rehabilitation process. This suggests that limiting rehabilitation work to the session itself can be discouraging, as stroke survivors must wait until the next session to continue their progress.

> "(…) it's also important to have, realistically speaking, multidisciplinary teams so that we can all understand the user "(RE 13, Wk 6)

> (When asked to write down what builds the sensation of a "Good Session", patients wrote:)
> "- Involvement between therapists and users (ability for therapists to understand us)

- When the therapist recognises some progression" (Group written conclusion, Wk 5)

"I learn an exercise with the therapist (...) Then I want to train, I want to exercise" (Pat 9, Wk 5)

Clinical Evaluation and Patient Selection

Selection Criteria

When considering the inclusion in a clinical program or research setting, participants emphasized the importance of stroke survivors' motivation to engage in the BCI-MI-VR intervention and the need to establish the true potential benefits of the technology. Clarifying the meaningful therapeutic value was noted, as well as the assessment of different clinical aspects.

For the assessment of upper limb impairment, the use of the Fugl-Meyer Assessment of Motor Recovery after Stroke was recommended. It was observed that stroke survivors with higher upper limb functioning levels tend to have greater difficulty accepting interventions that involve only motor imagery, without movement, which should be taken into account when determining the impairment level threshold for stroke survivor inclusion.

The intrinsic connection between motor and cognitive function was also addressed, with a recommendation for a comprehensive cognitive assessment. This assessment should evaluate the patient's spatial, temporal and personal orientation, as well as their ability to understand and follow instructions during the activity. If the stroke survivor lacks this capacity should be excluded. The Montreal Cognitive Assessment (MoCA) was suggested as an appropriate measurement tool for this purpose.

The importance of language assessment, particularly in the domain of comprehension, was also emphasized, due to its impact on the stroke survivor's ability to use the technology and understand tasks, thereby influencing the intervention's efficacy and benefits. Consequently, the presence of global aphasia was established as an exclusion criterion. Participants noted that the ability to understand simple commands is essential for effective participation.

Given the nature of the intervention, which relies on mental practice rather than physical movement, it was stated that this approach offers a valuable opportunity for inclusiveness. This could provide therapeutic options for stroke survivors who are frequently excluded from studies.

"If a person is disorientated in all three dimensions, they're hardly going to be able to do anything. [RE 3- Exactly, exactly. RE 11 - Huhum.] And we're wasting our time in rehabilitation work because it's very complicated. In other words, we must stabilize, understand what the person's initial cognitive part is and then work on this motor part intensively" (RE 13, Wk6)

> "There's so little (in studies) of this ability to include certain subgroups of users that we're talking about, that perhaps developing something for this fringe of users (...) (would be) quite relevant" (RE 1, Wk 1)

Assessment of Influencing Factors

From the perspective of workshops' participants, when integrating BCI into a rehabilitation program, several influencing factors must be taken into account to ensure its effectiveness. Participants emphasized the importance of assessing imagery capacity, as it can directly influence intervention outcomes. While not considered by participants as an exclusion criterion, evaluating imagery capacity helps tailor the amount of imagery training required before starting the actual intervention. Assessment tools mentioned include the Vividness of Visual Imagery Questionnaire, the Movement Imagery Questionnaire, and tasks such as the Left Right Judgement Task.

Affective changes and emotional stability may also play a crucial role, as they can impact motivation levels, which in turn affects intervention success. Therefore, the assessment of depression of anxiety with tools such as the Beck Depression Inventory or the Hospital Anxiety and Depression Scale was recommended by participants. From participants' viewpoint, emotional challenges, such as encountering activities that participants were once able to perform but can no longer do, may cause discomfort and need to be managed carefully.

The presence of neglect was frequently highlighted as a clinical trait to consider in participant selection and intervention planning. Participants noted that neglect can lead to alterations in spatial and body perception, influencing interaction with the interface and the ability to perform imagery tasks. While neglect may affect outcomes, participants emphasized that it should be assessed to determine how tasks can be selected or adapted, rather than represent an exclusion criterion. Concomitantly, many participants emphasized the potential of virtual reality as a training and intervention tool, suggesting that appropriate adaptations should support participation.

> "(...) The question of motivation. If the person is depressed, we can probably do all the work in the world but if we don't address the affective issue... the result may not be so positive. So we have to act on different fronts. So, it might be useful, or it should be compulsory, probably, to have a psychological assessment beforehand (Eng 1, Wk 6)

> "(...) spatial organisation, the ability to scan the image, the perception of space and body awareness... There are a number of things here that seem to me to be more cognitive than necessarily motor, because if in fact we're considering just imagery" (RE 2, Wk 3)

Recommendations for Task Design and Selection

Task Characteristics

Most stroke survivors and health professionals expressed a preference for tasks related to daily life activities. This preference was explained by the tasks' direct relevance to daily living needs and their strong connection to "muscle memory", which facilitates motor imagery. Participants also referred to these tasks as familiar, mundane or realistic, representing activities encountered in real-world, day-to-day life. Correspondingly, the incorporation of realistic tasks was highlighted as a motivational feature in upper limb rehabilitation sessions. Chart 1.1, found in the Appendix 4, lists relevant activities mentioned during the workshops.

Although the majority found daily activity-based tasks most relevant, some participants suggested that less common activities could facilitate rehabilitation by increasing motivation or providing abstraction.

Participants debated the relevance, advantages and nuances of unilateral and bilateral tasks and its influence on aspects of motor imagery, motor planning and neuroplasticity stimulation, with no clear consensus on which is better.

Unilateral tasks were recommended by some participants due to their potential to elicit more specific brain activation, thereby facilitating motor imagery and possibly enhancing signal capturing. These tasks may also reduce interhemispheric inhibition – a phenomenon in which the healthy hemisphere exerts inhibitory influence on the hemisphere targeted for rehabilitation, possibly leading to counterproductive effects. According to this point of view, the initiation of bilateral activities should only happen after mastery of unilateral ones (with the suggestion of starting with the less affected side), representing a progression.

On the other hand, some participants recommended the early integration of bilateral activities suggesting that their performance could enable the less affected hemisphere to support the learning process of the lesioned side. It was suggested initiating with tasks where the more affected side would have a "supportive role" of the movement of the less affected one, according to an asymmetrical execution- stated as more similar to daily life tasks. One participant stated that, in cases of severe disfunction, symmetric tasks might be more adequate.

The approach of incorporating both bilateral and unilateral tasks within the same session was also suggested, with the aim of leveraging the advantages of each. It was emphasized, however, that movements of the more affected side should occur with greater frequency, and the task order should be randomized to prevent habituation. On this case, there should be an option to select which arm to target, allowing for more focused practice on that side.

Additionally, the importance of respecting the nature of the task in real conditions was also mentioned to facilitate the access to motor memory, being that one activity that is typically unilateral or bilaterally executed should be carried out in that manner.

The use of specific activities to practice relevant movements was viewed to facilitate processes involved in movement planning and to increase engagement in the intervention. The movements and functions that were found relevant for stroke rehabilitation during the workshops are listed on Chart 1.2 (Appendix 4). Relatedly, participants noted that tasks engaging the upper limb in a more global and integrated manner activate a wider range of complementary brain circuits and are more aligned with everyday activities, as human motor performance rarely involves single-joint actions. Despite task completion is recognized as important and motivating, participants also discussed that, to facilitate motor imagery, especially at early stages, it might be necessary to break down tasks into smaller segments.

> "I always prefer training things that make sense to me in my day-to-day life, (...) things that are useful." (Pat 6, Wk 4)

> "To reduce the competition in terms of the cerebral hemispheres I would say that it could be unilateral. However, we know that bilateral tasks sometimes favour movement, active movement and rehabilitation. (...) I would invite unilateral activity and quite possibly try to inhibit the contralesional side." (RE 2, Wk 1)

> "Appealing to the reality of the activities, (...) for example, if I had an image of carrying a box with both hands, as it's a more symmetrical activity, it also appeals more to my register and the motor memory I have of the task. Maybe it doesn't make much sense to me to be lifting two glasses." (RE 1, Wk 1)

Personalized Task Selection

Participants defended that task selection should follow a personalized approach and consider both the user's preferences and relevant clinical traits. To ensure this tailored approach, participants stressed the importance of the therapist and stroke survivor having a variety of tasks from which to choose the one that best fits the stroke survivor's needs, goals and preferences. The practice of an activity that stroke survivors find significative will have a positive impact on their motivation and, consequently, will enhance functional gains. Thus, the selection of the task must be aligned with therapeutic and personal goals and should result from a collaborative decision process between the health professional and the user.

When considering clinical traits, it is essential to address not only motor impairments but also related symptoms and alterations that may influence motor planning and mental imagery. Additionally, factors such as pre-injury motor memory and hemispheric dominance can also affect the course and outcome of the intervention. This suggests that activities should be tailored to align with the stroke survivor's familiar patterns of movement for optimal results.

Imaging findings can also guide task selection by identifying preserved brain regions and helping tailor interventions to target specific lesions. This information enables the team to make more informed decisions about whether to promote contralesional or ipsilesional brain activity, optimizing the focus of the rehabilitation efforts based on the stroke survivor's unique neurological profile.

In cases of inattentional problems such as neglect, it is advisable to prioritize tasks that involve continuous stimuli that shift toward the neglected hemispace or provide alerts to capture attention on that side. This approach can help enhance awareness and engagement with the affected area.

In cases where participants experience difficulties with attention and concentration, it is likely that discrete tasks with clearly defined beginnings and endings would be more beneficial. Continuous rhythmic activities may reduce focus and engagement, making structured tasks a more effective option for maintaining attention.

> "We all have mental maps, (...) have several tasks that have significance, and the individual selects one of them. In each of them, also implement this possibility of variability." (RE 4, Wk 1)
>
> "The activities vary greatly, they're very personal." (Pat 10, Wk 5)
>
> "There's another thing that I think it should be done which is to analyse not only from a clinical point of view, but also with neuroimaging findings. (...) What area was spared or was it initially recovered after stroke? From that point it's very specific to the person. Was the stroke more localised to the primary motor area only? Or somatosensory and motor? Or there's pre-motor as well and other regions?" (Eng 1, Wk 6)

Guidelines for Structuring BCI Interventions

Starting Levels

The key concepts for the initial levels focus on simplicity, facilitated by task segmentation, and align with motor development theories that emphasize the primacy of gross motor skills. This approach ensures that foundational skills are established before progressing to more complex movements.

The simplicity of tasks shall be preconized to benefit both the process of mental imagery and adjusting to the capabilities of EEG for capturing brain activity. While EEG offers excellent temporal resolution, its spatial resolution is limited, making straightforward tasks more effective for analysis and interpretation. Considering motor imagination, the simplicity of the movement will help maintain the focus on the goal.

Participants noted that, especially in the early stages, segmentation can facilitate motor imagery, as it is challenging to visualize complex tasks with multiple movement components. Consequently, complexity should be viewed as a progression to be introduced only after mastering simpler tasks. However, even with this decomposition, participants emphasized the importance of balancing segmentation with maintaining focus on the overall task, thereby preserving the connection to movements in real-world contexts. One suggestion was to complement the segmented tasks with a video demonstrating the complete task to help reinforce this balance.

Participants also advocated for considering normal neuromotor development when constructing the various levels of tasks, prioritizing activities that involve gross motor skills before introducing fine motor activities.

> "Regardless of whether the patient is more able or less able, even for normal subjects, the task should be as simple as possible, simpler in terms of imagery. (...) we want a sensorimotor pattern captured that is representative of that task. If the task varies too much, or if it's fundamentally complex, I can't create an activation pattern that represents that task. This will then be very complicated..." (RE 10, Wk 3)

> "It's important to start by segmenting, with very simple things, because every part of the movement is difficult to imagine. For example, holding a fork it's very difficult to imagine because you must go over there, pick it up - each person picks it up in a different way - and keep holding it. So, starting off in stages and then gradually trying to add movements" (Eng 3, Wk 6)

Dimensions for Progressing

Progression is understood as the gradual increase in the difficulty level of a movement task. Task progression can be achieved by adjusting task components, modifying task parameters, or modulating technological features.

