D2.4
Stakeholder analysis

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Disclaimer

The REHYB Consortium consists of the following partners:

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3	Scuola Superiore di Studi Universitari e di Perfezionamento Sant'Anna (SSSA)	IT
4	Össur hf (OSS)	IS
5	TECNALIA Research & Innovation (TECN)	ES
6	Imperial College London (ICL)	UK
7	Institute for Bioengineering of Catalonia (IBEC)	ES
8	Technical University of Denmark (DTU)	DK
9	Stelar Security Technology Law Research UG (STELAR)	DE
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Executive Summary

The deliverable reports all activities performed under T2.4: Participatory design of the ReHyb system. The objective of this task is to apply a participatory design for guiding the agile system development of other WPs.

Relevant stakeholder groups of the ReHyb system have already been identified in D2.1. These stakeholder groups are further analysed within this deliverable D2.4. By means of onion diagrams and stakeholder matrices, identified stakeholder groups are graded regarding their influence and power with respect to the ReHyb system. This process was performed separately for the clinical and home setting. Those stakeholder groups which are identified as promoters (i.e., target stakeholder groups) of the ReHyb system are highly involved in the participatory approach. Workshops, interviews, questionnaires, and clinical trials are performed involving all target stakeholder groups to empower the users by considering their needs and interests in the next steps of the developmental process.

Results of the stakeholder analysis reveal that in addition to the stroke patient, primary caregivers, the non-medical and medical treatment staff, external relations (for home setting only), and financial providers are identified as target stakeholder groups. Within the T2.4 investigations, these six target stakeholder groups provided insights into their needs and interests when it comes to the application of the ReHyb system in the clinic or at home. Different aspects of the ReHyb system were evaluated by different stakeholder groups as listed in Table 1.

Table 1. Overview of aspects investigated in the identified target stakeholder groups within T2.4.

Patients after stroke	Medical treatment staff
Feasibility of using: 1) FES 2) Serious gaming 3) Robotic devices 4) any combination of modules (FES + robotic, FES + serious gaming, robotic + serious gaming) 5) Characteristics such as medication (to inform the digital twin) or anthropometrics (to individualize the fitting of the FES garment)	Experiences and interests in using: 1) FES 2) Serious gaming 3) Robotic devices 4) any combination of the modules (robotic + serious gaming)
Primary caregivers	**Financial providers**
Technical affinity to estimate whether they will be able and willing to use the technology.	Identification of country-specific financial processes behind therapies and devices in the clinic and behind the prescription for home use.
External relations	**Non-medical support staff**
Identification of processes behind the implementation of medical devices for home use in the ambulatory setting	Elaboration of hygiene requirements

Results of the performed investigations are reported in chapter 3 of this deliverable.

Table of content

1. Introduction

This chapter provides the overview and structure of the deliverable as well as the relation to other work packages.

1.1 Overview & Structure of the deliverable

Within this deliverable, the stakeholder groups which have been identified within the framework of Task (T) 2.1 and described in Deliverable (D) 2.1 are further analysed to investigate their opinions, needs and wishes regarding the ReHyb system. Therefore, first, the importance and roles of the stakeholders were identified using onion diagrams and stakeholder matrices (chapter 2). The succeeding chapter 3 presents the results of the different activities performed to involve these stakeholders in the development and design process. These activities include for example pilot studies, interviews or workshops that were conducted to investigate the opinion of the key stakeholders and to get some first hands-on-experiences on components or future modules of the ReHyb system. As such, the modules functional electrical stimulation (FES), serious gaming, digital twin and robotics were investigated, separately or in combination. To evaluate the utility of these components and their combinations in the target user group of patients after stroke, commercially available FES-devices (Fesia grasp (Fesia Technology, ES) and Stiwell Med 4 (MED-EL, AT)) and gaming solutions (Rehabilitation gaming system (Eodyne, ES)) were used in pilot studies examining these modules and their interaction and utility as orthotic device. Additionally, workshops and evaluations were organised to investigate mock-ups or the usability of the actual ReHyb devices or parts therefrom to directly inform the technical development on the usability. These involvements of the stakeholders as key pillar of the participatory design are reported in this chapter. Finally, in chapter 4, the conclusion of these stakeholder analyses is presented.

1.2 Relation to other work packages

Under the Work Package (WP) 2 framework (Use case definition), this deliverable focuses on ReHyb stakeholder analysis. The WP2 provides crucial information to both the technical and clinical ReHyb partners: as visible in Figure 1, the information gathered during the use case definition is the starting point for the technical development of the ReHyb system. WP2 futher aids to identify relevant criteria to be used during the evaluation of the feasibility and usability of the ReHyb system (WP 9).

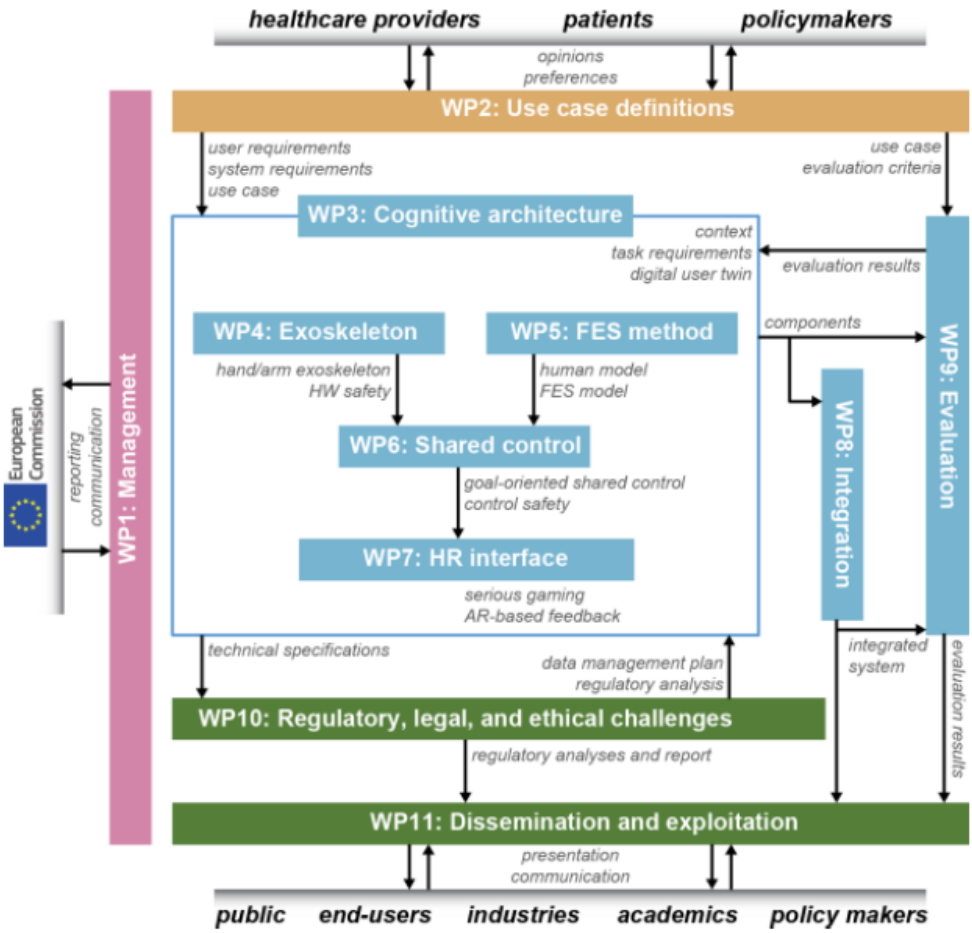

Figure 1. Link between Work Packages (Source: Grant Agreement).

So far, the use case scenarios, including personas and stakeholders have been identified (see D2.1) and functional and system requirements have been derived therefrom (D2.2). In this subsequent step, the stakeholders and their needs, and decision-making power are explored in terms of their potential impact on the ReHyb system's feasibility and usability. It is expected that the results of this deliverable will be useful for the development of the ReHyb system according to the stakeholder's needs, the definition of variables for the study design of the ReHyb system evaluation and the identification of some potential advantages and drawbacks that the system may face during the definition of the strategy for the market entering phase.

2. Stakeholder analysis

To achieve a target-oriented design and development of the ReHyb system, the participatory approach has been a key component of the development process in the ReHyb project. In a first step, as reported in D2.1, the stakeholders were identified, and their roles were explored. In this project the post-stroke patient has been considered as the main stakeholder and has therefore been intensively analysed as a first step in D2.1, where their characteristics, needs,

and interests were empirically investigated. This built the starting point of the ReHyb system development as a necessary step to tailor the product to the end-user's needs. In the subsequent step, further and deeper information on key stakeholders has been collected and analysed, and some other stakeholders have been identified as being the most relevant. They are therefore targeted and analysed regarding their roles and relationships in view of the potential use of the ReHyb system. This is an important step to successfully implement a rehabilitation pathway which includes the use of the ReHyb system and/or some of its modules. Some specific clinical, social and financial aspects must be taken into consideration and, with them, the "…actors who have an interest in the issue under consideration, who are affected by the issue, or who –because of their position- have or could have an active or passive influence on the decision-making and implementation processes" (1) need to be brought on board.

2.1 Stakeholder Analysis and Process

Following the general methodology of a stakeholder analysis, a list of relevant stakeholders of the ReHyb system was provided as a first step, together with their general characteristics, their roles, interests and expectations, in D2.1. Overall, ten different stakeholder groups (SH) were identified. The same groups have been maintained in this report, but some of their names or composition have been changed or broadened, as may be observed in Table 2[1].

Table 2. The different stakeholder groups of the ReHyb system.

	Stakeholder group	Description
SH1:	Patient	patient after stroke in rehabilitation hospital or at home
SH2:	Primary caregivers	e.g., partner, (grand)children, parents, best friends, legal representative
SH3:	Secondary caregivers	e.g., distant relatives, former partner/family member, close and distant friends
SH4:	Medical treatment staff	e.g., physicians, therapists, nurses in the rehabilitation center
SH5:	Non-medical support staff	e.g., medical aid commissioner, social service, hygiene, bioengineer in the rehabilitation center
SH6:	Fellow patients	e.g., roommate, fellow patient

[1] Note: In D7.2, another way of classifying the stakeholder groups was applied. The group of medical treatment staff (SH4), primary caregivers (SH2) and secondary caregivers (SH3) were introduced as Primary Care Circles, Primary Support Circles and Secondary Support Circles, respectively.

SH7:	External relations	e.g., general physician, outpatient therapist, nursing service
SH8:	Financial providers[2]	e.g., insurance companies, annuity insurance, National Health System (NHS), hospital authorities, out-of-pocket payer)
SH9:	Governmental authorities	e.g., job center, social welfare agencies, district / regional administrations
SH10:	ReHyb system provider	technical partners of the ReHyb consortium

In this second step of the in-detail stakeholder analysis, the interests, positions, influence power, and relations of the stakeholders were analysed by means of stakeholder matrices and onion diagrams. Even if literature indicates a general lack of empirical indicators to identify the variables involved, in general a stakeholder's "*Interest* refers to their concerns about how a particular [issue] will affect them (2); *position* reflects their level of support for or opposition to the [issue] (3); and *power* is their ability to affect the [issue] reflecting their resources and ability to mobilise them" (4).

To focus the analysis, four conditions must be taken into consideration:

1. The ReHyb system pursues the approach to support and serve the patient in both settings, the (rehabilitation) hospital and at the patient's home, therefore, even if this first phase will be focused on the development and deployment of the system in a hospital setting, it has been considered useful to include the home setting as part of the analysis. However, the prescription of the system for home-use might be handled during the hospital stay, so the following analysis in the hospital setting considers the prescription process. In other words, when talking about the home setting, we assume that the system is already available for the patient to be used at home.
2. The ReHyb system will include two different exoskeletons, the high-powered exoskeleton, the characteristics and dimensions of which make it usable only in a hospital setting, and the spring-loaded exoskeleton, which may be used both at hospital and at home settings. Thus, it must be kept in mind that whenever talking about using ReHyb system at home, it refers mainly to spring-loaded exo and its potentially integrated modules.
3. Since the roles of the stakeholders may vary not only according to the setting but also depending on each country's healthcare policies and systems, the feasibility and usability of the ReHyb system will be tested in two different countries to start with, namely Germany and Italy. Considering that one of the aims of the project is to be able

[2] The name of this stakeholder group was changed. It was observed that in some countries the NHS or private administrations in other countries the insurance companies may be the main "payer". In terms of stakeholder analysis they are now grouped as "financial providers" to include them all.

to successfully position the system in different marketplaces, some parts of these analyses are based on a discussion with the whole consortium from six different countries during the 5th plenary Meeting @IBEC (see Figure 2). After an adaptation by SK, the refined results of the analysis were presented and approved by the consortium at the 6th plenary Meeting @Tecnalia. Valduce and SK subsequently finalised the analysis. During this process, regional differences of the stakeholders' roles were recognized. We aim, within this deliverable, at pointing out some of the regional differences. Still, there may be some country-specific situations regarding the processes and roles that cannot be exhaustively covered in this deliverable.

4. According to the project proposal, this in-depth analysis will include the design, development, and preliminary tests of the system.

Figure 2. Stakeholder analysis together with the consortium at the 5th plenary meeting.

In the following, the results of these analyses are displayed in onion diagrams which allow to visualize the different potential stakeholders in a series of concentric circles according to their significance in relation to the system itself and the main relationships between them, and stakeholder matrices which allow to observe the level of stakeholders' interest and their ability to influence the system characteristics in terms of feasibility and usability.

2.2 Onion Diagram

According to the onion diagram methodology (5-7) the innermost circle contains the ReHyb system itself. The ten different stakeholder groups are then placed in the different layers of the onion depending on their degree of relation to the ReHyb system. The circles expanding the onion diagram indicate different stakeholders of decreasing significance. As such, the onion

diagram shows who works closely with the system and who may have an important impact on its design, use and/or on the decision of its use. After the stakeholder groups are accordingly aligned, differently coloured arrows indicate the *Human Relations*, the *Money Flow* and the *Information Flow* among the different stakeholder groups. The directions of the arrows represent one-way or two-way flow direction. These relations are defined as follows:

- *human relations:* Any relationship in addition to an information relaying an emotional / subjective perception is considered a "*human relationship*", such as relationships considered friendship or collegial. In this case, a mutual exchange of subjective perceptions was defined before, during or after an interaction with the ReHyb system.
- *money flow:* The "*money flow*" indicates the direction in which a "*money flow*" runs in relation to the ReHyb system and between which stakeholders a "*money flow*" may happen.
- *information flow:* In the following, *"information flow*" refers to communication activities that relate exclusively to the ReHyb system characteristic.

The resulting onion diagrams are shown in Figure 3 and Figure 6. Figure 3 shows the onion diagram for the ReHyb system in a hospital environment, whereas Figure 6 depicts the situation in a home environment. They have been considered separately since the stakeholders' position, relationships and their significance change from one setting to the other.

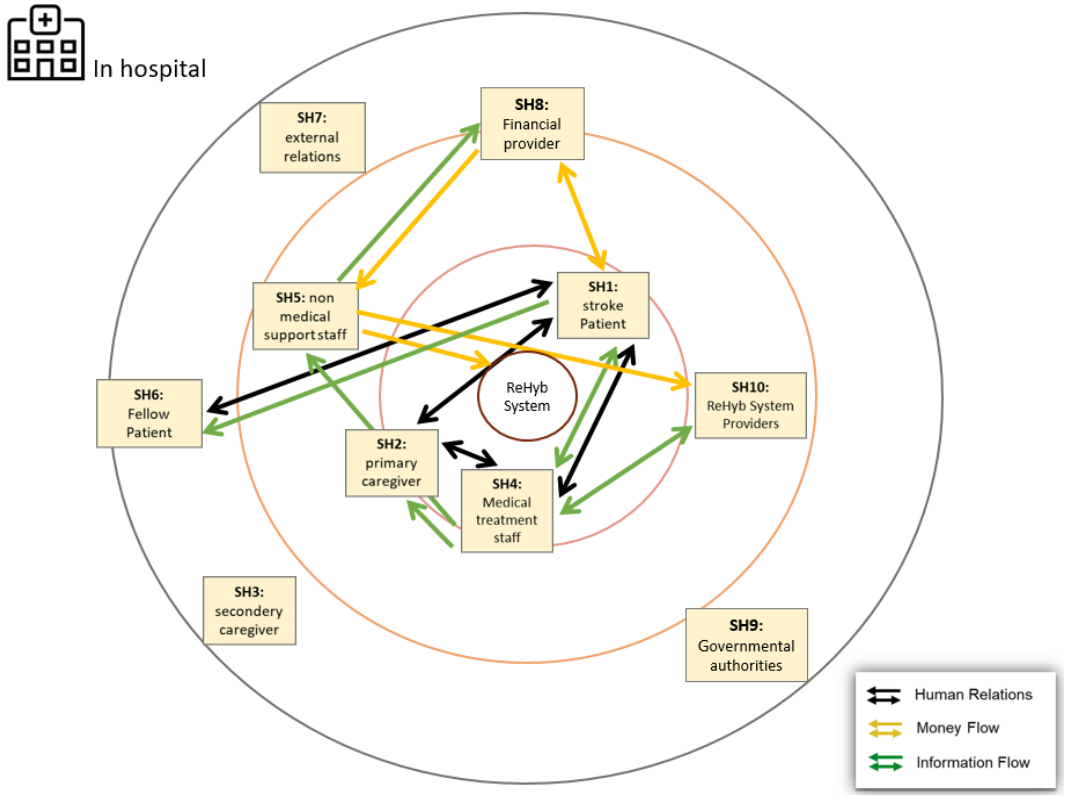

Figure 3. The onion diagram for the hospital application of the ReHyb system.

As may be observed in the first layer of Figure 3, the most relevant actors in the clinical setting are the post-stroke patient, the medical treatment staff and the primary caregiver. The strong relationships between these stakeholders indicated by the black and green arrows, is detailed by the exemplary process represented in Figure 4.

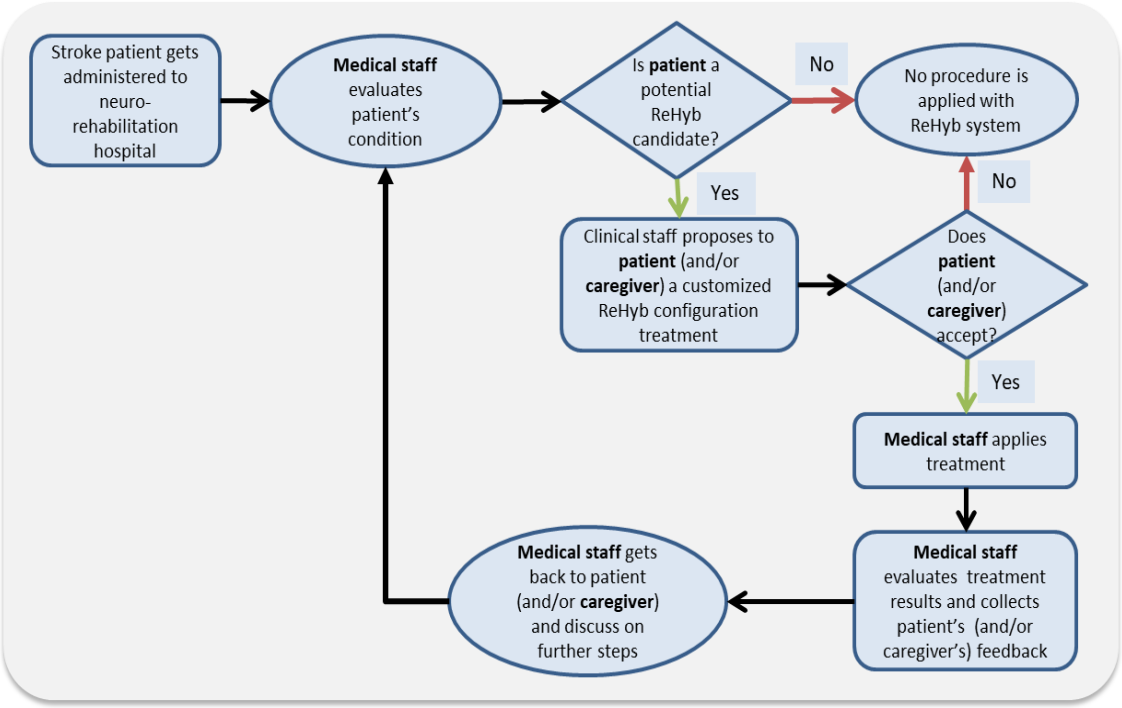

Figure 4. Example of first layer process involving the stakeholder groups SH1, SH2 and SH4 regarding human relations and information flow.

A key stakeholder group in the clinical setting is the medical treatment staff since it is involved in human relations, information flow and even indirectly in the money flow. In fact, they administer the ReHyb system and, therefore, inform the patient about its functionalities, apply the therapy, and collect the feedback from the patients. They may communicate with the ReHyb system provider for further training and/or development of the potentialities of the system and with the primary caregiver who may support or oppose the use of the system. Moreover, they are the link to the relations regarding the financing of the ReHyb system, as they communicate with the non-medical support staff of the clinic, who is involved in the money flow together with the other financial providers and the system providers. As an example, the medical doctors or therapists might decide that they want to use the ReHyb system in the hospital and eventually buy the device. This role may differ between different hospitals and countries - for example, at Valduce, it's primarily the medical doctors that will decide upon the use of a therapy device, while at SK, the therapists have a greater influence on the decision of use and purchase of therapy devices. They will then inform the financial department of the hospital, which will

need to approve the foreseen investment and subsequently will handle all the payments. The exemplary process of this investment procedure, as it is at Valduce hospital, is displayed in Figure 5. Details in these processes may vary depending on the region and hospital. Another country-specific difference to the onion diagram in Figure 3 is present in the financing structure in Denmark, where an additional money flow goes from governmental authorities (SH9) to financial providers (SH8).

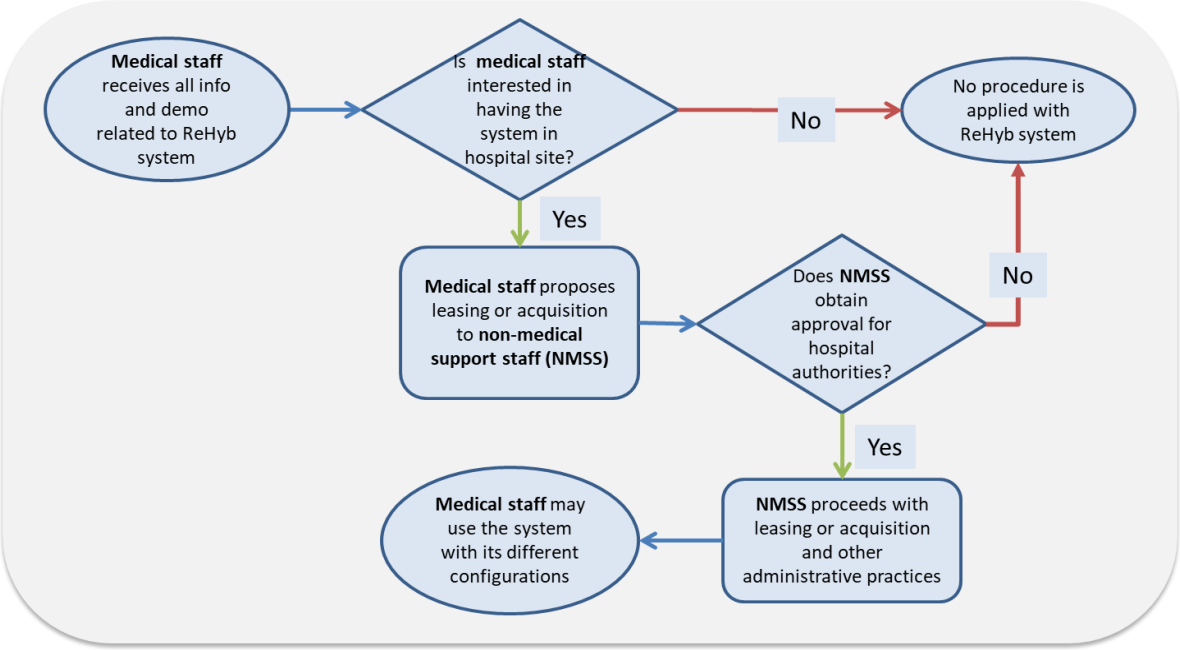

Figure 5. Exemplary second layer process: Device procurement process at Valduce hospital

In the second layer of the onion diagram, the ReHyb provider and non-medical support staff are present. They will be mainly involved in the financial issues and other administrative processes (e.g., interaction of financial support in clinic, investment decisions for rehabilitation devices) to ensure the availability and correct functioning of the system in its different modules and configurations in the hospital setting.

The next closest stakeholders are the financial providers. Therefore, it needs to be distinguished between the different possibilities of financial providers: they might represent insurance companies, National Health System (NHS) or the hospital finance department. Although the insurance companies or NHS cover most of the rehabilitation stay for the post-stroke patient, they are not as relevant in this context. This is due to the fact that most European countries use diagnosis-related groups (DRGs) according to which a reimbursement of the hospital stay is calculated. Therefore, a fixed amount per DRG has been established either by pure DRG or by a combination of DRG and length of stay, and not per type of therapy applied. Thus, in the context of buying a ReHyb device for hospital use, the finance department of the hospital acts

as financial provider. They accept or decline the proposed investments. But the proposal is entered by the medical treatment staff (such as depicted in Figure 5), which emphasises again the importance of considering them to successfully place and use it in a hospital setting.

