

# Real World Evidence: Report of Relevant Results

## Patient-Centered Outcomes Research



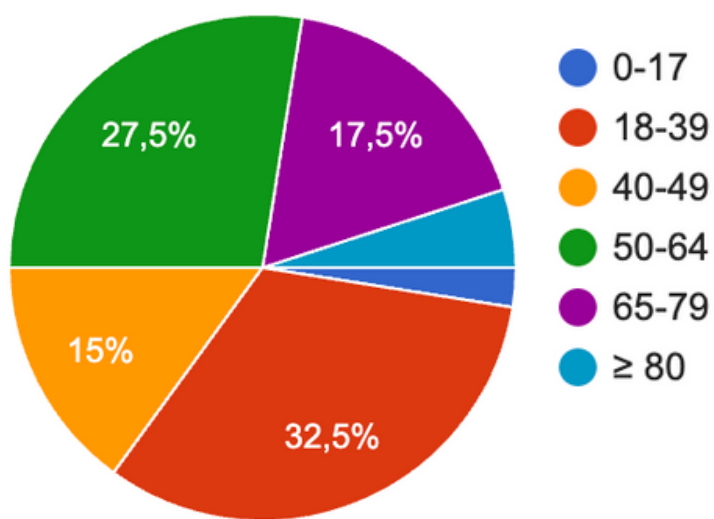
This Patient-Centered Outcomes Research describes the data reported by 40 patients following the use of KINESIX VR in different neurorehabilitation centers and units in Spain, Chile, and Mexico between June 2021 and March 2023.

# Product Data: Report of Relevant Results

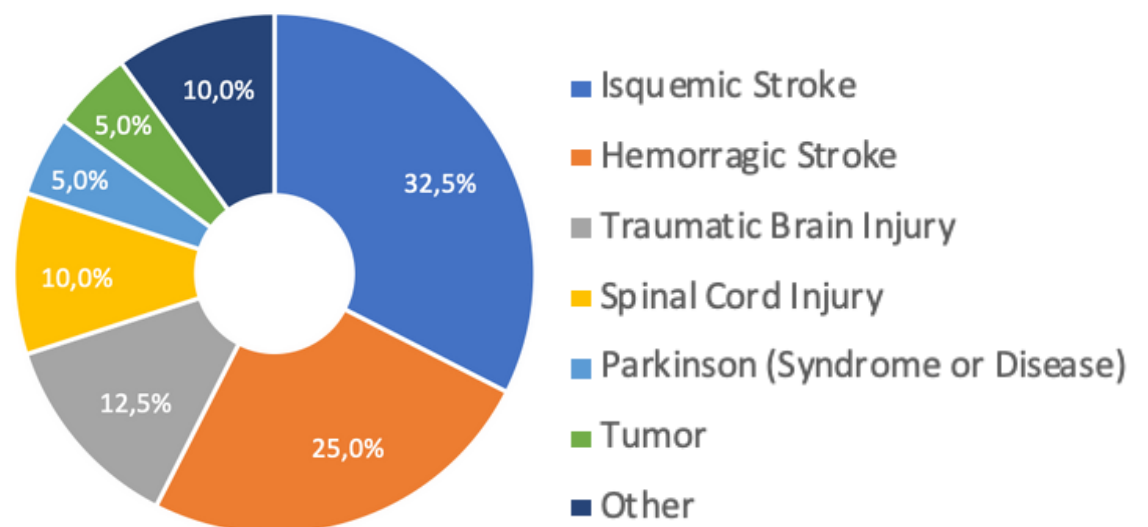
## STUDY PARTICIPANTS

The participants of this study encompass heterogeneous characteristics in demographic and clinical attributes, similar to a typical population of neurorehabilitation centers or units.