Due to the challenge of visualizing movements with multiple components and their correct timing, progressively adding components to a task was viewed as a valid method, with the caveat that this should only occur after the previous movement has been mastered. This type of progression may require more time and is likely to be achievable only over the long term, rather than in a single session. Although increasing the difficulty of the imagery task represents a form of progression, participants noted that it may be challenging to capture a distinct cerebral activation pattern using EEG. This makes it difficult to verify whether the stroke survivor is accurately modifying their brain activation patterns in line with the task they are being asked to perform.

Imagining familiar movements is perceived as easier due to the facilitation provided by motor memory, which is informed by prior experiences. Consequently, the introduction of less familiar and more innovative tasks is regarded as an effective strategy for increasing the difficulty of intervention. Additionally, it could also be a way of maintaining motivation levels throughout the sessions.

Another suggested method for increasing task difficulty is by modulating the threshold of imagination, defined as the intensity of brain signals required to elicit movement in the virtual environment. According to this method, the task being performed does not necessarily need to change.

The relationship of the activity to real-world contexts can enhance the perception of task difficulty. In this type of progression, visual alterations of the object based on difficulty, along with cognitive cues provided by technology that confirm thoughts about the object, were seen as facilitators of the sensation of increased difficulty. Similarly to conventional scenarios, participants suggested that increasing the range of motion of a movement could serve as an effective method for progression.

Introducing a dual cognitive task or increasing the feedback stimuli during motor imagery could raise the task's difficulty. The dual task, such as exploring the environment, shifts the user's attention away from the primary motor goal, adding cognitive load and making the task more challenging.

> "That's not to say that you can't do something more sophisticated. Some people have done decoding, but it's not easy [RE 3- But it's not easy]. It's true that if you think about various movements, different segments of the upper limb are located in slightly different regions, but the imagery patterns are typically a little blurred" (Eng 1, Wk 6)

> "I think that initially we should also start with more familiar tasks and as activation improves, possibly as a matter of motivation, novelty and stimulating more cortical representation, we'll move on to new tasks" (RE 5, Wk 2)

Progression Criteria

Progression criteria act as an indicator that the user is ready to advance to a more challenging task level. Discussed criteria encompass various aspects, including human assessment and technology-assisted feedback, to determine when it is appropriate to increase task difficulty.

Participants suggested that the decision to progress to a more challenging task could be made collaboratively by the stroke survivor and the health professional, according to the stroke survivor's performance and insights. This approach aligns with the core principles of individualization and collaboration, fostering a shared decision-making process within the therapeutic alliance. Ideally, task progression would be based on the stroke survivor's improvement performance over time. Progression could also be activated according to a time principle, where it would occur after a time of accurately performing the proposed task. Using gamification, scoring systems were also identified as a potential tool for guiding progression. In this context, accurate repetitions of movement imagery could be tracked, and upon reaching a predefined number, progression to the next level could be unlocked.

Considering performance monitoring, EEG potential could also be leveraged to provide an objective measure for determining the ideal moment for progression. Participants suggested that the connectivity of different electrodes can be monitored, and an increase in connectivity may serve as an indicator that the imagery activity is becoming more robust, suggesting a readiness to advance to the next level.

> "Here you could also make a system of trying and counting successes of repetitions like in gaming, for example, but then with the user's decision. [RE 3 - But including the user's decision]." (Eng 2, Wk 6)

> "One possibility is to look at the connectivity of the EEG [Eng 1- Yes] because, in principle, if the connectivity is too great between several zones, there will be greater recruitment because there is a lot of effort being made. As connectivity becomes more concentrated [RE 3 - Exactly], it means that the person is optimising the task they are training for. Connectivity with the EEG can help. With this type of set, it will be electrode-based connectivity, you can't do the other part, which is regional" (Eng 2, Wk 6)

Session Duration

One of the aspects discussed regarding the design of BCI-based motor imagery interventions was the optimal session duration. The ideal length should balance the achievement of meaningful neural changes with maintaining motivation to ensure effectiveness and sustained engagement. Participants suggested that sessions should not exceed 20 minutes, citing the difficulty of maintaining adequate attention levels due to the repetitive nature of the tasks and their high cognitive demands.

Rehabilitation experts reported a higher recurrence of fatigue during upper limb rehabilitation compared to interventions targeting other objectives, indicating that upper limb recovery is a more demanding activity. Since the intensity of the task can be experienced differently and have varying consequences for each individual, fatigue emerged as a reliable and person-specific indicator. It is crucial to measure fatigue to determine the appropriate endpoint for each session or to identify the need for breaks, thereby minimizing the phenomenon of reduced motivation. Rest was found to be beneficial in promoting recovery processes that help the brain assimilate new skills and consolidate gains, therefore, optimizing the learning process. The importance of integrating BCI therapy with conventional therapy was emphasized by participants, stating that if it respects patients' fatigue and tolerance levels, it could have better benefits if occurred before conventional therapy.

> "Usually, it's always the activities with the upper limb that cause the most fatigue (...) Or, they can disperse more the attention." (RE 2, Wk 1)

> "We have to assess from person to person and understand how long the patient can hold out. Some can take 15 minutes, others 10" (RE 12, Wk 6)

> "Because in practice we'll be teaching the brain to think about motor skills again. Therefore, for learning, we need breaks, we need repetition. So, it's more advantageous to do repetitions and perhaps shorter cycles than doing a one-hour session, no?" (Eng 1, Wk 6)

Key factors influencing motivation

Variability

Variability was defined as the variation of a task without altering its inherent nature or difficulty. Stroke survivors expressed the negative impact of continuous repetition on their motivation, noted evoking feelings of monotony and making it difficult to maintain attention and focus on the task. Variability was proposed as a means of "repeating without repeating," serving as a monotony breaker and aligning tasks more closely with real-world contexts, where pure repetition is rarely encountered. Although it is important, participants cautioned that variability should be introduced progressively to avoid disrupting focus on the task.
Participants suggested that alternating the type of feedback provided could help break the cycle of demotivation and inattention. The effectiveness of offering varied, tactile, visual and auditory stimuli was explored as a means to provide novel information, promoting the maintenance of user engagement. Incorporating variability in visual content was frequently mentioned as a key strategy. Additionally, the introduction of fictional elements, characters, or well-known celebrities could enhance task variability and further engage participants.

> "And for some people this can be demotivating, doing the same task over and over again." (Pat 17, Wk 5)

> "Here, although it's the same manual clamp for the car, it has a different abduction and external rotation component. But to put several doors, or a house door, or a shop door where it's always the same movement, that's repeating without repeating. Because it varies according to the context, but the task is really the same" (RE 2, Wk 1)

Gamification

Creating gamified VR scenarios through the introduction of game-like elements into the tasks, namely, scoring, was recognized for its ability to reduce the focus on the movement itself, ultimately facilitating execution. Through the power of abstraction, stroke survivors reported experiences of achieving greater range of movements than they had initially thought possible, especially compared to tasks that required more concentrated effort when engaging in game-based therapies. This de-emphasis on strict focus helped alleviate the negative emotions typically associated with challenges in arm movement. Furthermore, gamification was seen to support repetitiveness, which, in turn, promotes the learning process.

Participants noted that assigning scores to task performances could leverage this playful atmosphere. Since individuals may respond differently to gaining or losing points, participants suggested that the scoring system could be adjusted by the health professional, representing an additional method for personalizing the intervention.

> "(when playing) I would relax and practise the movements in a pleasant and emotionally unburdened way." (Pat 13, Wk 5)

> "Of course, if a person loses, they can become demotivated. You can always do gamification to win badges, to win... medals and to win points and to win anything and never lose. Which is one of the gamification options." (Pat 10, Wk 5)

Activity Demand

This dimension was recognized as having a significant impact on motivation because when tasks are perceived as too difficult, stroke survivors may feel discouraged, while tasks that are considered too easy fail to provide adequate challenge - leading to similar feelings of demotivation.

To address this issue, participants proposed that the intervention program should include a graduated system for task selection that enables the identification and selection the optimal level of difficulty, based on each stroke survivor's capabilities. Participants stated that it is essential to implement an ongoing process of monitoring and adjustment that may involve either increasing or decreasing task difficulty. Employing a rationale based on small incremental steps would allow for the inclusion of intermediate levels, thereby preventing tasks from being excessively easy or overly challenging.

> "I think that (...) the activity can be graded, and the therapist himself defines what kind of activity he can do, doesn't he? And how difficult is it for that patient?" (RE 3, Wk 1)

> "So it's roughly this game theory. You want to be in the sweet spot between the difficulty of the task and your competence. (…) So the difficulty has to be such that I can overcome it. If I can't, you adjust the difficulty. That's how you progress. And that's what best keeps the attention and engagement of the participant, the patient." (Eng 1, Wk 6)

Technology Features

Set-Up Considerations

Regarding the physical position of the patient, although the intervention does not involve movement, participants identified two key variables that should be considered: comfort and the promotion of postural stability. Therefore, appropriate back support should be provided and if possible, support for the upper limbs on a table or equivalent surface. This was considered to promote an external contextual organization that could facilitate a greater focus on brain activation.

When providing the instructions for the task to be performed, previous action observation through video was considered a facilitative strategy for explaining tasks to stroke survivors, particularly in aiding communication with those who have language impairments. Additionally, it was seen to enhance the precision of motor imagery-related brain activity.

"To me it makes sense that the person is comfortable, right? In a comfortable position and that there won't be confounding variables around while he is doing this, right? (for example) The person being unbalanced and trying to manage what is the real body with the virtual body (would be confusing or distracting)" (RE 10, Wk 3)

"(...) to ensure that the task is recognised, not only in its context, but also in its objective, having an example of a person reproducing the movement would be important because it has cortical representation (...) which would give a better feedforward." (RE 2, Wk 1)

Providing Feedback

The immersive virtual environment was viewed as beneficial for creating enriched contexts that facilitate neuroplasticity through meaningful, multisensory, and enjoyable stimuli. However, while coincident stimuli can enhance neuroplasticity, participants noted that in individuals with attention deficits, perceptual disturbances, or sensory impairments, overstimulation could lead to negative effects. This highlights the need for personalized feedback, allowing adjustments in the quantity and intensity of stimuli to meet individual needs.

Regarding visual feedback, participants raised several considerations. Human-like features appear to be more interesting and meaningful to users, with recommendations to match skin tone and, ideally, clothing. However, the use of "extraordinary" characteristics may also serve as a motivational factor and help distract from the movement, potentially enhancing the abstraction benefits. The visualization of movement through an avatar can sometimes aid in the perception of that movement. One participant with perceptual changes noted that after observing a doll in a game during an occupational therapy session, her understanding of postural alignment improved, increasing her bodily awareness. Additionally, related to body schema, participants mentioned that the presence of both upper limbs within the field of vision would be mentally beneficial and help with organization. Given the neurological changes often present in stroke survivors, it was suggested that some participants may not tolerate the use of virtual reality glasses. In such cases, the alternative use of a large screen was proposed to induce a sense of immersion without preventing the user from completing the task.

Considering haptic feedback, stroke survivors highlighted the importance of receiving tactile stimulation, in addition to visual engagement, also relating it with the fact that tactile sensory modality is sometimes diminished. The most frequently mentioned type of tactile input was vibration, with the suggestion that its characteristics could vary depending on the nuances of the task and scenario. The use of Transcutaneous Electrical Nerve Stimulation (TENS) was also highlighted as a promoter of cortical reorganization, enabling adjacent circuits and neurons near the lesion site to contribute to the development of new cortical organization.

In addition to observing the movement in virtual reality and receiving the haptic feedback, stroke survivors expressed that it would probably be more meaningful and beneficial for them to experience the movement, including proprioceptive feedback as a feature. Consequently, it was suggested that either simultaneously or following the imagined movement, a device (e.g. glove) should facilitate actual hand movement.

The use of a robotic device was mentioned and justified by the fact that attempting to move the hand would increase muscle tone.