The third and more distant layer shows the presence of secondary caregivers, fellow patients, external relations, and other governmental authorities. The role of fellow patients and secondary caregivers is mainly related to direct human relations with the post-stroke patient and, in this way, additional information about the experience with the system may be shared and spread.

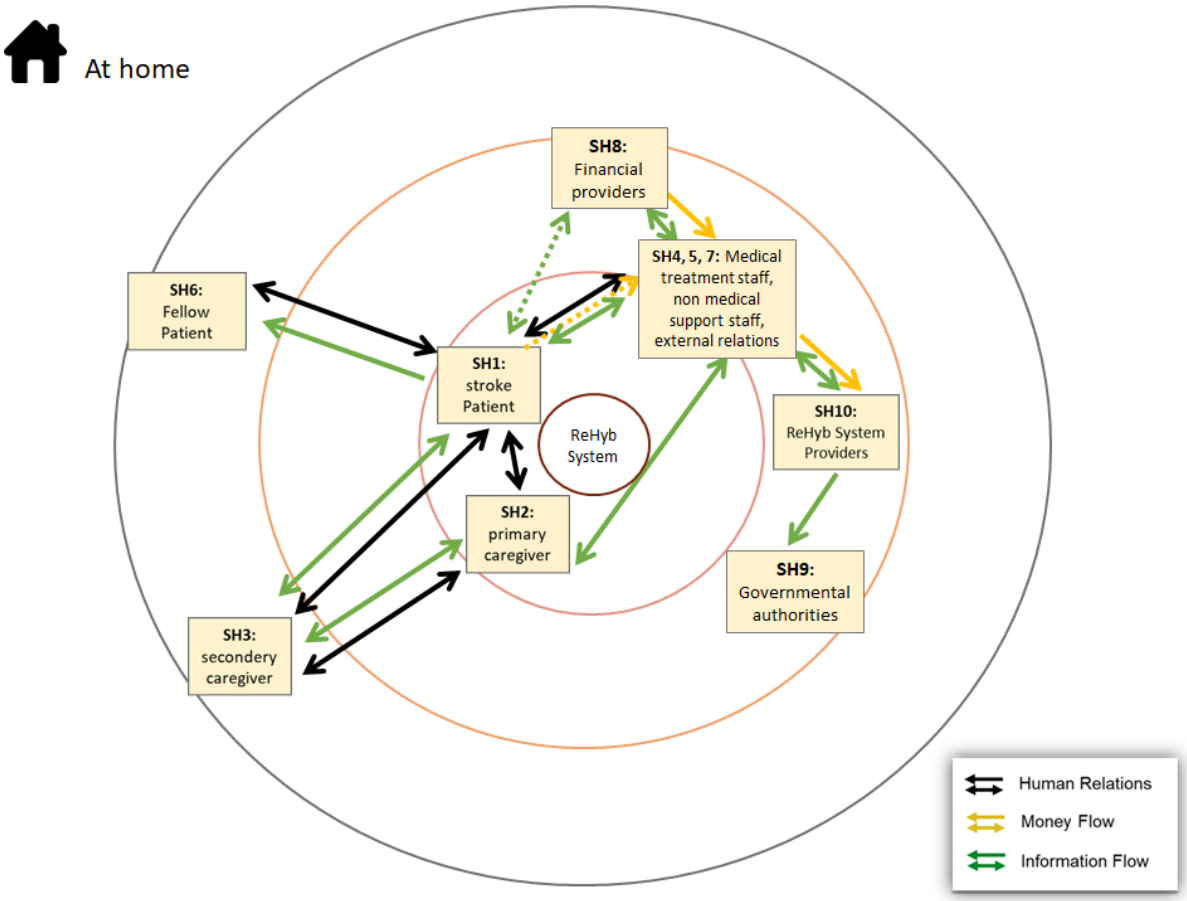

Figure 6. The onion diagram for the home application of the ReHyb system.

When it comes to applying the ReHyb system at the patient's home, following points change (see Figure 6):

1. Roles grouped in "medical treatment staff", "non-medical support staff" and "external relations" enter the first circle since they may be responsible for the prescription and/or acquisition process after the patient was discharged (e.g., by general physician in the group of "external relations"). Due to national differences, we grouped the three stakeholders together. In Italy, the hospital staff (SH4 and SH5) follows the patient after

discharge and is still involved in their therapy, while in Germany, the hospital staff gives the patient in the hands of the outpatient therapists and general physicians (SH7), so the hospital staff is no longer in contact with the patient after discharge.

2. In general, human relations, information and money flow become more intensive with "external relations" actors.
3. Financial providers (i.e., insurance companies, hospital authorities, NHS or even the patient and primary caregiver if out-of-pocket) changes from the third to the second circle, since they will be responsible for the funding of the device.
4. Stakeholders grouped as "Governmental Authorities" enter the second circle since they may have an important role in the process of approval and acquisition of the device.
5. Fellow patients leave the scheme by virtue of their remoteness with respect to the process that follows.
6. Human relations and information flow with secondary caregivers are intensified even though they remain in the third circle.

To receive a funding option (by an insurance or NHS) for using a medical device at home (as training or assistive device), a prescription of the device by a **medical doctor** (either a medical doctor at a hospital or in an ambulatory setting, e.g., a general practitioner) is always required. As already mentioned under bullet point a), it is very common that medical or assistive devices for home-use are already organised as part of the discharge planning while the patient is still in the hospital. The processes in the different countries and hospitals may vary slightly, as can be observed by the two following flowcharts (Figure 7 and Figure 8) that display the situation in Valduce hospital and Schoen Clinic. It is noteworthy that at Valduce, the medical staff of the hospital may also prescribe the devices for patients that are in a home setting, as they may also have the role of being their outpatient doctors. This is not the case at SK, where only prescriptions for inpatients are conducted.

In both countries, the financial provider may cover the costs for the device only if it is listed by the NHS in Italy or in the "Assistive devices directory" ("Hilfsmittelverzeichnis des GKV-Spitzenverbandes" https://hilfsmittel.gkv-spitzenverband.de/home) in Germany. The "Gemeinsamer Bundesausschuss (G-BA) decides upon the listing of a product in this directory. The health insurances in turn have special contracts with medical supply stores, which may limit the choice of an individual model of a certain device (8). However, the listing in the "Assistive devices directory" is a prerequisite but not a guarantee for the cost coverage by the health insurance. In case this request is approved, the health insurance will pay for the device (except for the small amount of statutory co-payment to be covered by the patient) and the medical aid supplier will supply the device. In case the health insurance denies the cost coverage, the patients/relatives have the possibility to enter an objection to this decision.

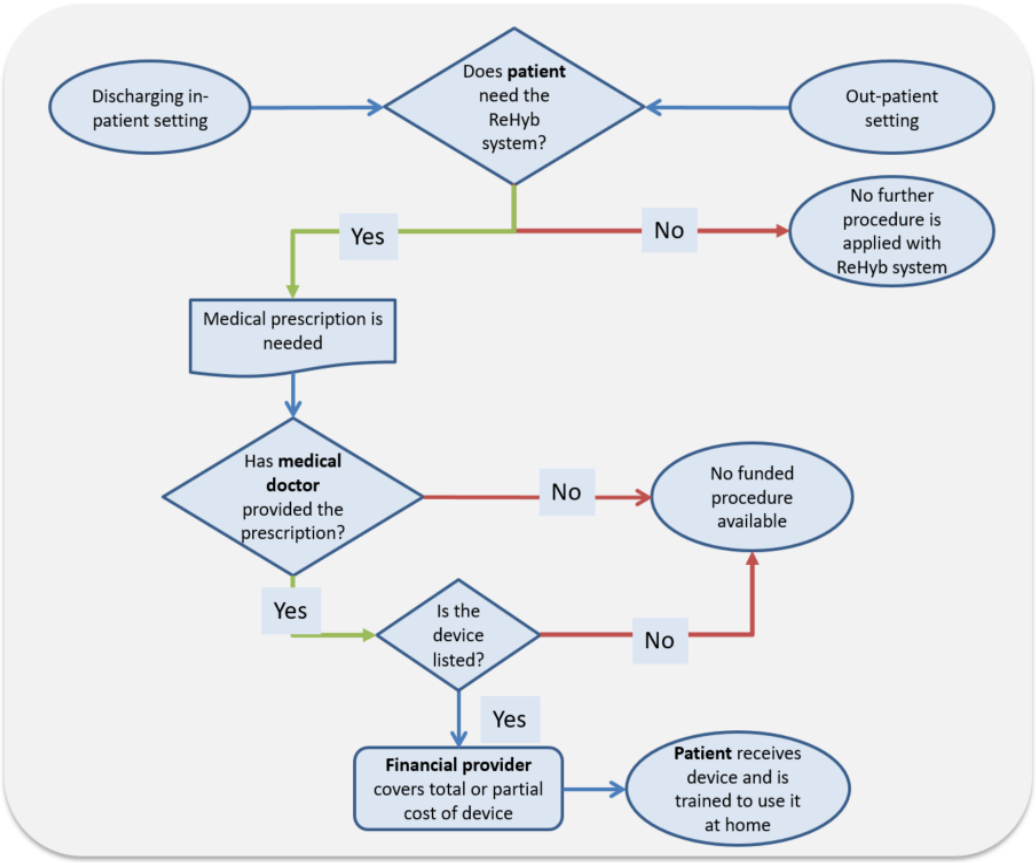

Figure 7. Flowchart for prescription of the ReHyb device for home application as it is in Valduce (IT).

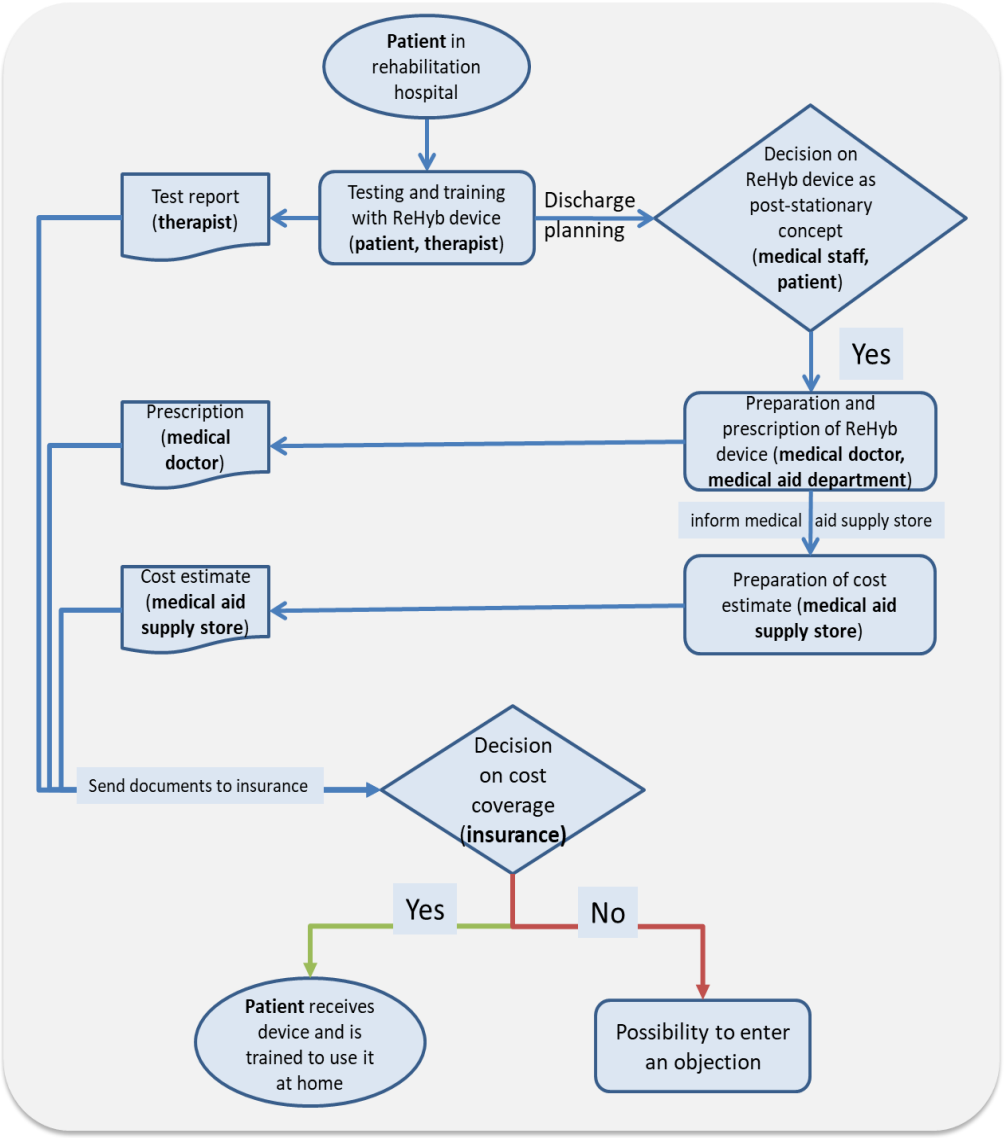

Figure 8. Flow chart of the prescription process of a medical device for home-use following the hospital stay as organised from the hospital in the course of the post-stationary-management at SK.

Compared to the hospital setting, at home the primary caregivers (e.g., family and close friends) also have a higher relevance as there are more possible interactions with the ReHyb system - they might be involved in the usage of the ReHyb system (e.g., when assisting the donning/doffing, the administration of the gaming/therapy or maintenance/cleaning of the device).

2.3 Stakeholder matrix

The stakeholder matrix (9-11) is a very important tool because it captures the stakeholders' ability to influence the system. Within such a stakeholder matrix, the different stakeholder groups are placed according to their influence on using the system and their interests in the

system. Following this 2-dimensional placement of stakeholders, each group will be located in one out of four categories. Each category indicates the extent to which the stakeholder group should be informed during the development process:

- Green – Latent stakeholder groups. They need to be satisfied by the outcome of the project but may not require regular attention during the project itself → Address their concerns.
- Grey – Apathetic stakeholder groups. They should be monitored by the project manager in case their interest or power changes. But they require almost no attention at that point in time → Keep them informed.
- Blue – Defenders. They will support the project and its aims and should be given regular updates to keep them included and motivated → Involve them as needed.
- Red – Promoters. They should be devoted with special attention to managing closely. These are the stakeholders with the largest capacity to promote the project within the business but also have the largest capacity to derail it if not carefully handled → Involve them extensively.

As already mentioned, stakeholder analysis may change depending on aim, time dimension, context of application and level of the analysis (local, regional, national, or international). As already done when using onion diagram, stakeholder matrix will include the two main contexts of application of ReHyb system, namely rehabilitation hospital and patient's home. Following the rules outlined above, stakeholder groups who are situated in the red sector will be extensively involved and thus, they will be considered the target stakeholder groups of this deliverable. Home setting will be considered as future implementation of the accomplished system.

To define the position of the different stakeholders in the matrix and their main opinions, some pilot studies, workshops, and interviews were conducted. The results for the clinical setting are visualized in Figure 9 and for the home setting in Figure 10.

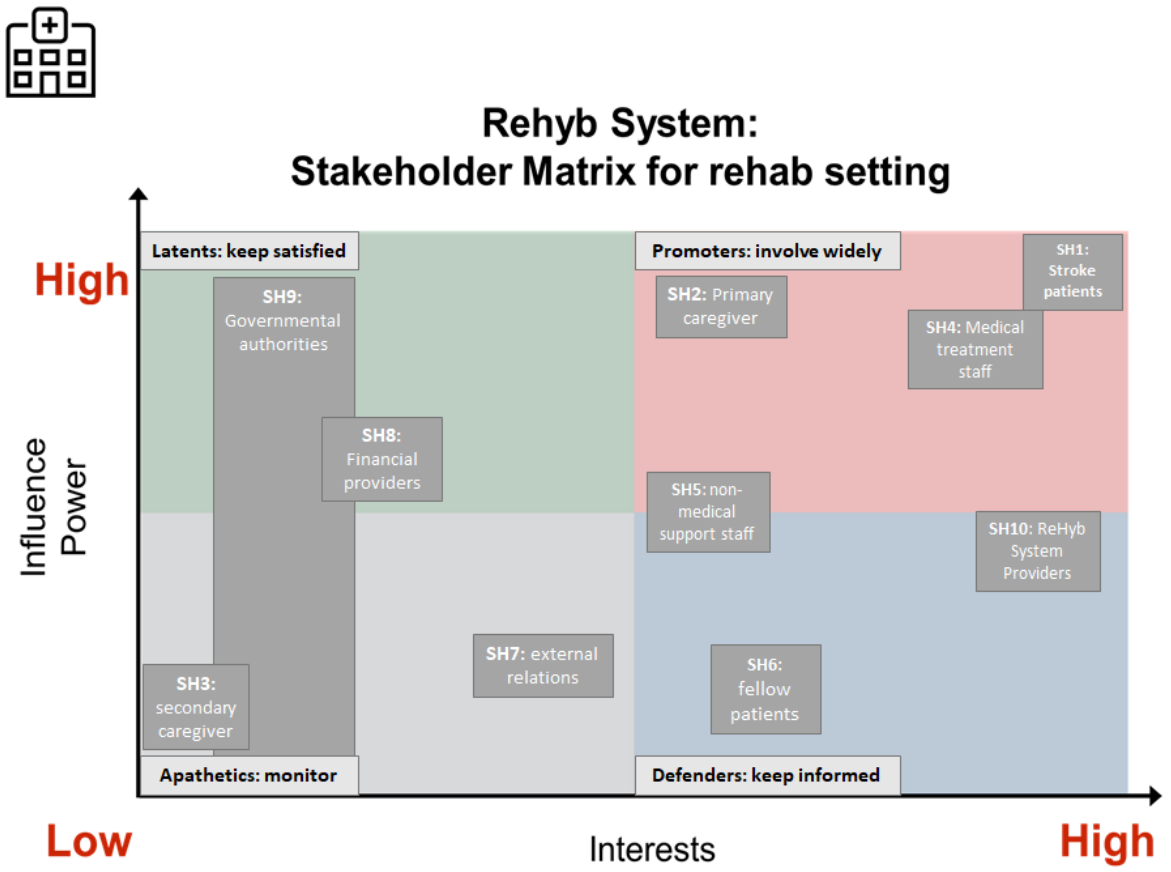

Figure 9. Stakeholder matrix for clinical setting.

The rationale for the stakeholder distribution in the matrix for the hospital setting is provided in Table 3.

Table 3. Involvement of the main stakeholders according to matrix for clinical setting.

Stakeholders	**Involvement in the issue (role)**
SH1: Patient	Post-stroke patients will be the end-users. They may suggest some of the characteristics they would like to find in the system. Their opinion about the system feasibility and acceptability will be very important for design issues.
SH2: Primary caregivers	They are main supporters of end-users and their opinion on usability of the system will be important.
SH3: Secondary caregivers	Their role in this phase is very weak.

Stakeholders	Involvement in the issue (role)
SH4: Rehab. clinic: Medical treatment staff	In the sense of administering the device, they are end-users as well. Additionally, they will propose who, how, when, and how often patient may use the system. For their decisions they will need data coming from the system, they will train SH1 and SH2 and will monitor the system functionalities and eventually, the clinical results obtained.
SH5: Rehab. clinic: Non-medical support staff	Their influence power is rated as medium, since there are some hygiene requirements to be fulfilled, which will be checked by the hygiene department (country-dependent).
SH6: Rehab. Clinic: Fellow patients	No major influence on the market role of the ReHyb device. Nevertheless, they should be kept informed as they are potential future ReHyb users.
SH7: External relations	As defined in this document, their role will become active in further phases of the project (e.g., outpatient medical staff for further therapy prescription and supervision after discharge).
SH8: Financial providers	Even though the interest of acquiring a new device will be raised by medical treatment staff, the hospital authorities need to give their consent.
SH9: Other governmental authorities	As long as regulatory requirements (e.g., Medical Device Regulation (MDR), CE-certification) are fulfilled, they have no major influence and interests.
SH10: ReHyb system provider	They are the system configuration designers and manufacturers of the system. They will be involved in training, technical support and consulting.

The following matrix represents the influence power and interests of all stakeholder groups when it comes to the application of the ReHyb system at the patients' home.

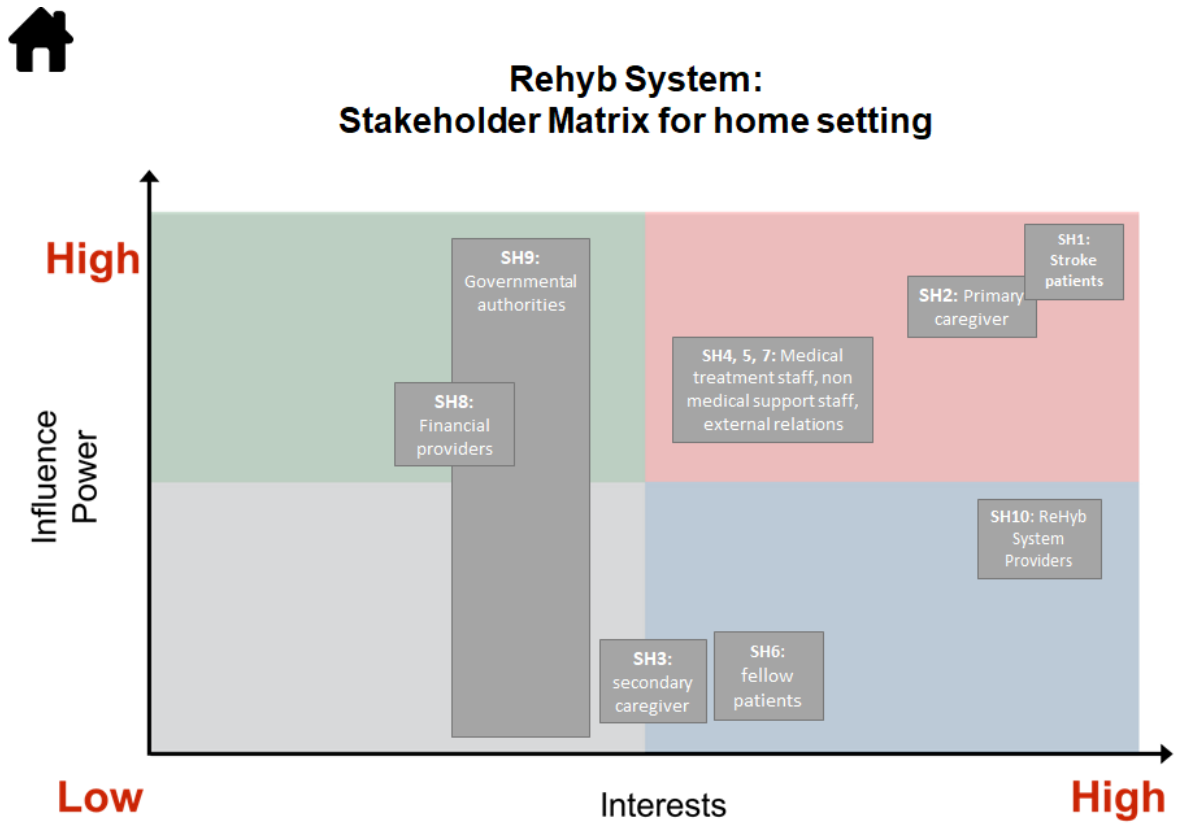

Figure 10. Stakeholder matrix for home setting.

The rationale for the stakeholder distribution in the matrix for the home setting is provided in Table 4.

Table 4. Involvement of the main stakeholders according to matrix for home setting.

Stakeholders	**Involvement in the issue (role)**
SH1: Patient	Post-stroke patients are the end-users. They have a very high interest in using the system at home but the financial decision is not always in their hands, it may depend on financial providers and/or other agencies regulations.
SH2: Primary caregivers	As supporters of end-users, they may help in the decision-making process.
SH3: Secondary caregivers	Basically supportive.

Stakeholders	Involvement in the issue (role)
SH4, 5, 7: Rehab. clinic: Medical treatment staff, Non-medical support staff, External Relations	Their role is mainly related to prescription and monitoring processes. In some countries the in-clinic medical treatment staff monitors the patient after discharge, in other countries, the patient will be supervised by external relations (e.g., outpatient medical staff) in the home setting.
SH6: Rehab. Clinic: Fellow patients	No major influence on the market role of the ReHyb device. Nevertheless, they should be kept informed as they are potential future ReHyb users.
SH8: Financial providers	They show a high power of influence on potential system availability as they provide the funding.
SH9: Governmental authorities	Their role will depend on national or regional regulations. In some countries they decide on financial issues, in others it is only necessary to fulfil their requirements.
SH10: ReHyb system provider	This actor will be the provider and technical support of the system.