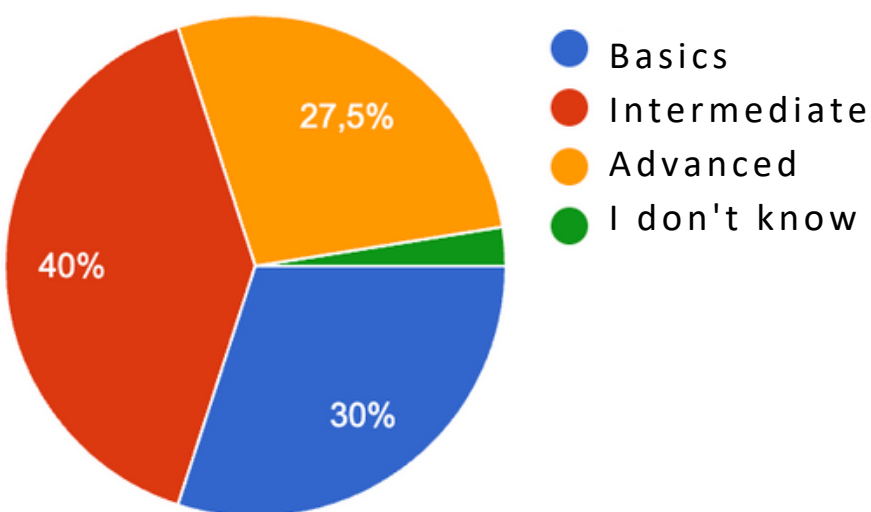
**Ages:**



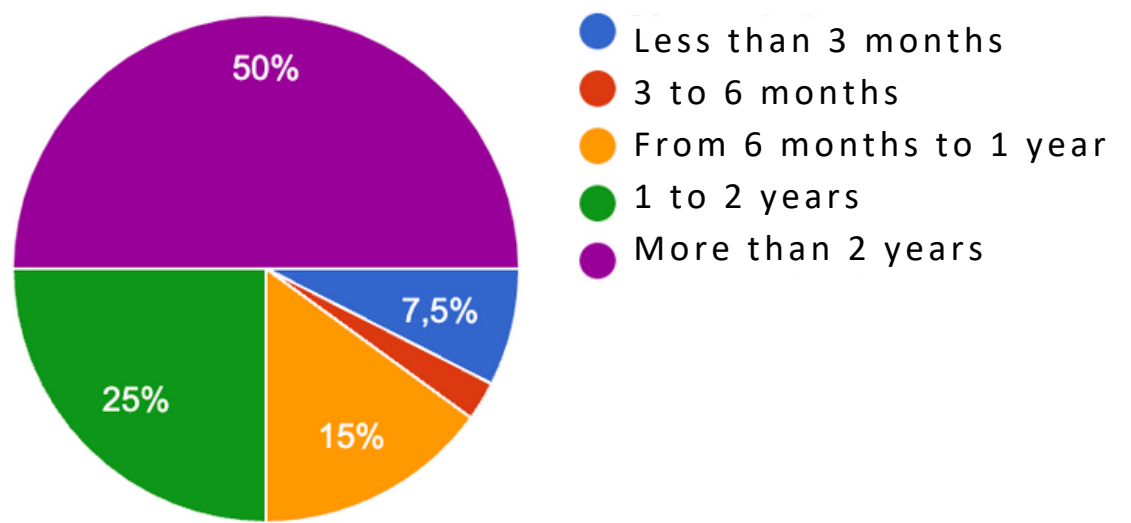
**Neurological conditions**



**Level of informatics or technological competencies:**



**Time of condition**



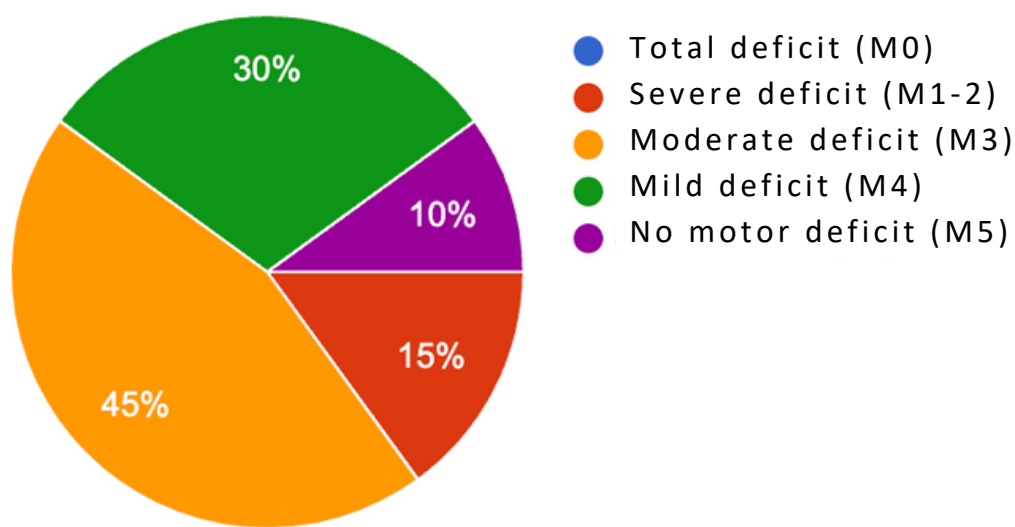
With the aim of highlighting patient involvement in the continuous optimization of KINESIX VR, a patient-centered outcomes research was initiated in June 2021. In this long-term study, patients provided data on various aspects related to the use of KINESIX VR from the prototype version to version 1.0. They tested the system and evaluated relevant aspects related to the implementation of technological innovation, such as acceptability, usability, safety, and management of the virtual rehabilitation service. The total sample to date (March 2023) consists of 40 adult patients with different perceived levels of informatics competencies, different neurological conditions (stroke, traumatic brain injury, spinal cord injury, among others), and at various stages of their condition (early/late subacute and chronic). This clinical and demographic diversity corresponds to typical populations undergoing neurorehabilitation in a specific unit or center.