> “I think the strategy here is that you're adding stimuli or cues, that the brain can pick up to support the final intention. So, this question of the shark is excellent, because in practice I'm going to have extra motivation here. By activating the amygdala I'm going to look for other resources to carry out the task.” (Eng 1, Wk 6)

> “So, the only thing you have to do is open and close the glove, when we think about opening and closing. And that would solve the feedback, the haptic feedback, of what the person does... [Pat 9 - Exactly! It's the moment our brain recognises, we can a...] Because our hand doesn't close, does it? But if I think about closing and the hand closes, it might be interesting.” (Pat 10, Wk 5)

Discussion

By undertaking a multi-perspective qualitative study, this study aimed to explore the insights from both rehabilitation experts, stroke survivors and biomedical engineers. From the analysis of the results, six themes emerged with key recommendations for the design and implementation of a BCI-MI-VR tool for upper limb post stroke rehabilitation, which can significantly enhance the effectiveness of stroke rehabilitation. By integrating the perspectives of diverse stakeholders, the study ensures that the BCI-MI-VR tool is not only technically sound but also user-friendly and tailored to the needs of stroke survivors.

Patient Centered Care

The individualization of treatment throughout the intervention process, associated with multidisciplinary teamwork and shared decision-making emerged from the study as important, representing also essential pillars of the Patient Centered Approach, as described by the World Health Organization (WHO) [51]. It is a recommendation in line with international guidelines for UL rehabilitation after stroke and the global guidelines for the provision of health care [11,26,27,52].

This collaboration has the role of establishing treatment goals in a shared manner, having in mind the patient’s functionality. According to the assessment carried out by the team, a discussion must be conducted with the patient and his carers to set personal goals, directly influencing the treatment plan [11,52], according to a patient-centered approach. This means that goal establishment must consider that the needs of each individual vary influenced by stroke type, symptoms and individual’s cultural and psycho-social circumstances and must be well-documented, specific and challenging [52]. These principles are in line with the recommendations pointed out by our participants to have in account when designing and implementing BCI-MI-VR-based technologies. Accordingly, setting goals was also one of the factors that stroke survivors from our study mentioned positively influenced their experience in rehabilitation and their motivation. In line with our results, Maiselli et al. [53] and Isbel et al. [54] also state that the inclusion of stroke survivors and health professionals for the development of technologies is important to optimize stroke survivors' adhesion and motivation.

In a qualitative study specifically considering recommendations for virtual reality-based interventions development, stroke survivors stated that the accompaniment by a therapist, at least occasionally, is important for them, to receive specialized counseling and orientations [54]. This is also in line with what participants from our study shared. On the other hand, it was stated that being able to perform rehabilitation activities autonomously is important and motivational for their rehabilitative process. Establishing its association with the self-efficacy theory, Kim et al. [55] demonstrates that combining autonomy support (providing individuals the ability to control their own behavior) with an information technology device enhances upper limb performance and promotes the use of the more-affected UL after stroke.

Clinical Evaluation and Patient Selection

Regarding assessment aspects, the importance of an extensive, complete and in-depth assessment of different aspects - beyond motor skills, including cognitive, emotional, and communicative domains - was made clear by our participants to ensure the effectiveness and appropriate delivery of care. In the study conducted by Isbel et al. [54], participants also established the importance of a comprehensive person-centered assessment, in order to establish the UL impairment level and the person's skills and interest in using the technology.

For a truly holistic, biopsychological assessment of the stroke survivor, WHO created International Classification System (ICF) [56]. Despite the recommendations for stroke assessment across three dimensions (Body functions and structure (impairment), Activities (limitations); Participation (Restriction))[56], most research primarily addresses structural factors, with only a portion including activity [57].

Considering body functions and structure assessment, workshop participants recommended the use of Fugl-Meyer which in line with international guidelines for stroke assessment on the structural dimension both in clinical and research context [58,59]. For assessing the activity dimension, the Action Research Arm Test (ARAT) is the recommended measurement instrument [59]. Although current recommendations rely on clinician-scored evaluations, these are subjective and often lack sensitivity to subtle motor changes during rehabilitation [60]. Integrating instrumental evaluations, like inertial motion sensors, into clinical assessments of upper limb impairment could enhance the accuracy of upper limb impairment assessment through traditional methods and provide novel insights into functional domains and motor behavior [61]. These could provide complementary information from patient-reported outcome measures relating to activity and participation to fully assess UL impairment [11]. In the context of investigation of upper limb-oriented interventions, international guidelines also recommend measuring the quality of movement performed. In this domain, 3 measuring instruments are recommended as performance assays (2D reaching; Finger individuation and Grip/pinch strength) and a 3D functional drinking task [62].

In line with recommendations from our participants, given that the intervention is fundamentally based on motor imagery—requiring stroke survivors to engage in task imagery - it is essential to establish clear criteria to assess this capability effectively [25,26]. Assessments must include motor imagery ability and consider neuropsychological aspects such as attention and concentration [21].

In this respect, there was some contradiction in the opinion of different participants regarding impairments in attention, perception and mental imagery capacity. With regard to imagery capacity, it was considered that a low performance on an evaluation scale should not be an exclusion criterion but should influence the degree of imagery training to be carried out with the participant, which is sustained by some of the evidence found. Based on an observational study on influencing factors on motor imagery, Poveda-García et al. [24] found a significant correlation between MI ability and upper limb movement, functionality, and strength, suggesting functional equivalence between MI and actual motor execution. Authors state that these findings may relate to decreased cortical representation of the upper limb due to disuse from impaired movement. Additionally, visual–spatial skills were correlated with MI visualization quality, indicating that altered visual-motor skills may impact both MI and movement. Rienzo et al. [30] found similar evidence but stated that, according to the evidence found, visuo-spatial and perception impairments seem to have more influence in MI tasks of implicit and not explicit nature once implicit MI involves manipulation of mental representations of affected body parts. Considering neglect, there is evidence showing that, not only contralesional upper limb visuomotor MI tasks reduced some neglect symptoms (copying and drawing tasks) but also enhanced UL sensation [63]. These clinical traits are more commonly associated with parietal left hemisphere lesions and [64] states that parietal stroke survivors are often excluded from motor practice studies. Even so, this lesion location alone does not necessarily predict MI capacity, as neuroplasticity may allow other brain regions to compensate for the damaged areas [30].

These findings should be carefully considered, as characteristics like neglect, perceptual impairments, and visuomotor deficits may not justify excluding stroke survivors from studies or clinically implementing BCI-MI-VR that involve explicit MI. However, these factors could influence the required motor imagery training and task difficulty selection. Additionally, it alerts for the fact that stroke progression stage may influence intervention effectiveness.

Recommendations for Task Design and Selection

In order to be relevant and enhance therapeutic benefits, participants said that the tasks executed through BCI-MI-VR technology should be related to everyday life, be based on activity practice and incorporate the potential of bilateral and unilateral activities. Accordingly, rehabilitation principles to augment motor control and restore sensorimotor function recommend task-specific and meaningful training in a repetitive manner [27] and be functional-based [26,65]. As a factor influencing the meaningfulness of the task, participants in our study mentioned the importance of the activities being based on ADLs, as they represent more useful activities when transferred to real needs. These results are in line with those collected by Isbel et al. (2024) in a study of the same nature, with participants stated that the use of daily encountered activities is not only more relatable but also more motivating.

Although the paradigm of BCI-MI-VR does not involve motor practice, it has overlapping principles with task-practice interventions, extensively scientifically supported [26,27,65,66] and its principles may be useful for task design. Hubbard et al. [67] proposed the following criteria to describe and orient task-practice interventions: 1) training should be relevant to the patient, (2) should be repeated, (3) provided in a randomized order, (4) contain tasks that are part of a whole task (Reconstruction) and (5) feedback should be provided (Reinforcement). One of the principles presented by Van Wegen & Rietberg [65] for task practice is that the specificity of treatment effects is not only related with the movements itself but also with the practice environment (i.e. using context-specific tasks in a relevant environment to the stroke survivor. This is a perspective that VR can leverage, being able to represent different kinds of scenarios, allowing the correct selection for stroke survivors' needs.

This recommendation is significant because, although current VR development guidelines consider the importance of task relevance [68], a meta-analysis conducted [7] on the design characteristics of various BCI paradigms reveals a gap. The analysis found that the most common BCI tasks involved motor attempt or imagination of grasping and extending the fingers, multi-joint movements (including wrist, elbow, and shoulder), or the movement of individual fingers. Some studies used target-chasing tasks, while only two studies included activities related to daily living (drinking water, moving an object to different shelves, using two hands to move a towel, pouring water into a glass, and eating). These findings contrast with the preferences of our participants and the rehabilitation guidelines, which emphasize a preference for practicing specific, everyday tasks instead of movements. Based on these results, it is crucial to steer BCI task development towards activities that mirror daily life functions. Aprigio et al. [31] provide an overview of the tasks used for MI, which are based on daily life activities and reveal to be similar to those mentioned as important by our participants.

When considering the practice of bilateral or unilateral activities, evidence shows contradictory evidence, similarly to our findings, noting that the effects of one type of activity over the other are unclear and that, although the benefits offset the risks, the efficacy of bilateral arm training is not well-established [8,29]. Evidence shows that there is no superiority of effect between bilateral arm training (BAT) and unilateral arm training (UAT) for motor impairment or functional performance [69] and clinical guidelines recommend that bilateral arm training should not be preferred over unilateral arm training for enhancing motor function in the upper extremities (Level A evidence) [27].

When comparing bilateral-arm training with conventional therapy or with UAT, it is found that bilateral activities have a positive influence on upper limb motor function post stroke on body function outcome measures [70–72], but it favors unilateral activities when considering activity assessment [71]. In line with the participants' recommendations, Hse [26] recommend that both bilateral and unilateral arm training must be considered, taking into account the task and level of impairment. When assessing success factors, S. Chen, Qiu, et al. [69] found that BAT might be more beneficial to mildly impaired individuals in the chronic phase, if applied with higher dose of intervention and when practicing functional activities.

Similarly to the evidence presented for task-based interventions, these studies have motor practice as a basis. However, they are included here due to the lack of specific research comparing mental practice of unilateral versus bilateral activities. The authors found that this evidence may provide relevant insights for developing BCI-MI-VR tasks based on the premise of cortical activity overlapping between motor practice and motor imagery, as previously noted.

When considering activity selection, participants found that a personalized approach and shared decision-making with the stroke survivor should be followed. This aligns with recommendations from Isbel et al. [54], who identified this strategy as a way to enhance motivation and engagement through the possibility of choosing from a variety of options. According to other qualitative study shared decision-making enhances the personalization and meaningfulness of upper limb intervention after stroke [73].

Individualized decision making serves the purpose of respecting personal preferences but also accommodating different clinical traits. Considering adaptations to neglect suggested by our participants, the scanning strategy towards the neglected side or the provision of cues is also stated by the Stroke Foundation [52] and Canadian Stroke Best Practice recommendations [27], establishing the bridge with reduction of impairments in activities of daily living. Additionally, visual scanning training [29] recommend the utilization of mental imagery practice.

Guidelines for Structuring BCI intervention

The importance of activity grading was seen as important for better alignment with the stroke survivor's abilities and rehabilitation goals. Isbel et al. [54] also highlighted the importance of activity grading and progression, emphasizing that the clinician's clinical reasoning is essential in managing and guiding these aspects. Consistent with the recommendation to grade activities and adjust difficulty to match the stroke survivor's abilities, Proulx et al. [39] emphasize the importance of tailoring tasks to individual progress. They advocate for adaptable difficulty levels and appropriate task demands, noting that active practice intensity requires continuous attention and focus from the stroke survivor.

Consistent to the suggestion of task segmentation made by participants, recommendations present that upper limb rehabilitation training should be structured to simulate either partial or complete tasks necessary for activities of daily living with the use of the affected limb (i.e. folding, buttoning, pouring, and lifting) [27]. Considering randomization and segmentation, findings from our study are also in line to Hubbard et al. [67] task-practice paradigm.