Summary of main points of Chapter 2

1. Stakeholder analysis is a dynamic process in which actors, their position, roles, power of influence and interests will vary according to the time dimension (or phases), context of application and level of the analysis. Stakeholder groups who are situated in the red sector are involved extensively and thus the target stakeholder groups of this deliverable.
2. The result of the stakeholder matrix revealed that in addition to the stroke patient, primary caregivers, and the non-medical and medical treatment staff are located in the red sector, at the rehabilitation clinic (see Figure 9) as well as at home (see Figure 10). In case the national structures do not foresee the medical treatment staff of the clinic to follow-up the patient after discharge (e.g., in Germany), external relations take over the role of this stakeholder group in the home setting. Financial providers are also rated medium to high on the influence power spectrum in both application scenarios as they play an important role in the financing of assistive devices and therapeutic equipment.
3. As a consequence of what has been presented so far, the six target stakeholders (SH1, SH2, SH4, SH5, SH7, SH8) identified by the analysis in chapter 2 of this deliverable were further investigated regarding their opinions, needs and feedback on the different modules that are being integrated within the ReHyb system. These results are presented in the following chapter.

3. Findings and Analysis of the most important Stakeholders of ReHyb

The primary stakeholders as defined by the analysis in chapter 2 of this deliverable were further investigated regarding their opinions, needs and feedback on the different modules that shall be integrated within the ReHyb system. These results are presented in the following chapter.

3.1 SH1: The Patient with ReHyb system

In order to provide a wish list to the technical partners including features that are desired by the patients, a survey was conducted on the population of patients after stroke (see D2.1). Fifteen collected questionnaires (ten on robotic devices, five on FES) at SK provided information about the opinions, experiences, and values of patients after stroke in using either robotic devices or FES during upper limb therapy. Among others, patients were asked about their perceived level of comfort and tiredness, and about which characteristics they would like to find in this technology.

Participants were on average aged 57 ± 15 years. The ratio of female and male patients was 1:2.75. In total, 80% of the patients wished for the option to use the device at their homes after discharge. They explained that this would enable them to practice more frequently without the need to “get transported” to the clinic daily, from which they expected further functional improvements. However, as a prerequisite for home-use, patients mentioned that the device must be easy to use, including easy handling and clear instructions for self-administration. One-third of patients desired more variation in tasks and an adaptation of how much support they receive, based on their individual capacity. Patients further appreciated therapy in which Activities of Daily Living are included. By using real objects and practicing bimanual tasks, patients expected to profit from a skill transfer to activities in their daily life.

In summary, there were three wishes of the patients:

1. Possibility to use the system at home;
2. Individualized variation in tasks and degree of assistance;
3. Using real objects and practicing bimanual tasks.

3.1.1 Feedback on the FES module

Following these wishes, the potential of FES in assisting during daily activities was investigated with the vision of using the module throughout the day after discharge. Therefore, two studies were conducted at SK, using a portable stimulator (Fesia Grasp (Fesia Technology, Spain) with multi-array electrodes (see ethical application for pReHyb-1A and pReHyb-1B in D10.2). Within both studies, FES was applied to the forearm muscles to stimulate finger extension and flexion. During stimulation, the muscle activity of finger extensors and flexors and elbow extensor and flexor was measured by electromyography (EMG) sensors, and hand

movements were captured by tracking reflexive markers with a Qualisys motion capture system (see Figure 11). Additionally, electroencephalography (EEG) measures were performed in the pReHyb-1A study. The objective of the studies was to:

1. Optimize the FES control mechanism to trigger the required movement;
2. Analyse the time until fatigue and how it can be detected by grip force, EMG, and kinematics;
3. Identify which objects can be grasped when showing different levels of impairment.

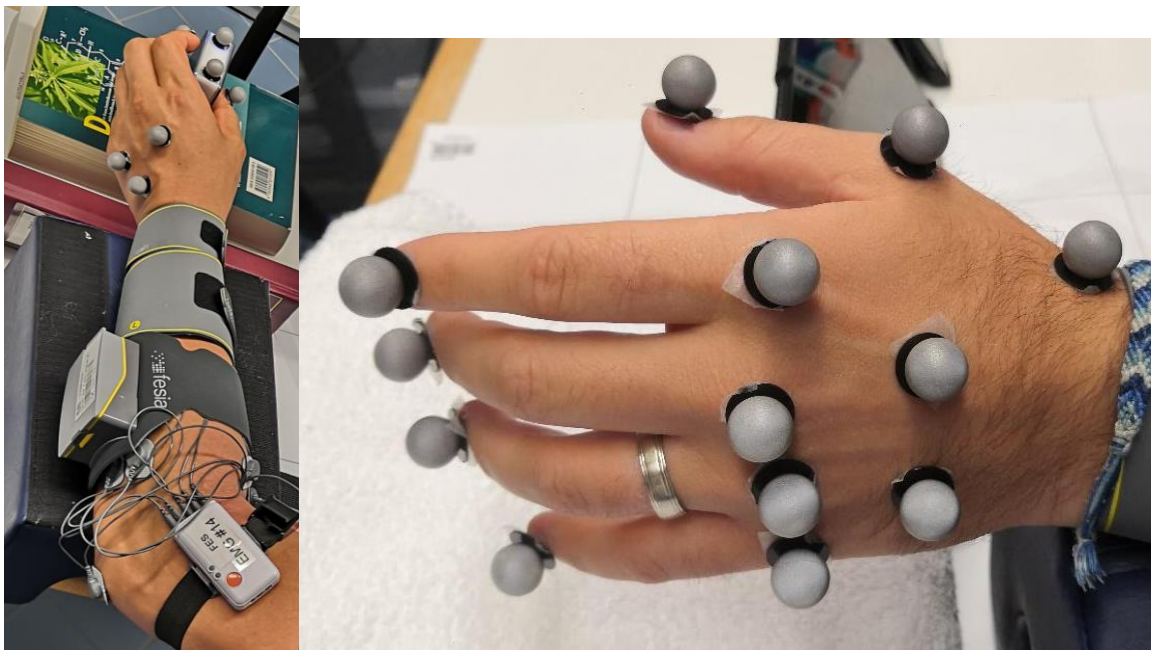

Figure 11. The study setup of pReHyb-1A and pReHyb-1B.

Counting both studies together, 30 hemiparetic patients after stroke were included. Patients' characteristics are reported in Table 5 including the Medical Research Council (MRC) Scale.

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Table 5. The patients' characteristics of the pReHyb-1A and pReHyb-1B population.

n	Sex	Age (mean ± SD)	MRC_ext (mean ± SD)	MRC_flex (mean ± SD)	aetiology	affected side
30	11f/19m	65.1 ± 13.6	1.4 ± 1.3	1.8 ± 1.3	22i/10h	19r/14l

Note: f – female; h – haemorrhagic; I – ischaemic; l – left; m – male; MRC_ext – Medical Research Council Scale of wrist extension; MRC_flex - Medical Research Council Scale of wrist flexion; r – right.

The result of grasping the sensorized object (pReHyb-1A) will provide insights into FES control methods (see D5.1 and D6.3) and into the duration until signs of muscle fatigue appear.

Further, the orthotic effect of FES in assisting during daily life (pReHyb-1B) will be investigated by means of the second task of the study. Results will be reported in D9.3.

As a part of the stakeholder analysis, the experiences of patients after stroke in using the stimulator are reported.

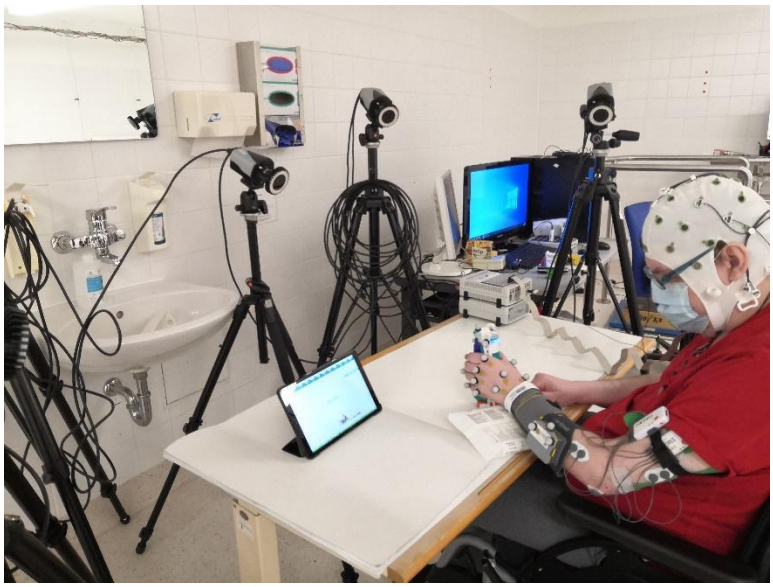

Figure 12. Grasping a sensorized object with support from FES while EEG, EMG and motion capture data is recorded.

Patients after stroke were assisted in or facilitated to the grasp of a **cylindrical sensorized object** (i.e., GripAble (Gripable Limited, UK); pReHyb-1A). The task included repetitive squeezing of the object at different force levels (2N, 4N, 6N, and 8N), which were visualized on a tablet game (Figure 12). Finger extension was not part of this task. There were three different task conditions:

1. No voluntary effort, FES only;
2. Voluntary effort only, no FES;
3. Voluntary effort together with FES support.

On a five-point Likert scale, ranging from completely disagree (1) to completely agree (5), patients rated the stimulation to be comfortable (mean: 3.7, SD: 0.6). However, the stimulation intensity was of course not set above a comfortable level. In addition to that, patients indicated that the stimulation improved their task performance (mean: 3.8, SD: 0.8). A patient with mild-moderate impairment (MRC wrist flexion: 3/5, grip force of paretic hand: 9 N) added that the stimulation was especially beneficial when higher grip forces were required.

The following observations were subjectively collected by the investigator and not assessed in a standardized way. Some patients with visuospatial impairments profited from the stimulation in terms of attention shift and timing of the grasp. Subjectively, gripping and relaxation of

fingers in the respective periods of the task were less delayed when stimulation was applied and assisted the patients during the task.

Besides this overall positive feedback from the patient after the experiment, some limitations were observed by the participant during the task:

- For some patients with severe motor impairment, the circumference of the GripAble was too big. Their fingers did not surround the object in an optimal way, so grip higher force might have been required to squeeze the object compared to the optimal gripping position.
- In most cases, we observed that the stimulation without voluntary effort was insufficient to reach the upper grip force levels in the tablet game. Depending on the sensitivity of the patient, the stimulation intensity was increased to reach higher grip force levels. However, at a certain point (around + 6 mA to the initial intensity setting), the grip force showed no further increases even when applying a higher stimulation intensity.
- For those patients who were more sensible, an increase in stimulation intensity led to pain. Thus, the intensity was not further increased than the maximally tolerated threshold and higher grip force levels were conclusively unreachable. Interestingly, it was observed that discomfort or pain was mostly reported when muscles were stimulated without voluntary contraction. It seemed like voluntary effort might have distracted the patients from the sensation or the stimulation might have been perceived as less intense when muscles were in a self-contracted state.

During the functional grasp of **real objects,** assistance from the stimulator enabled most of the participants to grasp and place the objects (pReHyb-1B). According to their comments, we have extracted the following aspects of the stimulation that facilitated a successful grasp (see Figure 13 for a summary):

- Finger opening can be stimulated to facilitate grasping an object. This was especially useful for patients who were able to stabilize the object due to residual flexor activity or spasticity. Most patients' impairment was in the hand opening and thus in releasing the object where the triggered finger extension facilitated to perform the grasp and place task.
- Not only the hand opening itself, but also the speed and dexterity when placing the object were improved by the stimulation. Patients who struggled in positioning the object on top of the Action Research Arm Test (ARAT) shelf placed the object more precisely on top of the shelf without accidentally hitting them and making them fall from the shelf.
- Another advantage of the stimulation of finger extensors was the temporary release of spasticity. Five of the recruited patients suffered from flexor spasticity in the upper limb. In three of the five patients, the spasticity was released after several stimulated finger extension movements. In two patients, spasticity was only released until the next flexion movement which prevented them from participating in the repetitive grasping exercise.

- The FES assistance had also a positive effect on the timing of the grasp. It seems like the stimulation improved the patients' ability to recruit different muscle fibers for different motion primitives during grasping. Especially, patients with visuospatial impairments were able to improve the quality of the grasp in terms of timing and smoothness of finger movements. One patient had the feeling that his muscles were "awakened" by the stimulation. Due to cognitive and attentional deficits, they had problems with the recruitment of the correct muscle fiber, which was better when adding FES.
- The setting of stimulation parameters for the first time evoked positive emotions in the patients. They were fascinated when seeing their hand moving.

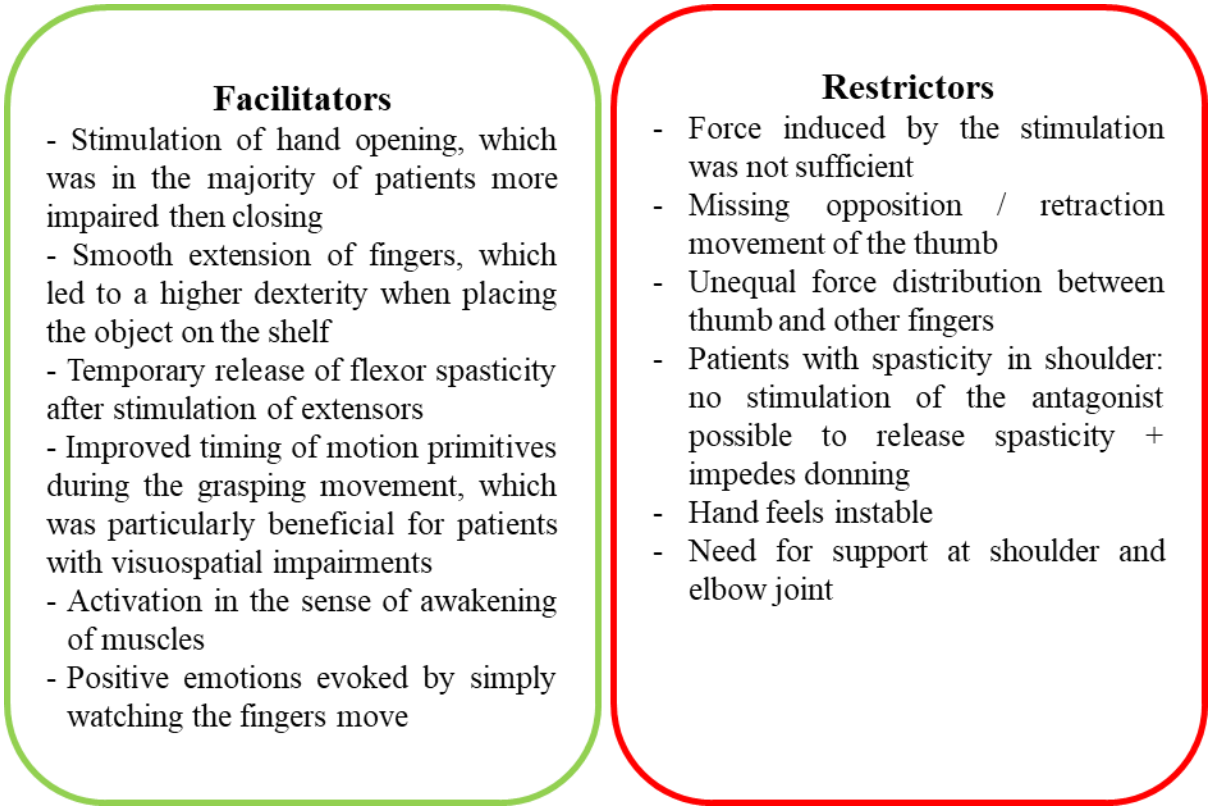

Figure 13. Summary of the feedback from patients on the FES module after participating in pReHyb-1A or pReHyb-1B study.

Beside all the positive feedback we have received from the included patients, there is room for improvement in the stimulation. Based on our observations and comments from the patients:

- the stimulated muscle force is not always enough to lift bigger and thus heavier objects (e.g., 10 cm cube) or to close the fingers far enough to grasp smaller objects (e.g., marble). Whenever we observed this problem either the patient's maximal tolerable stimulation intensity was reached, or an increase in intensity did not lead to further finger movement / higher force.

- the thumb has not received appropriate support from the stimulation. In most of the patients, it was not possible to trigger the required opposition/retraction movement of the thumb but rather a flexion/extension movement which was not useful when a cylindrical grasp was needed to lift the object. Additionally, the force which can be applied by the stimulated thumb was lower than the force of the other four fingers. This lack of support for the thumb had the result that the thumb slipped off the object and the object could therefore not be lifted.
- spasticity in the shoulder makes the application of the forearm stimulation with the Fesia Grasp difficult. On the one hand, the spasticity which brings the shoulder into internal rotation cannot be released by the stimulation, as we cannot stimulate an external rotation movement of the shoulder. On the other hand, an internally rotated shoulder impedes the donning of the electrode since the attachment of the garment works best if the upper limb is held away from the body.
- the control of their hand felt instable and tremulous when grasping objects.
- most of the patients are in need of support (e.g., anti-gravity support or spring-loaded exoskeleton) at the elbow and shoulder joints. Since the focus of this study was on the evaluation of the FES module, patients with paresis of the elbow or shoulder joint were allowed to guide the upper limb movement using the unimpaired arm (see Figure 14).

Figure 14. A patient after stroke participating in pReHyb-1B. The figure captures the patient's performance of the ARAT under assistance by FES and weight support by the unimpaired arm.

3.1.2 Feedback on the gaming module

When designing a visual gaming environment (e.g., screen-based, Augmented Reality (AR), Virtual Reality (VR)) for the rehabilitation after a stroke, some patient characteristics should be considered. On the one hand, impairments in visuospatial perception (VSP) are common after a stroke. Serious games are digital games that do not primarily aim for entertainment but for the transfer of information and support of motor and sensory training (12). The way impairments in VSP influence the application of serious games in a population of patients after stroke and how to tackle potential problems, was studied within the SPiAR trial at SK (see also WP7). On the other hand, the prevalence of a stroke increases with age, meaning that the target users of serious games are elderly patients. Since the older generation was not raised with modern technologies, it cannot be assumed that they are able to intuitively handle complex Graphical User Interfaces (GUI) and start the rehabilitation protocol. On the contrary, they might even deny the use of modern technology or potentially show problems in the ease of use due to a lower technical affinity. In an investigation initialized by DTU, the GUI of a tablet-based rehabilitation game was evaluated in the population of patients after a stroke at SK. Furthermore, patients after a stroke at SK and discharged patients, who again live at home, participated in a DTU-led workshop and gave feedback after testing different immersive gaming environments.

3.1.2.1 SPiAR study at SK

After a stroke, structures of the brain which are involved in VSP are damaged which leads to impairments in VSP, e.g. every fifth patient after a stroke is classified as being stereoblind (13). Neurorehabilitative therapy in form of serious games in an AR or VR environment requires the patient to reach out for and move holographic objects that are placed at different distances from the user. This indicates that the individual's VSP is crucial for the intended interaction in the AR environment and thus for benefitting from the AR intervention (14). To understand to what degree the distance estimation in a virtual environment is affected by deficits in VSP after a stroke we have conducted the SPiAR study with the objective of further specifying the system requirements to the individual patient characteristics. For a complete methodological description and the full analysis of results, we refer to our published article under (15).

Four different tasks which test the ability to judge distances and perceive objects in 3D were implemented in the AR environment by DTU (see Figure 15, already included in D2.1): the Perceptual Matching Task (PMT), the Alternative Forced Choice Task (AFCT), the Position Task (PT), and the 3D Detection Task (3DDT).

Perceptual Matching Task. In the PMT, two objects were presented at different distances from the participant. Subjects were instructed to actively adjust the distance of the right object (stimulus object) to the perceived distance of the fixed object on the left (target object) using the scroll wheel of a Bluetooth mouse. As the outcome parameter, the absolute deviation between the stimulus object and the fixed target object was calculated to evaluate task performance. The distance between the observer and the closest point of each hologram was compared.

Alternative Forced Choice Task. During the AFCT, participants were asked to identify which out of four holograms, randomly projected with different distances to the observer, was perceived to be the closest. As an outcome variable, the proportion of correctly performed test runs was calculated.

Position Task. In the PT, the user was asked to name the position of a holographic object that was presented either in front of, in the middle of, or behind a translucent cube. The outcome variable was the proportion of correctly performed tasks.

3D Detection Task. In the 3DDT, four spheres were presented to the user. Three of them were presented at the same depth plane and in two dimensions, while one was projected as popping out, which should be detected by the user. The outcome parameter was the lowest correctly identified stereoacuity level expressed in seconds of arc.

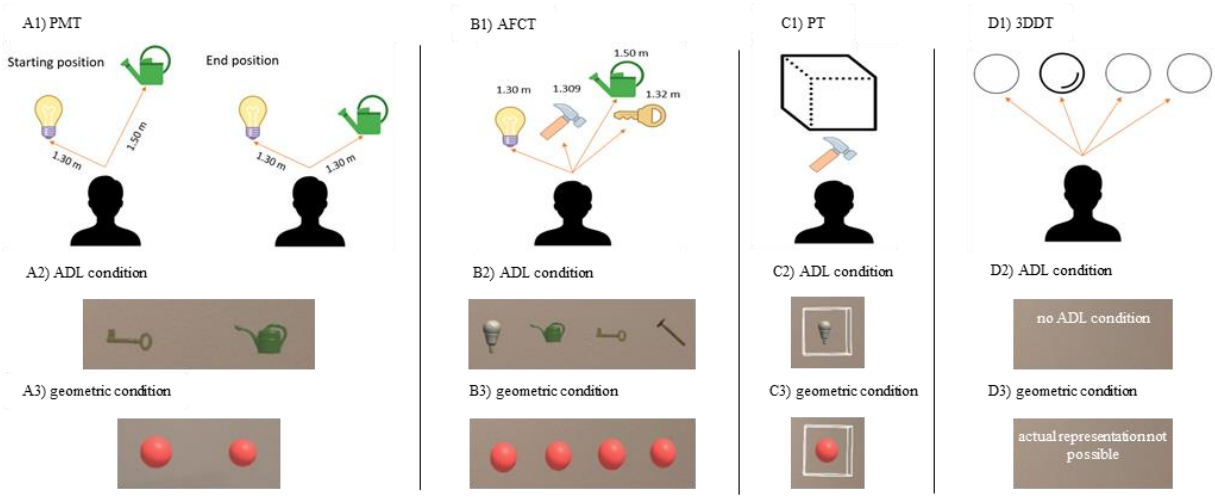

Figure 15. Tasks assessing the ability to judge distance (A1-C1) and to perceive 3D (D1) in AR. For the distance judgment tasks, either objects of Activities of Daily Living (ADL) were used (A2-C2) or geometric spheres were presented (A3-C3). A1-D1 show two-dimensional illustrations of the tasks, A2-C2 and A3-C3 show screenshots from the visual field of the user while wearing the Microsoft HoloLens®. CAVE: Screenshots deviate from the real projection of objects via the Microsoft HoloLens®. The impression of depth as displayed with the Microsoft HoloLens® cannot be displayed on a two-dimensional screen.

As the incentive behind this study was to improve the applicability of AR treatment in neurorehabilitation, potential users of AR therapy were addressed. Consequently, patients who received either robotic or AR treatment were screened for eligibility to participate (n=42). Inclusion criteria were the diagnosis of a stroke, without restrictions on the location of the lesion, since it is unclear whether or not the site of the stroke affects depth perception (16). Twenty patients (15 men, 5 women) participated in the SPiAR trial with a mean age of 64 years (*SD*: 14). Twelve patients showed impairments in stereovision. Of the 20 participating patients, 18 suffered an ischemic stroke, and two a hemorrhagic stroke. Eight patients were affected on the right hemisphere, four patients on the left, four patients on both hemispheres, and four patients on the brainstem. Different spatial and visual/ocular-motor impairments were

diagnosed: neglect (n = 2) hemianopia (left (n = 1), left and right (n = 1)), near exophoria (n = 1), heterotropia (n = 1), nystagmus left (n = 1) and reduced visual acuity (n = 2).

All patients have completed the four tests in the AR environment in addition to clinical tests to assess VSP (i.e., Titmus test, Lang II Stereotest, VOSP). Test results were analyzed in a linear model to investigate whether impairments in VSP are related to the performance in the AR tasks. The performance of matching geometric objects in the PMT was found to be predictable by the model (F (3, 19) = 5.537, p = .008). Spatial localization/visuoconstruction (i.e., VOSP) was significant for the deviation from the target sphere (p = .018). When comparing the distances of four objects in the AFCT, the quality of stereovision (i.e., Titmus test) was a significant predictor (p = .034). Regarding the performance of patients in the PT, where the position of the object was related to a translucent cube, results revealed that spatial localization/visuoconstruction (i.e., VOSP) tended to significantly predict the performance in the PT (p = .053). Lastly, the quality of stereovision (i.e., Titmus test) of patients after stroke with stereoimpairments tended to be significantly associated with the ability to perceive holograms as 3D in the 3DDT (rs (12) = .569, p = .054).

Summary of results and practical relevance for the ReHyb system

In summary, impaired stereovision affected the performance in one of three distance estimation tasks. While the quality of stereovision did not significantly predict the ability to accurately judge distances in the AR environment, spatial localization/visuoconstruction significantly was a significant predictor.