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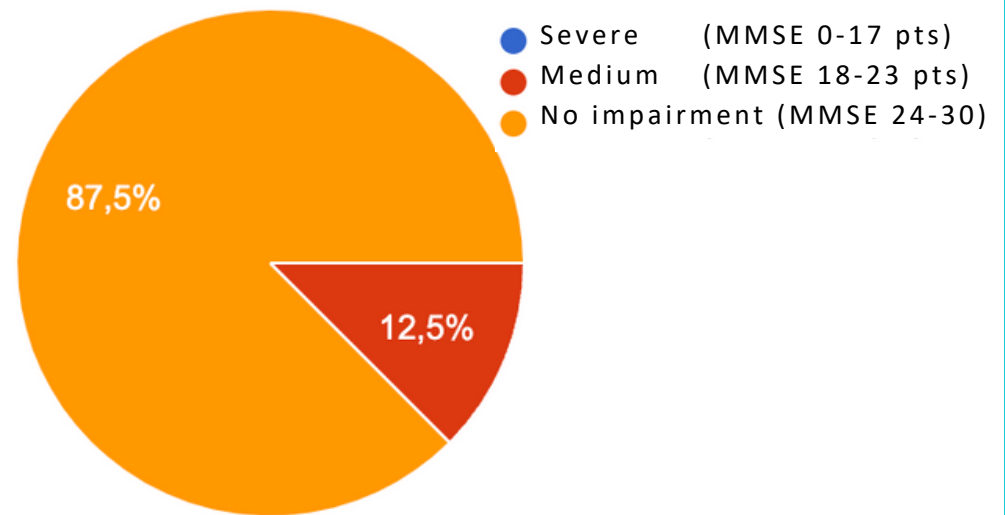
## DEFICITS CHARACTERISTICS

The majority of the participants exhibited weakness in its upper extremity (90%) and added proprioceptive deficit (52.5%). To a lesser extent, the sample presented moderate cognitive deficit (12.5%) and visual impairment (25%).

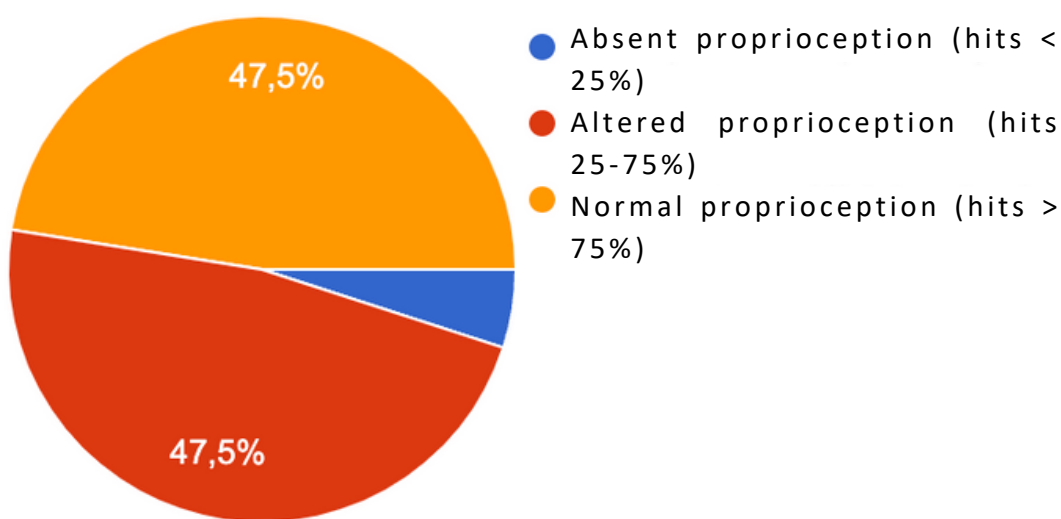
Grades of motor deficit:



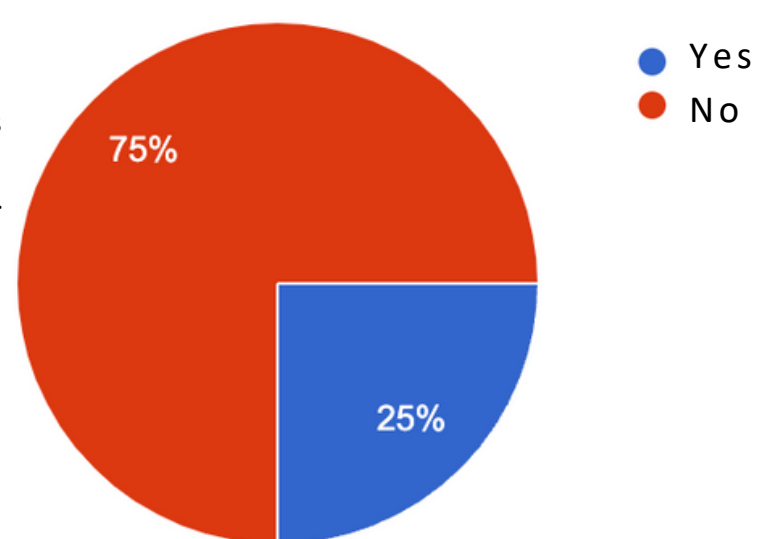
Grades of cognitive impairment:



Grades of proprioceptive deficit.