While task complexification was identified by our participants as a key method for progression, the use of EEG to capture brain activity may present challenges once it has a good temporal resolution but a poor spatial one [19]. Although BCI systems enable the recording of activity in cortical and subcortical networks, the detail and extent of captured information largely depend on the signal acquisition method. Capturing motor imagery activity is most effective in the premotor cortex, primary motor cortex, and supplementary motor area, which are activated alongside the basal ganglia and thalamus [74]. The fact that EEG is a non-invasive method makes that only the first are possible to read, having the necessity of utilizing intracortical electrodes for capturing basal ganglia and thalamus activity [16]. So the fact that the complexity of the task and imagery is increasing may not be fully encompassed by the signal being captured. These reflections arise from the concern that practicing an activity incorrectly, even through mental imagery, could reinforce neural circuits that are detrimental to motor practice. This underscores the importance of accurately measuring brain activity and ensuring that task imagery is appropriately aligned with the intended motor goal.

As briefly mentioned by our participants, utilizing high density mapping could increase spatial resolution but difficult signal-to-noise ratio across channels [75]. The challenges associated with processing data acquisition and pattern recognition in BCI-MI based interventions are increasingly being studied in order to overcome the challenges associated with using EEG and improving accuracy [76]. Saha et al. [16] theoretically explore the addition of other source capturing signals like fNIRS or MEG in a complementary way to EEG to boost classification performance. The recommendation to create more complex scenarios by increasing cognitive demands (e.g., by introducing additional stimuli) aligns with previous recommendations [39,77] and offers an alternative means of raising task difficulty. This method emphasizes cognitive mechanisms rather than relying solely on motor challenges, recruiting dual-task mechanisms as stated by participants.

According to the participants considering progression criteria, connectivity can serve as a complementary metric alongside stroke survivor and therapist input for determining readiness to progress. The usage of connectivity to assess motor imagery efficacy is consistent with findings by Bagarinao et al. [77], which indicate that motor imagery expertise leads to more targeted recruitment of motor networks in the brain and results in higher activation intensities. Considering the integration of BCI-MI-VR in clinical practice, participants stated it should be done in a complementary way to conventional therapy, which is corroborated by the findings of Kruse et al. [21], with MI acting as a priming tool with positive influence on impairment and activity outcomes in patients with stroke [78].

Key factors influencing motivation

While repetition is essential for neuroplasticity and learning, requiring substantial practice volume and intensity, it can present challenges for sustaining patient engagement and motivation. Additionally, motivation levels directly influence the process of upper limb rehabilitation [79], posing as a fundamental aspect of intervention planning. In line with our recommendation's, participants from Isbel et al. [54] also stated that motivation can be enhanced through realism, gamification, scoring and feedback.

Creating variability, without changing the nature of the task was one of the aspects covered by our participants. Van Wegen & Rietberg [65] establish the same recommendation according to Level 2 evidence, stating that the mentioned "repetition-without-repetition" has a positive role in motor learning. Although it may be difficult to capture or differentiate task variability via EEG signals, participants suggested incorporating variability through the scenario design itself. They emphasized, however, that this should be done carefully to avoid disrupting focus on the primary task.

Another strategy to support repetition while maintaining engagement is to keep task demands appropriately challenging, requiring continuous adaptation and progression [27]. In addition to supporting motivation, tasks should be both sufficiently challenging and adaptable to effectively promote motor learning [40]. Poveda-García et al. [24] state that motor function correlates with motor imagery capacity, this might suggest that task difficulty level should be aligned with motor function. In a related manner, Di Rienzo et al. [80] found that the difficulty of the task can also induce fatigue and boredom in tasks associated with low physical demands, one topic on favour of considering ideal task demand, in a study with 25 healthy participants.

Gamification is also a strategy with proven results on rehabilitation and associated with higher levels of motivation [81] and its addition to VR shows the improvements of the overall effect in comparison with only the virtual feedback [35].

Technology Features

VR-BCI-based technologies provide an exceptional opportunity to harness multisensory stimulation, enhancing the potential for motor learning. Participants highlighted the importance of being able to adjust type and intensity of feedback to each stroke survivor considering clinical traits such as difficulties with attention or tactile hypersensitivity (who would require less stimuli). In line with this recommendation, Proulx et al. [39] state that the decision-making process during treatment design for stroke individuals must consider: feedback delivery parameters; task complexity; heterogeneity of sensory deficits. The same authors argue that the intervention should combine different modalities of augmented feedback, carefully adapted to the specific condition of each individual (contrary to the 'good-for-all intervention' paradigm commonly found) and that, in the absent knowing how which feedback modality informs movement, multimodal feedback should be favoured.

In the paradigm for which the recommendations were studied, visual feedback would be provided through VR glasses. However, one participant mentioned that, if the user had no tolerance, a large screen could also be used. Although cybersickness is a phenomenon encountered in fully immersive VR [68], it seems to have greater advantages in terms of presence, which seems to enhance the system's effectiveness [82]. Providing visual feedback coincident with the task performed makes use of the mirror neuron system and is a form of action observation. The mirror neuron system promotes motor performance by stimulating internal modelling, consolidating sensorimotor representation and facilitating the learning or relearning of motor functions [83]. In this line, Poveda-García et al. state that utilizing motor observation in adjunction with motor imagery could increase success rates for upper limb rehabilitation [24,84]. In addition to the benefits of motor observation promoted using VR, the fact that a prior layout is given for motor imagination may be of interest since visual input influences motor planning [85], thus enhancing the imagery of the task. That is because vision plays an important role in modulating motor output, as it is what allows the brain to have a sense of the surrounding environment and to programme motor action in interaction with space, a capacity called visuo-motor coordination [86]. As suggested by participants, this could be held in account since the moment of providing task instructions, which could be made through video presentation.

The importance of managing sensorimotor tactile impairments when considering a BCI-MI-VR tool was also made clear during the workshops. The use of a glove was suggested to provide different vibratory stimuli in line with the scenario. In the opinion of the participants, the glove would allow both tactile stimulation and the promotion of movement, which was considered important to experience accompanying as motor imagination. Participants pointed out that the movement should be promoted by an external device since the motor attempt could trigger spasticity phenomena. The utilization of a haptic stimulation glove in association with semi-immersive reality and conventional therapy is described to promote significative effects on UL functionality outcomes both short- and long-term effect [87]. Participants also suggested that electrical stimulation, namely TENS, could be used to provide tactile feedback. This recommendation was associated with the painful complaints of a user with shoulder subluxation (pain was mentioned as a disabling symptom by users) and as a way of providing hand stimulation to promote cortical reorganisation. Sensory stimulation (namely TENS, biofeedback and acupuncture) can be considered as a complement to improve upper extremity function in UL rehabilitation, according to type B evidence [27]. The same guidelines recommend the use of functional electrical stimulation (FES) at the level of the wrist and forearm to reduce motor disability and improve function in acute and chronic phases of upper limb rehabilitation, according to type A evidence. In a meta-analysis comparing different design features of BCI interventions, the sub-group test between FES and robotics (hand exoskeleton, MIT-Manus Robot, robotic hand and arm orthosis and virtual hand), showed results in favour of the use of FES in improving the function of the UL (based on the FMA-EU only a measure of Structure and Function) [17]. Bai et al. [22] also compared the use of robotics, FES and visual feedback, showing results in favour of FES to improve UL function. In a related manner, although MI and motor execution share overlapping cortical substrates, one of their primary differences is the lack of movement in MI, which limits sensory feedback [30]. This distinction may influence motor execution-based BCI interventions higher efficacy on UL function rehabilitation [17,22]. The additional proprioceptive feedback from externally facilitated movement could amplify neural engagement, promoting more effective motor learning and recovery, while avoiding maladaptive patterns often associated with spasticity, as noted by stroke survivors in this study.

Limitations

Although the relatively large sample size (N=33) is a strength, participants' limited experience with the technology, owing to its innovative nature and lack of clinical implementation, suggests the need for a Delphi consensus study to validate the recommendations.

Many of the recommendations suggested were based on a theoretical foundation and construct validity. It will be important to develop efficacy studies that make it possible to adequately isolate the influencing variables and mechanisms of action. Future studies should allow analysis of the interaction between the different types and intensity of feedback (i.e. immersive and non-immersive VR) and its relationship with the characteristics of the task (i.e. unilateral and bilateral activities) and the user. When considering stroke survivors' characteristics, it will be important to stratify the data according to level of impairment of motor, sensory and somatosensory function, neuropsychological and perceptual alterations, stage of evolution and lesion location. Studies conducted should also establish the effectiveness of the intervention in the various dimensions of the ICF and the cost-benefit ratio for different intervention features.

The recommendations made have endeavored to take into account the real capabilities and constraints of technology. Technology should move towards improving its technological solutions to bring their characteristics closer to those of real life and provide answers to stroke survivors' clinical needs, seeking a balance between personalization and diffusion.

Conclusions

The BCI-MI-VR paradigm was very well received by participants in our study. The recommendations made regarding the development and implementation of BCI-MI-VR technologies will aid the technology's development and impact in UL rehabilitation, as they are based on concrete auscultation of all the stakeholders involved contributing to solution usefulness and, possibly, efficacy. The recommendations raised should be taken into account in the future to guide studies that allow the analysis of the relationship between different characteristics of the stroke survivor (i.e. injury aspects and degree of upper limb impairment), the motor imagery task (laterality, demand, nature) and the technological features (modality and intensity of feedback). This manuscript follows the principles and guidance for authors of the Journal of Medical Internet Research.

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Ethics

The study was approved by the Ethics Committee of the Polytechnic Institute of Setúbal (CE-IPS 35/2023) and Centro de Medicina de Reabilitação de Alcoitão (2013_013). All participants were informed of the aims of the study, procedure, risks, and confidentiality through an invitation letter (Appendix 5). Prior to taking part in this study the participants signed the informed consent form (Appendix 6).
Participants were also informed that workshops would be recorded, their identity would be kept confidential and that they had the right to withdraw from this project at any time without any prejudice.

Conflicts of Interest

Authors declare no conflicts of interest.

Abbreviations

BCI: Brain Computer Interface
MI: Motor Imagery
VR: Virtual Reality
UL: Upper limb
TENS: Transcutaneous Electrical Nerve Stimulation
BAT: Bilateral arm training
UAT: Unilateral arm training
FES: Functional Electrical Stimulation

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Appendix 1 – Summary of Workshop 5

Resultados do Workshop sobre a Reabilitação do MS após AVC com utilização de BCI-MI-VR

Em Janeiro de 2024, realizámos uma sessão de partilha entre utentes do CMRA, para perceber aspetos sobre a reabilitação do Membro Superior (MS) após AVC e a utilização de Interface Cérebro-Computador (ICC), Realidade Virtual (RV) e Imagética Motora (IM) na reabilitação. **Nesta sessão chegámos às seguintes conclusões:**

Sobre a Reabilitação do Membro Superior...

- ·**Objetivos** mais importantes:
  - Facilidade de realização das tarefas do dia-a-dia (comer, vestir, higiene) – aumento da funcionalidade;
  - Independência;
  - Participação nas dinâmicas familiares e interação (abraçar, dar aperto de mão, brincar com os netos);
  - Gestão dos Sintomas (dor, sensibilidade, destreza).
- **Fatores Facilitadores** da Reabilitação do MS:
  - o Trabalho por objetivos e alcance dos mesmos;
  - o Ajuste da exigência das tarefas;
  - o Relações interpessoais;
  - o Receber feedback positivo;
  - o Não repetitividade e monotonia das atividades;
  - o Ter motivação para a recuperação;
  - o Personalização da intervenção.
- Importância do **trabalho autónomo** de forma adicional ao **trabalho acompanhado** por um terapeuta

Sobre a Tecnologia...

- **Benefícios da Realidade Virtual e Gamificação**
  - Promove **abstração do** movimento
  - Diminui a **Carga emocional**
  - Aumenta a **motivação**
  - Facilita o **Movimento**
- **Feedback** importante: Sensitivo e de movimento
- **Avatar:** Características humanóides
- Deve ser um **complemento à Terapia Convencional**

Sobre a Tarefa...