With a testing duration of approximately 20 minutes and the projection of ADL objects in the user's near field, the design of AR tasks in the SPiAR study is closely related to a potential therapy session with the ReHyb system. The main finding of the SPiAR study is that post-stroke patients with impairments in VSP less accurately perceive the distance of virtual 3D objects. When applying AR in rehabilitation our findings may suggest including a test of each patient's ability to perceive 3D objects. On basis of this test, the AR display may be personalized, for instance in the use of holographic 3D cues or monocular cues (i.e., size, lighting, shading, texture, motion perspective).

Therefore we further investigated whether the use of monocular cues facilitates patients with visuospatial impairments to perceive depth in the AR environment as well as which monocular cues should be used by AR software developers (Figure 16).

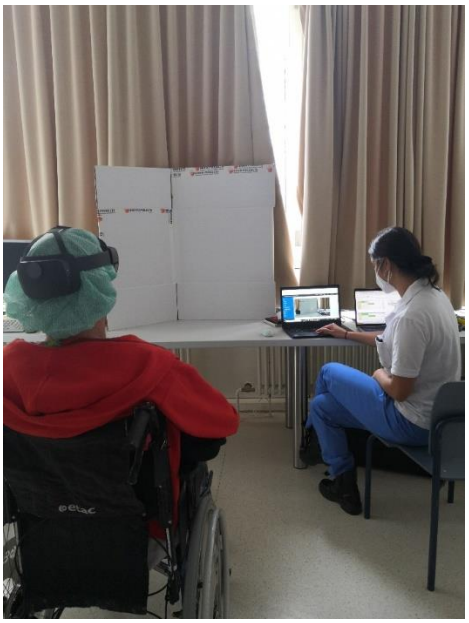

Figure 16. Testing the effect of different monocular cues on depth perception in the AR environment in a patient after stroke wearing the Microsoft HoloLens®.

Keeping in mind the patients' wish to individualize rehabilitation (see D2.1) our objective was to enable patients with impairments in VSP to perceive the distance of virtual objects and thereby adapt the rehabilitation environment to the patients' needs. To determine how to facilitate distance perception of holograms for patients with stereovision limitations, single monocular depth cues were added to the task in the AR environment. In addition to performing the test without the cue stimulus, patients repeat the task with the cue stimulus of interposition, the addition of shadows, and the depth cue of relative height (see Figure 17).

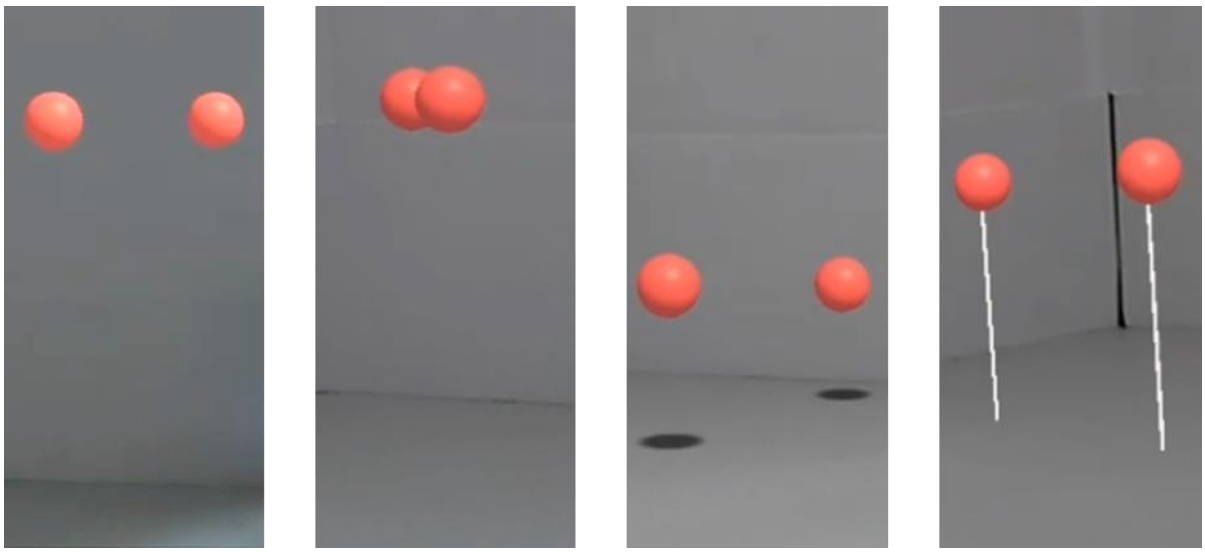

Figure 17. The PMT without monocular depth cues, with interposition, with shadows, and with relative height (left to right).

So far, one patient after a stroke has participated in the study, who showed limitations in stereo vision. Compared to testing without a cue stimulus, the patient's performance was significantly better when interposition was added as a depth cue ($p = .006$). In addition, interposition was significantly more helpful than using shadows ($p < .001$) or relative height ($p < .001$).

Conclusively, it was found that monocular depth cues have the potential to improve distance estimation in the AR environment. Interposition was particularly helpful and allowed the subject to adjust the distance of the two spheres so precisely that the deviation was less than 1cm.

3.1.2.2 GUI evaluation at SK conducted by DTU

This evaluation addresses the problem of how to integrate modern technologies into the patient‘s home environment without running the risk of the patient perceiving them as foreign bodies and blocking rather than supporting the rehabilitation process. With this objective, the focus is on the usability and user-friendliness of the individual technologies in order to make the process as pleasant as possible. Due to a possible change in motor, visual and cognitive functions after a stroke, the design of the GUI should be adopted to potential difficulties in starting and performing a rehabilitation exercise.

After discharge from the rehabilitation clinic, patients wish for the possibility to continue the rehabilitation exercises at home (see D2.1). Simpler devices, such as a tablet, might be the interface to choose for the first approach in making patients familiar with technology and studying potential barriers. For an app that is the main interface for the execution of exercises with a tablet, it is of great importance that the interface is understandable and intuitively usable. This means a very simple user interface, large font, and few layers. Using a tablet for the evaluation of the prototype turned out as a good decision since the survey of five therapists at SK revealed that more than half of the patients after stroke (n=6) use a smartphone (see Figure 18), which also has a touch interface and similar software. In contrast, the percentage of patients who are familiar with AR was estimated to be 0-5%.

Figure 18. Percentage of patients (n = 6) who are familiar with the respective device according to the opinion of their therapists. Bars represent the frequency of response in the categories 0-5%, 5-25%, 25-50%, 50-57%, 75-100%.

A prototype of a tablet app (see Figure 19) was designed by DTU with a special focus on user-friendliness. The rehabilitation exercises or games in the prototype are only a placeholder for the real exercises. However, it was also considered how these exercises could look like for a patient who performs the rehabilitation steps with the tablet at home. Following an assumption-based design process, the basis of the development was built by research planning, personas, desk research, and group discussions on hypotheses about a user-friendly interface for stroke patients. A field experiment followed to evaluate the success or failure of the design of some elements. This was done through interviews with six patients at SK and thus the build-measure-learn effect could be achieved, and the interfaces improved.

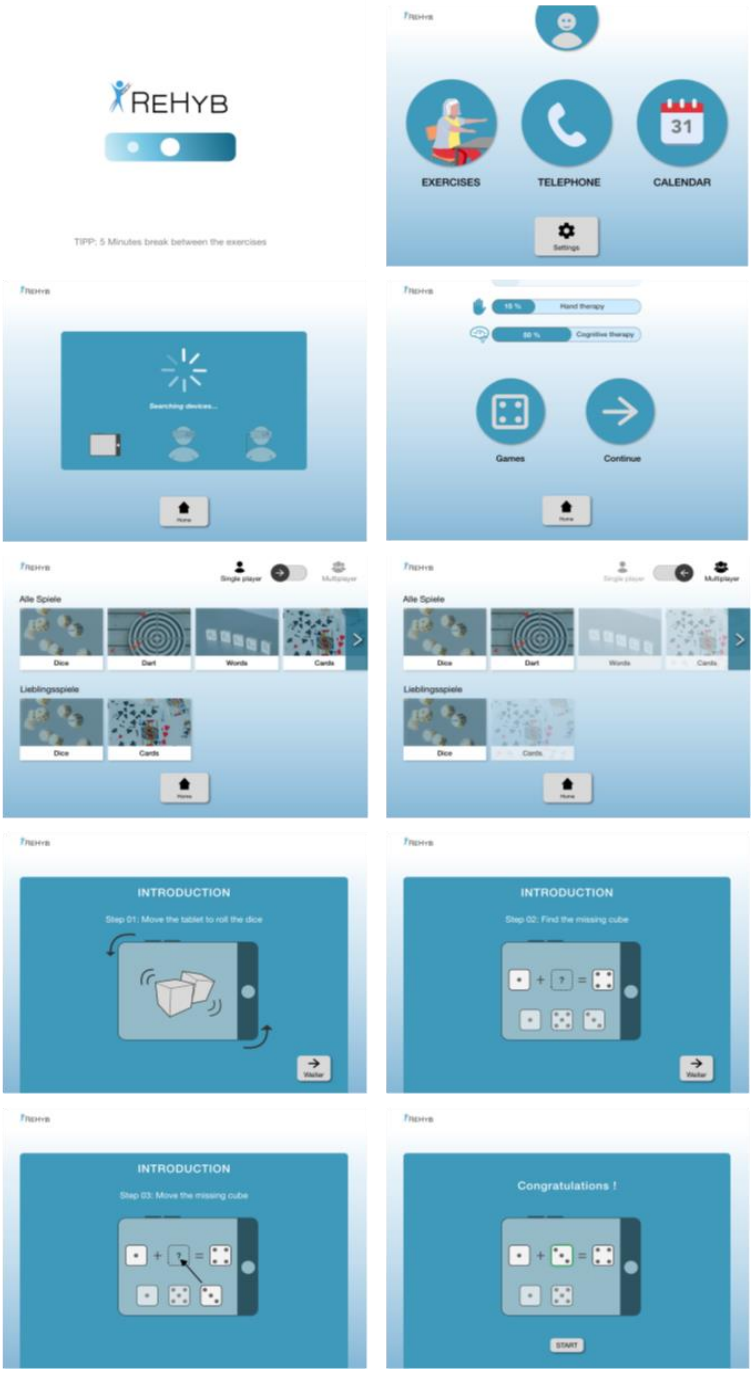

Figure 19. The Graphical User Interface of the tablet app.

The testing of the prototype was carried out in form of interviews by DTU with patients at SK. Due to the distance and the current COVID-19 situation, the interviews took place via video call. Great importance was given to the anonymity and data protection of the patients, so that only the interviewer could be seen, but not the patient. In order to support feedback and comprehensibility, a member of staff from SK was involved in each interview so that any ambiguities could be clarified and a smooth process could be guaranteed.

Six patients after stroke, four women and two men aged between 22 and 80 years participated in the evaluation of the GUI (see Table 6). Their technical affinity ranged from 2.6 to 4.47, assessed by the technical affinity questionnaire (TA-EG). Thus, not only patients with a high technical affinity (4, 4.47) were included, but also patients with a rather low affinity to technological devices (2.4, 2.6) participated in the evaluation. Since the technical affinity score is based on the factors Enthusiasm, Competence and the Positive and Negative attitude towards technical devices, the survey is representative of patients after stroke, independent of their technical affinity. Thus, findings should apply to patients after stroke who are less competent in using technological devices, but also to those who are enthusiastic and show a positive attitude towards new technology.

Table 6. The technical affinity of participants.

Age	Sex	TA-EG sum	Enthusiasm	Competence	Positive attitude	Negative attitude
80	f	2.6	1.2	2.5	4.6	2.2
22	f	3.6	3.8	4.3	3.0	3.6
73	m	4.0	3.8	4.0	4.2	4.0
65	f	2.4	2.2	2.8	3.2	1.6
81	f	3.2	1.8	2.8	5.0	3.6
46	m	4.5	5.0	3.5	4.6	4.6

Note: TA-EG: Technical Affinity Questionnaire; 1 = low affinity, 5 = high affinity.

During the interview, the prototype of the app was presented to the patient on a screen, which was of a size comparable to a tablet screen. Questions to proof how intuitively the patient understands the screen were asked and the patient was instructed to start a rehabilitation exercise or navigate back and forth in the menu. As an example, the following task was given: „Please start a rehabilitation exercise. What would you choose?" The hypothesis to be tested was that the rehabilitation exercise would be clearly different from other illustrations and therefore easily recognizable for the patient. This assumption would be proved if the patient chooses the right one in a short time and has no problems in performing it. The most interesting quotes and learnings from the various interviews are listed in Table 7.

Table 7. Quotes and learnings from the interviews.

01) „For me, the app would be too undemanding (simple) and therefore I would not use it.“	Patient 02
→ The patient can choose between two different interfaces. Whether very simple or somewhat more complex.	
02) „The 15% in hand therapy shows me how much time I spent on it.“	wrong answer, Patient 06
→ Visualization of the rehab overview need to be very simple and clear	
03) „I like to make notes about the activities of the day.“	Patient 03
→ Additional possibility to make notes in the calendar in order to process the experience more effectively.	
04) Patients all wanted to try it out, even if some were still a little overwhelmed by the technology	All patients
→ The big advantage was the fun and independence.	

These quotes emphasize that whether or not patients can handle the app, an enjoy using it is highly independent. For some patients it was too easy and thus not demanding enough to be motivated. For others, the GUI was not intuitive enough to understand what was presented on the screen or to start the rehabilitation exercise without support. Especially, older patients had additional problems in understanding the task instruction by interpreting the graphical illustration of how the exercise should be performed.

The feedback and input from the interviews with the target stakeholder group were valuable to revise the interfaces in order to meet the needs of the patients.

3.1.2.3 Stakeholder workshop on User Interface and serious gaming applications at SK conducted by DTU

In April 2022 DTU held a 2-day workshop at SK. The main focus of the workshop was the user interface design and the serious gaming aspect of the ReHyb system. A try-out session of existing serious gaming solutions for upper limb rehabilitation was organized, as well as meetings between patients, patient’s relatives, medical doctors, therapists, and researchers. Ideas for potential future serious gaming solutions were presented and stakeholders’ feedback regarding these ideas was collected. Patients and therapists were enthusiastic about the ideas for future rehabilitation and could already try out a combination of cyclic arm endurance training combined with a head-mounted virtual reality display. With this, DTU enabled the users to virtually cycle along lovely walking routes in Copenhagen, which delighted all participants. On the second day, healthcare professionals were invited to discuss and test user interface and gaming options further. Students from the DTU joined the workshop online and presented their recent developments on a Digital Twin application.

Feedback of a female patient in her 70's who has already been discharged (TA-EG: 3.2; Enthusiasm: 2.8, Competence: 2.8; Positive attitude: 4, Negative attitude: 3.2; mild hemiparesis) with her partner:

- sharing health information and progress with family and friends was not desired, as they rather showed interest during the first weeks after the stroke which declined after a few months (according to the patient due to only minor changes in the development of functional abilities);
- the patient saw the relevance of positioning QR-codes that start rehab exercises with ADLs as she experienced a decline in hand function since discharge, possibly due to non-use, especially in unilateral ADLs. These QR-codes are appreciated in the kitchen and the bathroom;
- she was enthusiastic about the idea of having a virtual avatar who motivates her to exercise and gives instructions and feedback on the performed task.

Feedback from a male patient in his 50s who was currently in rehabilitation treatment at the hospital (severe hemiparesis):

- sharing health information was positively rated, in his case with his best friend. Which information is shared with whom should be controlled by the patient;
- the patient was highly interested in using the presented technology and self-confident in / not afraid of using new technology at home. However, when trying to self-don and self-doff an assistive sleeve, he needed help;
- he likes the idea of arm cycling training in a VR environment. Personalization of the environment according to his hobbies (e.g., scuba diving) was suggested.

3.1.2.4 Actions on the Digital twin evaluation

A digital twin is one of the components of the future ReHyb system. As this technology is not yet ready to test, we investigated this technology and its possibilities for the patients and therapists by a) conducting a literature review, b) designing a study to investigate the hypotheses of a gaming solution with the inclusion of mental state data and c) testing and reflection of the gaming individualization options of the Rehabilitation Gaming System (RGS). The RGS is a commercial product created by SPECS/IBEC and Eodyne Systems S.L. It is a science-based information and communications technology (ICT) solution for the personalized rehabilitation of people suffering from motor and cognitive deficits after stroke. RGS is based on the integration of a wide range of ICT technologies, such as VR, Artificial Intelligence, learning and adaptive systems, image and scene analysis, wireless technologies, multimodal interfaces, simulation tools, sensors, telehealth and information systems and wearable physiological data sensors. One of the key features of the device is the training adaptation to individual performance.

Performed actions are described below.

a) Literature review on adaptive gaming solutions for stroke patients

To capture an idea of how digital twin methods are applied at the moment in upper limb serious gaming therapies for stroke patients, a scoping literature review was conducted. Therefore, studies published in English between 2016 and 2021 were searched in the databases PubMed, Cochrane and Google Scholar using selected search terms as well as in the reference lists of topic-related reviews. Searching "digital twin" or "artificial intelligence" in the context of serious gaming was unsuccessful, so different search terms were used, such as „stroke", „serious game", „virtual reality", „video games", „artificial intelligence", „individual adaptability", „adaptive level", „upper extremity", „upper limb", „stress level", „fatigue", „electromyography", electroencephalogram", „biofeedback". Studies were selected if they:

- targeted patients after stroke;
- had a serious gaming or virtual reality intervention for upper limb rehabilitation;
- included quantitative measurements of physiological data during the experiment;
- had adaptive regulation of the serious game while playing the game.

Five studies were finally included in the scoping review:

- **Wang et al. (2017)**: EMG and EEG based virtual reality game (17);
- **Diaz et al. (2018)**: Telerehabilitation with a robotic device, adapted according to stress and performance (project HomeRehab) (18);
- **Ballester et al. (2017)**: RGS (commercial system, eodyne SL, Spain) plus sensorized gloves (DGTech Engineering Solutions, Italy) plus EMG (19);
- **Batista et al. (2019)**: FarMyo Game based on EMG recorded with a Myo band. Uses performance for adaption of gaming difficulty (20);
- **Shin et al. (2016):** Rapael Smart Glove (commercial system, neofect GmbH) (21).

The gaming systems used were partly commercial (RGS, RAPAEL Glove) and partly custom-made. Most of the adaptation algorithms were based on the performance values of the patient. Only one study (17) used EMG and EEG to estimate fatigue and adapt the gaming scenario to the patient's mental state. Diaz et al. (2017) also included some kind of mental state measurement (e.g., skin conductance) to estimate the patient's stress. However, it is not totally clear how this measure influenced the game's adaptability. Most likely, they measured this before the exercise session and adapted the general support/gaming difficulty prior to starting the game to the patient's stress state. Table 8 shows an overview of the analysed studies.

Table 8. Study characteristics overview.

Study	physiological sensors	Adaptation of the serious game	Equipment used (commercial/non-commercial)	Type of study
Ballester et al. 2017	motion tracking (Kinect, data gloves)	Performance-based difficulty adaption (target: 60-80% performance)	Rehabilitation Gaming System (commercial)	Randomized Controlled trial
Batista et al. 2019	EMG	Performance-based difficulty adaption	Myo band for EMG acquisition, non-commercial software system	Proof-of-concept, single case study
Diaz et al. 2017	Joint position sensors (robot), Force sensor, skin conductance and temperature, pulse rate, respiration rate	Assist-as-needed robotic support based on performance and stress (stress level based on skin and vital parameters)	Based on commercial robotic gaming system "RoboTherapist 2D", adapted and extended; g.tec sensors	Usability pilot study
Shin et al. 2016	Motion and position (IMU and bending sensor) in smart glove	Performance-based algorithm in gaming software, aiming at creating a difficulty level with a 80% performance rate	RAPAEL Smart Glove (commercial)	Single blind, randomized controlled trial
Wang et al. 2017	EEG, EMG	Feature extraction and support vector machine to estimate fatigue from EEG and EMG → adaptive scene switching	Non-commercial	Proof-of-concept study, controlled non-randomized trial

This scoping review shows that there are generally not many studies that use adaptive games in neurorehabilitation. If so, mostly the performance within the game is the parameter that influences the game difficulty. As the game is mostly controlled via movements or muscle activation, it is these biosignals that the adaptation algorithms are based on. Only two studies (17, 18) use additional physiological parameters with the intent to measure the mental state of the patient and use it to shape the gaming situation also according to this state. Assuming that in a clinical setting there is always some kind of supervisor or therapist that will be able to adapt the gaming therapy in case the mental state of the patient differs, this might not be the case in a home environment. Thus, especially for the home setting, the inclusion of mental state might be beneficial. Diaz et al. (2017) used this measurement before starting the gaming session, to adjust the difficulty and/or support, whereas Wang et al. (2017) used fatigue measurements during the gaming session to achieve an online adaption of the game. All adaptive gaming therapies aim at generating a gaming situation that is challenging, yet not frustrating for the patient. Including mental states into this consideration is not yet thoroughly evaluated, but shows promising results (17). Especially for home use, it should be further studied.

b) Study design "Effect of game difficulty on physiological parameters during a serious gaming therapy"

To further investigate the effects of mental state on gaming performance and vice versa, a study was designed by IBEC in cooperation with SK and ICL. This was done as a substudy of the pReHyb studies and ethics was obtained in May 2021.

The objective of the trial is to evaluate the efficacy of the biosensors used in the ReHyb project and their coordinated interplay with the Digital Twin and the training scenario. This data from patients is also necessary to investigate how the fatigue level can be obtained from the sensors and how they can be used to train the architecture to adapt the training to the individual fatigue level and inform the first development stages.

Therefore, heart rate variability (**HRV),** electrodermal activity **(EDA),** and **motor coordination** (i.e., kinematic and surface electromyography data) were collected from the patients while playing the serious game.

Participants will perform two sessions on two consecutive days with a duration of about 30 min each. In addition to both gaming sessions, demographic and clinical data (e.g. Fugl-Meyer) will be assessed. Figure 20 shows the study procedure. It includes a baseline recording of physiological data prior to the experimental training session, as well as after the experimental training session. The training session itself comprises a serious game from the Rehabilitation gaming system which requires arm movements that are captured with a Kinect camera system. The difficulty of the game can be modulated, depending on the day. One Day, the participant performs the game with a fixed difficulty, where after every 2 minutes the difficulty level is modified pseudorandomly. The other Day, the game is played with adaptive difficulty, where the aim is to sustain a 70% level of challenge. Days 1 and 2 are consecutive but the conditions are randomized within subjects.

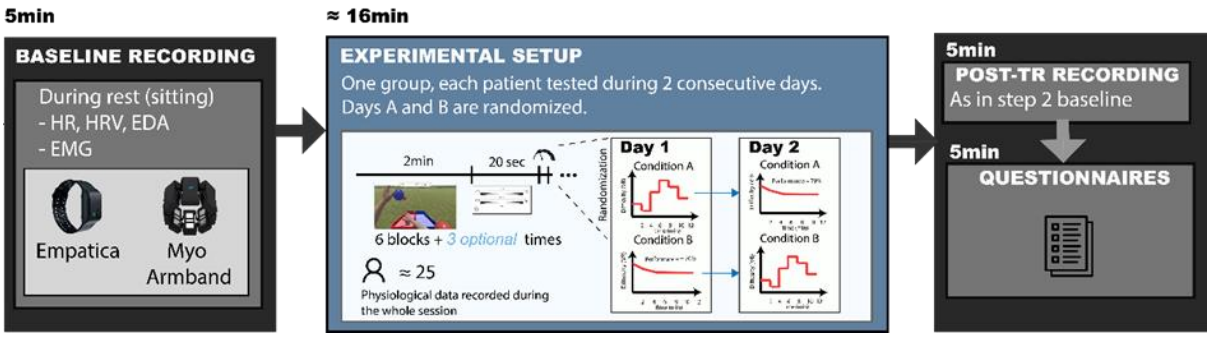

Figure 20. Study procedure of trial.

The results of the study will be reported in D3.2, D3.4 and D3.5.

c) Experiences from clinical studies using RGS adaptive gaming

The RGS gaming system was used to collect experiences regarding the game adaptability, while playing the Bubbles protocol (Bubbles, RGS (Eodyne SL, SP)). The game requires the patients to open their hands, reach out to a bubble coming out of a virtual pond, and then close their fingers. Although this game did not come with an automated adaption of the difficulty in the software version we used (other gaming scenarios have an automated adaption), there were some manual adaptation possibilities: First of all, the side where the bubbles appear can be chosen, which will be set according to the impairment. Further adaptability was provided by changing the frequency of the bubbles coming out of the pond (which increases or decreases the temporal demand) and the size of the bubbles (which requires more or less flexion of the hand and fingers). Smaller bubbles lead to higher points as they require more hand-closing to burst them. This paradigm, however, showed to have its difficulties in patients after stroke – a major part of these patients does not (only) have limitations in flexion, but also in the extension of fingers and hands, which impairs the hand opening rather than the hand closing. For those patients, achieving higher points by bursting the smaller bubbles, is just as easy as bursting the big bubbles with less points, as long as they reach the required hand opening to catch the bubble. And from our perception, the required hand opening was the same for all sizes. Still, there are a few patients that do struggle with hand closing and therefore can be motivated by the implemented gaming paradigm of achieving more points for smaller bubbles.