Presence of visual impairment:



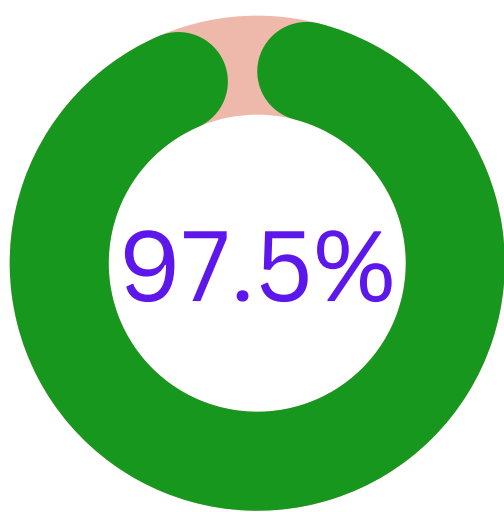
After a neurological injury or disease, it is common the presence of impairments in different functional systems with varying degrees of severity. In the majority of the study participants, some degree of motor deficit or weakness in the upper extremity was present (90%), with severity ranging from severe (15%) to moderate (45%) and mild (30%). Sensory alterations added to the motor deficit are also common in neurological conditions, in this sample nearly half of the individuals exhibited sensory alterations in the upper limb (52.5%). Other evaluated functional systems showed concurrent cognitive alterations of moderate degree (12.5%) and visual impairments (25%) due to neurological causes, such as homonymous hemianopsia, diplopia, or visuospatial hemineglect, and ocular alterations such as myopia and/or astigmatism. Rehabilitation plays a significant role in facilitating functional recovery and community participation of individuals with functional disabilities. The decision to offer rehabilitation or not is crucial in terms of health, social, and economic effects. (Noe et al., 2021)

# Product Data: Relevant Results Report

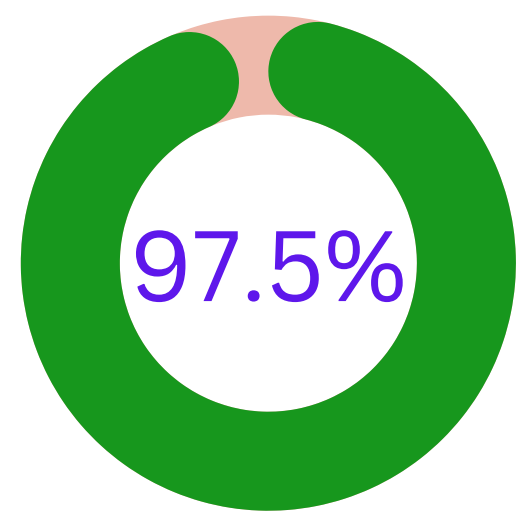
## ACCEPTABILITY FOR NEUROREHABILITATION

Favorable opinions have been obtained in the 4 key features provided by KINESIX VR. The 97.5% of users state that the system is easy to implement and provides additional value to usual neurorehabilitation. The 92.5% of users ensure that the training session with KINESIX VR is more motivating than the usual rehab session and 85% support the reduced need for assistance from the therapist.