- **Seleção Individualizada** em função do quadro clínico (Ex. Neglect) e preferências do utente;
- **Características da Tarefa**
  - Preferência por atividades do dia-a-dia;
  - Treino de movimentos específicos de forma complementar à realização de atividades;
  - Ficcional VS Realista - diferentes benefícios: abstração VS treino de atividade do dia-a-dia;
  - Preferência por atividades bilaterais.

Existem pontos com os quais discorda da maioria? Ou em que não conseguiu exprimir claramente a sua perspetiva?	Gostaria de aprofundar ou comentar alguns dos tópicos já discutidos?	Gostaria de acrescentar temas para discussão ou consideração futura?

Outros comentários:

Novamente agradecemos imenso a sua disponibilidade para participar e contribuir para o avanço da ciência para a reabilitação do Membro Superior!

Appendix 2 – Summary of Workshop 6

Resultados do Workshop sobre a Reabilitação do MS após AVC com utilização de BCI-MI-VR

Em Julho de 2024, realizámos uma sessão de partilha entre utentes, profissionais de sáude e engenheiros biomédicos, para aferir determinados aspetos sobre a reabilitação do Membro Superior (MS) após AVC e a utilização de Interface Cérebro-Computador (ICC), Realidade Virtual (RV) e Imagética Motora (IM) na reabilitação. **Chegámos às seguintes conclusões:**

Para a **implementação da intervenção** e realização de **estudos clínicos deve...**

- Assegurar-se a **cooperação** entre a **equipa clínica** e a **equipa de investigação;**
- Utilizar-se a referência de uma **base normativa;**
- Realizar-se uma **avaliação estruturada** que englobe:

Critérios de Inclusão

Motivação do Utente para a terapia

Critérios de Exclusão

Avaliação Cognitiva
Avaliação da Linguagem

Fatores de influência

Neglect
Capacidade de Imagética
Depressão

Estruturação da Intervenção

Duração da sessão

- Não devem ser ultrapassados os **20 minutos**.
- A **fadiga** deve ser um indicador da duração ótima.
- Realização de **pausas** visando **atenção** e **motivação**

Tipo de Atividades

- Atividades **Significativas**
- Inclusão de atividades **unilaterais e bilaterais** (distintos benefícios no planeamento motor)

Criação de Níveis

- **Níveis Iniciais:** movimentos simples e associados a motricidade grosseira;
- **Progressão**:
  - Componentes de movimento;
  - Complexificação da tarefa (motricidade fina);
  - *Threshold* de imagética;
  - Número de variáveis cognitivas;
- **Timming de progressão** definido pelo terapeuta e utente. Poderá ser complementado por medidas objetivas como a taxa de sucesso de tentativas ou a conectividade do sinal.

EEG pode apresentar constrangimentos na leitura de padrões de movimentos complexos

Informação imagiológica poderá ajudar a estabelecer o prognóstico e suportar decisões clínicas

Intervenção BCI **complementar a terapia convencional (TC).** Na ausência de fadiga, realizar sessão BCI de forma prévia a TC.

Appendix 3 – Thematic Analysis Synthesis

Theme	Subtheme	Participant	Citation
Importance of Patient Centered Approach	Individualization of Care	(Pat 2, Wk 4)	"Eu acho que em primeiro lugar, temos que dar consciência de que cada AVC é único e diferente dos outros, assim como que cada processo de reabilitação é único e diferente dos outros, assim como nós pessoas somos únicos, diferentes dos outros, não é?"
		(RE 13, Wk 6)	"Nós temos de colocar aqui o utente aqui no [Eng 1, Wk 6- Centro] no centro. Não é aqui à minha beira... mas é no centro"
		Group Written Conclusions, wk 5	P: Para vocês, o que é mais importante na recuperação do vosso braço? "*Participar com agilidade nas brincadeiras dos netos *Abraçar (dar aperto de mão) *Reconquistar a autonomia funcional; *Mão funcional --> As tarefas diárias (comer, vestir, cuidados de higiene)"
		Dialogue (Wk 5)	Pat 13- "Mas há esse negligenciar, como disse, e bem que é, é irritante porque nós não [Pat 15, Wk 5 -Não fazemos ideia que 'tamos a fazer] não percebemos porque é que isso acontece. Pat 17 - Sim e às vezes perdemos coisas que estão no tabuleiro [Pat 13, Wk 5 - Exato…] uma pessoa está só à procura do copo d'água. "
		Pat 15, Wk 5	Por exemplo, eu fui afetada do lado esquerdo e eu a noção que tenho é que deste lado do meu campo de visão diminuiu. Eu, por exemplo, se for a conduzir e por isso é que a única mais tentei, nem tento e adoro é porque se eu for a conduzir, há a possibilidade de eu não conseguir ver, por exemplo, uma pessoa está a aproximar da passadeira.
	Working as a Team	RE 13, Wk 6	É importante também ter equipas [RE 3, Wk 6- Multidisciplinares] realisticamente falando multidisciplinares para todos percebermos um pouco o utente.

		Group Written Conclusions, wk 5	P: Quais as características de "uma boa sessão"? "*Capacidade de envolvência entre os terapeutas e os utentes (Capacidade de os terapeutas entrarem em nós) * Quando o terapeuta reconhece alguma progressão"
		Pat 9, Wk 5	Eu aprendo um exercício com a terapeuta (...) A seguir quero treinar, quero exercitar
		RE 3, Wk 6	"Tem que ser um trabalho em conjunto. Não pode ser a equipa de investigação isolada sem trabalhar com a equipa clínica."
Clinical Evaluation and Patient Selection	Selection Criteria	Dialogue (Wk, 6)	RE 3 – "Até para a pessoa, se para ela, ela quer fazer ou não?" Eng 1 –"Exatamente exatamente exatamente isso é a primeira coisa sempre. RE 3 – "Aí primeiro é a pessoa se ela quer fazer ou não, isso é o mais importante."
		RE 13, Wk6	"Se uma pessoa tiver desorientada nas 3 dimensões, dificilmente vai ter capacidade para fazer seja o que for. [RE 3- Exato, exato. RE 11 – Huhum.] E estamos a perder o nosso tempo no trabalho de reabilitação porque é muito complicado. Ou seja, nós temos que estabilizar, perceber qual é que é a parte cognitiva inicial da pessoa e depois trabalhar esta parte motora de forma intensa
		RE 1, Wk 1	(…) Há tão pouco (em estudos) esta capacidade de incluir alguns subgrupos de utentes que estamos a falar que, se calhar o desenvolver algo para essa franja de utentes (…) (iria ser) bastante relevante
	Assessment of Influencing Factors	Eng 1, Wk 6	"O outro aspecto operacional que nós discutimos aqui bastante é, é a questão dos afetos (...). A questão da motivação. Se a pessoa estiver deprimida, provavelmente podemos estar a fazer todo o trabalho do, do mundo com quanto. Mas se não tivermos endereçar a questão afetiva…Se calhar o resultado poderá não ser tão positivo. Portanto temos de de atuar em em diferentes frentes. Portanto, poderá ser útil ou deveria ser obrigatório, provavelmente é, fazer uma avaliação psicológica prévia."

		Diálogo (Wk 6)	Eng 1- "Não, não quer dizer que seja de exclusão, mas, mas provavelmente [RE 3- Dá-nos um score…] será necessário… [RE 3 - Exato..] Mais intervenção no treino de imagética que poderemos." Eng 2 - "Sim, Exato." Eng 3 - "Sim mas não como exclusão imediata…" Eng 2 - "Exato, fazer um treino de imagética."
		RE 2, Wk 3	(...) quer à organização espacial, quer à capacidade de varrimento da imagem, da percepção do espaço e da noção corporal… Há aqui uma série de coisas que me parecem mais do foro cognitivo do que necessariamente motor, porque se de facto é só a imagética, (...)
Recommendations for Task Design and Selection	Task Characteristics	Pat 6, Wk 4	Eu prefiro sempre treinos de coisas que façam sentido para mim na minha vida do dia a dia, (…) coisas sempre que sejam realmente práticas, que tenham alguma utilidade.
		Pat 16, Wk 5	É como, por exemplo, a realidade virtual para ir ao supermercado. Nós estamos, não estamos focados em tirar da prateleira, mas sim em…estamos a ver o que nós queremos meter no cesto, não é? Digo, eu. É um bocado por aí, não, não focar tanto no movimento, mas sim na ação.
		RE 2, Wk 1	É para para fazer com que reduzamos a concorrência em termos dos hemisférios cerebrais e eu diria que poderia ser unilateral. No entanto, sabemos que tarefas bilaterais favorecem, por vezes esta …ahh ahh… o movimento, o movimento ativo e a reabilitação. (...) Eu penso que convidaria a uma atividade unilateral e muito possivelmente procuraria inibir o ladro, o lado contralesional.
		Eng 1, Wk 6	Mas aqui as 2 dá uma cue ao cérebro para, para imitar. De grosso modo, se a data science diz alguma coisa, ou da machine learning, é um transfer learning. Vamos transferir a aprendizagem de um membro para o outro
		Pat 9, Wk 6	Eu acho que bilateral faz todo o sentido. Exatamente para enganar.

		RE 1, Wk 1	Apelando à nossa realidade das atividades, (...) faz mais sentido, porque é efetivamente uma atividade assimétrica que nós fazemos desta forma. Mas, por exemplo, se eu tivesse uma imagem de carregar uma caixa com as duas mãos, como é uma atividade mais simétrica, também me apela mais ao meu registo e à memória motora que eu tenho da tarefa. Se calhar para mim não me faz muito sentido, estar a levantar dois copos.
		RE 5, Wk 2	São objetivos motores, e quando pensamos na mão temos três grandes objetivos motores, que é o alcançar, o agarrar e manipular. E que envolve o superior todo. E eu acho que as atividades deveriam envolver um membro inteiro, e não específica, porque se vamos focar só na mão, em termos de activação, vamos ativar predominantemente o circuito, claro, do agarrar, o da mão, não é? O que está relacionado pelo, pela mão, e estimulando menos o circuito do do do alcançar.
	Personalized Task Selection	RE 4, Wk 1	Todos temos mapas mentais, (…) em ter várias tarefas que tenham significância, e o indivíduo selecionar uma delas. Em cada uma delas, implementar também esta possibilidade de variabilidade. Isto no plano de sessão
		Pat 10, Wk 5	As atividades variam muito, são muito pessoais. Não é…
		Eng 1, Wk 6	Há aqui outra coisa que eu que imagino que deva ser feita que é a analisar, não só do ponto de vista clínico, mas ter um suporte também imagiológico. (…) Que área é que eu que salvou? Ou que se conseguiu recuperar inicialmente? [RE 3, Wk 6- Neuroplasticidade…Exato.] E a partir daí tem de ser muito específico para, para a pessoa. Olha, sim… foi mais localizado área motora primária apenas, ou somato-sensorial e motora ou tem pré motora também e outras regiões.
		RE 2, Wk 1	Se vocês pensam em alguma atividade em que é tenha que surgir um varrimento na imagem ou uma chamada de atenção ao lado esquerdo para depois, então desenvolver a tarefa pensando e imaginando o movimento com com com o braço esquerdo.