Additionally, a significant portion of patients after stroke do have cognitive impairments, which might also affect motor planning. From a motor planning perspective, big bubbles are easier to catch.

This dilemma shows the need to individualise even the gaming difficulty to each patient, as patients after stroke show very diverse and different impairment patterns. Therefore, a patient-specific goal-oriented adaptation of the gaming difficulty should be envisioned for the ReHyb system. Moreover, the motor component is not the only impairment with an impact on the individually perceived gaming difficulty: many patients after stroke have additional cognitive impairments that may hinder an understanding of complex gaming situations: in the bubbles example, this was especially evident with the red bubbles: They required the patient to grab the bubble with one hand but the transfer it to and subsequently burst it with the other hand. This bimanual task was too complex for some patients which were frustrated from not achieving this task (e.g. because they kept on handling them as "normal" bubbles). Thus, for the bubbles scenario, it would be helpful to adapt the cognitive aspect of the game by adapting the appearance of different coloured bubbles.

To conclude, all serious gaming scenarios for neurorehabilitation should pay attention to the motor and cognitive demand. And further on, both dimensions (cognitive and motor) include different functions to address, e.g. movement directions, movement precision, attention, and memory, which should be individualizable to the patient.

3.1.3 Feedback on the Robotic module

A first demo-workshop was performed at Valduce on September 28 and 29, 2020. The event was organized by VALDUCE, IUVO, SSSA and IBEC.

The objective of the workshop was to perform demonstrations of the robotic technologies to get preliminary feedback about the use of an exoskeleton for shoulder anti-gravitational support to perform neurorehabilitation protocols in AR/VR environments. The assessment of the experimented technology was mainly implemented using questionnaires addressed to healthcare operators and patients.

The platform employed during the demonstration was an integrated system of the following technologies:

- Muscular Aiding Tech Exoskeleton (MATE) (https://mate.comau.com/)

The MATE exoskeleton, designed and developed by Iuvo S.r.l. and manufactured by Comau S.p.a., is a passive spring-loaded exoskeleton conceived to support the upper limb of operators in industrial settings in all those working tasks requiring prolonged shoulder elevation. The exoskeleton supplies an auxiliary variable torque on the shoulder joint to partially compensate for the gravitational torque generated by the weight of the upper limb. Notably, the MATE technology was already available within the IUVO portfolio, but with a completely different application target. Nevertheless, it was included in the demonstration to identify relevant features to be included in the alpha prototype of the ReHyb Spring-Loaded exoskeleton (ReHyb-SL).

- RGS (https://specs-lab.com/portfolio-items/neuro-rehabilitation/)

The RGS is specified in section 3.1.2.4.

Results of the evaluation of the combination of the MATE and RGS is reported under the respective section including feedback on integrated modules (see section 3.1.4.3).

The activities addressed two clusters of users: healthcare operators and patients. This section of the deliverable reports the activities involving patients (SH1). Eight patients (1 tetraplegic, 7 post-stroke patients) were recruited according to the inclusion and exclusion criteria reported in Deliverable D2.1. Participants were asked to provide their subjective impressions while using the system and compiled a custom version of the System Usability Scale (SUS) questionnaire to assess its usability. Results refer mainly to post-stroke patients being the target of this project.

Seven patients answered the questionnaire, resulting in an average score of 67.4 (Figure 21). RGS was appreciated by patients since they reported average scores above the threshold in the specific items of the questionnaires. In addition, some of the scores showed a neutral position with respect to the possibility of using the two modules (RGS and exoskeleton) independently.

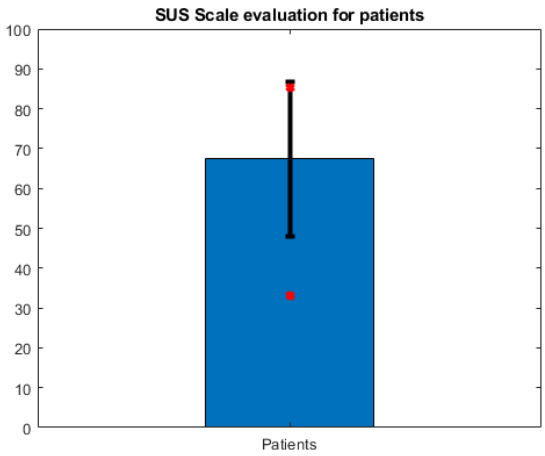

Figure 21. SUS scale results collected SH1 from first workshop at VALDUCE concerning the MATE exoskeleton.

Overall, the integrated system was appreciated in terms of autonomy, safety, and easiness of use. All patients stated that they would like to use the combined technologies during rehabilitation sessions, and at home as well.

First-sight impressions from patients have been implemented in the design process of the spring-loaded exoskeleton. Due to confidentiality, the participants' feedback and the resulting implementations will be reported in D4.4.

A second demo-workshop was held at VALDUCE premises in two different sessions, one on November 18th and 19th 2021, and another on December 13 and 14, 2021.

- **First session (November 18 and 19, 2021):**

In this session, two exoskeletons were presented to clinical staff and patients, namely, the alpha prototype of the ReHyb-SL, which had already incorporated the observations made during the first workshop, and the alpha prototype of the High-Powered exoskeleton (ReHyb-HP), which is intended to be used only in a hospital setting and specifically dedicated to patients with lower neuro-motor functional response on the upper limb.

- **Second session (December 13 and 14, 2021**):

In this session, only the alpha prototype of the ReHyb-SL was presented to patients. In total, during this second workshop six medical doctors, four physiotherapists, two bio-engineers and eight post-stroke patients participated and gave their opinion on the devices.

For what concerns the ReHyb-SL, patients declared they appreciated the perception of help in some movements, especially the possibility to execute movements that they usually find very difficult to perform. Nevertheless, they would have liked the exoskeleton to be less cumbersome and be able to be used in a wheelchair. Overall, the usability of the ReHyb-SL was rated by the SUS with an average score of 71.4 (Figure 22), so already higher than the MATE. These workshops have been a valuable opportunity for collecting inputs to be integrated into the beta ReHyb-SL design. In-depth results of the workshop with the ReHyb-

SL and how feedback was addressed in modifying the alpha prototype towards the beta prototype will be reported in the confidential Deliverable D4.4.

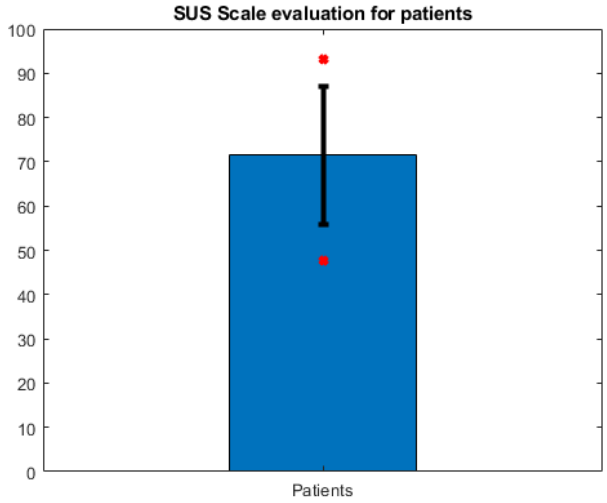

Figure 22. SUS scale results collected SH1 from second workshop at VALDUCE concerning the alpha ReHyb-SL.

Regarding the ReHyb-HP, patients feedback was addressed in modified according to Table 9. Patients considered it very useful to perform some movements and exercises without having the exoskeleton interfere with their wheelchair on the back side. Additionally, upper-arm cuff should have been wider to fit bigger arms, and it was highlighted the need for a hand/wrist support to fix the hand posture. Finally, the embedded back support was considered not useful when using the wheelchair. Given the clinical conditions of some patients, more stable trunk support was required.

Table 9. Suggestions from patients, and how they were addressed in modifying the prototype

Usability attributes	Suggestion	Modification
Performance	The exoskeleton should not interfere with the wheelchair on the back side	The kinematic passive chain of the exoskeleton was modified. Moreover, a commercial wheelchair compatible with the mechanical structure of the robot was introduced
Adaptability	The upper-arm cuff should be wider for bigger arms	The commercial cuff was not substituted. However, it was slightly repositioned to have the attachment point more distally and favor a better fitting

Usability	It was highlighted the need for a hand/wrist support	No modification since a wrist module was already designed and intended to be integrated
Functionality	The backpack was considered not useful when using a wheelchair	The back support was integrated into the new wheelchair, to maximize its utility, and enable its usage.
Functionality	Better trunk support is required	A new commercial chest harness was integrated into the current back support. The latter was firmly fixed on the back of the seat.

Moreover, feedback was gathered also from questionnaires administered to the majority of patients that participated in the workshop (n=5). Data collected was organized by adopting the SUS, and it is reported in the following Figure 23. Results report an average score of 89.37.

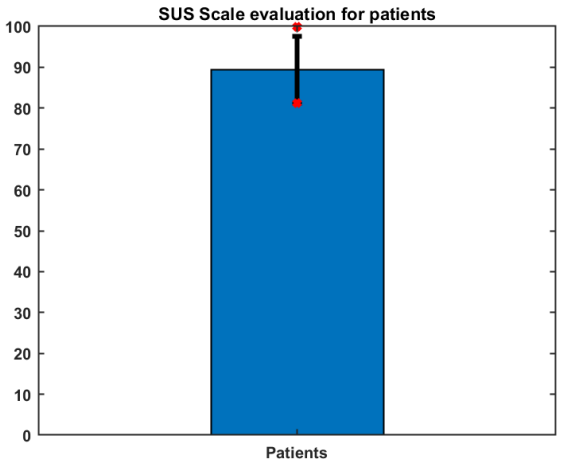

Figure 23. SUS scale results collected SH1 concerning the ReHyb-HP.

3.1.4 Feedback on combined/integrated modules

Different combinations of modules were evaluated in the population of patients after stroke. Literature was systematically searched for randomized controlled trials (RCTs) in which the effect of combined robotic and FES therapy was investigated (22). Furthermore, the usability of combining FES and the Bubbles protocol of the RGS (see D2.1) and of combining robotic and different RGS protocols were assessed in a study at SK and a demonstration at VALDUCE, respectively.

3.1.4.1 Systematic review and meta-analysis on the effect of hybrid neuroprostheses

In this systematic review, RCTs were analysed which investigated the effect of hybrid neuroprostheses, taking into account the different study characteristics and their influence on the outcome in upper limb functions.

In order to systematically search for literature on the effect of hybrid neuroprosthesis, the following inclusion criteria were defined according to PICO(S): P (population) – patients after stroke, I (intervention) – simultaneous use of actuated robotics plus electrical stimulation at the upper limb, C (control) – no simultaneous use of actuated robotics plus electrical stimulation, O (outcome) – upper limb function, S (study design) – RCT.

Following the literature search in four different databases, n = 500 studies were identified. After duplicates were removed (n=130), 256 studies were excluded when screening the abstracts and titles since the intervention did not include hybrid neuroprostheses. Further, 114 full texts were screened of which 108 did not meet the inclusion criteria (wrong study design, wrong intervention, wrong comparison, or no available full text). In the end, six studies were included in the systematic review (Table 10).

Table 10. Study and population characteristics of the included randomized controlled trails.

Source	Year	n	mean age (y)	time since stroke (mo.)	comparison	interventio n duration	FM-UE
Grigoras et al. (23)	2016	25	63.8	23-56	conventional	2 weeks	19
Hu et al. (24)	2015	26	47.4	21-108	robotic	7 weeks	15
Huang et al. (25)	2020	30	58.7	38-133	robotic	7 weeks	27
Lee et al. (26)	2015	39	54.0	10-43	robotic+sham	4 weeks	29
Miyasaka et al. (27)	2016	30	60.9	2-3	robotic	2 weeks	18
Qian et al. (28)	2017	24	59.6	1-5	conventional	4 weeks	21
overall	2015-20	174	57.4	1-133		4.3 weeks	21.5

The meta-analysis of differences between intervention and control group in the upper extremity portion of the Fugl-Meyer (FM-UE) after the intervention revealed a significant positive effect of the therapy with hybrid neuroprostheses ($p < .001$, Figure 24). The mean difference between

intervention and control groups was 9.06 points on the FM-UE scale. Since values after the intervention were compared without relation to baseline values, the results of the study by Grigoras et al. (23) were not included in this meta-analysis due to significant baseline differences in the FM-UE score between the intervention and control group.

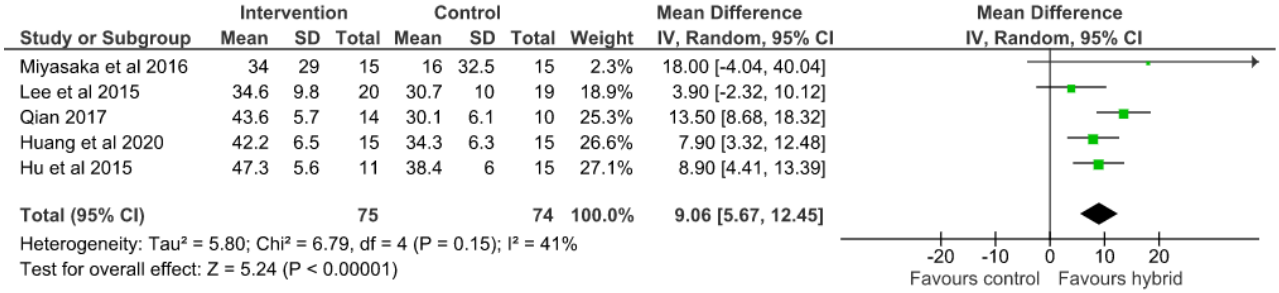

Figure 24. Pooled effect on the FM-UE score after the intervention.

At three months follow-up, there was still a significant positive effect of the therapy with hybrid neuroprostheses on upper limb functions ($p < .001$, Figure 25). The FM-UE score of patients in the intervention group was on average 7.74 points higher than in the control group. However, the results of Miyasaka et al. (27) were not included in the follow-up analysis, since they did not conduct another assessment at three-month post intervention.

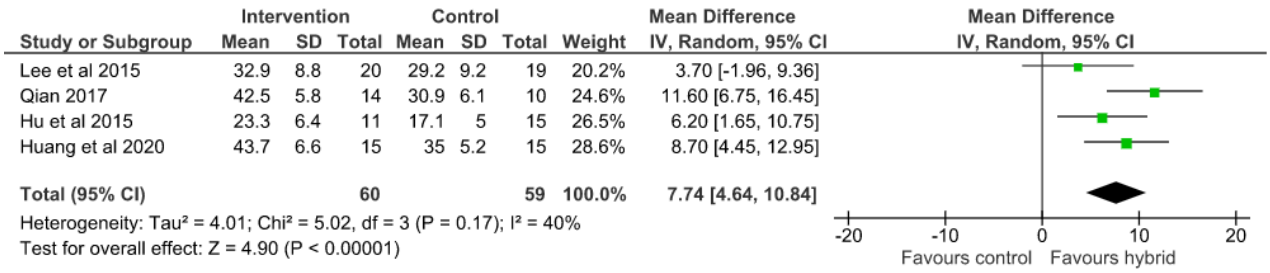

Figure 25. Pooled effect on the FM-UE score at three month follow up.

The meta-analysis of FM-UE values after the intervention included five studies, of which three found a significant positive effect of hybrid neuroprostheses (24, 25, 28) while two revealed no significance (26, 27). In Miyasaka et al. (27), only two weeks of intervention were performed, which was the shortest intervention duration used. Robotic therapy shows a dose-response relationship when motor functions are aimed to be recovered (29). Conclusively, this might be one reason, why there was no significant effect of the intervention in Miyasaka et al. (27). Further, this study recruited the population group with the highest age. Since age is one factor influencing the recovery potential after stroke (30), it might be another explanation for why this study did not reveal a significant effect on upper limb functions. In Lee et al. (26), the patient population reached a FM-UE value of 29 points at baseline, which means that the

included participants had less upper limb impairment compared to the other studies. Since this study did not find a significant effect of the treatment, it might indicate that the combined approach is rather beneficial for patients with more severe upper limb impairment.

Surprisingly, the effect of the therapy seems not to be influenced by the time since the stroke. Both, a study with subacute patients (28) and studies including chronic patients up to eleven years after stroke (24, 25) found a significant treatment effect.

Summary of results and practical relevance for the ReHyb system

Interventions on the upper limb using the combination of robotic therapy and electrical stimulation show a positive effect on upper limb functions in patients after stroke, compared to conventional therapy or robotic therapy without stimulation. This effect, which favours the use of hybrid neuroprosthesis, remains three months after the intervention was terminated.

Some factors were identified which might influence the effectiveness of such a hybrid therapy:

- the intervention duration, which should be chosen to be at least 4 weeks when evaluating the effectiveness of a hybrid system;
- the age of patients, meaning that younger patients are expected to have greater improvements;
- the severity of upper limb impairment, showing that moderately-mildly impaired patients might not profit from the ReHyb-High Powered system.
- The time since the stroke did not affect the success of the intervention, indicating that subacute and also chronic patients could be recruited when evaluating the effectiveness of a hybrid system.

3.1.4.2 Combination of FES and gaming environment

Both, FES and VR / serious gaming (SG) therapies are used in upper limb stroke rehabilitation. A combination of both approaches seems to be beneficial for therapy success. However, evidence for this novel approach is still scarce, and controlling FES stimulation remains a challenge. Therefore, within the pReHyb study 2A, we investigated whether the combination of the bubbles protocol (also mentioned in section 3.1.2.4) and contralaterally EMG-triggered FES (using the Stiwell Med 4 (Med-El, AT)) is feasible in the hospital setting, and which patients might benefit from the additional use of FES (Figure 26). This is vital for informing and supporting the appropriate choice of modules of the ReHyb system.

In a randomized crossover trial patients performed two consecutive sessions of gaming alone and two gaming sessions supported by contralaterally EMG-triggered FES. The usability of the therapy system was assessed using the Intrinsic Motivation Inventory, Nasa Task Load Index, and System Usability Scale after each condition. Gaming parameters, fatigue level, and technical documentation add further information on feasibility.

Figure 26. A patient with a left-sided hemiparesis training with the Rehabilitation Gaming System with FES support. Note: The patient removed the face mask for the photo. Consent for the use of the photo was obtained.

Ten subacute patients after stroke (64±14 years) with a hemiparesis of the upper limb (MRC ≤ 4) completed the study. Both conditions were perceived as enjoyable and usable. The additional use of FES enabled six severely impaired patients (MRC 0-1) the execution of the gaming therapy and therefore increased the usability for those patients. However, for patients with mild to moderate impairment (MRC 3-4) it provided no or little additional immediate benefit and was more coordinatively demanding.

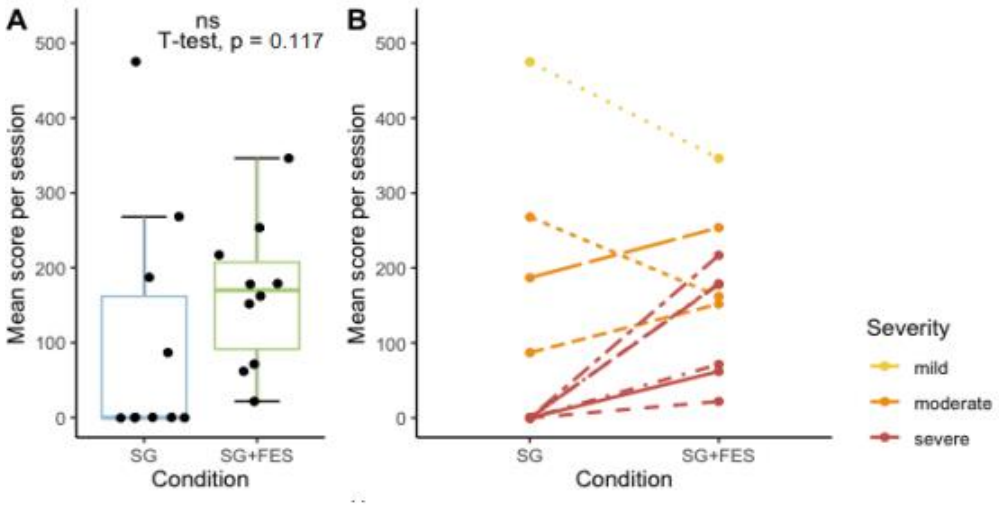

Figure 27. Mean score achieved per session per condition (A) and grouped by severity of impairment (B). Note: Individual data points are represented by dots.

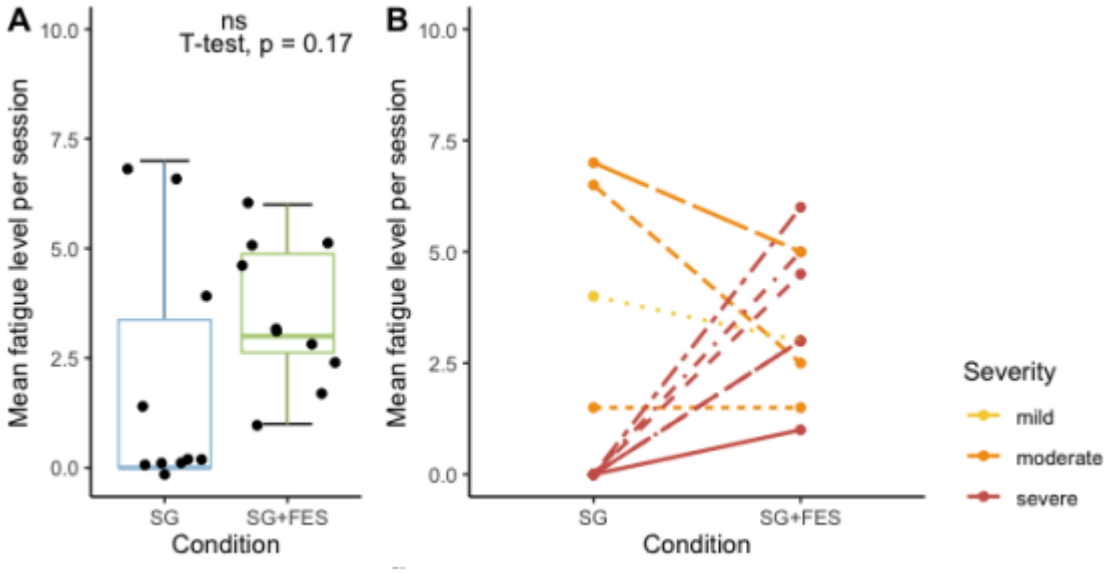

Figure 28. Mean perceived fatigue level per session per condition (A) and grouped by severity of impairment (B). Note: Individual data points are represented by dots.

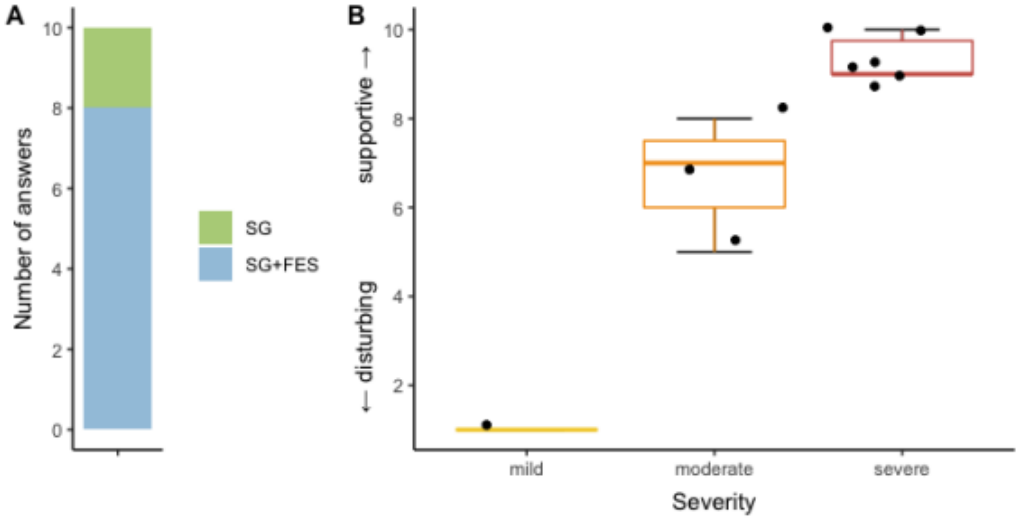

Figure 29. Patient`s preferential condition (A) and perceived level of FES support grouped by severity of impairment (B) and rated on a scale from 0 (disturbing) to 10 (supportive). Individual data points are represented by black dots.

This preliminary work demonstrates that the combination of SG with contralaterally triggered FES is feasible and well-accepted among patients after stroke in the clinical setting. It seems that the additional use of FES may be more beneficial for severely impaired patients as it enables the execution of the serious game and thus increases the usability of the gaming therapy (Figure 27-Figure 29). These findings provide valuable implications for the development of rehabilitation systems by combining different therapeutic interventions to increase patients' benefits.

3.1.4.3 Combination of robotic and gaming environment

As mentioned previously, patients evaluated the combination of the RGS and the MATE within a workshop in September 2020, organized by VALDUCE, SSSA, IUVO and IBEC. Eligible patients wore the MATE exo while playing different protocols of the RGS.