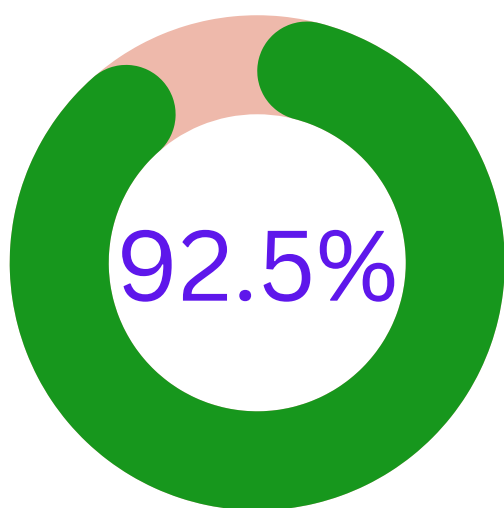
PROVIDES ADDITIONAL VALUE



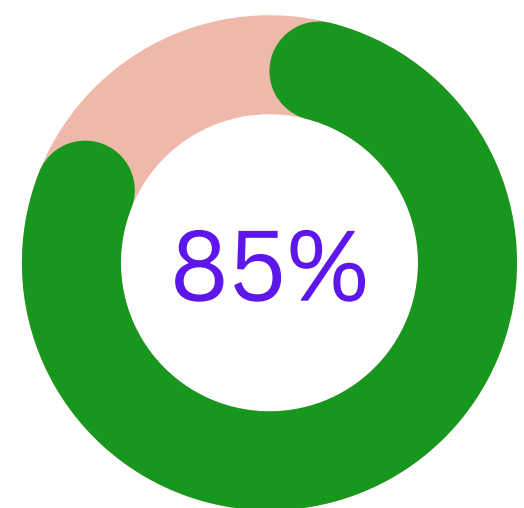
EASY INTEGRATION TO RHB



MORE MOTIVATING THAN THE USUAL RHB



REQUIRED LESS THERAPIST ASSISTANCE THAN THE USUAL RHB



(+) POSITIVE

STRONGLY AGREE

AGREE

NEUTRAL

(-) NEGATIVE

DISAGREE

STRONGLY DISAGREE

In order to measure the level of acceptance of implementing this technology in different neurorehabilitation centers and units, 4 statements were proposed on which users indicated on a Likert scale (1= Strongly disagree to 5= Strongly agree) the level of disagreement or agreement regarding them. The statements were related to 4 key features provided by KINESIX VR, described as: "This system provides additional value to my usual rehabilitation", "It's easy for this system to integrate into my usual rehabilitation", "The rehabilitation session with the system was more motivating than the experience with usual rehabilitation", and "The rehabilitation session with the system required less therapist assistance than the experience with usual rehabilitation". Favorable values have been obtained in all 4 relevant aspects, with 97.5% of users positively affirming that the system is easy to implement and adds value to usual neurorehabilitation. The 92.5% of participants agree that the training session with KINESIX VR is more motivating than usual treatment, and 85% of users support the lower need for rehabilitation therapist assistance.

# Product Data: Relevant Results Report

## SYSTEM USABILITY

Different characteristics that contribute to the perception of usefulness of KINESIX VR have been described, including being entertaining, motivating, providing a better sense of movement, offering greater feedback, and requiring active motor effort, among others.

### DESCRIPTIVE ANALISYS

#### **If you do, why do you think this treatment will be useful for your rehabilitation?**

- *"Because it's enjoyable, entertaining, and motivating".*
- *"Because I feel like I move my arm more easily".*
- *"By using it, I can move my arm better than I thought I could".*
- *"Because it integrates my arm".*
- *"Because it's useful for instability".*
- *"Because it's innovative and different".*
- *"Because I believe it will help me improve".*
- *"Because it provides more feedback".*
- *"Because it requires effort from my upper limb".*
- *"Because I'm standing with a new experience".*
- *"Because it can help with the mobility of my arm".*
- *"Because it can be done at home".*



In order to understand the different opinions of the participants about the perceived usefulness of KINESIX VR, they were allowed to respond openly to the question: "If you do, why do you think this treatment will be useful for your rehabilitation?" A list was compiled with the responses provided, which were copied textually, and in cases of duplication, they were grouped into one suitable phrase. Different key characteristics that contribute to the perception of usefulness of the system have been described, such as: entertaining, motivating, better sense of movement, more feedback, demand for motor effort, among others.

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## Usability of the System

The efficacy of KINESIX VR for performing motor training in an enjoyable and successful way is 84.5%, the efficiency for performing exercises clearly and controlled is 83%, and the user satisfaction for training without discomfort and with a sense of therapeutic usefulness is 90%.

### ENJOYMENT LEVEL



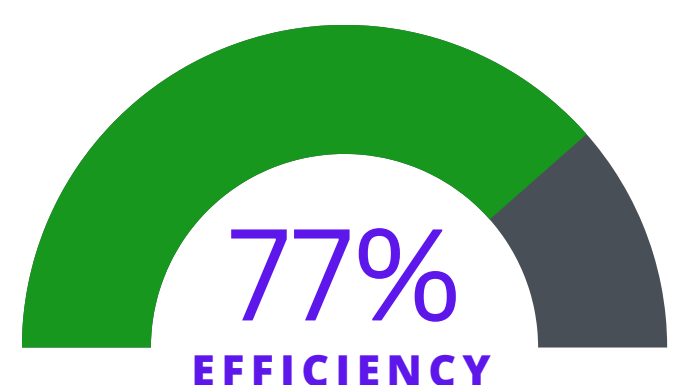
### SENSE OF SUCCESS



### INFORMATION CLEARNESS



### CONTROL CAPACITY



### NO DISCOMFORT



### THERAPEUTIC USEFULNESS



#### Likert scale:

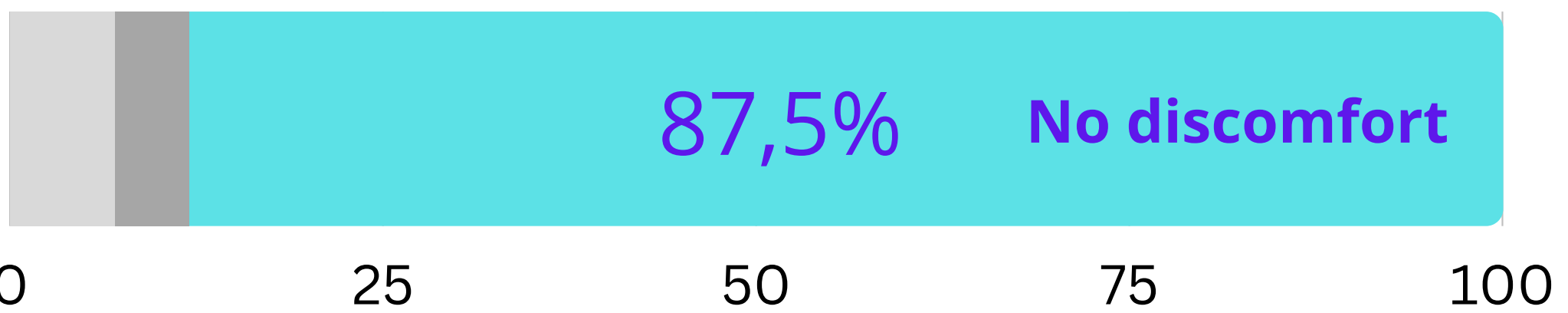
5 - Very much (100%) to 1 - Not at all (0%)