Guidelines for Structuring BCI Interventions	Starting Levels	RE 10, Wk 3	Independentemente seja um utente com mais capacidades, menos capacidades, mesmo para normais, a tarefa deve ser o mais simples possível, mais simples de em termos de imagética. (...) queremos um padrão sensoriomotor captado que seja mais ou menos representativo daquela tarefa. Se eu, se eu variar muito a tarefa ou se a variável, ou se a tarefa for complexa de base, eu não consigo criar, um, um padrão de ativação que representa aquela tarefa. Isto depois vai ser muito complicado...
		RE 8, Wk 2	(...) fazer esta decomposição, mas mantendo um foco em objetivo e à atividade, mesmo que estejamos a trabalhar apenas numa pequena porção, de maneira a manter todo o potencial de ativação da imaginação motora e a correlação depois com o movimento, mesmo que seja só o início do movimento (...)
		Eng 3, Wk 6	Mas lá está convém começar segmentado. Mesmo com coisas muito simples porque cada, cada parte do movimento é difícil de imaginar. Por exemplo, agarrar um garfo. É muito difícil imaginar fazeres isto. Porque já tens provavelmente, ires até lá, agarrares, cada pessoa agarra de uma forma diferente e ficar a agarrar. Portanto, começar de forma faseada com movimentos à vez depois ir tentando gradualmente acrescentá-los [RE 11- Também acho que sim, é um bocadinho melhor]
	Dimensions for Progressing	Eng 3, Wk 6	Claro que isto não pode ser feito numa única sessão, portanto, nós tínhamos pensado em termos de uma progressão, acho que nós tínhamos pensado mais a longo prazo e não na sessão em si. Portanto é longo prazo e lá está, tentar ir, acrescentando mais às, às sessões. (...) Portanto, fazer um primeiro movimento que neste caso seria, por exemplo, agarrar no garfo ou na faca e depois pronto ter um, quando a pessoa já tivesse bem, ter um segundo movimento.
		Eng 1, Wk 6	Não quer dizer que não se consiga fazer qualquer coisa mais sofisticada. Há quem tenha já feito decoding mas mas não é fácil [RE 3- Mas não é fácil]. É verdade que aqui se pensar em vários movimentos tiver diferentes segmentos do membro superior estão localizados em regiões ligeiramente diferentes, mas os padrões de imagética tipicamente são um bocadinho blurred.

		RE 5, Wk 2	A novidade é motivadora, não é? Se for uma tarefa associada ao jogo mais motivador é (...) o pior é imaginar uma tarefa nova, ou seja, por um lado vai ser mais dificil imaginar(...) Eu acho que inicialmente também começar por tarefas mais familiares e à medida que a ativação vai melhorando eventualmente por uma questão de motivação, de novidade e de estimular mais a representação cortical, vamos passar para tarefas novas (…)
		RE 7, Wk 2	(…) aumentar os efeitos diastratores ou enriquecedor do ambiente, pode ser interessante, sem dúvida
		Eng 1, Wk 6	Sim. Por exemplo, em termos de imagética, pode ser o, o threshhold que tu precisas ultrapassar para considerares que a imagética teve sucesso (...) Aqui será imaginar o movimento… aí... podes ter de de imaginar com maior intensidade.
	Progression Criteria	Eng 2, Wk 6	"Aqui também se poderia fazer um sistema, por exemplo também funciona no gamming por exemplo, pode-se fazer um sistema de tentativa e de contagem de sucessos de repetições [AS- Humhum], mas depois com a decisão do utente. [RE 3, Wk 6- Mas incluindo a decisão do utente]"
		RE 6, Wk 2	Se fizerem isto tipo, jogo através do do scores, não é? Quando atingem determinado score de ativação, não é um determinado ponto, pode passar ao próximo nível que tem mais variabilidade.
		Eng 2, Wk 6	Uma possibilidade é ver a conectividade do EEG [Eng 1, Wk 6- Sim] porque em princípio se a conetividade for muito grande entre várias zonas, haverá um recrutamento maior porque está a haver um grande esforço. À medida que a conetividade for mais concentrada [RE 3, Wk 6- Exato], significa que a pessoa está a otimizar a tarefa que está a treinar. A conetividade com o EEG poderá ajudar. Com este tipo de set, será uma conetividade baseada nos elétrodos, não dá para fazer a outra parte, que é a regional, não é?
		RE 3, Wk 6	Pela minha experiência, é que o terapeuta e o utente [Eng 1, Wk 6 – Os dois, exato], os dois em conjunto, é que definem "Olha, agora vamos passar para o nível seguinte" [Eng 1, Wk 6- É que definem]

	Session Duration	RE 12, Wk 6	Então temos que ter esse ajuste, só que se ajuste é como diz a [Eng 1, Wk 6- Ou fazer um treino] RE 13, tem que ser muito pessoa a pessoa e perceber… quanto tempo é que consegue aguentar. Algumas aguentam 15 minutos, outras 10 e depois já vem um pouco da parte do, do profissional [HS- Sim] que ele está a tentar balizar a intervenção
		RE 2, Wk 1	"Normalmente são sempre as atividades com o membro superior, as atividades que provocam mais fadiga. Não te sei dizer quanto tempo é que é o mais indicado, ou na clínica como é que normalmente as pessoas começam a bocejar mais cedo do que, quando é o trabalho de controlo postural, por exemplo. Ou, ou podem dispersar mais…. A atenção."
		Eng 1, Wk 6	Porque na prática, aquilo que nós vamos estar a fazer é ensinar o cérebro a pensar novamente em motricidade. Portanto e para aprendizagem, precisamos de pausas, precisamos de repetição. Portanto, é mais vantajoso fazer repetições e ciclos, se calhar mais curtos do que vamos fazer uma sessão de 1 hora, é?
		Eng 2, Wk 6	É que sem estas pausas não há depois os restantes processos bioquímicos ou eletroquímicos que estabilizam a neuroplasticidade que se conseguiu, o ensino, que se conseguiu a nível cerebral. Portanto, também é preciso haver estas pausas.
		Eng 3, Wk 6	Sim, eu estou só a dizer que 20 minutos de seguida é impossível. 20 minutos de seguida a pessoa não consegue [Sim, depende da tarefa que se tenha] movimentos repetitivos.
Key factors influencing motivation	Variability	Pat 17, Wk 5	E para algumas pessoas isso pode ser desmotivador, estar sempre a fazer a mesma tarefa.
		(RE 2, Wk 1)	Aqui, apesar de ser a mesma pinça manual para o automóvel, tem uma componente de abdução e rotação externa que é diferente. Mas colocar várias portas, ou uma porta de casa, ou a porta de uma loja, ou em que é sempre o mesmo movimento, isso é repetir sem repetir. Porque varia ao contexto, mas a tarefa é realmente a mesma

	Gamification	(Pat 13, Wk 5)	Eu descontraía e treinava os movimentos de uma forma agradável e sem carga emocional.
		Pat 10, Wk 5	Claro que existe, quer dizer ó… uma pessoa perde, pode se desmotivar. Pode-se fazer a gamificação sempre para ganhar uns badges, para ganhar os... medalhas e para ganhar os pontos e para ganhar o que for e nunca perder. Que é uma das opções da gamificação.
	Activity Demand	RE 3, Wk 1	Eu acho que (...) pode ser feito graduação da atividade e o próprio terapeuta é que define que tipo de atividade é que pode fazer, não é? E qual é o grau de dificuldade para aquele doente?
		Eng 1, Wk 6	Portanto, é grosso modo, esta teoria de jogos. Tu queres estar no que se chama o sweet spot entre a dificuldade da tarefa e a tua competência. Portanto e tens de conseguir encontrar aqui um match. Portanto, a dificuldade tem de ser tal que eu consiga ultrapassar. Se eu não consigo, vais ajustando a dificuldade. Consigo? Vais assim progredindo. E é isso que melhor mantém a atenção e o engajamento do participante, do doente.
Technology Features	Set-Up Considerations	RE 10, Wk 3	Para mim faz-me sentido que a pessoa esteja confortável, não é? Numa postura confortável e que não tenha outras variáveis parasitas à volta enquanto está a fazer isto, não é? A pessoa estar desequilibrada e a tentar gerir o que é o seu corpo real, com aquele corpo virtual.
		RE 1, Wk 1	acho muito importante neste tipo de terapias ah… esta organização do contexto e desta (...) esta posição inicial do indivíduo. Esta preparação para o movimento, independentemente de não existir um movimento, ainda, será muito importante. Lá está na preparação para, depois, a própria atividade.
		RE 2, Wk 1	(...) para garantir que a tarefa de alguma forma reconhecida, não só no seu contexto, como no seu objetivo, ter um exemplo de uma pessoa a reproduzir o movimento seria importante até porque tem representação cortical. (…) que daria um melhor feedforward.

	Providing Feedback	Eng 1, Wk 6	Aqui acho que a estratégia, é estares a, estares a adicionar estímulos ou cues, pistas, nos quais o cérebro pode ir buscar, também. Acaba por suportar a intenção final. Portanto, é aqui esta questão do tubarão é excelente, porque na prática vou ter aqui uma motivação extra. A atívar a amígdala, fica aos gritos e vou buscar outros recursos para executar a tarefa.
		Pat 10, Wk 5	Portanto, será, a haver uma coisa destas, será ter parâmetros que o terapeuta poderá ajustar a cada utente.
		RE 12, Wk 6	Ah... e portanto, para além disso outra coisa que o Pat 17 também nos disse muito, que o afeta muito, é não ter a sensibilidade, não ter a parte dos estímulos. Então pensou-se também em associar à atividade essa... Como por exemplo os estímulos aaah... vibratórios, ter um.. Por exemplo, na alimentação ter diferentes texturas, se for carne, se for peixe, ter uma sensação diferente. Ah… se o copo estiver mais cheio ou menos cheio também ter esse feedback diferente por parte da aplicação. Se entornarmos também ter esse estímulo vibratório.
		Pat 10, Wk 5	Portanto, a única coisa que tem que se fazer é essa luva tem que abrir e fechar, quando nós pensamos em abrir e fechar [Pat 9, Wk 5- Exatamente.] E isso já ia resolver [Pat 9, Wk 5 - Eu penso que é isso mesmo] o ter um feedback ter um chama um haptic feedback, feedback háptico, do que a pessoa faz… [Pat 9, Wk 5 - Exatamente! É no momento em que o nosso cérebro reconhece, nós conseguirmos a..]. Porque a nossa mão não fecha, não é? [Pat 9, Wk5 -Exato] Mas se eu pensar em fechar e a mão fechar, é capaz de ser interessante.

Appendix 4 – Relevant Activities, Movements and Functions

Chart 1 - Relevant Activities	
Clapping Combing Cooking (baking cakes) Dressing and undressing Driving Eating & Drinking tasks - Grab the food, -Cutting - Bring into mouse - Grab a cup and drink	Hugging Holding a pet (pet it) Opening cans Opening pills Peeling fruit Shaking hands Sports activities Swimming Tidying the room

Chart 2 – Relevant Movements and Functions
* Reaching an object * Grasping an object * Manipulating an object * Movements: Shoulder rotation and flexion * Movements: Arm supination; Open and closing the hand

Appendix 5 – Invitation Letters

Carta Explicativa para os Utentes

O meu nome é Inês Oliveira e encontro-me a desenvolver um projeto no contexto do Mestrado em Prática Avançada de Fisioterapia em Neurologia da Escola Superior de Saúde do Instituto Politécnico de Setúbal (ESS-IPS). Este projeto é intitulado "Design colaborativo para reabilitação do membro superior de indivíduos com AVC utilizando realidade virtual e interface computador-cérebro" e sob a orientação da professora doutora Carla Mendes Pereira, e co-orientação da professora Ana Isabel Almeida, tendo sido submetido e aprovado pela comissão de ética do Instituto Politécnico de Setúbal. A recolha de dados no Centro de Reabilitação de Alcoitão (CMRA) foi ainda aprovada pela Comissão de ética do CMRA.
O AVC é a principal causa de incapacidade para indivíduos com mais de 5 anos, e a dificuldade de movimento do membro superior é a incapacidade mais frequente, sendo que 60% das pessoas não conseguem utilizar a sua mão para as suas atividades de vida diária, mesmo após 6 meses de reabilitação.
O nosso estudo pretende elaborar recomendações para futuras intervenções que utilizem a prática mental suportada pela tecnologia de interface computador-cérebro e realidade virtual para aumentar o resultado da reabilitação convencional que os utentes de AVC já costumam fazer.
No decorrer deste estudo serão recolhidas as opiniões de vários peritos em reabilitação, bem como a opinião de pessoas que passaram ou estão atualmente a passar pela reabilitação após AVC, incluindo o seu membro superior (braço, ombro ou mão). Este projeto está organizado em 3 fases distintas:
1) workshops realizados com peritos de reabilitação do membro superior de utentes com AVC, com o objetivo de selecionar os movimentos e progressões que poderão levar a uma melhor reabilitação;
2) workshop com utentes com AVC, com o objetivo de definir quais os aspetos que possam ser importantes para tornar futuras intervenções mais convidativas e cativantes, recorrendo à sua experiência com reabilitação.
3) workshop com utentes, peritos e engenheiros digitais/biomédicos para informar sobre a construção de futuros protótipos de intervenção.