RGS was appreciated by patients since they reported average scores above the threshold in the specific items of the questionnaires. In addition, some of the scores show a neutral position with respect to the possibility of using the devices independently.

Overall, the integrated system has been appreciated in terms of autonomy, safety, and easiness of use. All patients have stated that they would like to use the combined technologies during rehabilitation sessions and at home as well.

The aspects appreciated the most by post-stroke patients were the combination of the technologies and the capability of the exoskeleton to simplify the execution of certain movements. All post-stroke patients found the system useful and interesting.

Some of the relevant observations arising from the workshop in relation to gaming environment are:

- Need to make the location of objects more evident:
  The dimension of the screen employed during the demonstration may have had an impact on the perception of the distance of virtual objects. A bigger screen could help match the real task with the VR environment. However, how different sizes of the screen affect the exercises has not been tested yet.
- Need to improve the VR representation of the limb during complex movements:
  Some improvements concerning the VR representation are currently ongoing.
- Lack of protocols including “bringing objects to the body” (e.g., hand-to-mouth, comb the hair):
  There are tracking issues that limit this implementation in VR environment, but AR could overcome this issue since the proximity of the body can be tracked in different ways.
- Need to adapt the difficulty of the task to reduce compensatory movements:
  The system already includes an automatic adaptation of the task’s difficulty according to the patient’s performance and in general, it depends on how clinicians will manage the patients. Specifically concerning compensatory movements, the difficulty will depend on what clinicians advise.

3.1.5 Further stakeholder characteristics

For the development of a rehabilitation system, it has been important to gather some patient-specific information in order to adapt the device to be implemented in different patient groups. This information includes anthropometric data to assure the correct fitting of the device, medication that might have an influence on the data that will be processed by the digital twin,

and, in the context of using a new technology in an older population, the patients' technical affinity.

3.1.5.1 Anthropometric data of patients' forearm

Tecnalia developed a prototype of the FES garment to verify that any of the chosen sizes could fit the anthropometric measurements of post-stroke patients present in the clinical centers. This prototype was used to verify its final configuration from the size point of view. In this sense, seven patients at Valduce premises were invited to volunteer for trying the sizes (Figure 30).

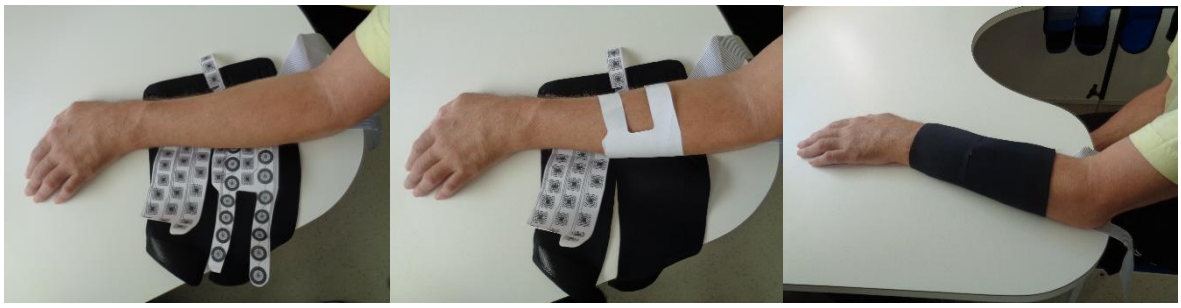

Figure 30. Testing the fitting of the proposed FES garment on patients' forearms.

People of different weights and sizes were invited. Table 11 shows the results.

Table 11. Anthropometric data of invited post-stroke patients.

	Sex	Forearm circumference flexed	Wrist circumference	Forearm Length	Height	Weight
	m	26.5	17	28	185	60
	f	35	22	25	166	134
	m	28	19.5	26	175	65
	f	21	15.5	22	152	43
	m	25	16.5	28	175	68
	f	24	17.5	21.5	162	75
	f	25.5	17	23	148	67
M		26.4	17.9	24.8	166.1	73.1
SD		4.4	2.2	2.7	13.3	28.6

To better fit the FES garment to the addressed patient group, i.e., patients with paresis of the upper limb, an additional 26 patients were measured for their arm anthropometric measures at SK (Figure 31). The sample with a mean age of 67 (14) years included 8 female and 18 male participants of whom 12 had their paresis on the left and 14 on their right body side.

For this sample the following measurements were calculated, displaying the mean value, the standard deviation in brackets, and the minimum and maximum values measured:

- forearm circumference [mm]: 274 (29), 215-330
- wrist circumference [mm]: 188 (21), 159-264
- forearm length [mm]: 271 (26), 230-335

Figure 31. Collection of anthropometric measurements of patients after stroke.

3.1.5.2 Medication

SK conducts a retrospective analysis of stroke patients' medication in the course of their rehabilitation stay. Those patients who have received serious gaming therapy were analyzed as a subgroup. The objective of this analysis is to provide an overview of which medication is prescribed in the post-stroke population and how it influences the physiological parameters of the patient. Especially the influence of drugs on physiological parameters is of interest for the

ReHyb project with regard to the idea to enable an automated control of the ReHyb system using a digital twin.
In total 235 individuals after a stroke were screened, of which 198 are available for analysis of their medication intake and rehabilitation regime. Specifically relevant regarding the rehabilitation regime, were the scheduled interventions which included any form of serious gaming. The sample consisted of 79 women and 119 men, with a mean age of 71.70 (SD 13.2) years, and a Barthel Index of 34 points at admission and 45 points at discharge. Patients stayed in the hospital for a mean duration of 39 days and a maximum stay of 292 days.

The analysis of the administered medication and its influence on physiological parameters used to generate the Digital Twin is currently in progress.

3.1.5.3 Technical affinity and technology acceptance

The Technical Affinity of our target stakeholder group, the post-stroke patient, has been assessed and described in D2.1. In general, post-stroke patients interviewed have a rather positive attitude toward technology.

From these findings, we expect that this stakeholder group will be open to testing the ReHyb system and will not refuse to use it *a priori* due to skepticism, or the fear of not being able to use it. Whether or not this hypothesis applies to our patient population was investigated by a survey at VALDUCE. In this sense, a potential relationship between the Technical Affinity (assessed by the TA-EG) and the Acceptance of Technology (assessed by the Unified Theory of Acceptance and Use of Technology (UTAUT)) was investigated, also under consideration of age and gender, by a survey involving 50 patients that are usually treated with some kind of robotics technology at VALDUCE. The study population included different neurological pathologies, such as stroke (28%) and spinal cord injury (26%). Within this patient group, the whole spectrum of age groups was covered. About one-third of the participants were females and two-thirds were males.

Analysis of correlation has been used as an investigation tool to search for possible relations between the two questionnaires' results under the question: Is a good acceptance of technology somehow related to technological affinity?

From a general point of view, the data shows that when dealing with technology applied to rehabilitation treatment, the acceptance is positive even if the affinity could be rated mid-low and it was not possible to find a correlation between the two questionnaires. Only in the stroke group, a slight positive correlation was found but the size of the sample was very small (see Annex I for the full analysis).

Regarding the use of the two questionnaires, since they are not correlated, they could show the real level of acceptance of the ReHyb technology perceived by the subjects without some possible bias due to subjects' technology affinity.

3.2 SH4: Medical treatment staff

From a survey with experienced medical treatment staff at SK (average experience: 7.8 ± 6.4 years; see D2.1), we know that they have some wishes when it comes to using robotic devices, FES, or therapy games in neurorehabilitation. These wishes are listed in Table 12 according to their relevance.

Table 12. High-priority wishes of medical treatment staff at SK. Blue background indicates that the wish is covered in the following investigations.

Robotic therapy	FES therapy	Therapy games
Include Activities of Daily Living: transfer tasks to daily life by using real objects and bimanual tasks	Easy handling and clear instructions for self-administration of the device	Easy handling and clear instructions for self-administration of the device
Variation in tasks and games to adapt to patients' individual capacities	Combination of FES and robotic	Variation in tasks and games to adapt to patients' individual capacities
Combination of VR and robotic	Activation of small muscles should be possible	Include Activities of Daily Living: transfer tasks to daily life by using real objects and bimanual tasks
Portable / light device	Increase safety, robust and functioning system	Increase safety, robust and functioning system
Easy handling and clear instructions for self-administration of the device	Motivational aspects such as goals, VR, feedback, trigger emotions	Recognize if patient performs compensational movements
Motivational aspects such as goals, VR, feedback, trigger emotions		Motivational aspects such as goals, VR, feedback, trigger emotions
Repetitive training		Portable / light device
		Coordination tasks

Those wishes which are coloured in blue were covered in the following investigations of the different modules within the stakeholder group of medical treatment staff.

3.2.1 Feedback on FES module

The Fesia Grasp Stimulator was demonstrated and tested by six occupational therapists at SK. Based on their feedback and on the experience of applying the stimulation to patients after stroke within the pReHyb_1A and pReHyb_1B studies (see ethical application in D10.2), the following strengths and limitations of the device can be formulated.

Strengths of the stimulator:

- The attachment of electrodes is much easier than with single-array electrodes. Anatomical knowledge about the muscles is no longer a prerequisite. This might enable

the prescription of the system to patients for home use. The therapists would be really interested in a study, in which the feasibility of using the stimulator at home is investigated.

- Selective muscle recruitment is possible through the multi-array electrodes, enabling stimulation of the single-motion primitives of a grasp.
- The stimulator is connected via Bluetooth. Thus, no wires are involved during the stimulation, which enables the patient to move freely while performing grasping movements. The wireless system also offers the opportunity to use it during ambulation.
- Botox injections can be enhanced by stimulation at a frequency of 8 Hz after injection. This spreads the muscle and contributes to a better Botox distribution. Using multi-array electrodes, the injected muscle can be targeted more specifically.
- Some patients after stroke can apply force to an object but are not able to open their hand to place the object. For those patients, the stimulation works great.

Limitations of the stimulator:

- In occupational therapy, therapists would not use FES without EMG triggering. EMG is definitely needed to make the task more functional.
- The duration of the stimulation ON and OFF phases should be set individually. This setting is currently missing. When using the functional grasp protocols to support grasping, transporting, and releasing objects, some patients require a longer time to transport the object. Here, the training would benefit from increasing the ON phase of finger flexion.
- The stimulation is applied rapidly. Having a smooth transition from OFF to ON phase would be beneficial since the target object is sometimes hit and knocked over by the fingers due to the rapid hand opening. Similarly, the transition from hand opening to hand closing should be smoother by an increase in the stimulation rise time. The rapid hand closures require anticipation ability regarding the point at which the fingers will close. The object has to lie at this point in order to be grasped. Especially, patients with visuospatial deficits have problems in anticipating and thus positioning their hand accordingly.
- The stimulator cannot support thumb opposition and reposition. Thumb opposition would be necessary for patients with moderate and severe hemiparesis when grasping small objects, such as a marble. Thumb reposition is missing when opening the hang to grasp bigger objects, such as a 10 cm cube. When grasping this cube supported by the stimulation, the thumb extension does not lead to a grasp around the cube, which makes it impossible for patients with hemiparesis to lift the object.
- Stimulating the antagonist muscles in patients with spasticity has a great short-term effect on reducing muscle tone. After stimulating finger extensors, the flexion of the fingers decreases, and the hand can be stimulated to grasp objects. However, in patients with flexion synergy, the shoulder shows an internal rotation due to spasticity. Since

there is no stimulation on the antagonists of the shoulder, this muscle tone cannot be released and has a negative impact on the transport of objects.

- Another problem that comes with spasticity in the internal rotation of the shoulder is that it makes donning the garment more difficult. It is hard to fasten the Velcro between the body and arm, when the patient keeps the arm very close to the body, which is the case for the spasticity of internal rotation muscles. One solution could be to place the Velcro at the lateral side of the garment.
- There is the need for different electrode sizes. For patients with a thin forearm, the electrode is too big and the longer part of it overlaps. On the other hand, the garment is too small for patients with a bigger forearm and the Velcro cannot be closed.
- Indicators on the outside of the garment about the position of the single cathodes would be good to have in order to make the selection of the cathodes easier. This could easily be implemented by numbering of anodes in the GUI and on the outside of the garment in order to identify the targeted stimulation area.

Strengths of the application on the tablet:

- The GUI is intuitive and easy to use.
- Each session is automatically documented.
- Stimulation settings are saved and thus do not need to be set every time.
- There is the possibility to take videos that are saved in the corresponding patient's folder.

Limitations of the application on the tablet:

- Videos that demonstrate the movement should mimic the movement simultaneously with the actual movement. Patients tend to imitate the screen. However, during thumb extension, the thumb is for example stimulated to stay open the whole time while the video shows a flexion followed by an extension movement.

The identified strengths and limitations can be generalized for stimulators with multi-array electrodes and Bluetooth connection. The feedback on the GUI could also be relevant to the design of gaming interfaces.

In addition to the collection of feedback from therapists on the Fesia Grasp, a survey (n = 25) was conducted on the use of FES in general. This survey mainly involves experiences of medical treatment staff (30%), scientists (35%), and engineers (26%), who are either experts in applying FES on patients' upper extremities (56%) or lower extremities (52%) or have used FES with able-bodied subjects (36% upper extremities, 24% lower extremities). The results of our survey show that:

- FES is mainly combined with robotic devices (39%), followed by the combination with AR/VR (17%), cycling (9%), and treadmill or rowing (4%);

- the purpose of using FES is therapeutic with the aim to see improvements after usage (82%), but also assistive with the aim to improve functions during usage (64%). One-quarter of participants use FES for strength training;
- the majority wishes FES to be controlled by task performance (82%) and 50% by EMG or EEG. Controlling FES according to the patient's needs was rated higher than simply triggering the on- and offset of FES;
- about half of the participants see the main implementation barriers for FES in its cost (52%) and the donning time (48%);
- the most important aspects of usability are ease of use (84%), effectiveness (79%) and comfort (53%).

The following word cloud (Figure 32) represents the most frequently mentioned hurdles when it comes to making FES more accessible for in-clinic or home use.

Figure 32. Hurdles when it comes to making FES more accessible for clinic or home use.

Participants also described their positive and negative experiences with FES use (Figure 33).

Figure 33. Positive and negative experiences in FES use.

Lastly, the word cloud in Figure 34 summarises which improvements are needed for the application of FES.

Figure 34. Improvements needed for the application of FES.

3.2.2 Feedback on the Gaming module

In cooperation with DTU, different GUIs were evaluated in the group of medical treatment staff at SK. A tablet-based rehabilitation game was evaluated by means of questionnaires and a DTU-led workshop was conducted in which therapists gave feedback after testing different immersive gaming environments.

3.2.2.1 GUI evaluation at SK conducted by DTU

A questionnaire-based survey involving 6 therapists from SK was conducted by DTU with the objective to get insights into the therapists' opinions on the requirements and functions of a tablet-based rehabilitation exercise.

According to the responses of the therapists, a tablet-based treatment should incorporate the following features in order to be used by the patient without the supervision and guidance of a therapist:

- the patient's progress in the rehabilitation should be overviewed;
- the design of the GUI and the rehabilitation exercises should be simple and include motivational elements;
- the games should be variable and applicable to different capabilities;
- games should also target cognitive and perceptual recovery;
- games should include components of everyday life and promote the transfer of learned skills in daily life;
- the GUI should be intuitive and easy to handle;
- the application should include auditory signals/verbal instructions;
- the most important aspects on the screen should be highlighted.

In general, the therapists' attitude towards a tablet-based training that reduces the need for supervision is positive. Self-training offers independence to the patient and opens the following possibilities:

- Simultaneous care for more patients

- Only assistance is necessary
- Increased motivation through more independence
- Increased feasibility
- The games are pre-set and do not need to be planned
- Better overview of the therapy process
- Independence leaves more time for rehabilitation control
- Contact with far-away patients

Choosing an easy-to-use interface (e.g., tablet) for a minimally-supervised training at the patients' home turned out to be the basis of the digital rehabilitation process. This will provide patients with affordable independence in a short period of time without being too technically overwhelmed. Nevertheless, the benefits of AR should not be neglected. Thus, these more complex technologies should be used in the earlier phase of the rehabilitation process, when patients have the support of therapists in the clinic.

In order to investigate, to what extent the implementation of AR/VR-device is feasible in a rehabilitation center, one part of the survey was to find out to what extent the therapists are aware of AR and VR technologies. It turned out that all therapists had a good to a very good understanding of these technologies. This is partly due to the fact that various modern rehabilitation measures are already being used at SK. In order to achieve a better understanding of the analysis of the exercises from the therapists‘ point of view, the most important criteria in an evaluation of the exercise process were determined:

- Development of functional performance
- Duration of exercise
- Type of exercise that has been performed
- Process of improvement
- Number of breaks in the exercise
- Continuous and regular analyzations
- Level of complexity
- Independence of the patient
- Quality of the movements

In summary, the evaluation of a GUI for minimally-supervised rehabilitation exercises from a stakeholder perspective revealed that therapists welcome such a therapy option. Their feedback is valuable to define certain design aspects to successfully implement the application in a patient population and to be useful for therapists. Further, the suggested approach of using more complex devices, such as AR, in a clinical environment and choosing rather simple interfaces, such as a tablet, for home-based therapy was approved by the survey within the stakeholder group of medical operators.

3.2.2.2 Stakeholder workshop on User Interface and serious gaming applications at SK conducted by DTU

DTU had prepared a workshop to evaluate a developed prototype application for a home-based rehabilitation that can be supervised online by a therapist. Feedback from therapists of SK was collected regarding 1) the GUI, and 2) general aspects needed for a home-based rehabilitation scenario.

The initial prototypes of dashboards for therapists were designed to make sure the prototypes achieve the needs of the therapists. In order to enable the users to use the dashboards easily, the structure has been kept flattened. Instead of linking a lot of pages to the main page, the navigation bar allows therapists to choose the categories as easily as possible.

The design process itself was iterative and followed a stakeholder-oriented approach. Therefore, initial prototypes of dashboards for therapists were designed using the design tool "Figma" under consideration of current design trends and UX design principles. These initial design prototypes were subsequently evaluated through actual stakeholders from Schön Klinik and adjusted according to the corresponding feedback. Apart from the dashboards being generally perceived as useful, the main critical points were:

- Serious design: The initial dashboard design was perceived as not serious enough. According to the feedback, it is unnecessary to include design elements such as smiley faces.
- Simplicity: The initial design contains too much (unnecessary and unclear) information and colors should have higher contrasts for better readability.
- Assessment support: The dashboards should support regular (manual) assessments of patients. Furthermore, more specific information about the patient's state is required.
- Patient parameters: The therapists perceived the representation of the patient's physical and cognitive states through a general score as problematic as the National Institutes of Health Stroke Scale (NIHSS) scale (currently used) and the patient's state in general are very complex and entail way more different aspects. Thus, the various aspects describing the patient's state have to be represented explicitly through absolute values (not relative percentages - which instead would be more relevant for the patients).
- Activity analysis: Visualizing the patient's activities via graphs can be hard to read by the therapist. However, combining visualizations with 3d avatar representations was perceived as much more useful.
- Avatar: The idea of using avatars to directly visualize patient data was perceived with huge interest. However, while the avatar used to show data to patients in other dashboards (see patient and 3rd-party dashboards described in D3.5) should be customizable and optically correspond to the patient, the avatar used for the therapist dashboard should be as plain and generic as possible to prevent distraction.
- Communication: The dashboard should support the communication with patients, e.g., through a communication plan.

- Calendar: The idea of an integrated calendar was perceived as helpful in order to streamline the therapists' scheduling process with the patients' calendars and set, for example, appointments.

After receiving feedback, the dashboard design was updated accordingly. The following describes the main sections of the resulting dashboard:

- The "Overview" page

This page (Figure 35) serves as the therapist dashboard's starting page. It provides a general overview of the patients' activities as well as a number of management tools such as an integrated calendar and appointment reminders that support the therapists throughout the working day.

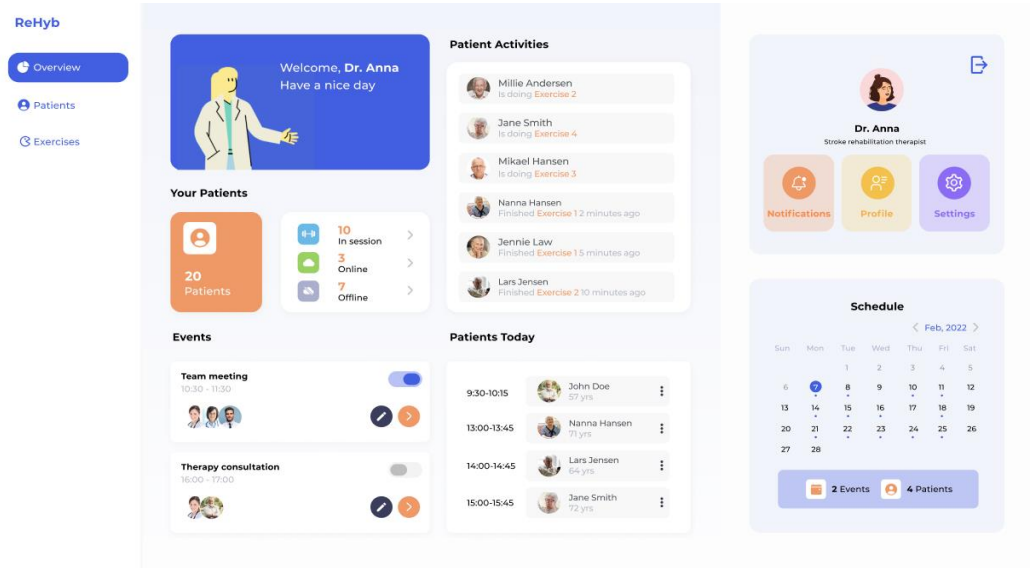

Figure 35. Evaluated prototype of the "Overview" page for the therapist.

- The "Patients" page

The "Patients"-page (Figure 36) provides a list of all patients currently enrolled in the therapy. Furthermore, it shows each patient's current activity status indicating whether the patient is offline, online, or currently absolving in an exercising session as well as if the patients haven't absolved exercises for a longer time and thus might require intervention.

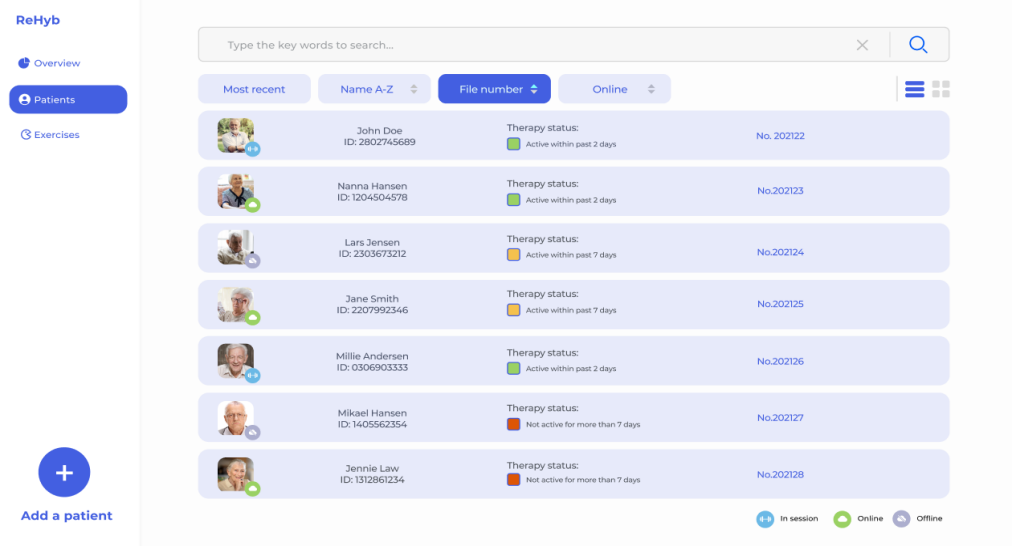

Figure 36. Evaluated prototype of the "Patients" page for the therapists.

- The patient’s "Therapy Management” page

When selecting a specific patient from the patient overview list, the therapist gets redirected to the patient’s therapy management page (Figure 37). This page provides a detailed overview of the patient's physiological and cognitive state variables stored within the patient’s digital twin. Using a timeline slide bar, the patient’s current state further can be compared to previous points in time, thus giving an overview about the patient’s development. In addition, the therapy management window contains a calendar that provides an overview of completed as well as upcoming sessions and allows for scheduling new exercises by selecting date, time, duration, and the serious game that should be played during the session. By selecting a completed session within the calendar, the therapist can rewatch the patient’s performance through an avatar. Additionally, enhanced analysis tools such as point clouds can be used to visualise the patient’s concrete movements while heat maps could show which areas around the considered body part were touched the most often, thus providing an estimate of the patient’s range of motion which – again through a time slider – can be compared to past states.

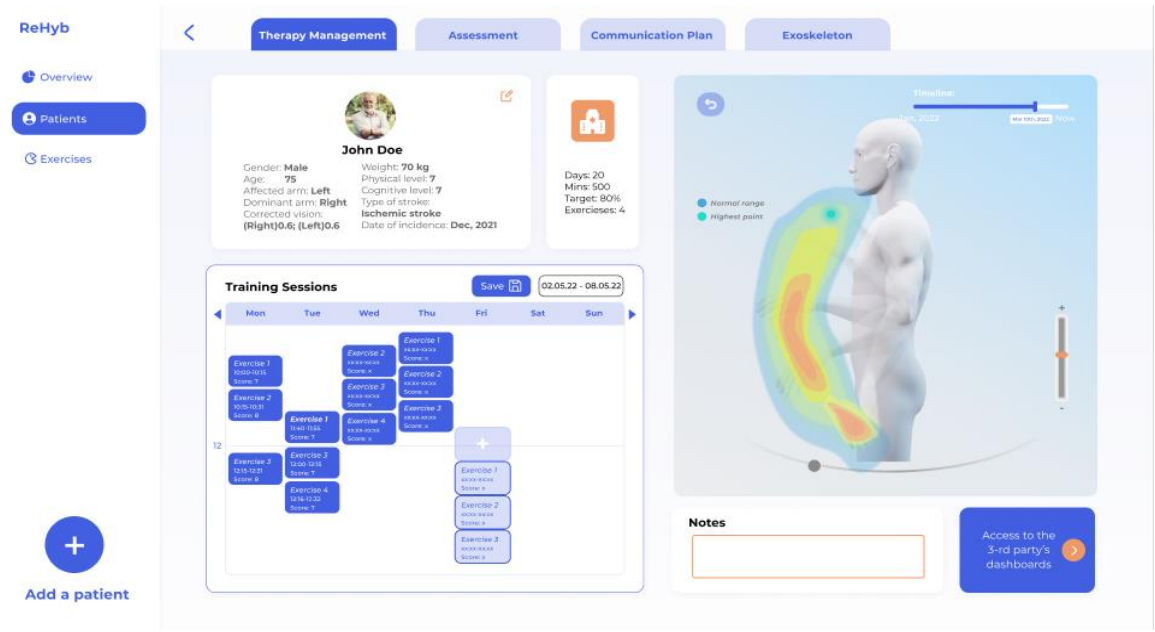

Figure 37. Evaluated prototype of the "Patient's general information" page for the therapist.

- The “Assessment” page

In accordance to the received feedback, a specific tool for supporting manual assessment sessions was integrated. Therefore, the assessment page (Figure 38) supports the assessment of physiological factors such as muscle strength and spasticity, sensorimotor functions such as sensation, pain and passive joint motion, and the assessment of the patient’s overall mental health. In order to ensure medical correctness and consistency, the assessment tool is based on profound medical scales such as the Fugl-Meyer scale for upper-extremity. Further, spasticity is quantified through the Modified Ashworth Scale and he mental health assessment follows the World Health Organisation’s five-point well-being scale. Therefore, the assessment tool provides the possibility to also track information about the patient that are not automatically predictable by the ReHyb system’s prediction modules.

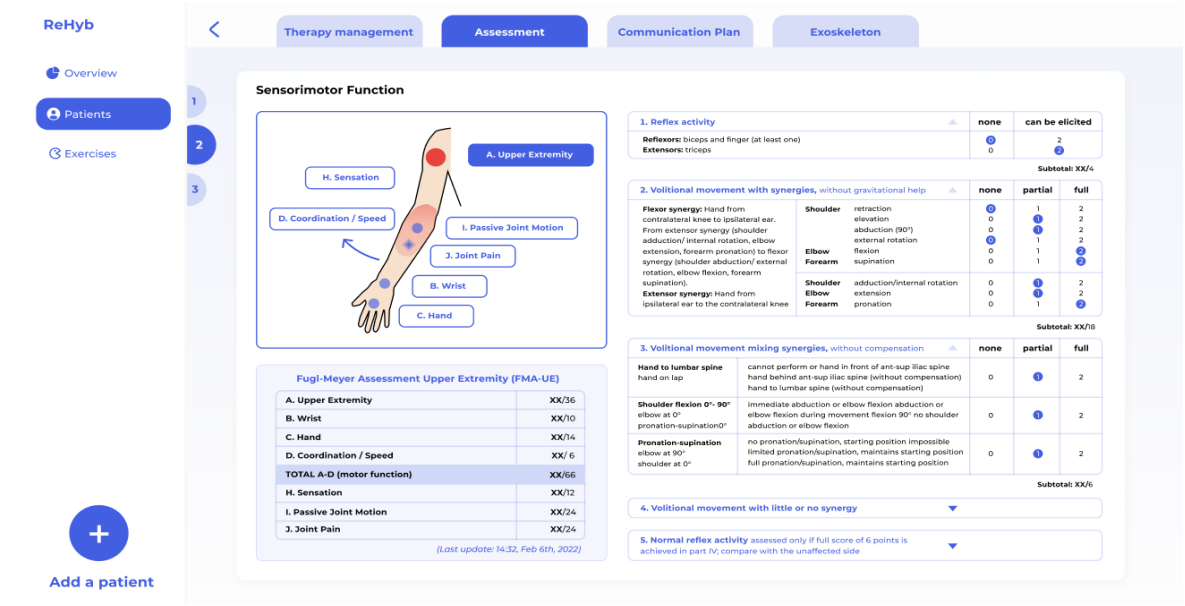

Figure 38. The “Assessment” page.

- The “Communication Plan” page and the “Exoskeleton” page

In addition to the assessment tool, the therapist dashboard further supports the communication between therapist and patient during manual assessments as well as the interaction between therapist and ReHyb system. Therefore, the “Communication Plan”-page (Figure 39) provides a simple tool that allows to take notes concerning past and future assessment sessions, for instance to specify when, what and how information should be communicated to the patient. The “Exoskeleton” page (Figure 39), on the other hand, allows for parameterizing the ReHyb modules, for instance by setting patient-specific parameters.

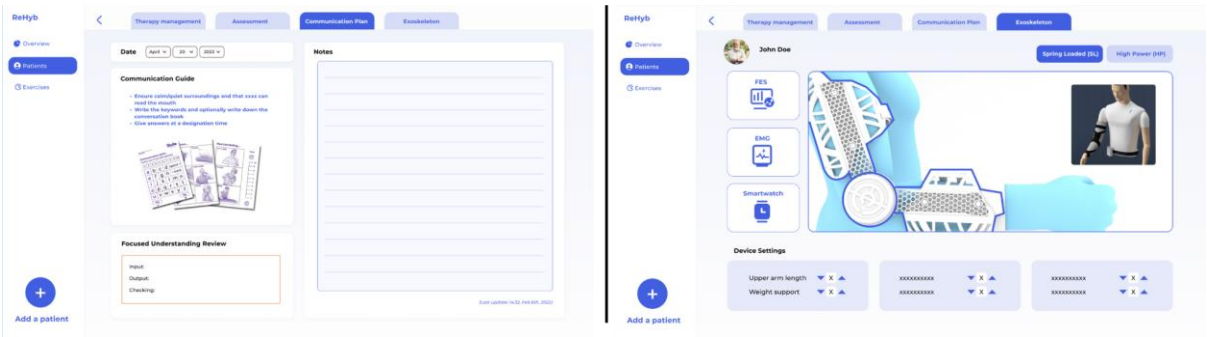

Figure 39. Evaluated prototypes of the "Communication Plan" and “Exoskeleton” pages for the therapist.

3.2.3 Data collection for the Digital twin

To assess different stakeholder’s ability to detect and label compensatory movements (CM) in stroke patients, we performed data collection in two phases. First, stroke patients at VALDUCE performed movements according to a protocol (see D2.3) and were videotaped. Also, motion

data was captured using Qualisys. Second, stakeholders reviewed these videos to label the movements. Beside investigating the stakeholder's ability to detect and label CM and the interrater agreement, the motion capture data will feed the digital twin, so the digital twin can detect and inform about different types of compensation strategies based on the therapists' annotations.

Since this deliverable addresses the stakeholder analysis, the following section focuses exclusively on the description of the annotation procedure.

Using a video editing software tool, each of the videos was cut to one individual repetition of movement for each participant. In total, there were 292 unique repetitions of the movements across the five experiments for the seven patients. To determine the number of videos to be annotated by the stakeholders in around one hour, a physiotherapist annotated 75 randomly chosen videos in the annotation software. All testing was conducted at SK or TUM.

The CM labels (Table 13) were selected and refined by a physiotherapist involved in the ReHyb project. They were all the possible upper extremity movements that could be performed on a joint level that is defined on the different movement planes. For example, by sitting in a chair, there are three possible movements for a torso: flexion/extension, lateral flexion, or rotation. The finger joints were not chosen because these joints would not be analyzed in the kinematic data analysis for the robotic arm.

Table 13. Compensatory movement labels in annotation tool.

torso: flexion / extension
torso: lateral flexion
torso: rotation
shoulder: flexion / extension
shoulder: internal / external
shoulder: abduction / adduction
shoulder: elevation / protraction
elbow: flexion / extension
elbow: pronation / supination
wirst: flexion / extension
wrist: ulnar / radial
no compensation

The stakeholders viewed each video of a movement and were asked to select any movement impairment they saw from the predetermined list (Table 13). They were instructed to either select “no compensation” or if they observed a type of compensation, to select any number of the compensatory movement types they observed. There was a “Comments” field where they were able to add any additional comments they viewed as appropriate. Each video presented was a full movement (resting position to either reaching for the handle or lifting the tray to chest level and returning to the resting position) and they were able to watch the video as many times as they preferred. However, each rater was asked to only observe the first portion of the movement (reach to handle or lift tray to test). This was to prevent confusion if there were different CM present when the participant was returning their arm to the resting position. The outcome variable of the annotation task was the type of compensation chosen for each video, represented as a categorical variable. Results will be reported in D9.2.

3.2.4 Feedback on the Robotic module

As described in section 3.1.3, a workshop was performed including patients after stroke and also healthcare operators. In the following section, the feedback coming from medical treatment staff is reported.

Healthcare operators both from VALDUCE and SK attended the first workshop (September 28 and 29, 2020). For VALDUCE: 13 medical doctors, 13 physical therapists, 4 neuropsychologists and 1 bioengineer. For SK there were 3 team members, all physical therapists. Overall, 6 medical doctors, 6 physical therapists and all SK members experienced the integrated system (MATE + RGS), whereas the others only observed the demo.

Feedback was gathered in the form of questionnaires administered to the majority of users that participated in the workshop; specifically, 9 healthcare operators provided their answers. The answers of participants to the SUS regarding the usability of the MATE showed an average score of 67.7 (Figure 40).

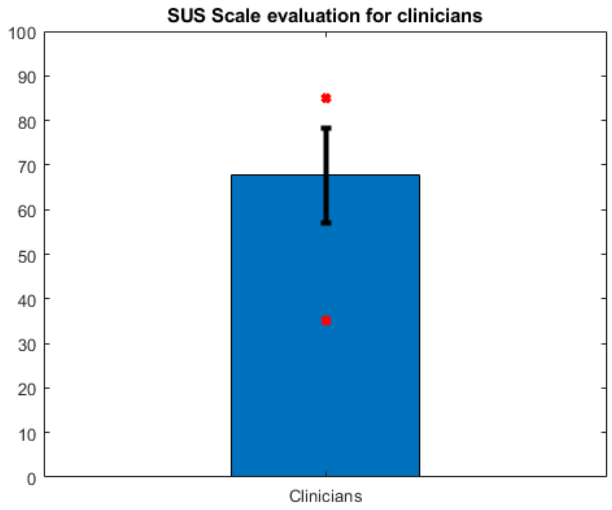

Figure 40. SUS scale results collected SH4 from first workshop at VALDUCE concerning the MATE exoskeleton.

After implementing the feedback on the MATE to the design of the alpha prototype of the ReHyb-SL, participants rated the usability of this device in a second workshop even higher, with an average score of 83.1 on the SUS (Figure 41).

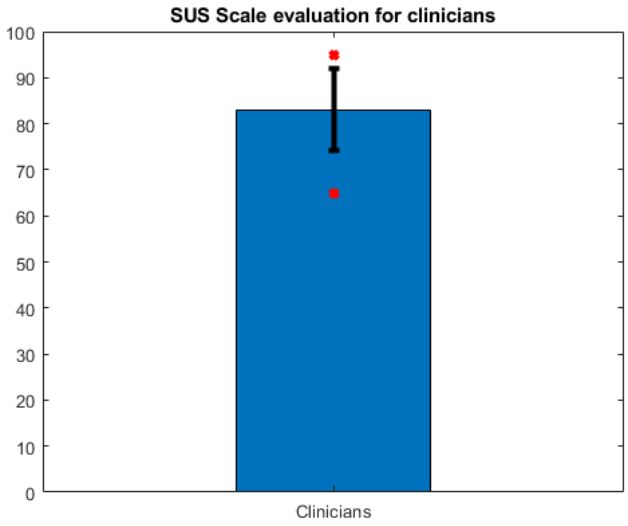

Figure 41. SUS scale results collected SH4 from second workshop at VALDUCE concerning the alpha ReHyb-SL.

These workshops were a valuable opportunity for collecting inputs to be integrated into the beta ReHyb-SL design and increase its usability.

Regarding the ReHyb-HP exoskeleton, fluidity of movements and transparency was very much appreciated. Some suggestions for improvements were related to the need of:

- a wider upper cuff, which should cover the arm posteriorly;
- lowering the arm cuff, to avoid discomfort after prolonged use;
- a hand/wrist support to fix the hand posture;
- a more stable trunk support;
- a more suitable seat, to improve the comfort of the patient;
- a smaller back of the chair to ease the alignment of the robot;
- contralateral arm support could help and provide cognitive input during rehabilitation exercises;
- passive mobilization on proximal joints should be smoother at slow velocities.

Useful exercises that could be implemented on the ReHyb-HP exoskeleton were:

- functional movements based on pre-recorded trajectories on healthy subjects;
- simple but synergic movements involving more joints (e.g., shoulder flexion/extension plus elbow flexion/extension, or shoulder abduction/adduction plus shoulder internal/external rotation);
- assistive strategies based on the velocity error instead of position error with respect to a reference signal.

The aforementioned comments and suggestions were taken into account by technical partners, to enhance the usability of the platform and implement modifications for the beta prototype. Adaptations regarding wearability and comfort were mostly considered, summarized in Table 14.

Table 14. Suggestions from medical treatment staff for modifications of the alpha ReHyb-HP and how they were addressed.

Usability attributes	**Suggestion**	**Modification**
Adaptability	Wider cuff covering the arm posteriorly	It was not possible to have the attachment point posteriorly without redesigning completely the kinematic chain of the exoskeleton.
Comfort	Lowering the upper cuff, to avoid discomfort after prolonged use	The upper cuff slightly repositioned to have the attachment point more distally and favor a better fitting
Functionality	Hand/wrist support to fix the hand posture	No modification since a wrist module was already designed and intended to be integrated

Functionality	More stable trunk support	A new commercial chest harness is integrated into the current back support. The latter has been firmly fixed on the back of the seat.
Comfort	A more suitable seat, to meet the comfort of the patient	A commercial wheelchair is introduced, compatible with the current mechanical structure of the robot
Ergonomics	Smaller back of the chair to ease the alignment of the robot	A custom design for the back of the wheelchair is implemented
Functionality	Contralateral arm support could help and provide cognitive input during rehabilitation exercises.	The wheelchair features modular armrests. They can be removed to avoid interferences with the robot, while they can be maintained for the contralateral arm. The support is not adaptive.

Some of the suggestions from healthcare operators are coherent with suggestions from patients reported in section 3.1.3.
Feedbacks were gathered from SUS questionnaires also in this case; specifically, 7 healthcare operators provided their answers. Results report an average score of 77.14 (Figure 42).

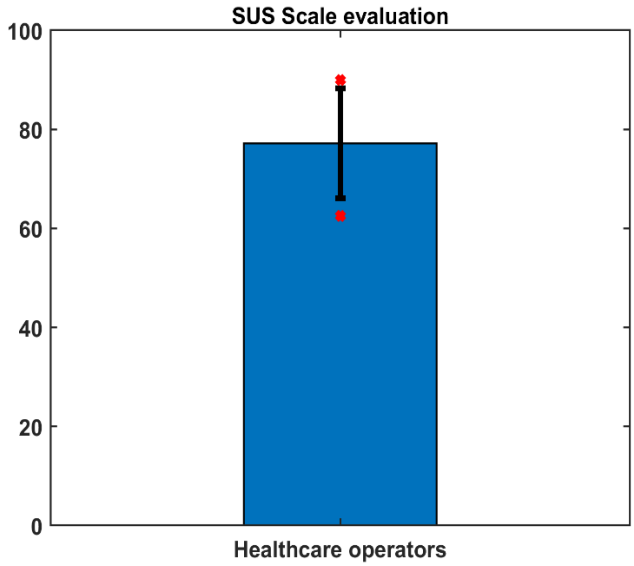

Figure 42. SUS scale results collected SH4 concerning the ReHyb-HP.

3.2.5 Feedback on combined / integrated modules

Members of SH4 tested the combination of the MATE exoskeleton and some of the RGS protocols. The following suggestions have been collected:

- switching from “MATE” to “no MATE” condition, some participants perceived to be more distant from the screen;
- the addition of a tracking system on the body (e.g., gyroscope, accelerometer) could make the kinematics inversion algorithm more robust (to avoid “shaking” of the virtual arm);
- adding sensors to the exoskeleton to monitor the upper limb and trunk kinematics;
- implementing a mechanism allowing selective block of the ROM (e.g., limiting the ROM in shoulder flex/extension at [0:90] degrees in the acute phase and increasing it while motor abilities improve);
- adding protocols/games to the RGS with functional exercises (e.g., bring hand to mouth or behind the head);
- adding bimanual exercises.

3.2.6 Further stakeholder characteristics

The technical affinity scores of the medical treatment staff of SK and VALDUCE have been reported in D2.1.

3.3 SH2: Primary caregiver

The patient’s relative who has participated in the DTU-led workshop on a developed prototype application for a home-based rehabilitation (see section 3.2.2.2) had a technical affinity value of 3.8. Thus, he has a rather positive attitude towards technical devices. He is enthusiastic in trying and using such devices (TA-EG Enthusiasm: 3.6), he sees himself as competent in the field of technology (TA-EG Competence: 4.3) and he gives technical devices a rather positive attitude (TA-EG Positive attitude: 3.8; TA-EG Negative attitude: 3.6).

SH2 will be extensively involved in T9.2, where the usability of the alpha-prototype will be evaluated. Results of this evaluation will be reported in D9.3.

3.4 SH8: Financial providers

A general description of the financing processes was already given in chapter 2.2 alongside the onion diagrams. Within this chapter, the financial provider shall be described in more detail. In chapter 2.2 the differences in the nature of this stakeholder in Italy and Germany were already pointed out. This chapter aims to depict the situation in European countries. Of interest in this context is especially the financing of therapies and assistive devices during a hospital (rehabilitation) stay and the financing of assistive and/or rehabilitation devices for home use. This is important to understand, as the system shall be available to all persons that can profit from the technology and not just to those that can afford it (Goal 10: Reduced inequalities and Goal 3: good health and well-being of the United Nation’s sustainable development goals). To achieve this goal, the institutions that act as financial providers in charge of financing the ReHyb system need to be identified and their needs have to be addressed.

Generally speaking, the health costs can be either covered by some kind of financial protection by the country (government schemes), health insurance (compulsory or voluntary) or by out-of-pocket payments by the patient. The portion of out-of-pocket payments on the health-related expenses varies along the different countries. Its need increases the risk of unmet medical needs or financial hardship that may lead to or increase poverty (31).

"In 2018, around 73% of health spending was financed through governments and compulsory insurance on average across EU countries (Figure 43). In Sweden and Denmark, central, regional, or local governments covered around 85% of all health spending. In Luxembourg, Croatia, Germany, France, Slovak Republic and the Netherlands, compulsory health insurance financed more than three-quarters of all health expenditure. Cyprus was the only EU country where less than half of all health spending was financed through government or compulsory insurance schemes (32).

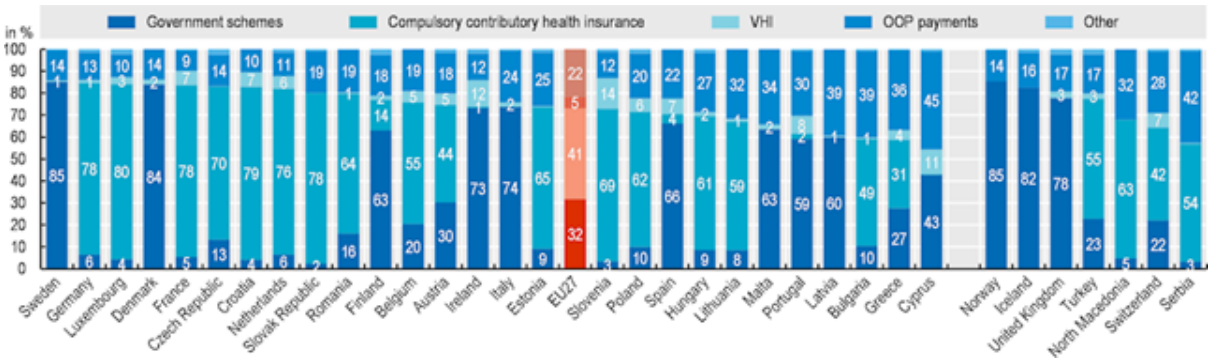

Figure 43. Health expenditure by type of financing, 2018 (or nearest year).

Note: Countries are ranked by government schemes and compulsory health insurance as a share of health expenditure. The EU average is unweighted. OOP: out-of-pocket payments, VHI: voluntary health insurance. The "Other" category refers to charities, corporations, foreign and undefined schemes."

In five EU countries – Cyprus, Latvia, Bulgaria, Greece and Malta – households' out-of-pocket payments accounted for more than one-third of health spending in 2018 (compared with an EU average of 22%), while only in Slovenia, Ireland and Cyprus did voluntary health insurance finance more than 10% of health spending (EU average: 5%)."

In this sense, in the EU "Financing schemes include government schemes, compulsory health insurance as well as voluntary health insurance and private funds such as households' out-of-pocket payments, non-governmental organizations and private corporations. Out-of-pocket payments are expenditures borne directly by patients, which can take the form of cost-sharing of services included in the publicly defined benefit package and also direct purchases of goods and services."(32)

Even if it has been recognized that “Member States have made significant attempts to promote equity of access to health care – by expanding coverage, increasing regulation of private health insurance, improving the design of cost sharing and making the allocation of resources more strategic”(33), medical technology financing systems vary widely among different countries and even among different regions of the same country. Consequently, the identification of key stakeholders will mainly depend on the knowledge about the decision-making process of payment and reimbursement in each site, hence, details should be given in further phases, once the system will be ready for entering the market.

3.5 SH5: Non-medical support staff

At SK, all medical products that are to be purchased by the hospital undergo evaluation regarding the cleaning/reprocessing by the hygiene department. This evaluation makes a decision point in the purchase of new products/equipment. Thus, it is very important to note and include their requirements during the development process of the ReHyb system. Therefore, an interview with a hygiene specialist at SK was conducted. The different ReHyb modules were explained to the hygiene department and comparable products were mentioned: The Fesia Velcro and the RGS sleeves were presented for review during the interview. The Armeo Spring and Armeo Power were given as examples of comparable devices for the exoskeleton. The HoloLens glasses are already known to the hygiene department. Resulting from this interview, the following requirements and barriers from a hygiene point of view were identified:

Requirements:

- In general, the material / device must be completely disinfected between patients.
- Anything that has direct contact with the patient must be disinfectable, either by wipe disinfection or by thermal-chemical washing (40°C).
- Manufacturer's guidelines must be followed in the clinic e.g., cleaning instructions.
- surface as smooth as possible to ensure effective wipe-disinfection

Barriers:

- Velcro is critical, as it cannot be completely disinfected
- not suitable for medical use are natural materials, like wood, that are not disinfectable

What if a material cannot be completely wipe-disinfected or washed?

This increases the risk of transferring multi-resistant germs. Therefore, patients with multi-resistant germs should not receive treatment with materials that cannot be completely disinfected. All other patients would need to disinfect their skin before applying the device in case the device itself cannot be effectively disinfected.

Regulations

The basis for these requirements is the recommendations of the Krinko (Commission for hospital hygiene and infection prevention in Germany). In general, other standards and the requirements of the manufacturer must be followed. If an infection should take place in the clinic, the clinic must prove that none of the devices have led to a transmission of the infection.

3.6 SH7: External Relations

To gather information on the processes and implementation requirements in an outpatient setting, we interviewed an experienced physiotherapist who has 6 years of experience in a clinical neurorehabilitation setting and 6 years of experience in an outpatient setting with neurologic patients in Germany with many home-visiting therapies. As a physiotherapist, he has mostly experience with FES on the lower extremity (e.g., for foot lifter weakness), which he has used predominantly in the clinical environment. He also has experience with robotics (e.g. Lokomat, GEO) and a bit of experience in serious gaming (which was coupled with a standing device or the Lokomat).

Compared to the usage in a clinical environment, where he used FES devices regularly with his patients, they are rarely used by patients in a home setting, although there might be patients that would profit from an FES device. However, there were some hurdles identified for the home use of medical devices, such as FES devices or orthotic devices, which are summarised below:

Hurdles of implementation of medical devices in the home-use environment

- little knowledge about the device and its therapeutic use by medical doctors (they won't prescribe it because they don't know it)
- prescription process for the therapists complicated and time-consuming → not feasible within limited therapy time
- fear of therapists that not enough training will lead to erononeous use of the system
- extensive training with the device is not possible in the small therapy times
- caregivers are not trained with the device (in case of dependent patients): the device will not be used
- optical and practical issues by the patients (e.g. device does not look good, clothes do not fit over/under it)
- cognitive impairments of stroke patients (e.g. they forget to use or how to use it)
- high costs (maybe no cost coverage by insurance/no means for out-of-pocket payment)

Still, the therapist emphasises the positive aspects of FES therapy and would appreciate its use in an outpatient setting. To overcome the hurdles mentioned above, he mentioned the following ideas: - a separate prescription code for device training - easier prescription processes - as easy and user-friendly as possible product - low costs to increase the cost coverage rates by the insurances/possibility for out-of-pocket payment.

Another possibility he mentioned, was the use of these devices in an outpatient therapy office. Therefore, the therapy office would need to buy the devices and could then use them during therapy with their patients. This, however, is only possible in offices that are spacious enough for the devices and their storage, and in case the office can afford the investment / or it is partly reimbursed by the insurances of the patients (e.g., the electrodes). Apart from these restrictions, he could very well imagine using the gaming system and the FES in such a setting. He could imagine that many patients would like these therapies as they are a good change from exercise routines and might increase the patient's motivation.

4. Conclusion

In-depth information on key stakeholders was collected and further analysed regarding their roles and relationships in view of the potential use of the ReHyb system. This is an important step to successfully implement a rehabilitation pathway which includes the use of the ReHyb system and/or some of its modules.

In general, Stakeholder analysis is a dynamic process in which actors, their position, roles, power of influence, and interests will vary according to the time dimension (or phases), context of application, and level of the analysis. For the ReHyb system stakeholder analysis we did take into consideration that on the one hand the system 1) addresses two therapy settings, hospital and home, 2) will provide two exoskeleton options, a high-powered and a spring-loaded exoskeleton, 3) will be initially tested in two European countries, Italy and Germany, and on the other hand, according to the project proposal, 4) the in-depth analysis includes the design, development and preliminary tests of the system.

By establishing the stakeholders' interests and influence, and their relation to the system and the other stakeholders, some differences have been found which will be taken into account for the prototype testing. Based on our findings, we will address different stakeholders who will be involved in the prototype testing based on the clinical site in which the evaluation takes place and also for the specific exoskeleton being tested. When analysing the ReHyb system for the hospital setting, differences have been found for both countries within the primary caregiver group. Within this group, some professions were found to have a higher impact during decision-making processes when, e.g., prescribing specific therapeutic interventions or investing in new therapeutic equipment. This will be taken into account for the prototype testing by involving more physicians or more therapists at Valduce or SK, respectively. We also will involve different stakeholders when testing the system for the home-use or clinical application. Mainly the role of the hospital medical staff is influenced by the country and the specific setting. In Italy, the hospital medical staff is still involved in the patient's treatment after discharge from the hospital while in Germany therapists mainly in private practices are involved in the post-stationary concept. In addition, we will involve different financial providers depending on the setting we are evaluating. While in the hospital the most influential financial provider is the hospital's financial department, the insurance companies have a more influential financial relation for home use.

As a consequence of the stakeholder analysis, the identified most relevant stakeholders (patients, primary caregivers, medical treatment staff, non-medical treatment staff, external relations, and financial providers) were investigated regarding their opinions, needs and feedback on several ReHyb modules that will be integrated into the final ReHyb system. The findings are reported within this deliverable and are also used to support the activities of several related WPs.

In testing single ReHyb modules, e.g., FES + real objects or FES + gaming, it was apparent that a fully integrated system would potentially be beneficial in most of the investigated patients. The option of an integrated system including the robotic module would provide anti-

gravity support to better perform arm activities or allow for better use of motion detection for example by means of the Kinect or Leap motion sensors or EMG data. Individual stakeholder needs were investigated also for the VR/AR applications or the GUI to provide specific user information. Specifically, patients with different motor and cognitive impairments were investigated to be able to better address individual needs.

Besides the activities performed to investigate different modules of the ReHyb system in several stakeholders, D2.4 also provides findings of literature reviews conducted to optimize the developmental process of the integrated system. Literature reviews were conducted for example on the implementation of a digital twin, the combination of FES and serious gaming, and the efficacy of hybrid neuroprostheses.

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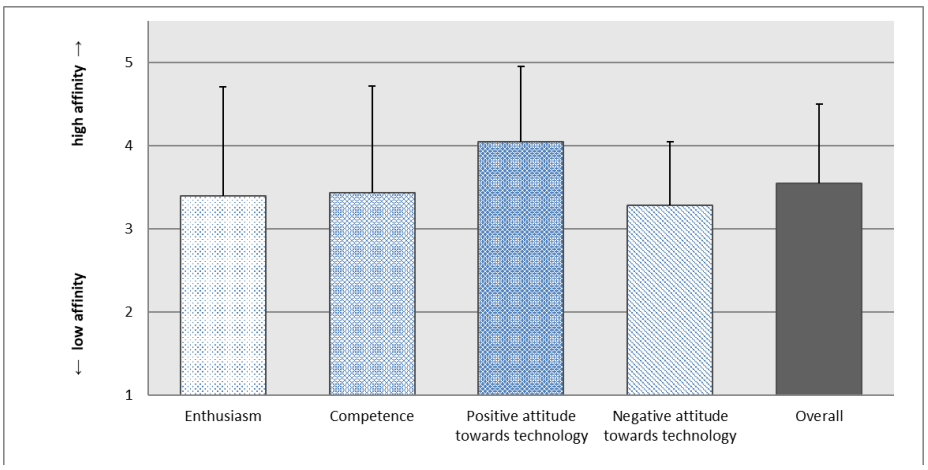
Definitions, Acronyms and Abbreviations

Acronyms abbreviations	Description
3DDT	3D Detection Task
ADL	Activities of Daily Living
AFCT	Alternative Forced Choice Task
AR	Augmented Reality
ARAT	Action Research Arm Test
CM	compensatory movements
D	Deliverable
DRG	diagnosis-related groups
EDA	electrodermal activity
EEG	electroencephalography
EMG	electromyography
f	female
FES	Functional Electrical Stimulation
FM-UE	upper extremity portion of the Fugl-Meyer
G-BA	Gemeinsamer Bundesausschuss
GUI	Graphical User Interface
h	haemorrhagic
HRV	heart rate variability
i	ischaemic
ICT	information and communications *technology*
l	left
m	male
MATE	Muscular Aiding Tech Exoskeleton
MDR	Medical Device Regulation
MRC	Medical Research Council
NHS	National Health System
NIHSS	*National Institutes of Health Stroke Scale*
NMSS	Non-medical Support Staff
NRSs	Numeric Rating Scales
PMT	Perceptual Matching Task
PT	Position Task
r	right
RCT	randomized controlled trial
ReHyb-HP	ReHyb High Powered exoskeleton
ReHyb-SL	ReHyb High Spring Loaded exoskeleton
RGS	Rehabilitation Gaming System
SG	serious gaming
SH	Stakeholder Group

SUS	System Usability Scale
T	Task
TA-EG	Technical Affinity Questionnaire
UTAUT	Unified Theory of Acceptance and Use of Technology
UX	User interaction
VR	Virtual Reality
VSP	visuospatial perception
WP	Work Package

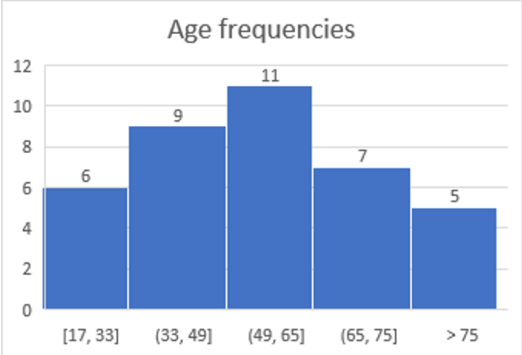
Annex I

The older generation, mostly not raised with technology, admits being afraid of technology use and describes a feeling of insecurity and incompetence. Furthermore, enthusiasm about technical devices is negatively correlates with age, just as self-efficacy, and competence in handling of devices. The skepticism regarding technology present in the elderly population should be considered when developing and implementing new technological devices for the elderly or in the field of neurorehabilitation.
The technical affinity of our target stakeholder group, the patient after stroke, has already been assessed and described in D2.1. For this and following assessments of technical affinity, we have translated the German questionnaire into Italian following Beaton's standardized protocol of transcultural translation. In our investigation, we have observed that the overall technical affinity of patients at SK and VALDUCE is rather in the middle between low and high affinity. Patients after stroke have a rather positive attitude towards technology.



Average affinity score for different categories in patients.

From these findings, we expect that patients after stroke will be open to test the ReHyb system and will not refuse using it a priori due to skepticism or the fear of not being able to use it. Whether or not this hypothesis applies to our patient population was investigated by a survey at VALDUCE. The relationship between the technical affinity (assessed by the TA-EG) and the acceptance of technology (assessed by the UTAUT) was investigated, also under consideration of age and gender, by a survey involving 50 patients that are usually treated with some kind of robotics technology in Villa Beretta Rehabilitation Center. The study population included different neurological pathologies, such as stroke (28%) and spinal cord injury (26%). Within his patient group, the whole spectrum of age groups was covered. About one third of participants were female and two thirds male.



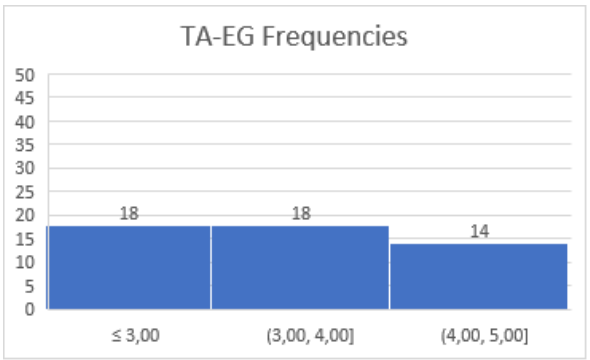
Age distribution of the study population.

The following table reports the average, maximum and minimum scores for TA-EG and UTAUT tests. As for TA-EG, 36% of the subjects show a negative technological affinity (score ≤3). As for UTAUT, the whole sample got a positive score (>4) which means good acceptance and use of technology.

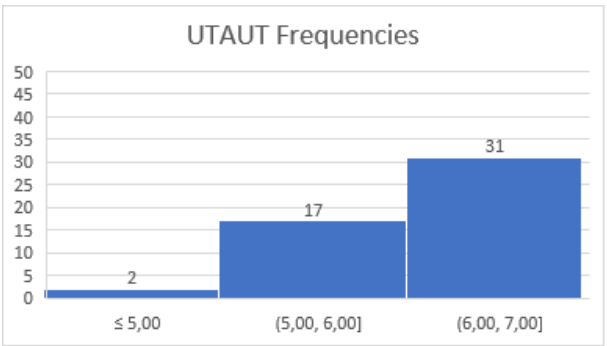
Average, maximum, minimum, and % of negative and positive scores for TA-EG and UTAUT.

	TA-EG	UTAUT
Average	3,43	6,04
Max	4,75	6,86
Min	1,75	4,82
% Negative	36%	0%
% Positive	64%	100%

The scores' frequencies for the two tests are displayed below, showing that the results of the UTAUT test are mostly (62%) very high.



TA-EG frequencies.

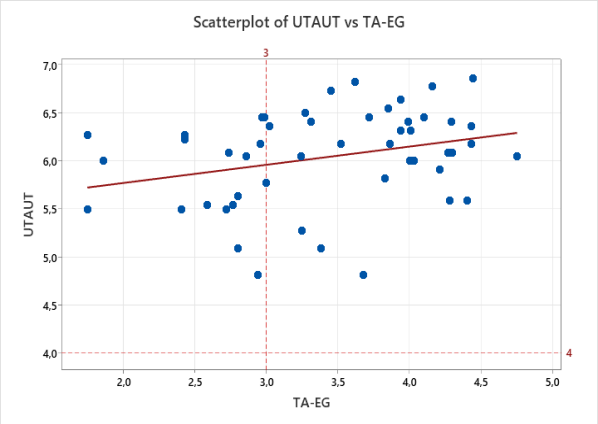


UTAUT frequencies.

Analysis of correlation between TA-EG and UTAUT

First, analysis of correlation has been used as an investigation tool to search for possible relations between the two questionnaires' results. Is a good acceptance and evaluation of the use of technology somehow related to the technological affinity?

The scatterplot shows a moderate positive association between TA-EG and UTAUT scores.



Scatterplot of UTAUT vs TA-EG.

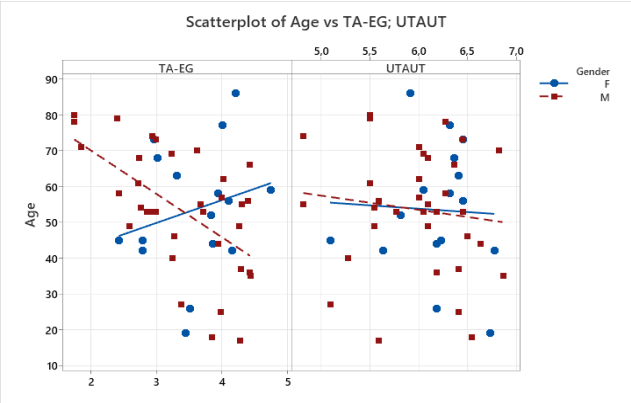
Spearman's correlation coefficient is equal to 0.314, which means there is a very low correlation between the two questionnaires, and we cannot draw statistical conclusions about their general relationship. Probably this low coefficient is due to the small sample (N=50). However, as we obtained positive scores about the acceptance of the technology, we can say that a good perception of the use of technology can be reached independently from the technological affinity. Provided that the technologies used for rehabilitation have been presented to the patients as something that will help their recovery, they don't feel them as an imposition. Both who are enthusiastic about technologies and innovation and those who are reluctant or do not care about them, can positively evaluate the use of technologies.

There is still a general positive tendency whereby the acceptance of technology seems to be higher if the technological affinity is higher, too.

Relations with age and gender

Other possible relations can be investigated considering age and gender. Consistently with the prevalence of male subjects (a higher number of observations), the only Spearman coefficient of correlation that gets close to be significant is the one calculated for males and TA-EG scores, and it is equal to -0.548 showing a mild negative correlation: as shown in the left scatterplot there is a tendency to a lower technological affinity as age increases. This is coherent with the possible resistances of the older generation to the world of technologies. Despite this, we saw

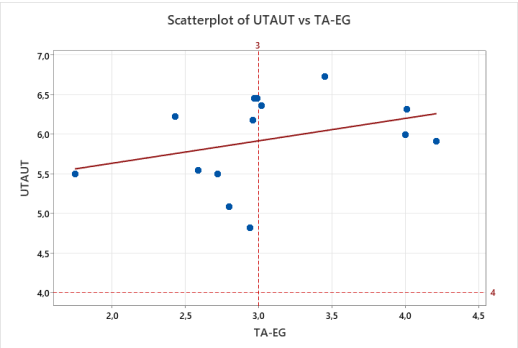
with UTAUT scores that good acceptance is not affected. In the right scatterplot we can see a slight cooling trend of UTAUT scores that seems to lightly decrease as age increases.



Scatterplot of Age vs TA-EG (left) and Age vs UTAUT (right) grouped by gender.

Analysis of correlation for different pathology: stroke patients

The analysis of possible correlations is made considering the different pathologies. Considering the group of subjects affected by stroke (14 subjects), the Spearman correlation coefficient is equal to 0.482, showing a slight positive correlation between TA-EG and UTAUT (p = .081).



Scatterplot of UTAUT vs TA-EG for stroke patients.

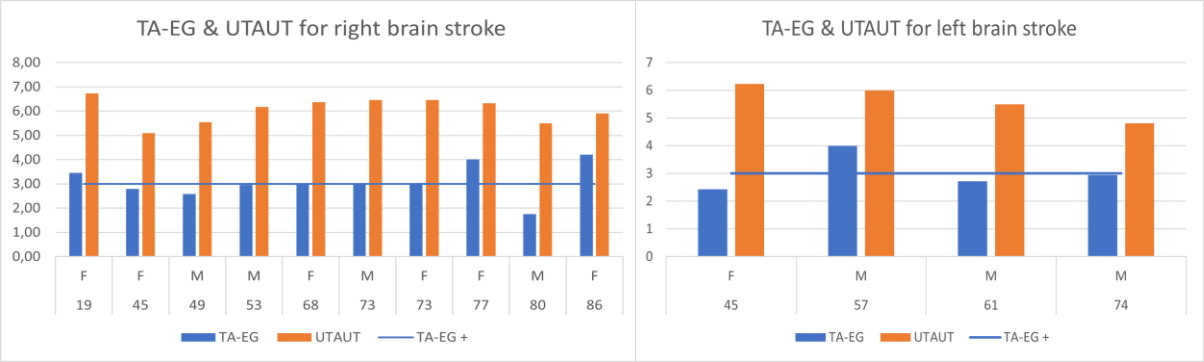
The same can be done considering separately patients with left and right brain stroke. Note that for left brain stroke there are only four observations. The following results show the questionnaires' scores for each patient of the two groups, considering also age and gender.

Results for right brain stroke patients.

	Age	Gender	TA-EG	UTAUT
PZ26	19	F	3,45	6,727
PZ42	45	F	2,8	5,091
PZ43	49	M	2,59	5,545
PZ31	53	M	2,96	6,182
PZ50	68	F	3,02	6,364
PZ19	73	M	2,99	6,455
PZ40	73	F	2,97	6,455
PZ46	77	F	4,01	6,318
PZ47	80	M	1,75	5,500
PZ39	86	F	4,21	5,909

Results for left brain stroke patients.

	Age	Gender	TA-EG	UTAUT
PZ48	45	F	2,43	6,227
PZ20	57	M	4,00	6,000
PZ41	61	M	2,72	5,500
PZ49	74	M	2,94	4,818



TA-EG & UTAUT scores for right brain stroke and left brain stroke patients ordered by age.

In the following, correlation values between UTAUT and TA-EG are reported for left and right brain strokes.

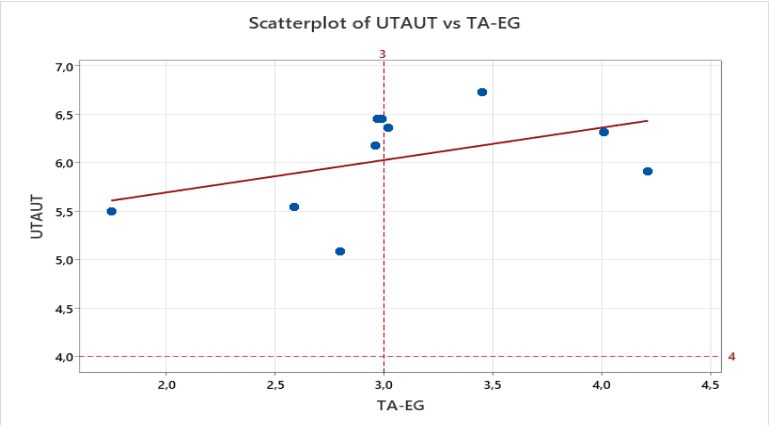
Pairwise Spearman Correlations Table for TA-EG vs UTAUT scores in left brain stroke patients.

Sample 1	Sample 2	N	Correlation	95% CI for ρ	P-Value
TA-EG	Age	4	0,400	(-0,924; 0,986)	0,600
UTAUT	Age	4	-1,000	(*; *)	*
UTAUT	TA-EG	4	-0,400	(-0,986; 0,924)	0,600

Pairwise Spearman Correlations Table for TA-EG vs UTAUT scores in right brain stroke patients.

Sample 1	Sample 2	N	Correlation	95% CI for ρ	P-Value
UTAUT	TA-EG	10	0,547	(-0,178; 0,887)	0,102

Last, the following figure depicts the distribution of UTAUT vs TA-EG scores for right brain strokes.



Scatterplot of UTAUT vs TA-EG for right brain stroke patients.

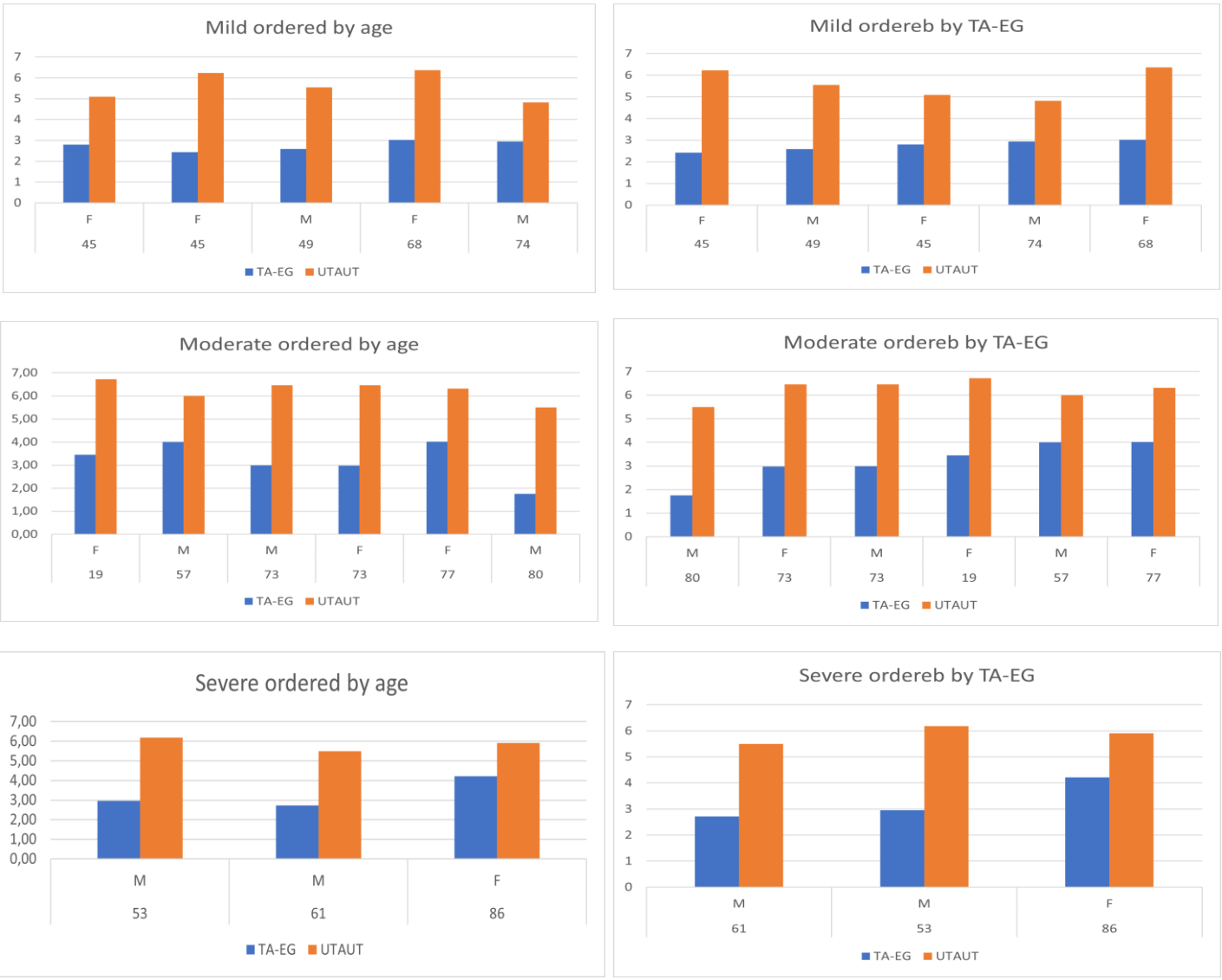
Considering the entire stroke group, the majority (64%) got a TA-EG score lower than 3. On the other side, more than 90% of the subjects got a UTAUT score higher than 5 out of a maximum of 7, showing that despite a low technological affinity, the opinion about the use of technology is very high.

Data were further analyzed considering the severity of the condition. Patients are classified in mild, moderate and severe using the motricity index scores as shown in the following table.

Stroke severity using MI scores for upper and lower limbs.

	MI - Upper limbs	MI - Lower limbs
Mild	62-100	59-100
Moderate	31-61	29-58
Severe	0-30	0-28

The following histograms display TA-EG and UTAUT scores for mild, moderate and severe stroke patients, sorted by age in the left column and by growing TA-EG in the right column.



Histograms of TA-EG and UTAUT scores for stroke patients considering severity.

From a general point of view, the data shows that in case of technology for rehabilitation the acceptance is positive even if the affinity in mid-low and it's not possible to find a correlation between the two questionnaires. Only in the stroke group, a slight positive correlation was found but the size of the sample was very small.

Regarding the use of the two questionnaires, since they are not correlated, they could show the real level of acceptance of the ReHyb technology perceived by the subjects without possible bias due to subjects' technology affinity.