Usability is a quality that assesses the degree to which a system can be used to achieve specific goals with efficacy, efficiency and satisfaction. In this case, it was evaluated using the User Satisfaction Evaluation Questionnaire (USEQ), designed and validated to measure the usability of virtual rehabilitation systems (Gil-Gómez et al., 2017). The questionnaire measures, on a Likert scale (1=Not at all to 5=Very much), the participant's opinion on 6 important attributes of the user experience. The results for the level of enjoyment were a mean [SD] of 4.33 [0.94], for the sense of success = 4.08 [0.83], clarity of information = 4.45 [0.68], control capacity = 3.85 [1.10], discomfort = 1.35 [0.77], and perception of usefulness for rehabilitation 4.33 [0.86]. Total mean satisfaction = 85.63% [5.63].

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## SAFETY AND TOLERANCE

KINESIX VR is a safe and tolerable system for people with different neurological conditions, showing low presence of cybersickness (12.5%) and zero cases of premature dropouts, compared to systematic review from other current-generation systems with cybersickness presence between 60-95% and premature dropouts between 6-12.9%.



### SEVERITY

### TYPE

### DURATION

Mild discomfort	3 cases	3 Dizziness	10-30 seg (2) / 30seg-1min. (1)
Moderate discomfort	2 cases	1 Blurred vision	<10 seg.
		1 Headache	1-5 min.

To supervise the safety and tolerance of KINESIX VR, the presence or absence of adverse effects (AEs) during and/or after its use was monitored. Participants reported the type of AE related to the use of the system, the severity of discomfort (no, mild, moderate, severe, or extreme discomfort), and its duration in minutes or seconds. Five cases of AE have been reported, of which one was a sensation of blurry vision with mild discomfort and a duration of <10 seconds; one case of headache with moderate discomfort and a duration of 1-5 minutes; three sensations of dizziness, two with mild discomfort and a duration of 10-30 seconds, and one with moderate discomfort and a duration of 30 seconds to 1 minute. Evidence from a systematic review evaluating AEs presence in current-generation VR systems indicates that 60-95% of users experience some level of cybersickness (dizziness, nausea, or headache during or after virtual reality immersion), while 6-12.9% of participants prematurely dropouts their exposure. Only 12.5% of KINESIX VR users experienced cybersickness, and 0% prematurely ended their training.

(Caserman et al., 2021)

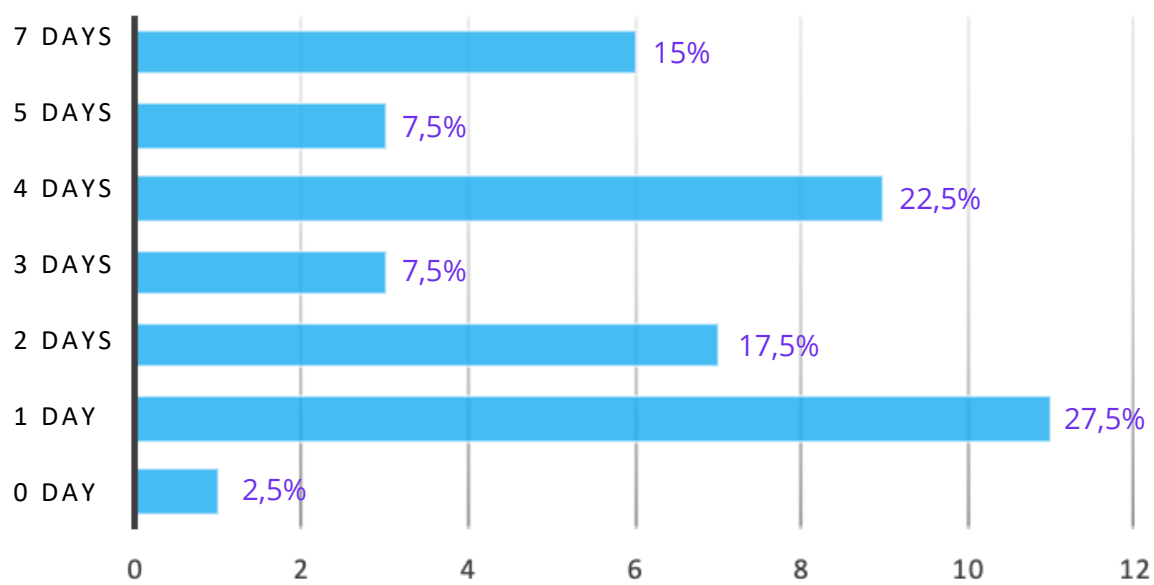
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## SERVICE MANAGEMENT

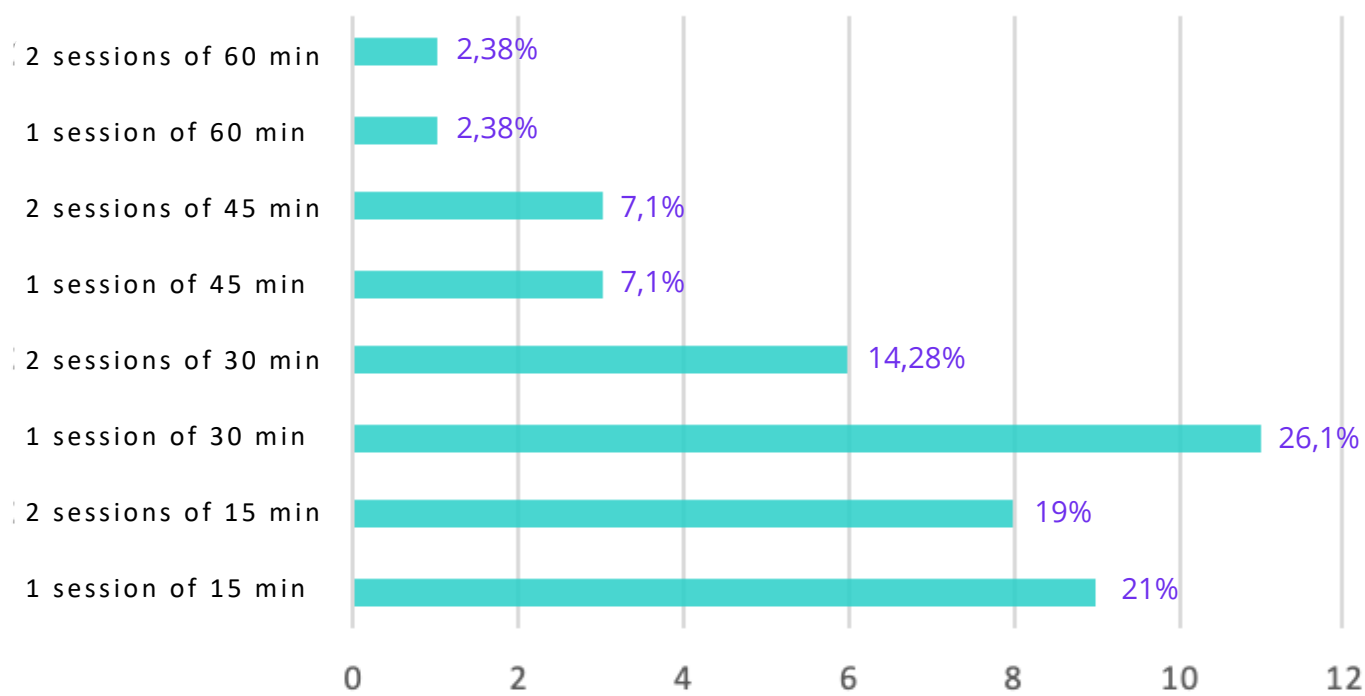
There is a good disposition to complementarily increase the dosage of motor training with KINESIX VR, optimizing the insufficient average of 32 movement reps per conventional upper limb rehabilitation session. It also allows for spaced practice, which counteracts the suppression of repetitive training.

### TRAINING DOSE PREFERENCES

Amount of days per week



Number of sessions and daily time



User preferences have been reported regarding the weekly frequency of training with KINESIX VR, the number of daily sessions, and the duration of each session.

The most reported weekly training frequencies were 1 and 4 days per week, however the answers were heterogeneous without a clear preference. On the other hand, the daily training time tended to be 1 or 2 short sessions (30 or 15 minutes) over longer ones (45 or 60 minutes). KINESIX VR not only allows additional motor training dosage increase, a key aspect for functional recovery and neuronal activity reorganization; but also, permit spaced practice, which means that training can be structured temporally to include periods of rest between repetitions or sessions, facilitating motivation and personalized motor learning enhancement. Spaced practice may counteract the suppressive effect of repetitive training, nullifying the priming or first exposure of the stimulus.

(Maier et al., 2019; Kimberley et al.,2010)

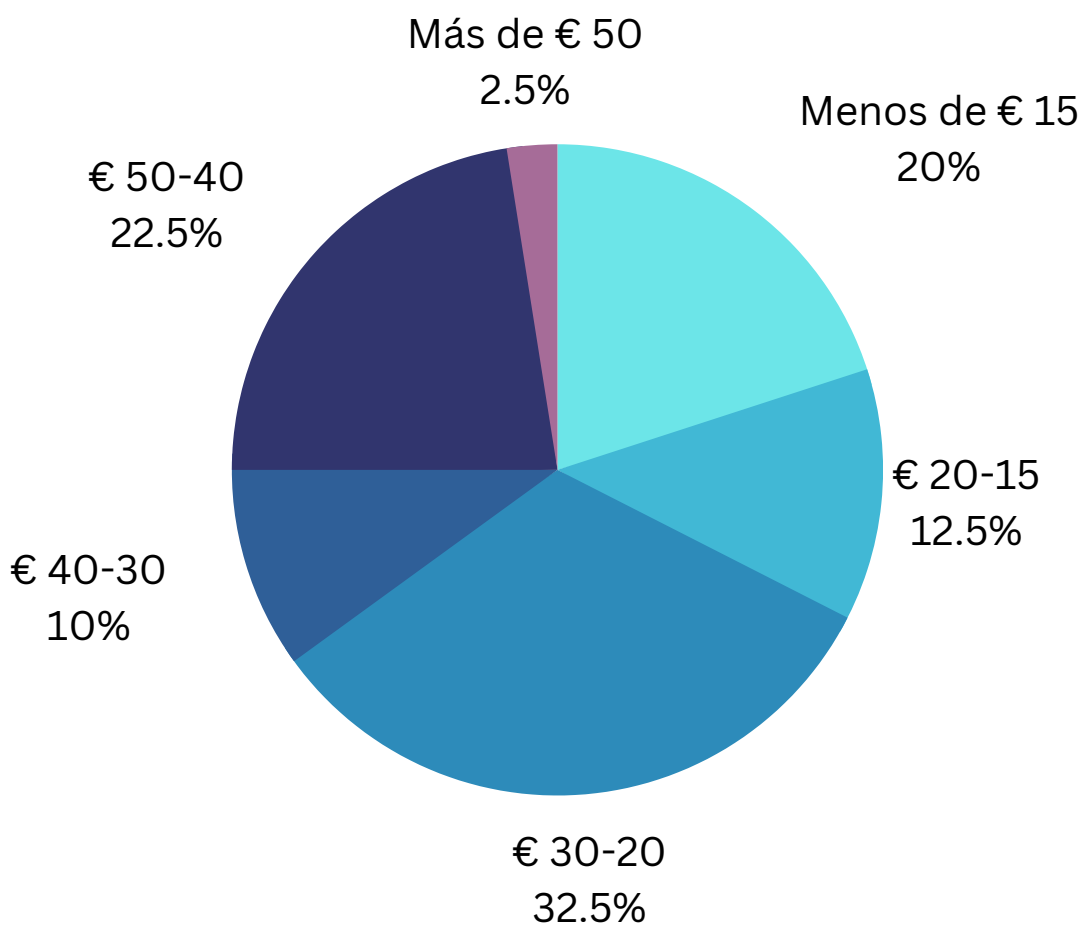


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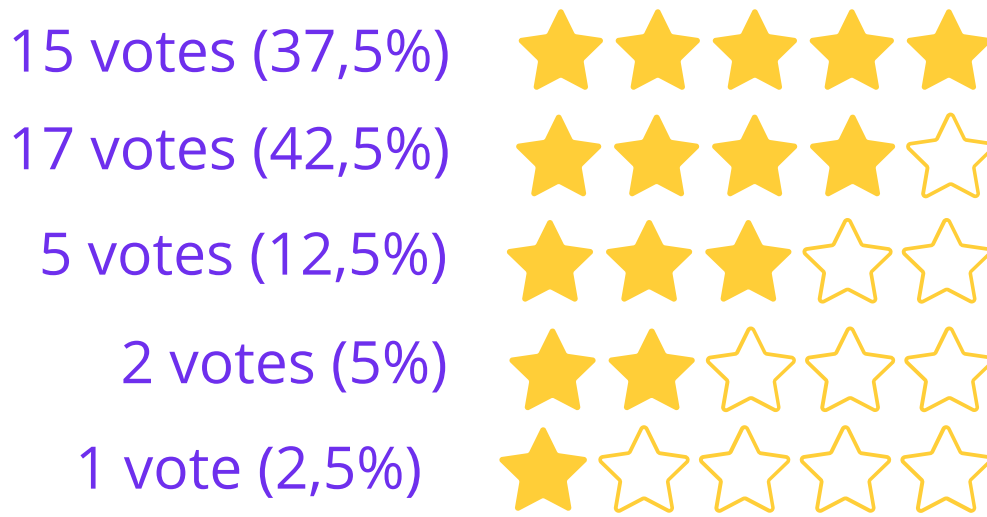
## SERVICE MANAGEMENT

The willingness to pay for a KINESIX VR session was favorable. Most of the price ranges voted were below usual rehab session price (€50). The most voted price range (32%) was €30-20. The general qualitative feedback for KINESIX VR is positively high, indicating that a good service and product is provided.

### WILLING TO PAY PER SESSION



### 5-STAR RATING



On average, one conventional rehabilitation session costs €50. Considering this background and in order to determine the willingness to pay for one session of rehabilitation with KINESIX VR, participants were asked how much they would be willing to pay for such a session. The willingness to pay was favorable and the majority of the price ranges voted were below conventional rehabilitation session price. The responses for price ranges were heterogeneous among the participants, with the most voted range (32%) being €30-20.

Finally, to determine the overall rating of KINESIX VR, a 5-star quality rating system was used, which values product and service from 1 to 5, where 5 is the highest qualitative rating. 80% of the responses fell between 5 and 4, indicating that a good service and product is provided.