Neste sentido gostaríamos de pedir a sua colaboração para tornar este projeto mais rico com a sua opinião e experiência pessoal. Consideramos que este estudo será de elevada relevância para contribuir para o aumento da efetividade destas intervenções, o que por sua vez, poderá contribuir para uma redução da incapacidade desta população.
Estando concluídas as fases 1 e 2 do projeto, serve a presente carta para convidar à sua participação na 3ª fase do mesmo. Esta implica a participação num workshop, que consiste numa sessão de diálogo e realização de atividades em grupo com outros utentes com sequelas de AVC, profissionais de saúde peritos em reabilitação e engenheiros biomédicos e de computação. Nesto âmbito será convidado partilhar a sua experiência e dar sua opinião em relação a diferentes aspetos da reabilitação do membro superior e da possibilidade de utilização de realidade virtual neste processo. A sessão contemplará ainda um pequeno

momento de experienciação da tecnologia de realidade virtual para aferição de certos aspetos como a experiência e relevância da atividade e o grau de conforto dos dispositivos em estudo (óculos de realidade virtual, touca de EEG). Esta sessão, com previsão de duração de 145 minutos, contará com entre 9 a 12 participantes, será moderada por dois investigadores e terá lugar numa sala num local tranquilo do CMRA para reduzir o risco de interrupções.

O workshop será gravado e filmado para permitir aproveitar todas as opiniões e ideias discutidas e uma melhor análise do conteúdo da discussão sendo que em todos os momentos a sua identidade e privacidade será protegida. Após o workshop será pedido que preencha um pequeno formulário de avaliação da experiência e de avaliação do próprio workshop. Mais tarde receberá um resumo do que foi discutido ao que poderá acrescentar algum esclarecimento ou comentário, se desejar. Para potenciar a assiduidade e pontualidade dos participantes serão enviados dois lembretes na aproximação da sessão, pelo contacto que lhe for mais confortável. Cada participante terá de assinar um formulário de consentimento informado em que autoriza a utilização dos seus dados pessoais.

Qualquer participante poderá retirar a sua participação do estudo a qualquer momento devendo para esse efeito contactar a investigadora principal por correio eletrónico (inescrmoliveira@gmail.com), nesse momento pode também decidir se pretende que os seus dados e comentários sejam excluídos do estudo. A remoção da sua participação no estudo não terá nenhuma consequência ou penalização.

A identidade de todos os participantes será protegida utilizando um sistema de codificação para se referir a cada participante na transcrição do workshop durante a análise dos dados, bem como na publicação do estudo. A equipa de investigação utilizará a gravação e outros dados fornecidos apenas para os objetivos académicos e profissionais deste projeto.

Toda a informação recolhida no decorrer deste estudo será armazenada num dispositivo de armazenamento de dados da responsabilidade da investigadora principal, com proteção de password e acedidos apenas pela equipa de investigação. A sua identidade será preservada em todos os momentos, sendo que, após a análise da gravação da sessão, a sua transcrição será realizada com um sistema de codificação para identificar cada participante. Os dados recolhidos serão eliminados após um período de 3 anos subsequente à publicação dos resultados.

A participação neste estudo é voluntária e não contempla qualquer compensação para os seus participantes. Ao colaborar neste estudo abdica de qualquer reivindicação sobre as declarações que prestar, ou que forem descritas por outros participantes.

No decorrer da sessão, pressupõe-se a utilização de RV por um curto período (aproximadamente 5 minutos), sendo que, na utilização de realidade virtual, se encontra descrita a possibilidade de alguns efeitos secundários como náuseas, perturbações visuais (Ex.: Fadiga visual), dores de cabeça, tonturas, dores corporais e hipertonicidade. Tendo em conta o facto de os sintomas serem de intensidade ligeira, a evidência cientifica apresenta a realidade virtual como uma intervenção segura e potencialmente eficaz que deve ser estudada e integrada na prática clinica. A utilização de realidade virtual será acompanhada por profissionais de saúde e garantida a suspensão imediata da utilização do aparelho na eventualidade de aparecimento de sintomas. Adicionalmente, o potencial

inconveniente previsto é o dispêndio de tempo na participação do workshop, deslocação, preenchimento de rápido questionário pós-workshop e leitura do resumo do workshop (com oportunidade de realizar esclarecimentos ou comentários adicionais).
Caso tenha alguma preocupação ou dúvida sobre algum aspeto do estudo poderá contactar o membro da equipa de investigação responsável: Inês Oliveira, através do email: inescrmoliveira@gmail.com ou a orientadora científica: Carla Pereira: carla.pereira@ess.ips.pt. Caso pretenda fazer uma reclamação, poderá fazê-lo através de correio eletrónico para a Comissão de Ética (CE) do IPS, através do endereço eletrónico:
comissao.etica@ips.pt ou para a comissão de ética do CMRA.
Assim que o estudo esteja finalizado, será produzido um relatório/ tese. Caso queira receber este relatório, poderá solicitá-lo através do email: carla.pereira@ess.ips.pt. No relatório e outros documentos com apresentação dos resultados do estudo, não será apresentada informação individual dos participantes. Os resultados serão, sempre, divulgados de forma agregada, não possibilitando a sua identificação.
Com os melhores cumprimentos, e disponível para qualquer questão,

A equipa de investigação, Inês Oliveira (Investigador principal)	inescrmoliveira@gmail.com ; Telefone: 968471517 Instituição: ESS-IPS
Carla Mendes Pereira (Orientadora)	carla.pereira@ess.ips.pt; Telefone: 966217825 Instituição: ESS-IPS
Ana Isabel Almeida (Co-orientadora)	isabel.almeida@ess.ips.pt; Telefone: 917507211 Instituição: ESS-IPS

Carta Explicativa - Profissionais de Saúde

O Projeto “Collaborative design approach for stroke upper limb rehabilitation using virtual reality and brain computer interface”, pretende criar um conjunto de princípios orientadores de futuras intervenções que utilizem esta tecnologia como adjuvantes à reabilitação do membro superior de pessoas com AVC.
Este projeto está a ser desenvolvido no contexto do Mestrado em Prática Avançada de Fisioterapia em Neurologia da Escola Superior de Saúde do Instituto Politécnico de Setúbal (ESS/IPS). Este estudo foi aprovado pelas Comissões de Ética do Instituto Politécnico de Setúbal e do Centro de Medicina de Reabilitação de Alcoitão.

Relevância da sua participação

Convidamo-lo/a a participar neste estudo, na capacidade de perito clínico, visto que a sua experiência na reabilitação de utentes será crucial para o desenvolvimento deste estudo. Antes de tomar qualquer decisão, é importante que compreenda as razões pelas quais este estudo está a ser conduzido e o nível de envolvimento que lhe é pedido. Por favor, utilize o tempo que necessitar para ler a informação que se segue. Poderá falar com outras pessoas sobre este estudo, se o desejar e solicitar esclarecimentos junto do investigador principal ou membros da equipa de orientação. O seu contributo através da experiência clínica e conhecimento científico, irá permitir o estabelecimento de critérios orientadores para futuras intervenções.

Relevância deste estudo

Cerca de 60% das pessoas 6 meses após AVC reporta que a sua mão não é funcional para as atividades de vida diária, representando o sintoma mais comum nesta população. Intervenções de prática mental (ou imaginação motora) com utilização de interface computador-cérebro e realidade virtual já mostraram ser uma intervenção adjuvante eficaz para a reabilitação destes utentes, no entanto, o desenho destas intervenções

não teve em consideração os vários princípios relevantes para a reabilitação após lesão neurológica.

Consideramos que este estudo será de elevada relevância para contribuir para o aumento da efetividade destas intervenções, o que poderá contribuir para uma redução da incapacidade desta população. Cada participante terá de assinar um formulário de consentimento informado em que autoriza a utilização dos seus dados pessoais.

Colaboração dos participantes

O desenho colaborativo incluindo peritos clínicos, utentes com AVC e engenheiros informáticos/biomédicos pretende-se que contribua para o desenvolvimento de programas de intervenção com maior aceitabilidade e eficácia. O estudo apresenta 3 fases distintas:

1) workshop (dividido em duas sessões) realizado com peritos em reabilitação do membro superior em utentes com AVC, com o objetivo de delinear linhas orientadoras para intervenções de interface cérebro-computador com realidade virtual, focando na seleção dos movimentos e ambientes virtuais;

2) workshop com utentes com AVC, com o objetivo de definir aspetos que tornem futuras intervenções mais convidativas e cativantes, recorrendo à sua experiência nomeadamente em lidar com a sua incapacidade e participação em diversas situações para a sua reabilitação.

3) workshop com peritos, utentes e engenheiros digitais/biomédicos para informar sobre a construção de futuros protótipos de intervenção.

Estando concluídas as fases 1 e 2 do projeto, serve a presente carta para convidar à sua participação na 3ª fase do mesmo que contará com a realização de um workshop que reunirá utentes com sequelas de AVC, peritos de reabilitação e engenheiros biomédicos e de computação. Neste workshop os participantes terão a oportunidade de debater as recomendações sugeridas nas fases anteriores do projeto e perceber a sua viabilidade técnica, por forma a determinar as recomendações finais para a utilização da tecnologia

de Brain-Computer Interface, imagética motora e realidade virtual na reabilitação do membro superior após AVC. A sessão contemplará ainda um pequeno momento de experienciação da tecnologia de realidade virtual para aferição de certos aspetos como a experiência e relevância da atividade e o grau de conforto dos dispositivos em estudo (óculos de realidade virtual, touca de EEG). Por forma a potenciar a componente humana e interativa do momento e permitir a experienciação da realidade virtual, o workshop realizar-se-á em formato presencial, no Centro de Medicina de Reabilitação de Alcoitão (CMRA), em data em aferir de acordo com a disponibilidade de todos os participantes. Esta sessão, com previsão de duração de 145 minutos, contará com entre 9 a 12 participantes, será moderada por dois investigadores e terá lugar numa sala num local tranquilo do CMRA para reduzir o risco de interrupções. Para potenciar a assiduidade e pontualidade dos participantes serão enviados dois lembretes na aproximação da sessão.

Para além da participação nos workshops, será solicitado o preenchimento de dois questionários (em formato digital ou físico, de acordo com a sua preferência), sendo o primeiro de avaliação do próprio workshop (estimativa de preenchimento de 2 minutos), e o segundo, após a leitura do resumo da sessão realizada, de esclarecimento (estimativa de preenchimento de 2 minutos).

Cessação da participação

Qualquer participante poderá retirar a sua participação do estudo a qualquer momento, devendo para esse efeito contactar a investigadora principal por correio eletrónico (inescrmoliveira@gmail.com). Nesse momento pode também decidir se quererá que os seus dados e comentários já registados sejam excluídos do estudo. A remoção da sua participação no estudo não terá nenhuma consequência ou penalização.

Riscos e benefícios

No decorrer da sessão, pressupõe-se a utilização de RV por um curto período (aproximadamente 5 minutos), sendo que, na utilização de realidade virtual, se encontra descrita a possibilidade de alguns efeitos secundários como náuseas, perturbações

visuais (Ex.: Fadiga visual), dores de cabeça, tonturas, dores corporais. Tendo em conta o facto de os sintomas serem de intensidade ligeira, a evidência cientifica apresenta a realidade virtual como uma intervenção segura e potencialmente eficaz que deve ser estudada e integrada na prática clinica. A utilização de realidade virtual será acompanhada por profissionais de saúde e garantida a suspensão imediata da utilização do aparelho na eventualidade de aparecimento de sintomas.

Proteção e utilização de dados pessoais

O workshop será gravado para permitir uma melhor análise do conteúdo da discussão. Sendo o objetivo deste estudo o desenho colaborativo, irão usar-se ferramentas como o brain-storming e dinâmicas pergunta-resposta. A identidade de todos os participantes será protegida utilizando um sistema de codificação para se referir a cada participante na transcrição do workshop durante a análise dos dados, bem como na publicação do estudo.

Toda a informação recolhida no decorrer deste estudo será armazenada num dispositivo de armazenamento de dados, com proteção de password e acedidos apenas pela equipa de investigação, sendo a sua identidade mantida preservada em todos os momentos, após a análise da gravação da sessão, sendo a sua transcrição realizada com um sistema de codificação para identificar cada participante. Os dados serão destruídos após 3 anos ou após a publicação.

Contatos para esclarecimento ou reclamação

Caso tenha alguma preocupação ou dúvida sobre algum aspeto do estudo poderá contactar o membro da equipa de investigação responsável: Inês Oliveira, através do email: inescrmoliveira@gmail.com ou a orientadora científica: Carla Pereira: carla.pereira@ess.ips.pt. Caso pretenda fazer uma reclamação, poderá fazê-lo através de correio eletrónico para a Comissão de Ética (CE) do IPS, através do endereço eletrónico: comissao.etica@ips.pt

Plano de disseminação

Assim que o estudo esteja finalizado, será produzido um relatório/ tese. Caso queira receber este relatório, poderá solicitá-lo através do email: carla.pereira@ess.ips.pt. Como estratégia de disseminação considera-se a publicação em duas revistas com relevância no campo da reabilitação (Neurorehabilitation and Neural Repair; IEEE Transactions on Neural Systems and Rehabilitation Engineering) e duas conferências relacionadas com o tópico (Congresso Nacional do AVC; Congress on Neurorehabilitation and Neural Repair;). No relatório e outros documentos com apresentação dos resultados do estudo, não será apresentada informação individual dos participantes. Os resultados serão, sempre, divulgados de forma agregada, não possibilitando a sua identificação.

Com os melhores cumprimentos, e disponível para qualquer questão,

A equipa de investigação, Inês Oliveira (Investigador principal)	inescrmoliveira@gmail.com ; Telefone: 968471517 Instituição: ESS-IPS
Carla Mendes Pereira (Orientadora)	carla.pereira@ess.ips.pt; Telefone: 966217825 Instituição: ESS-IPS
Ana Isabel Almeida (Co-orientadora)	isabel.almeida@ess.ips.pt; Telefone: 917507211 Instituição: ESS-IPS

Carta Explicativa (Peritos Tecnológicos)

O Projeto "Collaborative design approach for stroke upper limb rehabilitation using virtual reality and brain computer interface", pretende criar um conjunto de princípios orientadores de futuras intervenções que utilizem esta tecnologia como adjuvantes à reabilitação do membro superior de pessoas com AVC.

Este projeto está a ser desenvolvido no contexto do Mestrado em Prática Avançada de Fisioterapia em Neurologia da Escola Superior de Saúde do Instituto Politécnico de Setúbal (ESS/IPS). Este estudo foi aprovado pela comissão de ética do Instituto Politécnico de Setúbal e pela Comissão de Ética do CMRA.

Relevância da sua participação

Convidamo-lo/a a participar neste estudo, na capacidade de perito tecnológico, visto que o seu conhecimento da interação da tecnologia com o utente, bem como de outras características da tecnologia será essencial para permitir a elaboração de recomendações adequadas. Antes de tomar qualquer decisão, é importante que compreenda as razões pelas quais este estudo está a ser conduzido e o nível de envolvimento que lhe é pedido. Por favor, utilize o tempo que necessitar para ler a informação que se segue. Poderá falar com outras pessoas sobre este estudo, se o desejar, e solicitar esclarecimentos junto do investigador principal ou membros da equipa de orientação. O seu contributo através da experiência clínica e conhecimento científico, irá permitir o estabelecimento de critérios orientadores para futuras intervenções.

Relevância deste estudo

Cerca de 60% das pessoas 6 meses após AVC reporta que a sua mão não é funcional para as atividades de vida diária, representando o sintoma mais comum nesta população. Intervenções de prática mental (ou imaginação motora) com utilização de interface computador-cérebro e realidade virtual já mostraram ser
uma intervenção adjuvante eficaz para a reabilitação destes utentes, no entanto, o desenho destas intervenções não teve em consideração os vários princípios relevantes para a reabilitação após lesão neurológica.
Consideramos que este estudo será de elevada relevância para contribuir para o aumento da efetividade destas intervenções, o que poderá contribuir para uma redução da incapacidade desta população. Cada participante terá de assinar um formulário de consentimento informado em que autoriza a utilização dos seus dados pessoais.

Colaboração dos participantes

O desenho colaborativo incluindo peritos clínicos, utentes com AVC e engenheiros informáticos/biomédicos pretende-se que contribua para o desenvolvimento de programas de intervenção com maior aceitabilidade e eficácia. O estudo apresenta 3 fases distintas:

1) workshop (dividido em duas sessões) realizado com peritos em reabilitação do membro superior em utentes com AVC, com o objetivo de delinear linhas orientadoras para intervenções de interface cérebro-computador com realidade virtual, focando na seleção dos movimentos e ambientes virtuais;
2) workshop com utentes com AVC, com o objetivo de definir aspetos que tornem futuras intervenções mais convidativas e cativantes, recorrendo à sua experiência nomeadamente em lidar com a sua incapacidade e participação em diversas situações para a sua reabilitação.
3) workshop com peritos, utentes e engenheiros digitais/biomédicos para informar sobre a construção de futuros protótipos de intervenção.

Estando concluídas as fases 1 e 2 do projeto, serve a presente carta para convidar à sua participação na 3ª fase do mesmo que contará com a realização de um workshop que reunirá utentes com sequelas de AVC, peritos em reabilitação e engenheiros biomédicos e de computação. Neste workshop os participantes terão a oportunidade de debater as recomendações sugeridas nas fases anteriores do projeto e perceber a sua viabilidade técnica, por forma a determinar as recomendações finais para a utilização da tecnologia de *Brain-Computer Interface*, imagética motora e realidade virtual na reabilitação do membro superior após AVC. A sessão contemplará ainda um pequeno momento de experienciação da tecnologia de realidade virtual para aferição de certos aspetos como a experiência e relevância da atividade e o grau de conforto dos dispositivos em estudo (óculos de realidade virtual, touca de EEG). Por forma a potenciar a componente humana e interativa do momento e permitir a experienciação da realidade virtual, o workshop realizar-se-á em formato presencial, no Centro de Medicina de Reabilitação de Alcoitão (CMRA), em data em aferir de acordo com a disponibilidade de todos os participantes. Esta sessão, com previsão de duração de 145 minutos, contará com entre 9 a 12 participantes, será moderada por dois investigadores e terá lugar numa sala num local tranquilo do CMRA para reduzir o risco de interrupções. Para potenciar a assiduidade e pontualidade dos participantes serão enviados dois lembretes na aproximação da sessão.
Para além da participação nos workshop, será solicitado o preenchimento de dois questionários (em formato digital ou físico, de acordo com a sua preferência),

sendo o primeiro de avaliação do próprio workshop (estimativa de preenchimento de 2 minutos), e o segundo, após a leitura do resumo da sessão realizada, de esclarecimento (estimativa de preenchimento de 2 minutos).

Cessação da participação

Qualquer participante poderá retirar a sua participação do estudo a qualquer momento, devendo para esse efeito contactar a investigadora principal por correio eletrónico (inescrmoliveira@gmail.com). Nesse momento pode também decidir se quererá que os seus dados e comentários já registados sejam excluídos do estudo. A remoção da sua participação no estudo não terá nenhuma consequência ou penalização.

Riscos e benefícios

O potencial inconveniente previsto é o dispêndio de tempo na participação do workshop, deslocação, preenchimento de rápido questionário pós-workshop e leitura do resumo do workshop (com oportunidade de realizar esclarecimentos ou comentários adicionais). A investigação não pressupõe a existência de danos ou riscos para os participantes enquanto peritos tecnológicos, não se antecipando que possa gerar ansiedade ou desconforto no participante.

Proteção e utilização de dados pessoais

O workshop será gravado para permitir uma melhor análise do conteúdo da discussão. Sendo o objetivo deste estudo o desenho colaborativo, irão usar-se ferramentas como o brain-storming e dinâmicas pergunta-resposta. A identidade de todos os participantes será protegida utilizando um sistema de codificação para se referir a cada participante na transcrição do workshop durante a análise dos dados, bem como na publicação do estudo.

Toda a informação recolhida no decorrer deste estudo será armazenada num dispositivo de armazenamento de dados, com proteção de password e acedidos apenas pela equipa de investigação, sendo a sua identidade mantida preservada em todos os momentos, após a análise da gravação da sessão, sendo a sua transcrição realizada com um sistema de codificação para identificar cada participante. Os dados serão destruídos após 3 anos ou após a publicação.

Contatos para esclarecimento ou reclamação

Caso tenha alguma preocupação ou dúvida sobre algum aspeto do estudo poderá contactar o membro da equipa de investigação responsável: Miguel Russo, através do email: miguel.russo@gmail.com ou a orientadora científica: Carla Pereira: carla.pereira@ess.ips.pt. Caso pretenda fazer uma reclamação, poderá fazê-lo através de correio eletrónico para a Comissão de Ética (CE) do IPS, através do endereço eletrónico: comissao.etica@ips.pt

Plano de disseminação

Assim que o estudo esteja finalizado, será produzido um relatório/ tese. Caso queira receber este relatório, poderá solicitá-lo através do email: carla.pereira@ess.ips.pt. Como estratégia de disseminação considera-se a publicação em duas revistas com relevância no campo da reabilitação (Neurorehabilitation and Neural Repair; IEEE Transactions on Neural Systems and Rehabilitation Engineering) e duas conferências relacionadas com o tópico (Congresso Nacional do AVC; Congress on Neurorehabilitation and Neural Repair). No relatório e outros documentos com apresentação dos resultados do estudo, não será apresentada informação individual dos participantes. Os resultados serão, sempre, divulgados de forma agregada, não possibilitando a sua identificação.

Com os melhores cumprimentos, e disponível para qualquer questão,

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Appendix 6 – Informed Consent Form

Formulário de Consentimento Informado

No âmbito do projeto "Collaborative design approach for stroke upper limb rehabilitation using virtual reality and brain computer interface" aprovado pela Comissão de Ética do Instituto Politécnico de Setúbal e Centro de Medicina de Reabilitação de Alcoitão, foi-me proposta a participação num workshop para design colaborativo para criar linhas orientadoras para o desenvolvimento de futuras intervenções de Interface Computador Cérebro com realidade virtual imersiva para o membro superior.

Este projeto está inserido na tese realizada por Inês Oliveira com orientação da professora doutora Carla Mendes Pereira, e co-orientação da professora Ana Isabel Almeida, no contexto do mestrado em "Práticas Avançadas em Fisioterapia Neurológica".

Na qualidade de investigador:

Confirmo que expliquei ao participante de forma adequada e inteligível, os procedimentos necessários do estudo. Respondi a todas as questões que me foram colocadas e assegurei-me de que houve um período de reflexão suficiente para a tomada da decisão do participante no estudo.

Na qualidade de participante:

Declaro que li e compreendi o conteúdo deste documento, bem como as informações verbais que me foram fornecidas pelo investigador.

Declaro que me foram comunicados os principais efeitos secundários na utilização de realidade virtual e assegurada a possibilidade de cessação imediata da atividade em caso de aparecimento dos mesmos.

Declaro que tive tempo para refletir sobre a minha decisão de participar neste estudo.

Foi-me garantida a possibilidade de, em qualquer altura, recusar participar neste estudo sem qualquer tipo de consequências.

Declaro que aceito participar neste estudo, e que tomo a minha decisão de forma livre e esclarecida e que permito a utilização dos meus dados para esta investigação, com as garantias de confidencialidade e anonimato que me foram dadas pelo investigador.

Aceito participar neste projeto. Nome: Data:

Assinatura:

Assinatura do investigador: