ÇUKUROVA UNIVERSITY
INSTITUTE OF NATURAL AND APPLIED SCIENCES

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Erkan ÖDEMİŞ

DEVELOPMENT OF A MULTIMODAL PARTICIPATION ASSESSMENT SYSTEM FOR UPPER LIMB REHABILITATION

DEPARTMENT OF ELECTRICAL AND ELECTRONICS ENGINEERING

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ABSTRACT

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In conventional and robotic rehabilitation, the patient's active participation in exercises is crucial for maximum functional output to be received from therapy. In rehabilitation exercises performed with robotic devices, the difficulty levels of therapy tasks and the device assistance are adjusted based on the patient's therapy performance to improve active participation. However, the existing therapy performance evaluation methods are based on either some specific device designs or certain therapy tasks, which limits their widespread use. Hence, there is a requirement to develop an independent performance measurement system. In this thesis, a patient performance evaluation method is proposed based on a multimodal sensor fusion formed by the trajectory tracking error signal and the patient's physiological responses (heart rate and skin conductance) during the upper extremity rehabilitation. The novelty of the system is assessing the patient's performance independently from any device designs or therapy tasks. The developed system also evaluates the patient's tiredness level and slacking, which are substantial factors affecting the therapy performance. The designed system is tested with healthy subjects and clinically with frozen shoulder syndrome patients. The experimental results showed that the proposed system evaluates subjects' participation successfully and adjusts the therapy tasks and difficulty levels of tasks according to subjects' performance and tiredness.

Key Words: Rehabilitation Patient Performance, Therapy Participation Assessment, Multimodal Sensor Fusion, Fuzzy Inference System

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Konvansiyonel ve robotik rehabilitasyonda, terapiden alınan maksimum fonksiyonel çıktıları elde etmek için hastanın egzersizlere aktif katılımı çok önemlidir. Robotik cihazlarla gerçekleştirilen rehabilitasyon egzersizlerinde, aktif katılımı artırmak için terapi görevlerinin zorluk seviyeleri ve cihaz yardımı hastanın terapi performansına göre ayarlanmaktadır. Bununla birlikte, mevcut terapi performans değerlendirme yöntemleri, yaygın kullanımlarını azaltan bazı spesifik cihaz tasarımlarına veya belirli terapi görevlerine dayanmaktadır. Bu nedenle, bağımsız bir performans ölçüm sistemi geliştirmeye ihtiyaç vardır. Bu tezde, üst ekstremite rehabilitasyonu sırasında yörünge izleme hata sinyali ve hastanın fizyolojik sinyalleri (nabız ve deri iletkenliği) tarafından oluşturulan çok modlu bir sensör füzyonuna dayalı olarak hasta performansını değerlendiren bir yöntemi önerilmiştir. Sistemin yeniliği, hastanın performansını herhangi bir cihaz tasarımından veya terapi görevinden bağımsız olarak değerlendirebilmesidir. Geliştirilen sistem, ayrıca terapi performansını etkileyen önemli faktörler olan hastanın yorgunluk seviyesi ve kaytarma durumlarını da değerlendirmektedir. Tasarlanan sistem sağlıklı deneklerle ve klinik olarak donuk omuz sendromu hastalarıyla test edilmiştir. Deneysel sonuçlar, önerilen sistemin deneklerin katılımını başarılı bir şekilde değerlendirdiğini ve terapi görevlerini ve görevlerin zorluk seviyelerini deneklerin performansına ve yorgunluğuna göre ayarladığını göstermiştir.

Anahtar Kelimeler: Rehabilitasyon Hasta Performansı, Terapi Katılımı Değerlendirmesi, Çok Modlu Sensör Füzyonu, Bulanık Karar Verme Sistemi

EXTENDED SUMMARY

Neuromuscular disorders due to reasons such as stroke and Spinal Cord Injury (SCI) limit the ability of patients to perform the activities of daily living (ADL). The recovery process after neuromuscular disorders is complicated, and details of the process are not entirely understood yet. However, over the last decades, with the advent of new brain imaging technologies, researchers have revealed a basic understanding of the factors that affect motor control functions and neural plasticity. Based on the searches, active ingredients that need to be found in therapy for increasing recovery can be grouped under three topics; a) challenging therapy, b) progressive and optimal adaptation, and c) patient motivation and active participation.

Physiotherapy and rehabilitation are widely used methods for treating patients with neuromuscular disorders. In conventional therapy, rehabilitation exercises are performed with therapists. Still, this method has some disadvantages, such as insufficient time spent with each patient or performance reduction of therapists in exercises due to overloading. On the other hand, performing exercises with robotic devices has appeared as a new approach to overcoming the disadvantages of conventional rehabilitation and obtaining active components of the therapy.

Rehabilitation robotics is one possible solution to provide challenging, progressive, and adapted therapy by changing the device assistance or task difficulty. Moreover, robotic devices can provide intensity by increasing the number of repetitions that a therapist could impose, as well as motivation with some task-specific exercises like virtual reality and gaming.

In robotic rehabilitation, the patient's active participation in the exercises is a crucial factor. With the active and voluntary participation of the patients in the exercises, maximum functional outputs and improved neural plasticity could be obtained from robotic rehabilitation. In the rehabilitation exercises with robotic

devices, the Assist-as-Needed (AAN) paradigm has emerged to ensure patients' active and voluntary participation. In the AAN approach, the robotic assistance provided to patients is determined based on the patient's performance. Also, therapy tasks and their difficulty levels are adjusted according to the patient's performance to ensure the exercises are challenging enough for the patient. In the AAN strategies, robotic assistance is applied when the patients diverge from reference trajectories or cannot complete the desired therapy tasks. Thereby, it is aimed to enable patients to participate more actively in the therapy exercises and to prevent passive training therapies that do not give much functional output.

The core of the AAN strategies is the patient performance evaluation method, which is the base for determining the robotic assistance provided to the patient and adjusting the therapy tasks. In the literature, different methods have been implemented for patient performance evaluation. However, the existing methods in the literature are based on either some specific device designs or some certain therapy tasks. Also, some performance evaluation methods neglect the patient's changing motor capabilities during the exercises.

To solve the problems mentioned above regarding the existing therapy performance evaluation methods, in this thesis, a new performance assessment method is proposed that evaluates patients' changing capacities and participation in therapy using physiological responses (Heart Rate (HR) and skin conductance) and exercise profiles. Physiological responses are good indicators for evaluating the patients' physical activities during the rehabilitation exercises. In particular, research over the past decade has shown that combining HR and skin conduction (or galvanic skin response (GSR)) signals would be a powerful method for estimating a person's physical and mental workload during virtual rehabilitation tasks. These studies reveal that heart rate signals and skin electrical conductivity are increased with high physical activity and decreased with reduced physical effort during the therapy exercises. Therefore, skin conductance and heart rate

signals are used in the proposed method for evaluating the patient's physical effort and voluntary participation in the therapy exercises.

The novelty of the designed approach is evaluating patient performance independently from any therapy tasks or the rehabilitation device designs. Moreover, the patients' tiredness and slacking during exercises are assessed by integrating multimodal sensor fusion, fuzzy response estimation, and therapy task management module. For ensuring the exercises are challenging enough for the patients, the proposed method adjusts the therapy tasks and the difficulty levels of the tasks according to the patient's performance and tiredness during the therapy process.

The developed method can be considered a complex system comprising five main parts; multimodal sensory subsystem, upper limb kinematic module, Patient Response Estimator Subsystem (PRES), therapy task management module, and Graphical User Interface (GUI). In the multimodal sensory subsystem, the patient's physiological responses and the upper arm joint angles are measured via sensors. The upper limb kinematic module estimates the arm movement of the patient by using the joint angles measured by BNO055 IMU sensors. In the PRES, the patient's therapy performance and status (tiredness and slacking) are assessed based on the physiological responses and exercise profile. The therapy task management module adjusts the therapy tasks and task difficulty levels based on patient responses. For rehabilitation exercises and interaction with the patient, a MATLAB® Graphical User Interface (GUI) is operated.

During the rehabilitation exercises, patient physiological responses are measured via HR and GSR sensors. For determining the trajectory tracking error signal, the desired therapy task is compared to the end-effector position of the patient obtained using the upper limb kinematic module. The PRES evaluates the patient's therapy performance, tiredness, and slacking based on the physiological responses and trajectory tracking error signals using a Fuzzy Inference System

(FIS). The therapy task management module adjusts therapy tasks and difficulty levels based on the PRES's outputs.

The developed system's effectiveness was tested experimentally with healthy subjects on five therapy tasks. Also, additional experiments were performed with healthy subjects for different cases while measuring the subjects' surface Electromyogram (sEMG) signals. After completion of the experiments with healthy subjects, the efficacy of the proposed participation assessment method was tested on patients with frozen shoulder symptoms in a clinical environment. In the clinical study, the patients' progress during the therapy was evaluated with clinical measurements and scales and compared with the performance evaluations of the system.

Results of experiments with healthy subjects have shown that the system evaluates subject performance successfully and adjusts the difficulty levels of therapy tasks according to the subjects' performance & voluntary engagement. The developed system has also thoroughly assessed the tiredness and slacking of the subjects during the rehabilitation exercises. In addition, clinical findings revealed that the progress and improvement of the patients during the therapy period, which was evaluated with clinical measurements and scales, coincided with the weekly changes in the system's performance evaluations and the weekly changes in the patients' exercise levels.

The proposed method offers a low-cost solution for the performance assessments of the patients during the rehabilitation exercises, and it is suitable for use in-home and clinical treatment environments. The proposed system also could be implemented for performance evaluation in conventional therapy and sports exercises.

GENİŞLETİLMİŞ ÖZET

İnme ve Omurilik Yaralanması (OY) gibi nedenlere bağlı nöromüsküler bozukluklar, hastaların günlük yaşam aktivitelerini (GYA) yerine getirme becerilerini kısıtlar. Nöromüsküler rahatsızlıklardan sonra iyileşme süreci karmaşıktır ve sürecin detayları henüz tam olarak anlaşılamamıştır. Bununla birlikte, son yıllarda yeni beyin görüntüleme teknolojilerinin ortaya çıkmasıyla birlikte, araştırmacılar, motor kontrol fonksiyonlarını ve nöral plastisiteyi etkileyen faktörler hakkında temel bir anlayış ortaya çıkarmıştır. Yapılan araştırmalara göre iyileşmeyi arttırmak için terapide bulunması gereken temel faktörler üç başlık altında toplanabilir; a) zorlayıcı terapi, b) gelişme ve optimal adaptasyon ve c) hasta motivasyonu ve aktif katılımı.

Fizyoterapi ve rehabilitasyon, nöromüsküler bozukluğu olan hastaların tedavisinde yaygın olarak kullanılan yöntemlerdir. Konvansiyonel terapide rehabilitasyon egzersizleri terapistler eşliğinde gerçekleştirilir. Bununla birlikte bu yöntemin, her hastayla yeterince zaman ayırılamaması veya terapistlerin aşırı iş yükü nedeniyle egzersizlerde performansının düşmesi gibi bazı dezavantajları vardır. Öte yandan, egzersizlerin robotik cihazlarla yapılması, geleneksel rehabilitasyonun dezavantajlarının üstesinden gelmek ve terapinin aktif bileşenlerini elde etmek için yeni bir yaklaşım olarak ortaya çıkmıştır.

Rehabilitasyon robotiği, cihaz yardımını veya görev zorluğunu değiştirerek zorlayıcı, ilerleyici ve uyarlanmış terapi sağlamak için olası bir çözümdür. Ayrıca robotik cihazlar, bir terapistin uygulayabileceği tekrar sayısını artırarak yoğunluk ile sanal gerçeklik ve oyun oynama gibi terapi görevine özgü bazı alıştırmalarla motivasyon sağlayabilir.

Robotik rehabilitasyonda hastanın egzersizlere aktif katılımı çok önemli bir faktördür. Hastaların egzersizlere aktif ve gönüllü katılımı ile robotik rehabilitasyondan maksimum fonksiyonel çıktılar ve gelişmiş nöral plastisite elde edilebilir. Robotik cihazlarla yapılan rehabilitasyon egzersizlerinde, hastaların aktif

ve gönüllü katılımını sağlamak için Gerektiği Kadar Yardım (GKY) paradigması ortaya çıkmıştır. GKY yaklaşımında hastalara sağlanan robotik yardım, hastanın performansına göre belirlenir. Ayrıca, egzersizlerin hasta için yeterince zorlayıcı olmasını sağlamak için terapi görevleri ve zorluk seviyeleri hastanın performansına göre ayarlanır. GKY stratejilerinde, hastalar referans yörüngelerden saptığında veya istenen terapi görevlerini tamamlayamadığında robotik yardım uygulanır. Böylece hastaların terapi egzersizlerine daha aktif katılımını sağlamak ve fazla fonksiyonel çıktı elde edilemeyen pasif terapi egzersizlerinin önüne geçmek amaçlanmaktadır.

GKY stratejilerinin özü, hastaya sağlanan robotik yardımın belirlenmesi ve terapi görevlerinin ayarlanması için temel oluşturan hasta performans değerlendirme yöntemidir. Literatürde hasta performans değerlendirmesi için farklı yöntemler uygulanmaktadır. Bununla birlikte, literatürdeki mevcut yöntemler bazı özel cihaz tasarımlarına ya da bazı belirli terapi görevlerine dayanmaktadır. Ayrıca bazı performans değerlendirme yöntemleri, hastanın egzersizler sırasında değişen motor kapasitelerini ihmal eder.

Mevcut terapi performansı değerlendirme yöntemleri ile ilgili yukarıda belirtilen sorunları çözmek amacıyla, bu tez çalışmasında, hastaların değişen kapasitelerini ve tedaviye katılımlarını fizyolojik sinyaller (Kalp Atış Hızı (KAH) ve deri iletkenliği) ve hasta egzersiz profillerini kullanarak değerlendiren yeni bir performans değerlendirme yöntemi önerilmiştir. Fizyolojik sinyaller, rehabilitasyon egzersizleri sırasında hastaların fiziksel aktivitelerini değerlendirmek için iyi göstergelerdir. Özellikle son on yılda yapılan araştırmalar, KAH ve deri iletkenliği (veya galvanik cilt yanıtı (GCY)) sinyallerini birlikte değerlendirmenin, sanal rehabilitasyon görevleri sırasında bir kişinin fiziksel ve zihinsel iş yükünü tahmin etmek için güçlü bir yöntem olacağını göstermiştir. Bu çalışmalar, terapi egzersizleri sırasında yüksek fiziksel aktivite ile kalp atış hızı ve cilt elektriksel iletkenliği sinyallerinin arttığını ve fiziksel eforun azalmasıyla bu sinyallerin azaldığını ortaya koymaktadır. Bu nedenle, önerilen yöntemde hastanın fiziksel

eforunu ve terapi egzersizlerine gönüllü katılımını değerlendirmek için deri iletkenliği ve kalp atış hızı sinyalleri kullanılır.

Geliştirilen yaklaşımın yeniliği, hasta performansını herhangi bir terapi görevinden veya rehabilitasyon cihazı tasarımlarından bağımsız olarak değerlendirmesidir. Ayrıca, multimodal sensör füzyonu, bulanık yanıt tahmini ve terapi görev yönetimi modülü entegre edilerek hastaların egzersizler sırasındaki yorgunluk ve kaytarmalarını değerlendirilir. Egzersizlerin hastalar için yeterince zorlayıcı olmasını sağlamak amacıyla önerilen yöntem, terapi görevlerini ve görevlerin zorluk derecelerini hastanın terapi sürecindeki performansına ve yorgunluğuna göre ayarlar.

Geliştirilen yöntem beş ana bölümden oluşan karmaşık bir sistem olarak değerlendirilebilir; multimodal algılama alt sistem, üst ekstremite kinematik modülü, Hasta Yanıt Tahmincisi Alt Sistemi (HYTAS), terapi görev yönetimi modülü ve Grafiksel Kullanıcı Arayüzü (GKA). Multimodal algılama alt sistemde, hastanın fizyolojik sinyalleri ve kol eklem açıları sensörler aracılığıyla ölçülür. Üst ekstremite kinematik modülü, BNO055 IMU sensörleri tarafından ölçülen eklem açılarını kullanarak hastanın kol hareketini tahmin eder. HYTAS'da hastanın terapi performansı ve durumu (yorgunluk ve kaytarma), fizyolojik sinyaller ve egzersiz profiline göre değerlendirilir. Terapi görev yönetimi modülü, hasta yanıtlarına dayalı olarak terapi görevlerini ve görevlerin zorluk seviyelerini ayarlar. Rehabilitasyon egzersizleri ve hasta ile etkileşim için bir MATLAB® Grafiksel Kullanıcı Arayüzü (GKA) kullanılmıştır.

Rehabilitasyon egzersizleri sırasında hastanın fizyolojik tepkileri KAH ve GCY sensörleri ile ölçülür. Yörünge izleme hata sinyalini belirlemek için, istenen terapi görevi, hastanın üst ekstremite kinematik modülü kullanılarak elde edilen uç işlevci pozisyonuyla karşılaştırılır. HYTAS, bir Bulanık Karar Verme Sistemi (BKVS) kullanarak fizyolojik tepkilere ve yörünge izleme hata sinyallerine dayalı olarak hastanın terapi performansını, yorgunluğunu ve gevşemesini değerlendirir.

Terapi görev yönetimi modülü, HYTAS'ın çıktılarına dayalı olarak terapi görevlerini ve zorluk seviyelerini ayarlar.

Geliştirilen sistemin etkinliği, sağlıklı deneklerle beş terapi görevinde deneysel olarak test edilmiştir. Ayrıca yüzey Elektromiyogram (yEMG) sinyalleri ölçülürken sağlıklı deneklerle farklı durumlar için ek deneyler yapılmıştır. Sağlıklı deneklerle gerçekleştirilen deneylerin tamamlanmasının ardından, önerilen katılım değerlendirme yönteminin etkinliği, klinik ortamda donuk omuz semptomları olan hastalarda test edilmiştir. Klinik çalışmada, hastaların terapi süresince gösterdikleri ilerlemeler, klinik ölçümler ve ölçeklerle değerlendirilmiş ve sistemin performans değerlendirme verileriyle karşılaştırılmıştır.

Sağlıklı deneklerle yapılan deneylerin sonuçları, sistemin denek performansını başarılı bir şekilde değerlendirdiğini ve deneklerin performansına ve gönüllü katılımına göre terapi görevlerinin zorluk seviyelerini ayarladığını göstermiştir. Geliştirilen sistem, deneklerin rehabilitasyon egzersizleri sırasındaki yorgunluk ve gevşemelerini de kapsamlı bir şekilde değerlendirmiştir. Ayrıca klinik bulgular, klinik ölçümler ve ölçeklerle değerlendirilen terapi süresi boyunca hastaların ilerleme ve iyileşmelerinin, sistemin performans değerlendirme verilerinin ve hastaların egzersiz seviyelerinin haftalık değişimleri ile örtüştüğünü ortaya koymuştur.

Önerilen yöntem, hastaların rehabilitasyon egzersizleri sırasında performans değerlendirmeleri için düşük maliyetli bir çözüm sunmaktadır ve evde yada klinik tedavi ortamlarında kullanıma uygundur. Ayrıca bu sistem, geleneksel terapi ve spor egzersizlerinde performans değerlendirmesi için de uygulanabilir.

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LIST OF ABBREVIATIONS

AAN	: Assist-As-Needed
ADL	: Activities of Daily Living
BMI	: Body Mass Index
BMI	: Brain-Machine Interface
BT	: Bilateral Training
CIMT	: Constraint-Induced Movement Therapy
CoA	: Centre of The Area
DH	: Denavit-Hartenberg
DOF	: Degrees of Freedom
EDA	: Electrodermal Activity
EMG	: Electromyogram
e_x, e_y, and e_z	: End-Effector Pose Relative to the X, Y, and Z Axes
FIS	: Fuzzy Inference System
FSS	: Frozen Shoulder Syndrome
GAAN	: Greedy Assist-As-Needed
GSR	: Galvanic Skin Response
GUI	: Graphical User Interface
HR	: Heart Rate
IMU	: Inertial Measurement Unit
mAAN	: minimal Assist-As-Needed
MC	: Microcontroller
MNF	: Mean Frequency
MS	: Membership
P	: Power Spectrum
PC	: Personal Computer
PD	: Proportional-Derivative

PEL	: Patient’s Exercise Level
PID	: Proportional-Integral-Derivative
PJA	: Patient’s Joint RoM Angles
PPG	: Photoplethysmography
PRES	: Patient Response Estimator Subsystem
PSA	: Patient Self-Assessment Score
qn	: Normalized Value of the Quaternion q
R	: Rotation Matrix
RBF	: Radial Basis Function
RMS	: Root Mean Square
RoM	: Range of Motion
SCI	: Spinal Cord Injury
sEMG	: Surface electromyogram
SMERL	: Sliding Mode Control with Exponential Reaching Law
SPE	: System Performance Evaluation
SPSS	: Statistical Package for the Social Sciences
ST	: Standard Therapy
ST	: Strength Model
T	: Transformation Matrix
TENS	: Transcutaneous Electrical Nerve Stimulation
TM	: Task Model
UT	: Unilateral Training
VAS	: Visual Analog Scale
VASF	: VAS for Fatigue
VASP	: VAS for Pain
x, y, and z	: Rotation Angles Relative to the X, Y, and Z Axes

1. INTRODUCTION

Stroke and Spinal Cord Injury (SCI) are some of the most common causes of neuromuscular disorders (Patek and Stewart, 2020), which severely affect the ability of patients to pursue activities of daily living (ADL). Physiotherapy and rehabilitation are widely used methods for treating patients with neuromuscular disorders. In conventional therapy, rehabilitation exercises are performed under the supervision of therapists. Still, this approach has some disadvantages, such as insufficient time being spent with the patient or reduced performance of therapists due to work overload. On the other hand, performing exercises with robotic devices has appeared as a new approach to overcoming the disadvantages of conventional rehabilitation and obtaining components that need to be found in therapy, like being challenging and ensuring patient's active participation (Conroy et al., 2019; Moucheboeuf et al., 2020; Winstein and Kay, 2015).

Rehabilitation robotics can provide challenging, progressive, and adapted therapy exercises by changing the device’s assistance or task difficulty (Gassert, 2018). However, despite its advantages over conventional therapy, some researchers are skeptical about robotic rehabilitation and demand improved robotic rehabilitation devices and enhanced interaction with the patients (Chang and Kim, 2013).

In robotic rehabilitation, the patient's active participation in the exercise is a crucial factor. With the active and voluntary participation of the patients, maximum functional output and improved neural plasticity could be obtained from robotic rehabilitation (Hogan et al., 2006; Winstein and Kay, 2015). In the rehabilitation exercises with robotic devices, to ensure patients' active and voluntary participation, the Assist-as-Needed (AAN) paradigm has emerged (Proietti et al., 2016). The core of the AAN strategies is the patient performance evaluation method, which is the basis for determining the robotic assistance provided to the patient and adjusting the difficulty level of therapy tasks.

In the literature, many different patient performance evaluation methods have been proposed (Carmichael and Liu, 2013a; Krebs et al., 2003; Leconte and Ronsse, 2016; Pehlivan et al., 2016). However, the existing methods are based on either some specific device designs (Chen et al., 2016; Pehlivan et al., 2016) or certain therapy tasks (Leconte and Ronsse, 2016; Stroppa et al., 2017). Also, some performance evaluation methods neglect the patient's changing capabilities during the exercises (Carmichael and Liu, 2013a; Krebs et al., 2003).

1.1. Thesis Objective

In this thesis, our objective is to design a new performance assessment method that evaluates patients' changing capacities and participation during the therapy using physiological responses of the patient and exercise profiles. Our aim is to eliminate the above-mentioned shortcomings of the existing methods. To reach the objective, we state the following goals:

- Assessment of patient's therapy performance independently from any therapy tasks or the rehabilitation device designs.
- Evaluation of the patient's tiredness and slacking during the exercises which are substantial factors affecting the therapy performance.
- Ensuring that the exercises are challenging enough for the patients by adjusting the therapy tasks and the tasks' difficulty levels according to the patient's performance and fatigue during therapy.

The developed method was first tested experimentally with healthy subjects on five therapy tasks. Also, additional experiments were performed with healthy subjects for different cases while measuring their surface Electromyogram (sEMG) signals to demonstrate the effectiveness of the proposed method. After completion of the experiments with healthy subjects, the efficacy of the proposed

participation assessment method was tested on patients with frozen shoulder symptoms in a clinical setting.

1.2. Contribution of Thesis

The main contributions of the proposed system are stated as follows:

- The developed system presents a low-cost solution for therapy participation assessment that can be applied in any kind of rehabilitation exercise.
- It is suitable for home-based rehabilitation applications with added improvements.
- Since the system evaluates patient performance independently from any device design, it can also be used for performance evaluation in conventional therapy and sports exercises.

1.3. Thesis Outline

The organization of the thesis is as follows;

Chapter 1 presents the importance of robotic rehabilitation and the main drawbacks of the existing patient performance evaluation methods used in the robotic rehabilitation devices briefly. This chapter also explains the main objectives and contributions of the thesis.

Chapter 2 briefly introduces the history of conventional rehabilitation and current techniques. The ingredients of successful therapy are also outlined in this chapter.

Chapter 3 expresses the classification and details of the robotic rehabilitation devices. Besides, the AAN strategies and the existing patient performance evaluation methods in robotic rehabilitation are described in this chapter in-depth.

Chapter 4 explains the overview and the subsystems of the developed patient participation estimation system in detail.

In Chapter 5, the details of the experimental procedure with healthy subjects and the testing results of the method are provided.

Chapter 6 presents the results of the clinical trials on patients with frozen shoulder symptoms and the limitations of the proposed system.

Finally, Chapter 7 summarizes the proposed approach and contributions of the system.

2. CONVENTIONAL REHABILITATION AND ACTIVE COMPONENTS OF SUCCESSFUL THERAPY

In this section, the history of conventional rehabilitation and current therapy methods are briefly mentioned. Besides, the active components of the therapy, which are crucial factors for increasing the functional outputs received from the treatment, are explained.

2.1. Conventional Rehabilitation

Physiotherapy and rehabilitation are conservative treatment methods with a long history. The first applications in this area were carried out in 460 BC, first by Hippocrates and later by Galen, using massage, manual therapy techniques, and hydrotherapy for the treatment of patients (Özden et al., 2020). Modern physiotherapy began to develop in the early 19th century when American orthopedists trained some nurses and students to perform physical training and exercises for patients with poliomyelitis who had limited physical activity. During the polio epidemic in 1916, the need for physiotherapy applications increased, and the therapy content also improved. Between 1917 and 1918, physiotherapy was applied intensively for the soldiers injured in World War I, and the treatment used in this period was accepted as "Rehabilitation Therapy" (Can, 2016).

Until the 1940s, treatments based on exercise, massage, and traction were applied in physiotherapy programs. After the 1940s, new and specialized techniques for muscle strengthening began to be developed. In the 1950s, especially in the countries affiliated with the British Royal Society, manipulative methods started to be implemented for spine and extremity joint treatment in orthopedic patients. The emergence of manipulative treatment methods in physiotherapy and their use in clinics contributed significantly to the development of physiotherapy practices (Bialosky et al., 2012).

In the later period, physiotherapists turned to rehabilitation practices not only for orthopedic patients but for other patients in rehabilitation centers as well. Different therapy applications, such as the treatment of peripheral vascular diseases and chest physiotherapy for patients with respiratory problems, were performed during this period (Can, 2016).

With the development of technology, substantial progress has been made in the field of physiotherapy towards the end of the 20th century. These days, physiotherapy and rehabilitation are defined as a conservative science that uses applications such as functional exercises, heat, cold, electrical stimulation, manipulation, and mobilization after the diagnosis for the restoration of neuro-musculoskeletal and cardiopulmonary functions (Sharma, 2012). In addition, with the help of new neuroimaging technologies, recent studies have provided a basic knowledge of the factors in the field of rehabilitation that affect the recovery process after motor dysfunctions (Hogan et al., 2006; Tennant et al., 2012; Wiener et al., 2010; Winstein and Kay, 2015).

2.2. Key Factors of Therapy in Neuromuscular Disorders

The treatment of neuromuscular disorders after stroke or SCI is a complex process. Although some parts of the treatment process are still not fully clarified, based on recent research, the main components that should be in a successful therapy can be listed as follows (Winstein and Kay, 2015):

- Challenging Therapy
- Progressive and Optimal Adaptation
- Patient Motivation and Active Participation

2.2.1. Challenging Therapy

The therapy should be challenging enough to force the patient to gain new motor skills (Winstein and Kay, 2015). Challenge and difficulty are actually two critical factors for rehabilitation. The therapy should be challenging but should not be too difficult for the patient to perform. There is considerable evidence from neuroscience researches (Abe et al., 2012; Carey et al., 2005) so that the challenge in therapy tasks is beneficial for motor skills learning.

Tasks specificity of therapy is another important factor for improving motor control functions and neural plasticity. Task-specific practice increases the active participation and motivation of the patient (Winstein and Kay, 2015). Besides, Schaefer et al. (Schaefer et al., 2013) showed that stroke patients can transfer motor skills gained from a specific task exercise to other tasks, even to dissimilar ones. The selection of daily activity-related tasks increases the functional outputs received from the therapy (Timmermans et al., 2009). Improving neural plasticity requires optimal training intensity. Intensity implies that exercises' frequency, dose, and duration are essential parameters in designing any effective task-oriented exercise program (Winstein and Kay, 2015).

2.2.2. Progressive and Optimal Adaptation

Therapy and task difficulty should be progressive and optimally adapted to the patient’s capability. On the other hand, the practice should be neither too easy nor repetitive to challenge the patient, and it should not be too difficult, or else it will cause a failure of skill acquisition (Sanger, 2004). Moreover, improving neural plasticity needs sufficient repetition that is progressive and adaptive. This suggests that repetitive exercises for solving motor problems benefit plasticity and learning. Studies show that the mere repetition of simple identical tasks within the patient's capacity will not improve neuroplasticity and learning (Plautz et al., 2000). Most well-learned goal-directed practices are exercises in which the task trajectory is changed at every trial, but the goal or endpoint remains identical (Flament et al.,

1999). These findings are similar to Bernstein's observation that "practice is repetition without repetition" (Lee et al., 1991).

The timing of therapy is another important factor for recovery. If therapy starts immediately after stroke or SCI when the patient is in the acute phase, greater impact and higher functional benefits are obtained (Murphy and Corbett, 2009).

2.2.3. Patient Motivation and Active Participation

The factors that increase the patients' motivation augment the performance of the therapy and enhance recovery (Timmermans et al., 2009; Winstein and Kay, 2015). In task-specific exercises, the selection of tasks according to the patient's daily requirements increases the patient's participation and motivation (Gassert, 2018; Timmermans et al., 2009; Winstein and Kay, 2015). Giving numerical or audible feedback to the patient about exercise performance also enhances motor learning and positively influences motivation (van Vliet and Wulf, 2006). Leaving the timing of feedback to the patient makes him feel that he has control over therapy conditions, and this increases motor skill learning. (Wulf, 2007). Patients are more likely to use their non-paretic limbs. To encourage patients to use their paretic limbs more, Constraint-Induced Movement Therapy (CIMT) has emerged as a new approach (Bonifer et al., 2005). CIMT is a specialized task-oriented training approach that restricts the movement of non-paretic limbs of the patients in order to encourage them to use their paretic limbs more. However, a superior effect of CIMT compared to other therapy approaches was not reported (Kwakkel et al., 2016).

The evidence obtained from many researches suggests that recovery requires the active participation of the patient (Gassert, 2018; Hogan et al., 2006; Winstein and Kay, 2015). Doing passive exercises without the active participation of patients does not contribute much to recovery (Hogan et al., 2006). The physical support provided to the patient during the therapy must be continuously adaptable so as to maximize active participation (Dietz and Fouad, 2014). Active

participation of the patient during the therapy can be promoted through adaptive assistance, preventing slacking of the patient, automated task difficulty adaptation, and motivating feedback (Gassert, 2018).

Performing rehabilitation exercises with robotic devices is a new approach for obtaining the active components of successful therapy (Gassert, 2018). In the next section, all therapy components mentioned above are discussed together with the robotic rehabilitation approach.

2. CONVENTIONAL REHABILITATION AND ACTIVE COMPONENTS OF SUCCESSFUL THERAPY

Erkan ÖDEMİŞ

3. ROBOTIC REHABILITATION APPROACH AND ASSISTIVE DEVICES

This section describes the general features and classification of robotic rehabilitation devices. Besides, the properties of the AAN strategy in robotic rehabilitation, which is a critical approach to obtaining the active components of the therapy, are explained. In this section, the existing patient performance assessment methods that form the basis of AAN strategies are also analyzed.

3.1. Robotic Rehabilitation Devices

Robotic rehabilitation is the use of robotic and mechanical devices to assist and enhance patients' functions and has emerged as a new approach to obtaining the active components of the successful therapy mentioned in Section 2.2 (Gassert, 2018; Volpe et al., 2001). Rehabilitation robotics is one possible solution to provide challenging, progressive, and adapted therapy by changing the assistance or task difficulty based on the patient's performance (Gassert, 2018). Moreover, robotic devices can provide intensity by increasing the number of repetitions that a therapist could impose (Lang et al., 2009), and motivation with some task-specific exercises like virtual reality and gaming (Schweighofer et al., 2012; Winstein and Kay, 2015). Robotic devices can also evaluate therapy performance better with online measurements taken from the patient (Chen et al., 2016).

Robotic rehabilitation devices can be classified according to their applied segment, such as lower limb, upper limb, or whole-body (Gopura and Kiguchi, 2009). Robotic orthoses are assistive devices attached to the body to increase the performance of the limbs in the case of partial functional losses. Robotic arm orthoses for rehabilitation belong to the upper extremity class of rehabilitation devices (Gopura et al., 2016). The robotic arm orthoses could be categorized according to mechanical designs and control methods (Gopura and Kiguchi, 2009).

In the next section, rehabilitation strategies and the control structures of robotic orthotic devices in the literature are studied in detail and classified according to three main therapy approaches for robot-mediated rehabilitation; assistance, correction, and resistance (Marchal-Crespo and Reinkensmeyer, 2009; Proietti et al., 2016). The effectiveness of the controller structures is also analyzed with respect to the active components that are required to be found in therapy.

3.2. Therapy and Control Strategies of Upper Limb Robotic Exoskeletons

The controller structure of robotic arm orthoses is one of the essential factors affecting the success of the therapy modes. In the literature, different methods were used to classify the controller structures of robotic arm orthoses. In (Gunasekara et al., 2012), controllers were classified based on input signals of the controller, such as based on human biological signals, non-biological signals, and platform-independent control methods. In (Anam and Al-Jumaily, 2012), controllers used in robotic orthotic devices were categorized into three groups model-based, hierarchy-based, and physical parameters-based control systems. In this section, controllers used in robotic orthotic devices are grouped based on therapy strategies for robotic-mediated rehabilitation; assistance, correction, and resistance, as shown in Figure 3.1 (Proietti et al., 2016).

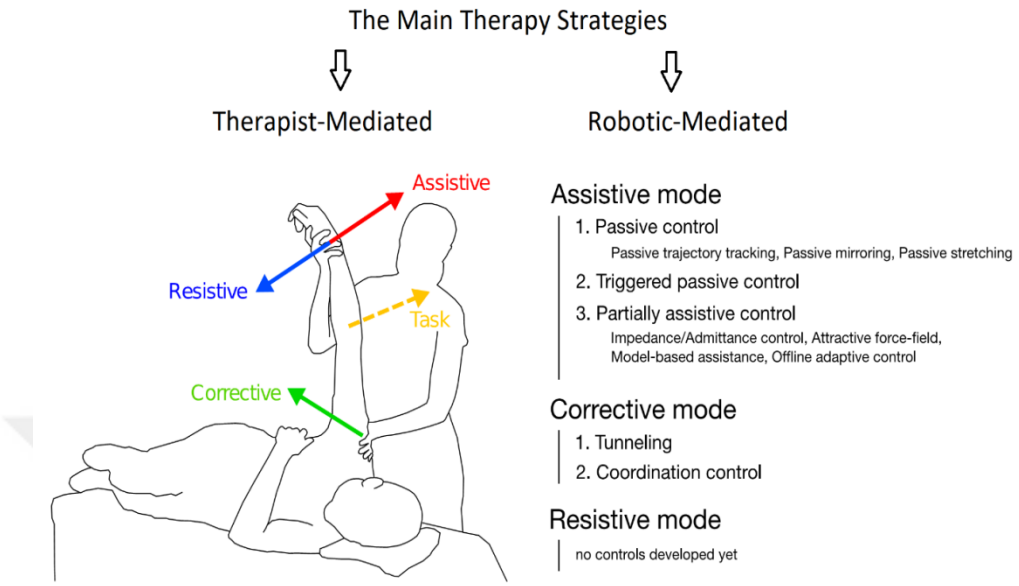

Figure 3.1. The main therapy strategies and implementations on robotic exoskeletons (Adapted from (Proietti et al., 2016))

Assistance means that the robot supports the weight of the impaired limb and provides external forces to complete the desired task. If the patient does not move their impaired limb, the task can still be completed depending on the assistance level. Correction describes the rehabilitation case where the device is only involved when the patient is not performing the task accurately by compelling the affected limb to pursue a predefined trajectory. Resistance represents the approach in which the robot applies forces opposite to the motion (like error augmentation) to make the task more complex and challenging for the patient. Thus, it is aimed to improve the motor skills of the patient and can adapt to external disruptive effects.

Current controller approaches for exoskeletons mainly involve assistive-corrective controllers, but each approach has various implementations using different controller techniques.

3.2.1. Assistive Controllers

There are three groups of strategies in assistive control approaches; passive, triggered passive, and partially assistive control (Proietti et al., 2016). The difference between passive and partially assistive controller approaches is slight. Both controllers behave similarly if the patient is not involved actively in the task. Also, in the triggered assistance approach, a different solution is usually suggested just to start the assistance. These controllers display either passive or partially assistive behaviors after the trigger occurs.

The motion of an exoskeleton can easily be controlled on a predefined trajectory with high gains and position feedback. This passive motion is widespread in rehabilitation during the acute stages of post-stroke when the patient's affected limb is generally motionless, and passive exercises are the only suitable solution for any improvements. However, controller gains must be carefully adjusted in order not to injure the patient in the high position errors due to lack of muscle capacity, spasticity, or other pathological synergies.

Passive control can be implemented using many different methods. Among these, probably the most easily applicable is the proportional-integral-derivative (PID) feedback controller, which usually adjusts the position or interaction force based on a known reference such as the trajectory or force field model (Carignan et al., 2009; Nef et al., 2007; Otten et al., 2015). Also, lately, more complicated methods have been proposed to enhance the physical interaction quality during passive motion of the patient’s limb. Rahman et al. proposed a sliding mode control with exponential reaching law (SMERL), which is a nonlinear control technique that minimizes the tracking error on state-space (Rahman et al., 2010). In another study, a fuzzy logic technique was adopted (Li et al., 2015). In this approach, adaptive fuzzy approximators predicted the dynamic uncertainties of the human-robot interactions for dealing with disturbances. In addition, an iterative learning scheme was applied to compensate for time-varying periodic disturbances arising from unmodeled system dynamics.

The triggered passive control approach relies on the user triggering the robot assistance. This technique frequently incorporates the brain-machine interface (BMI) into the control loop. In this approach, the device is generally controlled passively along predetermined trajectories after the triggering (Sakurada et al., 2013), (Chisari et al., 2012).

The efficacy of passive movements in increasing the functional output is limited since patients do not actively participate in performing therapy tasks (D. Lynch et al., 2005). In other respects, assistance is needed to decrease failure in therapy tasks and maintain patient motivation, therapy intensity, and reliance on using the affected limb. Rehabilitation devices need to allow shared control of movements with the patients when they have acquired even minimal motor skills (Hogan et al., 2006). Also, the devices should allow patients to do the movements without repressing any of their motor capability (Hogan and Krebs, 2004).

Partially assistive control strategies permit the patient to control the movement actively, also assisting them based on some performance indexes (Marchal-Crespo and Reinkensmeyer, 2009). The most common approach for providing partial assistance to the patient is to increase the compliance of the aforementioned passive controllers (Proietti et al., 2016). Impedance (Hogan, 1984) and admittance controllers are two of the most widely implemented strategies for the partially assistive approach (Frisoli et al., 2009; Krebs et al., 2003; Wen Yu et al., 2014). While the impedance control is a position feedback force controller, the admittance control is a position controller with force feedback in contrast to an impedance controller. In admittance control, the interaction forces between the patient and the exoskeleton must be measured to drive the device, and therefore the inertia and dynamic effects of the patient's impaired limb are considered. Thus, the admittance controller structures may be a more suitable solution for rehabilitation exoskeletons (Proietti et al., 2016).

In the literature, some researchers implemented impedance and admittance controllers by using more complex strategies. Frisoli et al. (2009), controlled the

exoskeleton by using two impedance controllers, one for assisting the subject through the end effector reference trajectory and the other to perform perpendicular corrections along the trajectory. Yu et al. (2011), designed a PID admittance control and lower-level linear PID control in task space. Admittance parameters were selected based on the human impedance properties. Kiguchi and Hayashi (2012), proposed a muscle-model-oriented electromyogram (EMG) - based control method for seven degrees of freedom (DOF) robotic arm orthosis SUEFUL-7. The controller consisted of input signal selection and an EMG-based impedance controller, as shown in Figure 3.2. Impedance parameters were tuned online based on the upper-limb posture and activity levels of muscles.

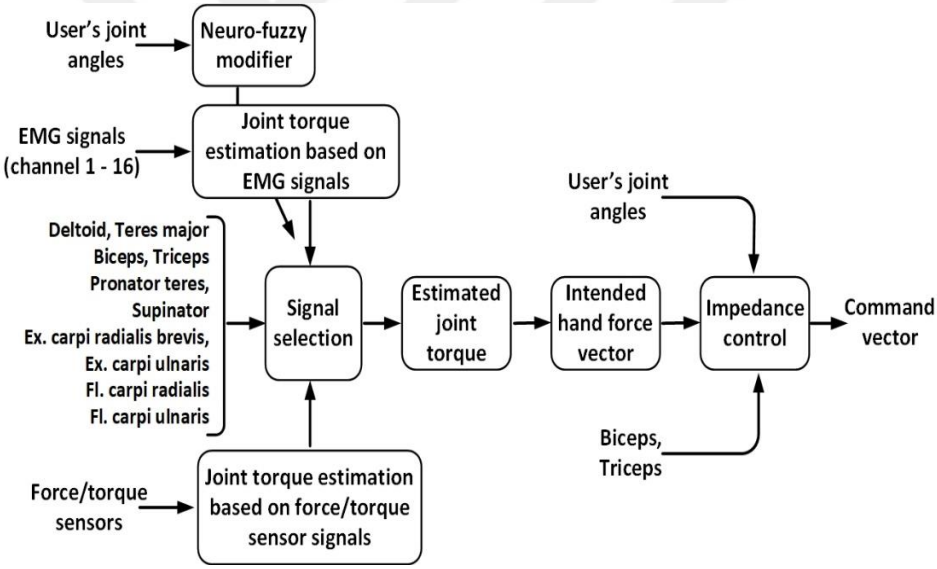

Figure 3.2. Controller structure of SUEFUL-7 orthosis (Adapted from (Kiguchi and Hayashi, 2012))

Besides the impedance and admittance control, other methods are used in the literature in assistive control strategies. These controllers could be grouped into three categories of assistance based on the attractive-force field, the human arm model, and offline adaptation (Proietti et al., 2016).

Kim et al. (2013), implemented an attractive force field to control the exoskeleton, and the controller was tested clinically with 15 participants. Patients performed bilateral training (BT), unilateral training (UT), and standard therapy (ST) exercises. In this controller approach, the changing motor capacities of patients according to the movement and movement direction have not been evaluated. Ding et al. (2008), proposed a model-based assistive control approach that estimates the muscle forces based on a motion capture system and a human musculoskeletal model. After assessing the muscle forces, the proposed controller structure changes the load of selected muscles by a power-assisting device for rehabilitation and sports training.

Using iterative approaches is another solution for determining the robotic assistance. Balasubramanian et al. (2008), implemented a control system with two layers where the outer loop controller produces the reference trajectory, and the inner loop contains an iterative learning controller in parallel to a PID feedback controller. Proietti et al. (2015), proposed an adaptive proportional-derivative (PD) controller on the joint level, in conjunction with a model-based feedforward gravity compensation that regulates the stiffness of the robotic exoskeleton. The main drawback of both approaches is that the adaptive gain parameters are updated after the task is completed. In these approaches, changing performances of patients during the therapy task is ignored.

3.2.2. Corrective Controllers

The main difference between assistive and corrective strategies is that assistive strategies can move the limb toward the therapy target if the patient is not involved in the movement, whereas corrective strategies cannot. Also, the input is usually the target trajectory with a time-dependent speed profile in assistive strategies. In corrective strategy, the desired path, which is time-independent, is selected as input. With this time-independent approach, the robotic device only corrects the current position in corrective strategies. Currently, there exist two

approaches that provide correction; tunneling and coordination control (Proietti et al., 2016).

In the tunneling approach, a virtual tunnel is created, and if the patient moves out of the tunnel during motion, feedback control takes the patient back into the channel. In (Guidali et al., 2011), a force field tunnel of cylindrical shape with an adjustable radius was implemented to assist the movement of the end-effector position in Cartesian space.

When considering corrective modes, the controller's aim is generally to arrange the coordination during the motion. As a corrective strategy, Brokaw et al. (2011), introduced a time-independent functional training algorithm. In this approach, the virtual haptic walls for each joint bring the patient closer to the ideal joint space trajectory while simultaneously acting on multiple joints' movements as a PD position controller. In (Crocher et al., 2012), principal component analysis was implemented to project tracking problems from the task trajectory space to the joint velocity space. In this study, the exoskeleton controller used velocity synergies designed to modify the coordination of active movements of the patient without restricting hand motion.

3.2.3. Resistive Controllers

The resistance mode, unlike the assist mode, aims to make the patient exert more effort by using some disruptive effects instead of assisting the patient's movement (Marchal-Crespo and Reinkensmeyer, 2009). The main approaches for the resistive controller are resistive force field and error augmentation (Marchal-Crespo and Reinkensmeyer, 2009; Proietti et al., 2016). Patton et al. (2006), have shown that amplifying the curvature error when treating patients who have a chronic stroke with a robotic force field causes subjects to move more straight, at least temporarily, when the force field is suppressed, compared with the reduction of the curvature error in the exercises. In a more complex approach, Lum et al. (2002), applied a resistive force proportional to the movement speed of the patient's

affected limb. Corrective and Resistive therapy modes are only suitable for patients with certain motor capabilities.

3.3. Adaptive AAN Control Structures and Assessment of Patient Performance

The evidence obtained from many studies suggests that recovery requires the active participation of the patient (Gassert, 2018; Hogan et al., 2006; Winstein and Kay, 2015). To ensure the patient's active participation, adaptive controllers, including the AAN paradigm, have emerged (Marchal-Crespo and Reinkensmeyer, 2009). In AAN strategies, the assistance to be applied to the patient is determined based on patient performance and participation. Adaptive AAN controllers can be categorized into three main groups (Luo et al., 2019) as performance-based (Badesa et al., 2016; Krebs et al., 2003; Leconte and Ronsse, 2016; Papaleo et al., 2013; Stroppa et al., 2017; Younis and Mounis, 2017), stiffness-based (Dos Santos and Siqueira, 2016; Ibarra et al., 2014; Perez-Ibarra et al., 2015), and model-based (Carmichael and Liu, 2013b, 2013a; Chen et al., 2016; Luo et al., 2019; Pehlivan et al., 2016; Wolbrecht et al., 2008).

The most important part of the AAN strategies is evaluating the patient's performance to determine when and how much assistance will be given to the patient. In the literature, many different patient performance and participation evaluation methods have been implemented (Carmichael and Liu, 2013a; Krebs et al., 2003; Leconte and Ronsse, 2016; Pehlivan et al., 2016). However, the existing methods have three main disadvantages:

- Dependence on specific robotic device design
- Applicability only to certain therapy tasks
- Neglecting the changing motor capabilities of the patient during a therapy task

Krebs et al. (2003), first implemented performance-based progressive robotic therapy. With this approach, patient performance was estimated based on the patient's active force and accuracy of the movement. The system's stiffness was specified by the patient's performance in the final reaching movement. Papaleo et al. (2013), proposed a patient-specific adaptive therapy for an upper limb robotic rehabilitation device, including a module for assessing patient biomechanical performance and a module for adjusting the robotic assistance, as seen in Figure 3.3. The parameters of these methods are defined as discrete values and updated when a therapy task is completed. That limits the system's adaptability and ignores the changing capabilities of patients during the exercises.

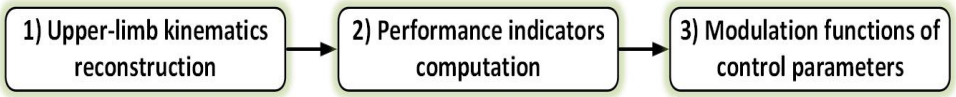

Figure 3.3. Block scheme of the module for assessing patient performance in (Papaleo et al., 2013)

Asl et al. (2020), proposed a field-based AAN scheme by building a desired velocity field around the reference trajectory and having a force field to avoid significant position errors. . In another study, Zhang et al. (2020) presented an AAN strategy that gives patients spatial freedom through a virtual channel around the predetermined exercise trajectory With these approaches, the constructed velocity field, and virtual channel are not patient-specific and can be limiting for capable patients. Some studies have used specific indices based on the performance or experimental measurements of the patient to evaluate their therapy engagement (Mounis et al., 2017; Stroppa et al., 2017). The disadvantage of these approaches is that the index calculation methods are only suitable for specific therapy tasks.

Leconte and Ronsse (2016), proposed a performance-based assistive strategy that measured the movement performance based on three features

(smoothness, velocity, and amplitude) of the patient's motion using an adaptive oscillator on rhythmic circular arm exercises. Assessing exercise performance using this approach is only appropriate for rhythmic circular therapy tasks. Lin et al. (2020), proposed an AAN strategy for wrist exercises that allows passive, active, or resistive rehabilitation. However, the parameters of this method are manually determined and are not tailored to the individual patient. Pehlivan et al. (2016), introduced a minimal assist-as-needed (mAAN) strategy that relies on patients' force estimation by using a Kalman filter. In another approach, Chen et al. (2016), used a dynamic model of the human arm and real-time measurements of the torque applied by the patient to simulate the patient's interaction forces. The main drawback of both approaches was that the estimation of the patient’s capabilities was based on the robotic devices' dynamic model. As the robotic device's mechanical structure becomes more complex, it becomes challenging to assess patient performance accurately.

Carmichael and Liu (2013a, 2013b), proposed a model-based AAN structure that estimates patient strength using a musculoskeletal model. In this approach, a Task Model (TM) calculates the force required to perform desired upper limb tasks, and a Strength Model (SM) uses the musculoskeletal model to predict the patient's strength capacity at the muscle level, as illustrated in Figure 3.4. However, the parameters of the musculoskeletal model used in this method are not tailored to the patient. To improve participants' voluntary efforts during rehabilitation exercises, Luo et al. (2019), proposed a greedy AAN scheme (GAAN) that utilizes the Gaussian radial basis function (RBF) to model patients' task performance based on average error. Patient performance depends on other factors such as tiredness, joint stability, comfort, and ability to coordinate movements (Hogan et al., 2006). Both approaches ignored these other factors.

Physiological responses (such as skin conductance, heart rate, respiration, and skin temperature) are good references for assessing a patient's physical activity and emotional state during rehabilitation exercises (Novak et al., 2011).

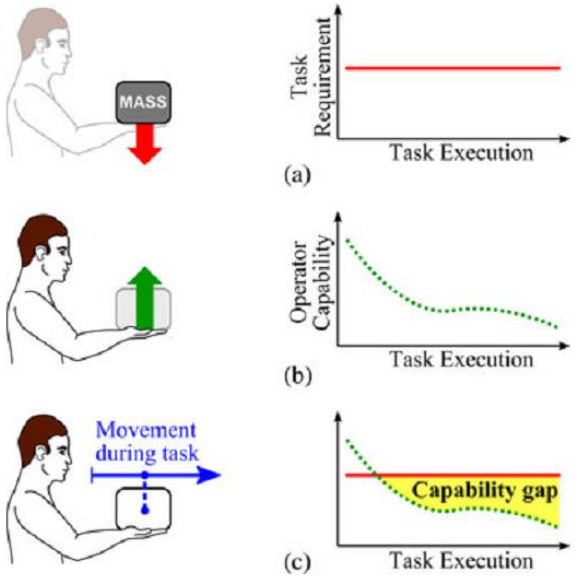

Figure 3.4. Implemented AAN strategy in (Carmichael and Liu, 2013a). (a) task model, (b) strength model, (c) required assistance

Some researchers have proposed stress level detection or emotion recognition based on physiological responses in the existing literature (Domínguez-Jiménez et al., 2020; B. Zhang et al., 2017). In another approach, some studies using physiological signals assessed patients' mental status like valence and arousal based on these signals (Badesa et al., 2016; Mihelj et al., 2009). In these studies, the researchers adjusted the therapy difficulty level according to patients' these psychological states. However, to the best of our knowledge, none of the previous research has used physiological responses to evaluate the patient's performance and therapy engagement.

Up to this point, the existing studies in the literature are summarized. The patient performance assessment methods in the current studies are based on either certain robotic device designs or specific therapy tasks. In addition, some studies neglect the changing capabilities of the patients during exercises. In order to overcome these disadvantages, a new performance evaluation system needs to be designed.

4. IMPLEMENTATION OF PARTICIPATION ASSESSMENT SYSTEM

In this thesis, in order to eliminate the shortcomings of the existing studies mentioned in the previous section, a participation assessment system was developed that evaluates the therapy performance of patients and other factors affecting the therapy performance, such as tiredness and slacking, independently from any robotic device design or therapy task. This section explains the architecture and subsystems of the developed patient participation assessment system in detail.

4.1. Architecture of Designed Participation Evaluation System

The developed method can be considered a complex system comprised of five main parts; multimodal sensory subsystem, upper limb kinematic module, Patient Response Estimator Subsystem (PRES), therapy task management module, and Graphical User Interface (GUI) (Ödemiş and Baysal, 2021). In the multimodal sensory subsystem, the patient's physiological responses (Heart Rate (HR) and skin conductance) and the upper arm joint angles are measured through sensors. The upper limb kinematic module estimates the arm movement of the subject. In the PRES, the patient's therapy performance and status (tiredness and slacking) are assessed based on the physiological responses and exercise profile. The therapy task management module adjusts the therapy tasks and task difficulty levels based on the patient's responses. For rehabilitation exercises and interaction with the patient, a MATLAB® Graphical User Interface (GUI) is operated. During the rehabilitation exercises, patient physiological responses are measured via HR and skin conductance sensors. The desired therapy task is compared to the patient's end-effector position obtained using the upper limb kinematic module to determine the trajectory tracking error signal. The PRES evaluates the patient's therapy performance, tiredness, and slacking using physiological responses and trajectory tracking error signals. Based on the PRES's outputs, the therapy task management

module adjusts therapy tasks and difficulty levels. An overview of the designed participation assessment system is given in Figure 4.1.

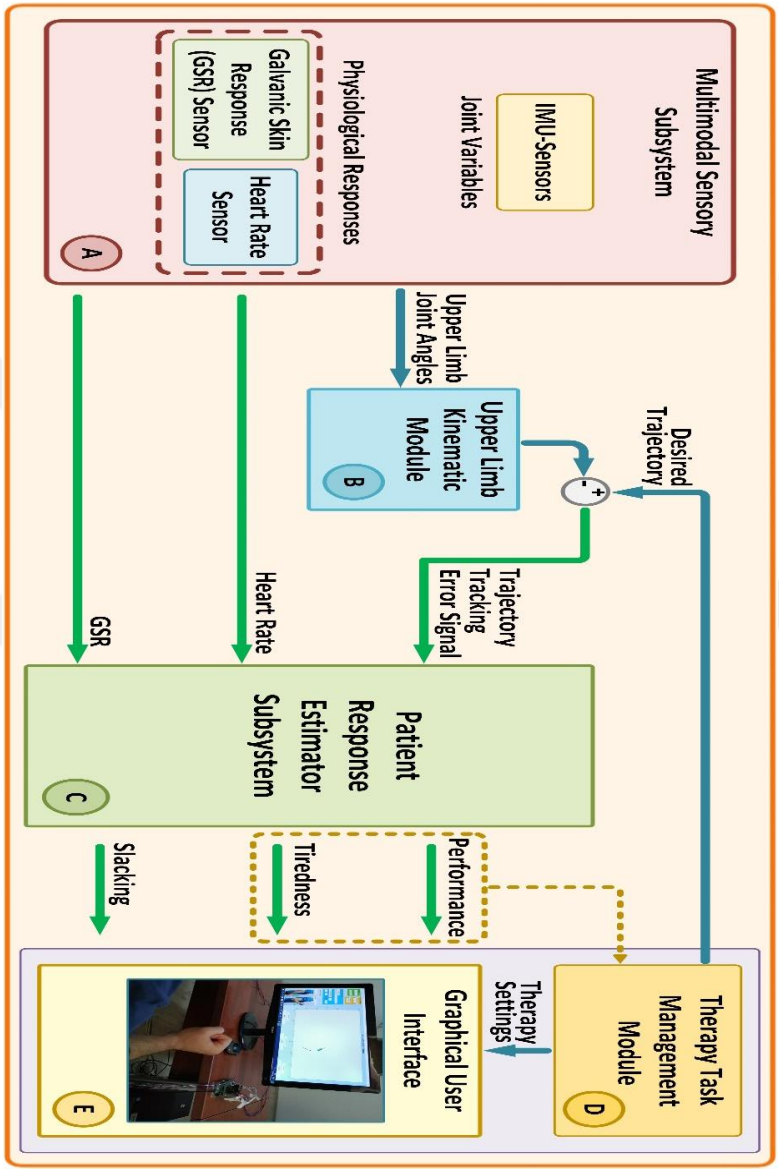

Figure 4.1. Overview of the participation assessment system. (a) Multimodal Sensory Subsystem, (b) Upper Limb Kinematic Module, (c) Patient Response Estimator Subsystem (PRES), (d) Therapy Task Management Module, (e) Graphical User Interface (GUI)

4.2. Multimodal Sensory Subsystem

In the designed structure, the multimodal sensor subsystem contains two sensory data; inertial measurement unit (IMU) sensors and physiological signals sensors, as shown in Figure 4.2. An Atmel microcontroller (MC) board is utilized in the multimodal sensory subsystem as a data acquisition board. All sensor data is transferred to the target PC via serial communication with a sampling rate of 10 Hz and processed by the MATLAB ® / Simulink model.

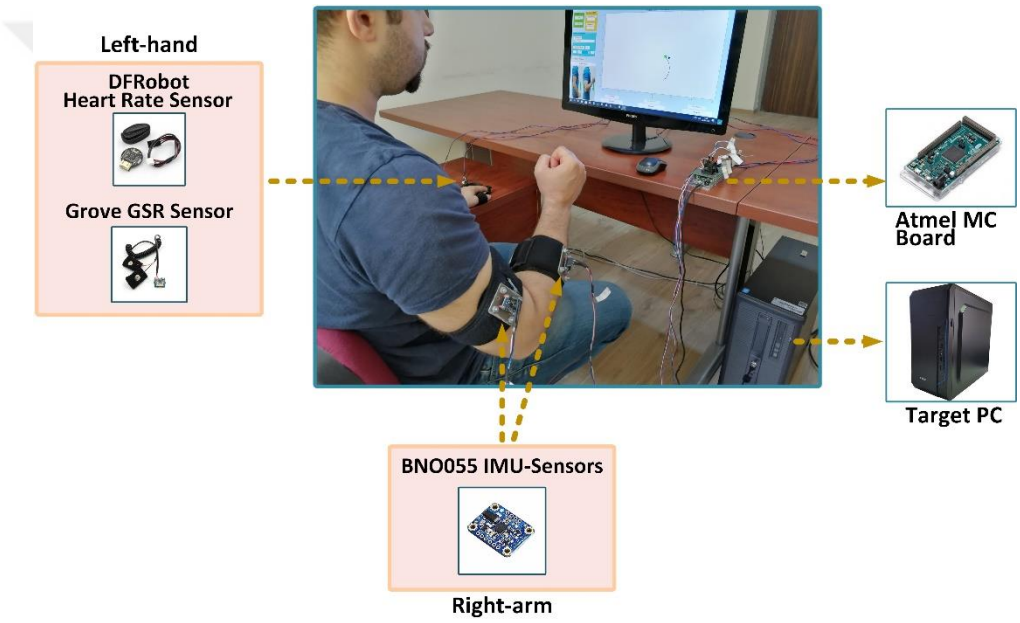

Figure 4.2. Sensors and data acquisition system

4.2.1. BNO055 IMU Sensors

For measuring the upper arm joints' angles and evaluating the desired trajectory tracking performance of the patient during therapy, two BNO055 IMU sensors are used. These sensors are mounted on the patient's upper limb using cuffs, one for the upper arm and one for the forearm, during rehabilitation exercises. The BNO055 sensor has high accuracy below one degree, and the sensor

calibration has been performed using the method specified in the sensor datasheet. (Bosch Sensortec, 2016).

BNO055 absolute orientation sensor is a 9 (nine) DOF low-cost sensor that uses sensor fusion of the accelerometer, magnetometer, and gyroscope data based on an ARM Cortex-M0 processor and provides absolute orientation information as quaternions, Euler angles, or vectors. Quaternions are four-element vectors that are used to describe any rotation in a three-dimensional coordinate system (Griffin, 2017). The quaternions are a reliable way to represent the rotation in robotics because they are compact and avoid the gimbal lock problem, which leads to a loss of degrees of freedom in the kinematic structures. A quaternion q is represented by four components (one real and three imaginaries) and can be expressed in Cartesian form as

$$q = a + ib + jc + kd \tag{4.1}$$

where a, b, c, and d are real numbers, and i, j, and k are the three orthogonal unit vectors.

The quaternion outputs of the BNO055 sensors have been transferred to the MATLAB® /Simulink model. These quaternion values have been converted to the rotation angles in the MATLAB®/Simulink environment by using Equations 4.2 - 4.5 (Diebel, 2006);

$$q_n = [\, q1, q2, q3, q4 \,] \tag{4.2}$$

$$R = \begin{bmatrix} r11 & r12 & r13 \\ r21 & r22 & r23 \\ r31 & r32 & r33 \end{bmatrix} \tag{4.3}$$

$$\left\{\begin{array}{l} x = \operatorname{asin}(r21), -\pi/2 < x < \pi/2 \\ y = \operatorname{atan}(r11, r12), -\pi < y < \pi \\ z = \operatorname{atan}(r31, r32), -\pi < z < \pi \end{array}\right\} \tag{4.4}$$

$$\left.\begin{array}{c} r11 = 2(q_2 q_4 + q_1 q_3) \\ r12 = q_1^2 - q_2^2 - q_3^2 + q_4^2 \\ r21 = -2(q_3 q_4 - q_1 q_2) \\ r31 = 2(q_2 q_3 + q_1 q_4) \\ r32 = q_1^2 - q_2^2 + q_3^2 - q_4^2 \end{array}\right\} \tag{4.5}$$

where q_n represents the normalized value of the quaternion q, R is the rotation matrix, x, y, and z are the rotation angles relative to the X, Y, and Z axes, respectively.

4.2.2. Physiological Responses

Physiological responses are good indicators for evaluating the patients' physical activities during the rehabilitation exercises (Novak et al., 2011). In particular, research over the past decade has shown that the combination of HR and skin conduction signals would be a powerful method for estimating a person's physical and mental workload during virtual rehabilitation tasks (Badesa et al., 2012; Novak et al., 2010). These studies reveal that heart rate signals and skin electrical conductivity are increased with high physical activity and decreased with reduced physical effort during the therapy exercises. Therefore, skin conductance and heart rate signals are used in the proposed method for evaluating the patient's physical effort and voluntary participation in the therapy exercises.

4.2.2.1. Heart Rate

Heart rate indicates the number of heartbeats in one minute and increases with sympathetic nervous system activity (Magder, 2012). The heart rate is measured using the DFRobot Heart Rate sensor, which uses the

photoplethysmography (PPG) technique. PPG is a non-invasive and low-cost optical technique that detects blood volume changes in tissues affected by heartbeats.

4.2.2.2. Skin Conductance

Skin conductivity (or galvanic skin response (GSR)) describes the skin's electrical conductivity, which varies with sweat gland secretion and represents sympathetic nervous system activity (Dawson et al., 2016). The sensor selected in this study for measuring the skin conductance is the Grove GSR sensor. GSR sensor calibration has been performed by the method specified in the user manual (Seeeduino, 2014). For eliminating noises, every ten sensor measurements are averaged in the embedded code, as suggested by the manufacturer.

As presented in Figure 4.3, the heart rate sensor is located on the subject's index finger, and GSR sensor electrodes are placed on the middle finger and thumb of the subject.

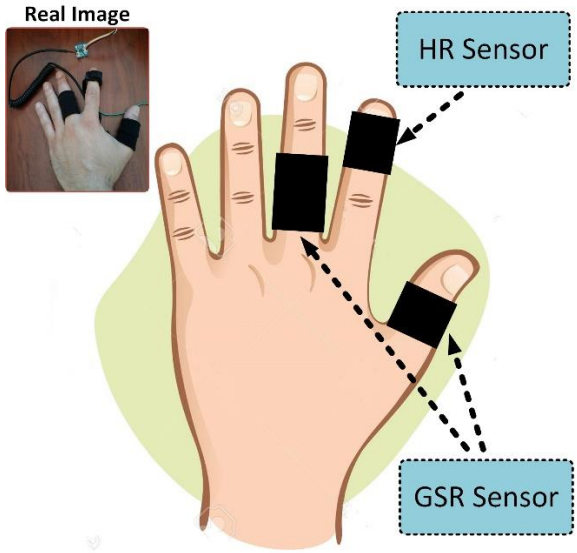

Figure 4.3. HR and GSR sensors

GSR sensor measures the microvolts between the middle finger and thumb. First, to obtain the skin conductance, human skin resistance (in ohm) has been calculated using Equation 4.6, given in the user manual. Then the human skin resistance has been converted to skin conductance.

$$Skin\ Resistance = ((1024 + 2xSensor_Reading)x10000)/(512 - Sensor_Reading) \quad (4.6)$$

4.2.2.3. Verification of Physiological Signal Sensors

Validation of the selected HR and GSR sensors was implemented using a BIOPAC® MP36 system. The BIOPAC® MP36 is a four-channel data acquisition system measuring a wide range of physiological signals like HR, GSR, and EMG (*BSL Hardware Guide*, 2021). HR and GSR signals have been measured simultaneously with selected sensors and the BIOPAC® MP36 system during the verification process. HR and GSR signals were measured on the BIOPAC® system using BIOPAC® SS4LA PPG and SS57L Electrodermal activity (EDA) transducers. HR and GSR signals measured by the selected sensors and the BIOPAC® system are given in Figure 4.4.

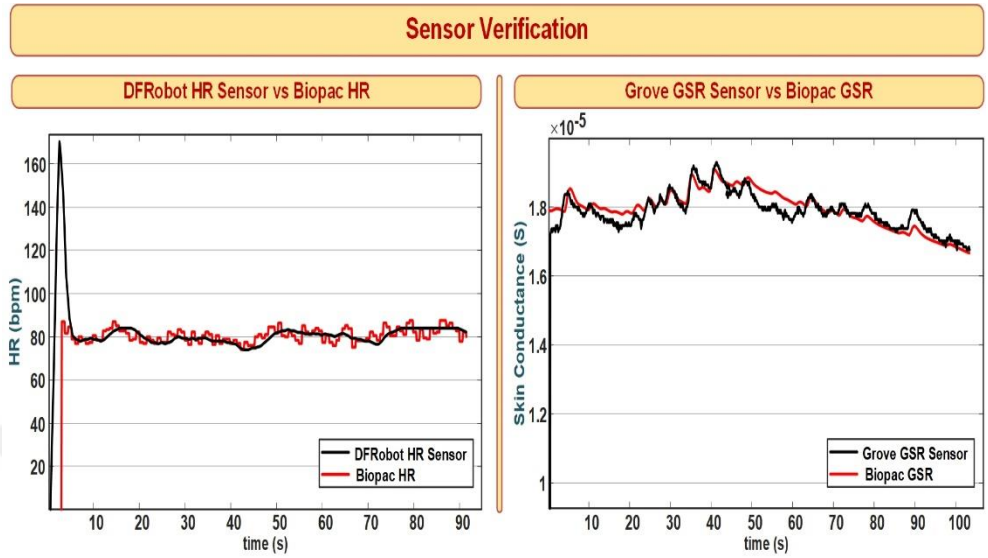

Figure 4.4. Verification of the selected HR and GSR sensors

4.3. Upper Limb Kinematic Module

A kinematic model of the human arm has been implemented to estimate the patient's arm movement during therapy exercises. The human upper limb can be represented as seven DOF mechanism, which has 3 DOF at the shoulder (flexion/extension, abduction/adduction, and internal/external rotation), two DOF at the elbow (flexion/extension and supination/pronation) and two DOF at the wrist (flexion/extension and radial/ulnar deviation). Elbow supination and wrist joints affect hand orientation and position. Therefore, the motion associated with these DOFs was neglected to estimate the human upper limb end-effector position, and a 4 DOF kinematic model that expresses the shoulder glenohumeral rotation and the elbow flexion was implemented. In the model, the end-effector represents the wrist. The human upper limb kinematic model is shown in Figure 4.5.

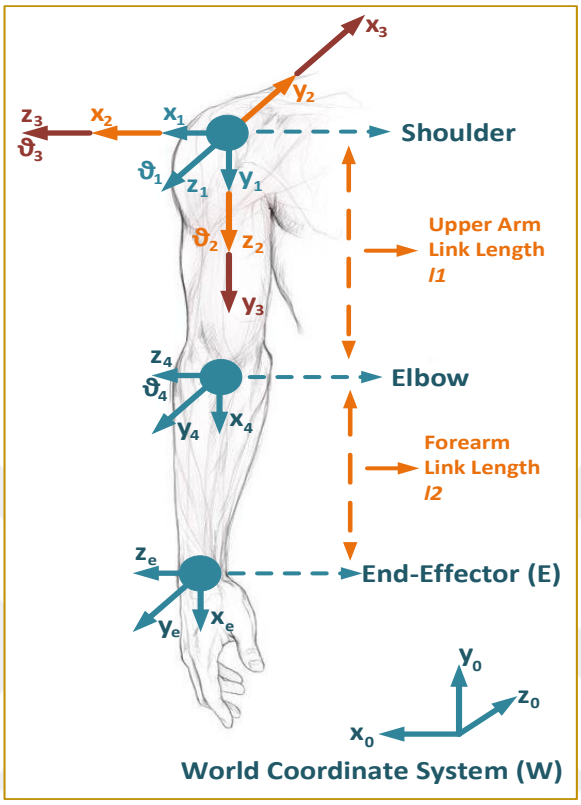

Figure 4.5. Human arm 4 DOF kinematic model

The Denavit-Hartenberg (DH) parameters of the kinematic model illustrated in Figure 4.5 are given in Table 4.1. DH parameters describe the relationship between the model's frames, and a_i is the link length, d_i shows the link offset, α_i is the link twist, and ϑ_i represents the joint angle.

Table 4.1 DH parameters of the human arm 4 DOF kinematic model

i	$\mathbf{a_i}$	$\mathbf{d_i}$	$\boldsymbol{\alpha_i}$	$\boldsymbol{\theta_i}$
1	0	0	π	0
2	0	0	-π/2	ϑ1
3	0	0	π/2	ϑ2+π/2
4	l1	0	0	ϑ3+π/2
5	l2	0	0	ϑ4

Based on DH parameters, the following arm transformation matrices have been defined.

$$ {}^{W}_{1}T = \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & -1 & 0 & 0 \\ 0 & 0 & -1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{4.7} $$

$$ {}^{1}_{2}T = \begin{bmatrix} c\vartheta 1 & 0 & -s\vartheta 1 & 0 \\ s\vartheta 1 & 0 & c\vartheta 1 & 0 \\ 0 & -1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{4.8} $$

$$ {}^{2}_{3}T = \begin{bmatrix} -s\vartheta 2 & 0 & c\vartheta 2 & 0 \\ c\vartheta 2 & 0 & s\vartheta 2 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{4.9} $$

$$ {}^{3}_{4}T = \begin{bmatrix} -s\vartheta 3 & -c\vartheta 3 & 0 & -l1s\vartheta 3 \\ c\vartheta 3 & -s\vartheta 3 & 0 & l1c\vartheta 3 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{4.10} $$

$$ {}^{4}_{E}T = \begin{bmatrix} c\vartheta 4 & -s\vartheta 4 & 0 & l2c\vartheta 4 \\ s\vartheta 4 & c\vartheta 4 & 0 & l2s\vartheta 4 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{4.11} $$

In Equations (4.7) to (4.11), $c\vartheta i$ represents the cosine of ϑi, $s\vartheta i$ represents the sine of ϑi, $l1$, and $l2$ are the upper arm and forearm link lengths, respectively. After the determination of the transformation matrices, the position and orientation of the end-effector relative to the world coordinate system have been calculated based on Equations (4.7) - (4.11),

$$ {}^{W}_{E}T = \begin{bmatrix} r11 & r12 & r13 & e_x \\ r21 & r22 & r23 & e_y \\ r31 & r32 & r33 & ez \\ 0 & 0 & 0 & 1 \end{bmatrix} = {}^{W}_{1}T\,{}^{1}_{2}T\,{}^{2}_{3}T\,{}^{3}_{4}T\,{}^{4}_{E}T \tag{4.12} $$

where e_x, e_y, and e_z are the end-effector pose relative to the X, Y, and Z axes of the world coordinate system, respectively.

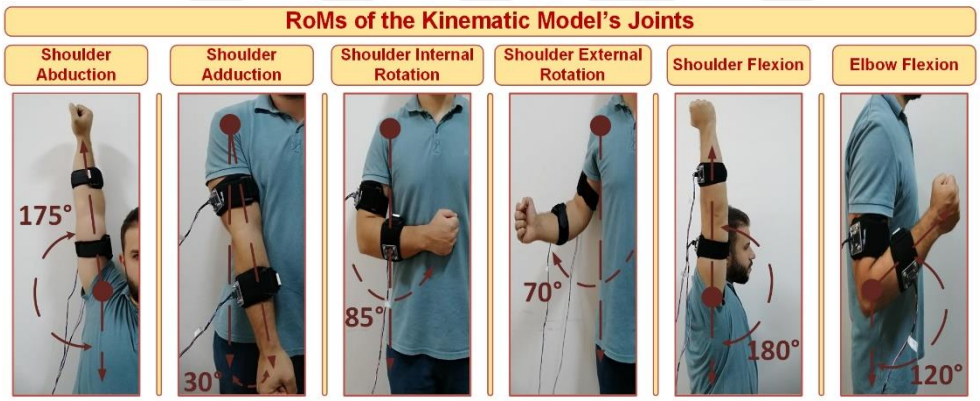

Figure 4.6. RoM values of the kinematic model joints

Table 4.2. Kinematic model joints' RoM values

Joint	Movement	RoM (°)
Shoulder	Abduction - Adduction	175 - 30
	Internal - External Rotation	85 - 70
	Flexion	180
Elbow	Flexion	120

Also, the range of motion (RoM) of the joints in the kinematic model is given in Figure 4.6 and Table 4.2. RoM values represent the angular movement range of the given joints.

4.3.1. Modeling of Human Arm Movement

During rehabilitation exercises, the patient's upper limb motion has been estimated using the implemented human arm kinematics and joint angles measured by IMU sensors, as shown in Figure 4.7. The joint angles calculated by Equation 4.4 and the implemented human arm kinematic model have been operated to estimate the human arm end-effector position for determining the trajectory tracking error signal during the exercises.

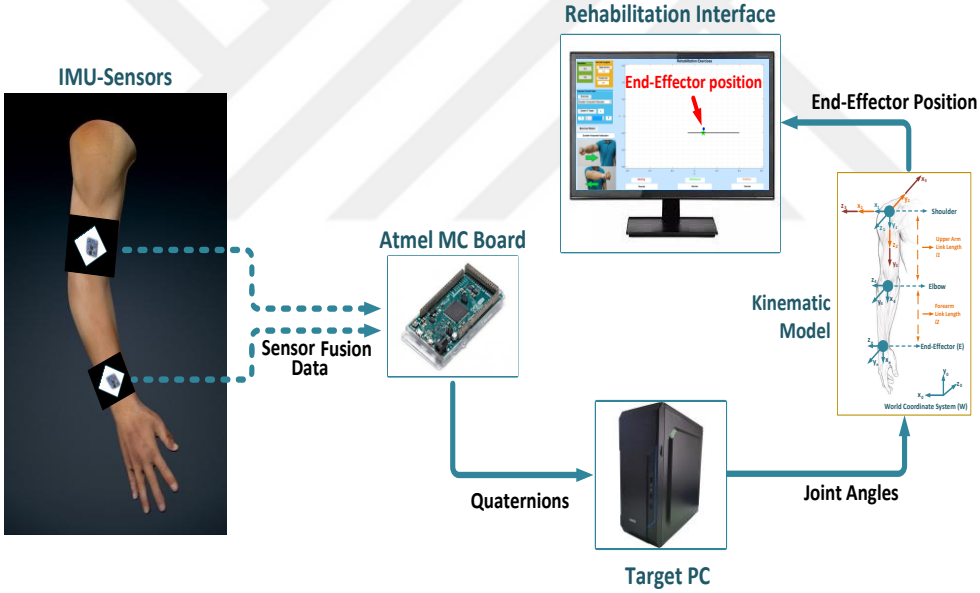

Figure 4.7. Modelling the human arm movement during the exercises

4.4. Patient Response Estimator Subsystem

PRES assesses the patient's therapy performance, tiredness, and slacking during the rehabilitation exercises using a Fuzzy Inference System (FIS) based on the fuzzy set theory. Fuzzy set theory, unlike the classical set theory, express the

partial set membership of an element as linguistic variables. In Fuzzy set theory, a fuzzy set A in the universe of discourse X is defined by (Kabir and Papadopoulos, 2018);

$$A = \{(x, \mu_A(x))\, x \in X\} \tag{4.13}$$

where $\mu_A(x)$ is a membership function and gets values between [0,1]. The value of the function $\mu_A(x)$ represents the degree of membership of x in A. The membership value of 1 means that the element is complete in set A and 0 implies that the element is not a member of set A. Additionally, values 0 to 1 represent a partial membership, where a higher value indicates a higher membership.

4.4.1. Fuzzy Inference System

The FIS is the process of mapping from a given input to an output using the fuzzy set theory and fuzzy logic (Azeem, 2012). The FIS has been applied to various problems such as robotics, control, biomechanics and has also been successfully used for medical applications. Fuzzy inference systems usually are implemented in Mamdani and Sugeno methods (Azeem, 2012). The Mamdani method was selected in this work due to its easy-to-apply intuitive structure and compatibility with human inputs (Izquierdo and Izquierdo, 2018; Sabri et al., 2013). Also, the Mamdani method can be performed with observation and following advice from physiotherapists.

The FIS contains three main units; fuzzification, decision-making, and defuzzification (Sabri et al., 2013). Fuzzification is an operation that converts an element of the discursive universe into a value belonging to a fuzzy set. The fuzzification process receives the elements $x, y \in X$ and produces the membership degrees $\mu_A(x)$, $\mu_A(y), \mu_B(x)$ and $\mu_B(y)$. The Decision-making unit performs the mapping of a given input to an output using membership functions, logical

operations, and predefined IF-THEN rules. This process maps the fuzzified inputs to the rule base and produces a fuzzified output for each rule. Defuzzification is a mathematical process used to convert fuzzy sets to real numbers. The Defuzzification unit transforms the fuzzy result of the interface into output. The defuzzification process used in this work is the centroid of the area (CoA) method, which is given in Equation 4.14.

$$CoA = \frac{\int \mu_A(x)xdx}{\int \mu_A(x)dx} \tag{4.14}$$

The proposed FIS was implemented using the Fuzzy Logic Toolbox of the MATLAB® software. The designed FIS takes the HR, GSR, the desired trajectory tracking error, and changes in these signals during the therapy exercises as inputs. The trajectory tracking error signal refers to the distance between the patient's end-effector position and the trajectory target. Because physiological signals can vary with environmental factors and individuals (Dawson et al., 2016; Magder, 2012), changes (increases or decreases) in these signals during exercise are considered in assessing patient performance and tiredness. In the proposed method, exerted physical effort by the patient during the therapy exercises is evaluated based on the changes in the HR and GSR responses. During the therapy exercises, trajectory tracking error is a driving signal for motor learning (Pehlivan et al., 2016). Therefore, to improve motor learning, we combined the trajectory tracking error signal and physiological responses to estimate the patient's performance during the therapy exercises. In the developed system, the trajectory tracking error signal changes are used for tiredness evaluation only.

The designed FIS has three outputs; *Performance*, *Tiredness*, and *Slacking*, as shown in Figure 4.8. In the figure, Δe(t), ΔHR and ΔGSR represent the changes in trajectory tracking error, HR, and GSR signals, respectively.

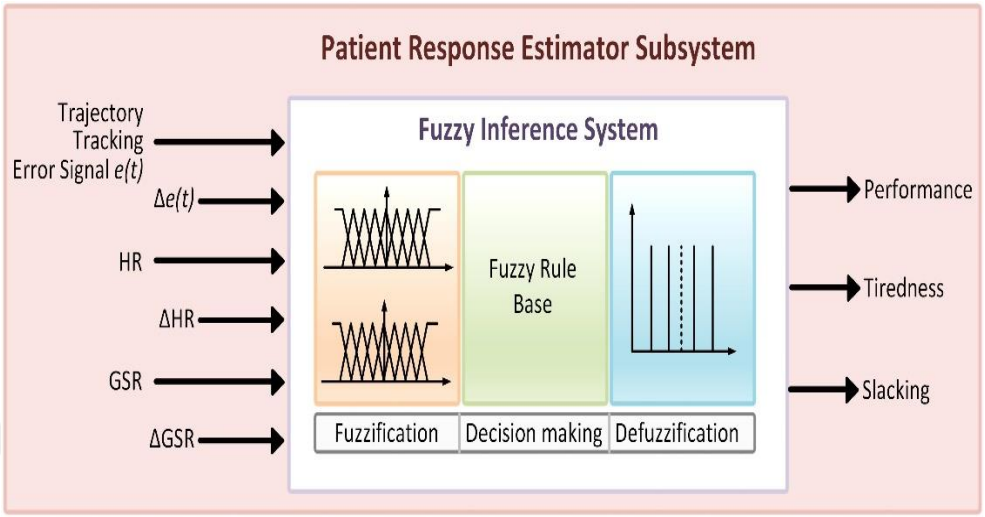

Figure 4.8. Details of the Patient Response Estimator Subsystem (PRES)

All input and output variables of the FIS are defined by membership functions $\mu_A(x)$ that can take values from “Low” to “High” and range from 0 to 1. The FIS membership function was determined experimentally and characterized based on the research in the literature (Dawson et al., 2016; Gordon et al., 2004). For determining the changes, the HR, GSR, and tracking error signals are averaged every five seconds of the simulation time and compared with their final mean values. If these signals increase or decrease, they take the "High" or "Low" value, respectively. The medium value refers to unchanged signals. The membership functions of all the inputs and outputs of the FIS are given in Figure 4.9.

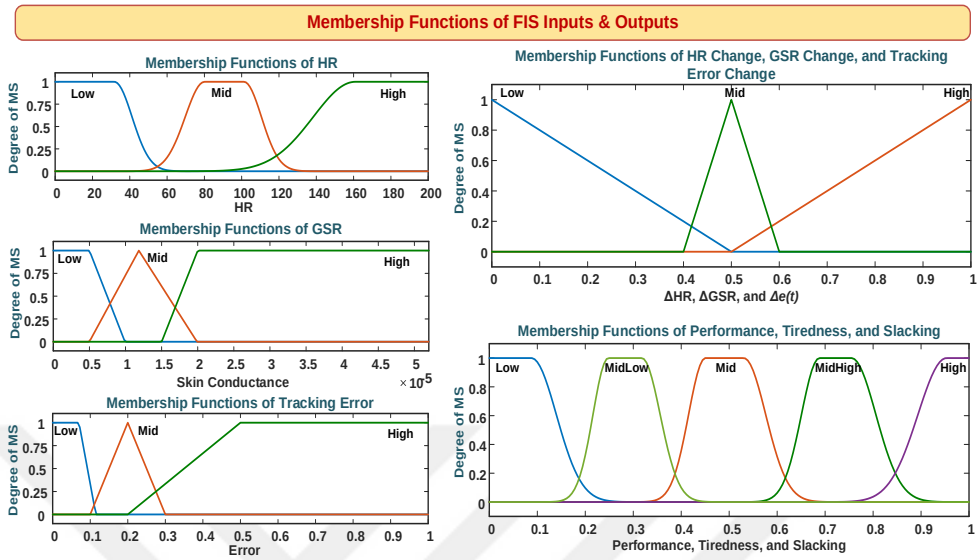

Figure 4.9. Membership (MS) functions of the inputs and outputs of the FIS

After defining the membership functions, a fuzzy rule-based module with 58 IF-THEN rules has been determined. All rules have been experimentally designed. Some examples of the rules are given in Table 4.3.

Table 4.3 Some examples of the FIS rules

IF-THEN Statements	
IF (*HR Change is High*) and (*GSR Change is High*) and (*Error is High*)	THEN (*Performance is Low*)
IF (*HR Change is Mid*) and (*GSR Change is High*) and (*Error is Mid*)	THEN (*Performance is MidLow*)
IF (*HR Change is Mid*) and (*GSR Change is Mid*) and (*Error is Mid*)	THEN (*Performance is Mid*)
IF (HR Change is Mid) and (*GSR Change is Mid*) and (Error is Low)	THEN (*Performance is MidHigh*)
IF (*HR Change is Low*) and (*GSR Change is Low*) and (*Error is Low*)	THEN (*Performance is High*)
IF (*HR is Low*) and (*GSR is Low*) and (*Error is Low*)	THEN (*Tiredness is Low*) and (*Slacking is Low*)
IF (*HR is Mid*) and (*GSR is Mid*) and (*Error is Mid*)	THEN (*Tiredness is MidLow*) and (*Slacking is Mid*)
IF (*HR is High*) and (*GSR is High*) and (*Error is High*)	THEN (*Tiredness is High*) and (*Slacking is Low*)
IF (*HR is Low*) and (*GSR is Low*) and (*Error is High*)	THEN (*Tiredness is Low*) and (*Slacking is High*)

4.4.2. Assessment of Patient Participation

4.4.2.1. Therapy Performance

As mentioned earlier, HR and GSR signals are good references for assessing patient physical activity during virtual rehabilitation tasks. Therefore, in the proposed method, performance evaluation is carried out using the tracking error signal with HR and GSR responses changes. For example, if the HR and GSR signals are decreasing and the tracking error value is "Low", this indicates that the patient has successfully performed the exercise; the exercise is not challenging enough for the patient. The performance of the patient is considered "High" for these conditions. Suppose the HR and GSR signals are increasing, and the tracking error is also high. This condition is assessed as the patient not being able to perform the exercise despite his/her effort, and the performance will be considered "Low". Patients' performance may change momentarily during exercise. These instantaneous performance variations should not be ignored. However, they can cause therapy task difficulty levels to change frequently when therapy tasks are determined based on the patient's performance. Therefore in order not to neglect the instantaneous performance variations of the patients and prevent the therapy task difficulty levels from changing too often due to these variations, the performance assessment was implemented by taking the mean of the PRES's performance output values every twenty seconds of simulation time. If the mean performance value is higher than 0.7, the therapy task's difficulty level is increased; if it is less than 0.55, it is decreased. The FIS performance output's surface view based on HR change, GSR change, and trajectory tracking error signals is given in Figure 4.10.

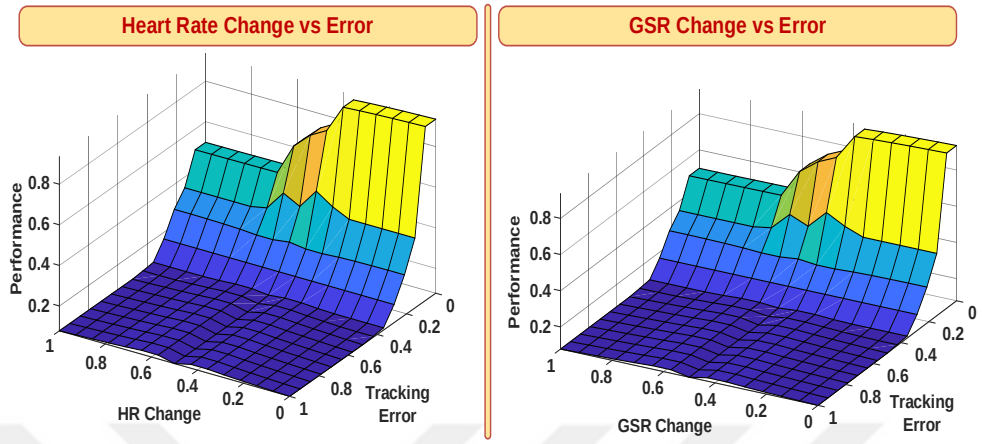

Figure 4.10. Surface view of FIS performance output

4.4.2.2. Tiredness

Patients may get tired during rehabilitation exercises, and that affects their therapy performance. When a patient does not successfully perform therapy exercises, it is essential to determine if this is due to fatigue or a lack of motor skills. For this reason, in this study, fatigue from continuous physical exertion has also been evaluated in addition to the assessment of patient performance. HR and GSR signals are accurate indicators for predicting a person's tiredness (Mohanavelu et al., 2017). Therefore, the tiredness assessment is performed based on HR, GSR, and the tracking error signal. For instance, if the patient's HR and GSR signals are high and the tracking error signal is medium, the patient's tiredness is rated as "MidHigh", if the tracking error signal is high, then the patient's fatigue level is assessed as "High". For improving the tiredness estimation, alteration of the tracking error signal was also used in the evaluation. If the patient's HR, GSR, and the trajectory tracking error signal increase, tiredness is considered "MidHigh". Tiredness assessment is performed by averaging the tiredness output values from the PRES for every ten seconds of the simulation time. The averaging operation prevents momentary changes in HR and GSR signals from affecting tiredness evaluation. If the patient's mean tiredness value is

greater than 0.7, the therapy difficulty level is reduced, independently of the performance evaluation.

4.4.2.3. Slacking

Especially during rehabilitation exercises performed with robotic devices, patients may exhibit a slacking motor control behavior that will allow robotic devices to control tasks (Wolbrecht et al., 2008). The slacking assessment is also realized in this work to detect this type of motor behavior. The slacking evaluation is achieved in a reverse manner to the tiredness assessment. If the patient's HR and GSR signals are low and the tracking error signal is high, the patient's slacking is evaluated as "High". If the estimated slacking value is greater than 0.7, a patient warning message appears on the GUI screen.

Upper and lower boundaries of the performance, tiredness, and slacking assessment, with default values of 0.7 and 0.55, have been determined experimentally. These limits can be changed using the sliders on the GUI screen to make the exercises easier or more difficult, depending on the patient's level of impairment. Algorithms performed to evaluate performance, tiredness, and slacking are shown in Figure 4.11.

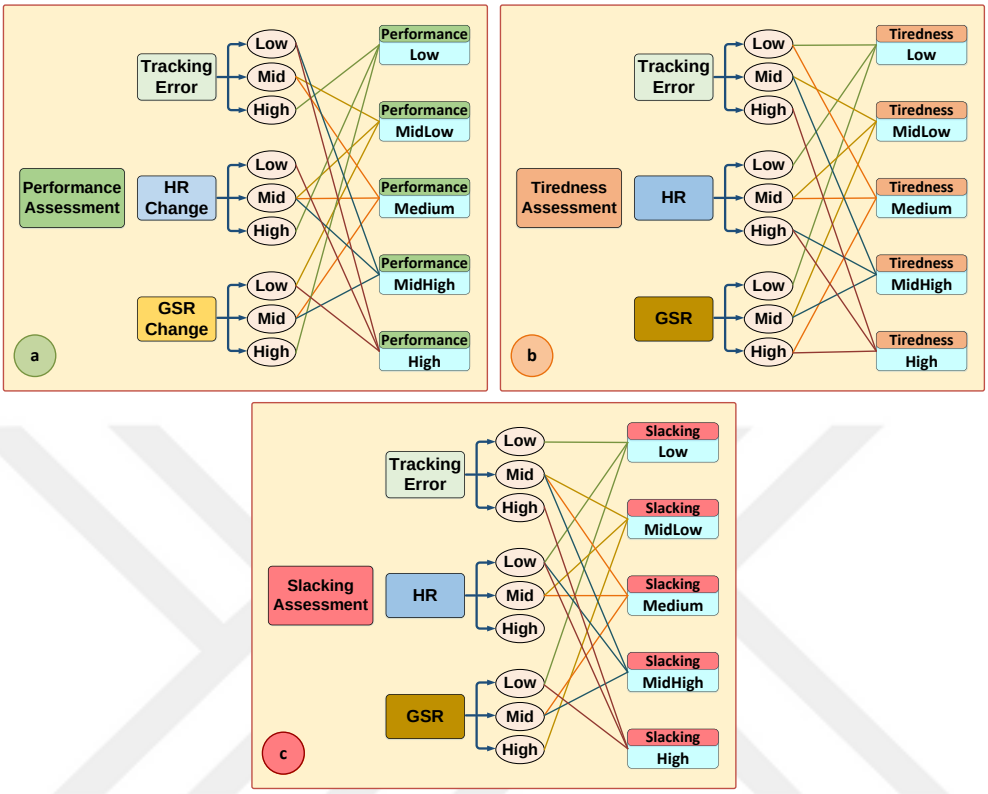

Figure 4.11. Implemented algorithms for (a) performance, (b) tiredness, and (c) slacking assessment

4.5. Therapy Task Management Module

For evaluating patient performance, an adaptive rehabilitation protocol has been designed. In the developed system, therapy tasks are specified based on the patient's participation. During the rehabilitation exercise, the therapy tasks are adjusted by the task management module according to the PRES' performance and tiredness outputs. As the rehabilitation exercises, five different well-known therapy tasks were selected; Elbow Flexion, Shoulder Scaption, Shoulder Horizontal Adduction, Forward Elevation, and Diagonal Shoulder Raise (Ellenbecker, 2006; Gibbons, 2019; O'Sullivan et al., 2014). The exercise patterns of these therapy tasks are given in Figure 4.12.

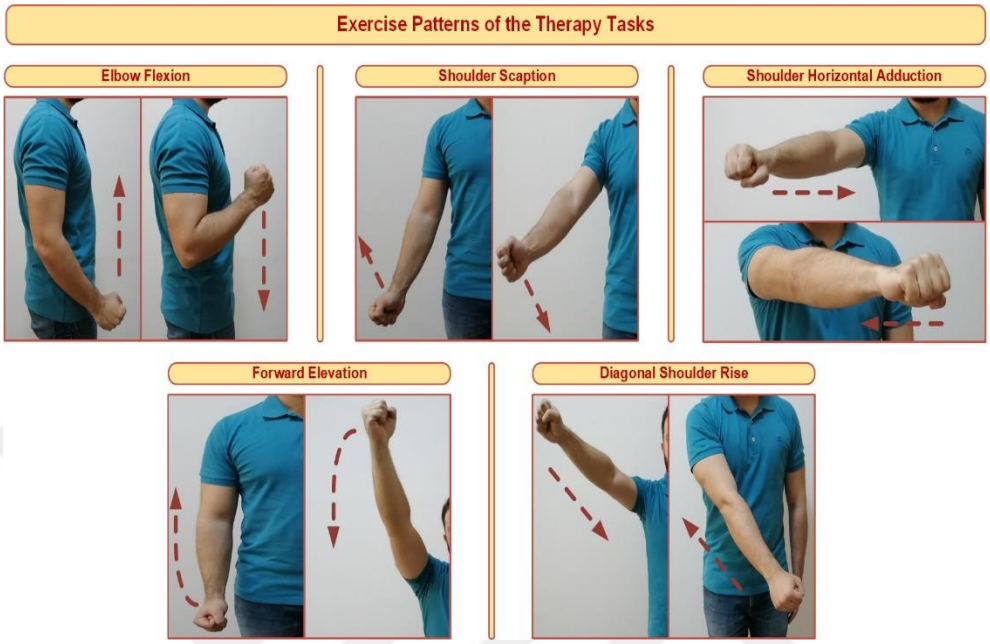

Figure 4.12. Exercise patterns of the selected therapy tasks

The selected therapy tasks are associated with ADL, like reaching, feeding, or drinking, which increases the functional outputs received from the therapy (Gassert, 2018). In the developed system, based on the patient's needs and impairment level, the required ones from these therapy tasks could be selected and implemented. Also, the affected muscles from these therapy tasks are given in Table 4.4 (Muscolino, 2017).

Table 4.4. Therapy tasks and affected muscles

Therapy Task	**Affected Muscles**
Elbow Flexion	Biceps, Brachialis, Brachioradialis
Shoulder Scaption	Deltoids, Serratus Anterior
Shoulder Horizontal Adduction	Deltoids, Pectoralis Major
Forward Elevation	Deltoids, Pectoralis Major, Coracobrachialis, Teres Major
Diagonal Shoulder Raise	Infraspinatus, Teres Minor, Upper Trapezius, Deltoids

Desired trajectories for selected therapy tasks have been experimentally determined by repeatedly performing the tasks in the designed system. The determination of the desired trajectories for Elbow Flexion and Diagonal Shoulder Rise exercises are also illustrated in Figure 4.13. In the figure, point A shows the starting point of the tasks, and point B represents the endpoint of the desired trajectories. The desired trajectory path for the patient’s end-effector has been given on a parallel to the frontal plane of the patient.

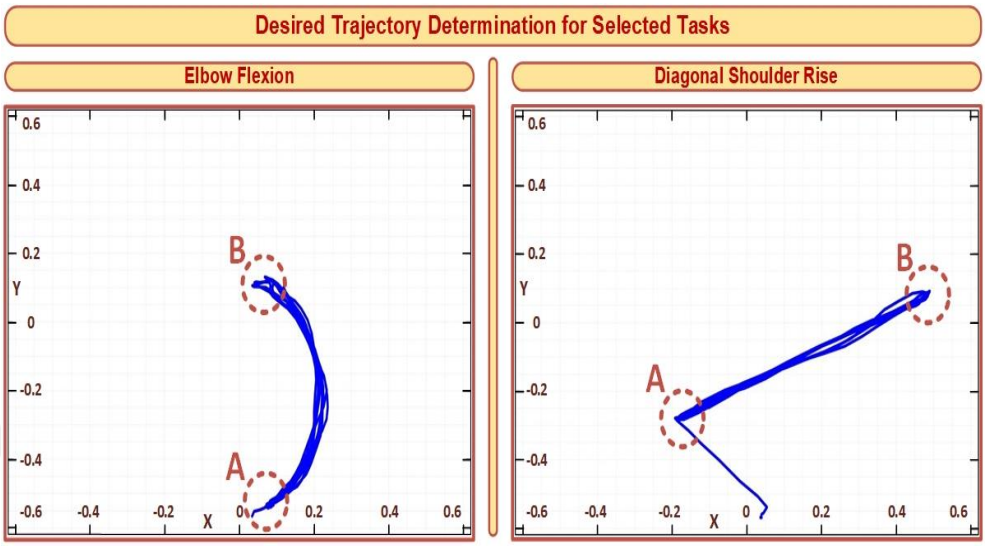

Figure 4.13. Determination of the selected tasks' trajectories for the patient's end-effector

4.6. Graphical User Interface

Rehabilitation exercises have been performed using the MATLAB® GUI screen. On the exercise interface, the black line indicates the desired trajectory path, the green pentagram marks the desired trajectory target, and the blue circle represents the patient's end-effector position, as shown in Figure 4.14. Based on the patient's participation and disability level, the upper and lower limits of the performance, tiredness, and slacking assessment could be varied using the sliders on the GIU screen. In addition, there are illustration figures of the exercise patterns on the rehabilitation interface. During the therapy exercises, the patients were asked to catch the green pentagram, the trajectory target, on the desired trajectory path.

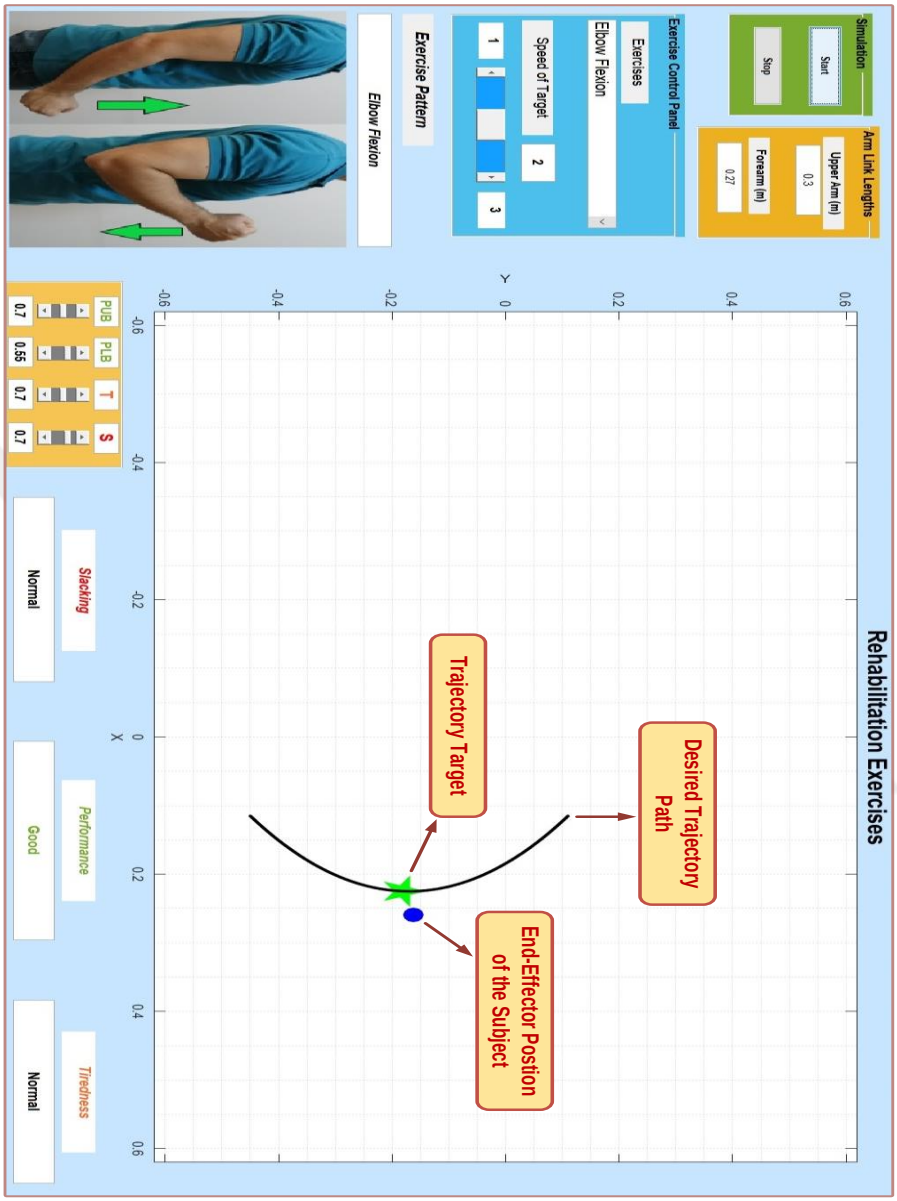

Figure 4.14. Rehabilitation exercises interface

Each of the selected therapy tasks has three different speed levels for the trajectory target. Thereby, three different levels of difficulty have been defined for the tasks, and a total of fifteen difficulty levels have been obtained, with three levels for each task. The transition between therapy tasks and difficulty levels of these tasks has been performed by the therapy task management module according to the performance and tiredness output of PRES, to ensure that the exercise was sufficiently challenging for the patient.

Giving patient feedback on exercise performance improves motor learning and positively affects motivation (Winstein and Kay, 2015). Therefore on the GUI screen, the patient was provided with motivational feedback about his/her performance, tiredness, and slacking status. In addition, upper arm and forearm link lengths (l_1 *and* l_2 in Equations 4.10 and 4.11) utilized in upper limb kinematic model calculations can be entered patient-specifically via the interface. The desired trajectory paths are adjusted based on the patient's upper arm and forearm lengths.

5. EXPERIMENTS WITH HEALTHY SUBJECTS

This chapter presents the details of the experiments performed with healthy subjects to evaluate the effectiveness of the developed system and the obtained experimental results.

5.1. Profile of Participants and Experimental Protocol

The proposed method was tested firstly with fifteen (nine male and six female) healthy participants to evaluate the efficiency of the system before clinical trials, as implemented in the literature (Badesa et al., 2016). All subjects were healthy, with no major cognitive or physical deficits. The selected subjects were aged between 17 and 60; the mean age is 37.3 years, and the standard deviation is 12.2 years. Baseline characteristics of healthy subjects are given in Table 5.1.

Table 5.1.Baseline characteristics of the healthy participants

Characteristic	***Value***
Gender	***no. (%)***
Male	9 (60)
Female	6 (40)
Age	***yr.***
Mean	37.3±12.2
Range	17 – 60
Dominant Hand	***no.***
Right	13
Left	2

In the preliminary duration of the exercises, the subjects were informed about the therapy tasks and the experimental protocol. An adaptation period of a few minutes was given to the subjects without performing any therapy exercises. After the adaptation period, the participants were given a 5-minute rest period. The subjects carried out the experiments by sitting on a chair in front of the GUI screen, as shown in Figure 5.1.

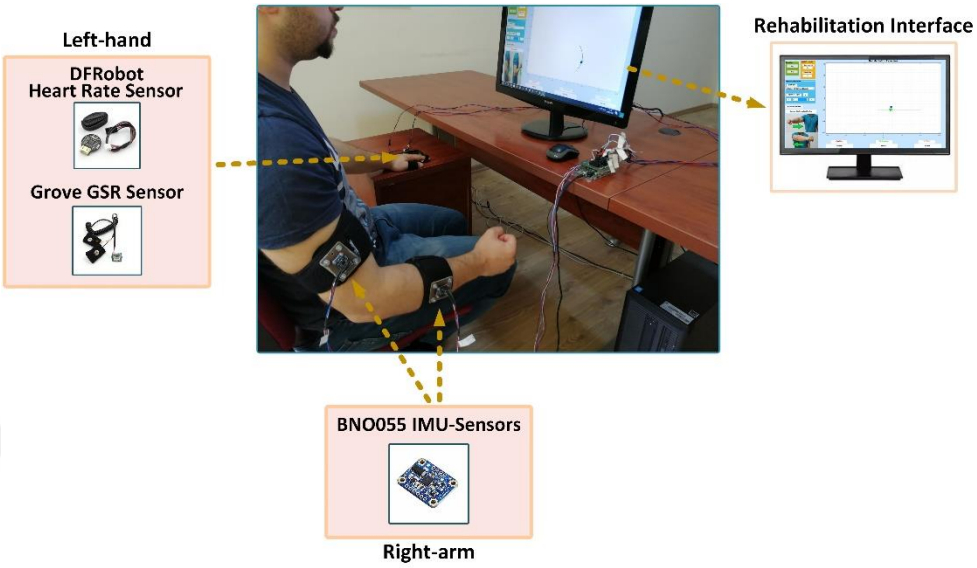

Figure 5.1. Setup for experiments with healthy subjects

The IMU sensors were attached to the subjects' right arm. The HR and GSR sensors were placed on the left hand of the subjects. Since the change in physiological responses was used to evaluate patient performance, no baseline measurement was required. During the exercises, the subjects were asked not to move their left hands to which the HR and GSR sensors were attached for not to affect the measurements.

5.2. Experimental Results of Healthy Subjects

During the experiments, the participants were asked to follow up on the trajectory target on the GUI screen as closely as possible for each therapy task. Subjects have no physical problems like being hungry or tired when performing the exercises. The subjects performed the exercises for ten to twelve minutes, depending on their performance. Five selected therapy tasks were implemented in the experiments performed with healthy participants. The initial therapy task is always elbow flexion. In Figure 5.2, the performance assessment of all the subjects is given together for comparison.

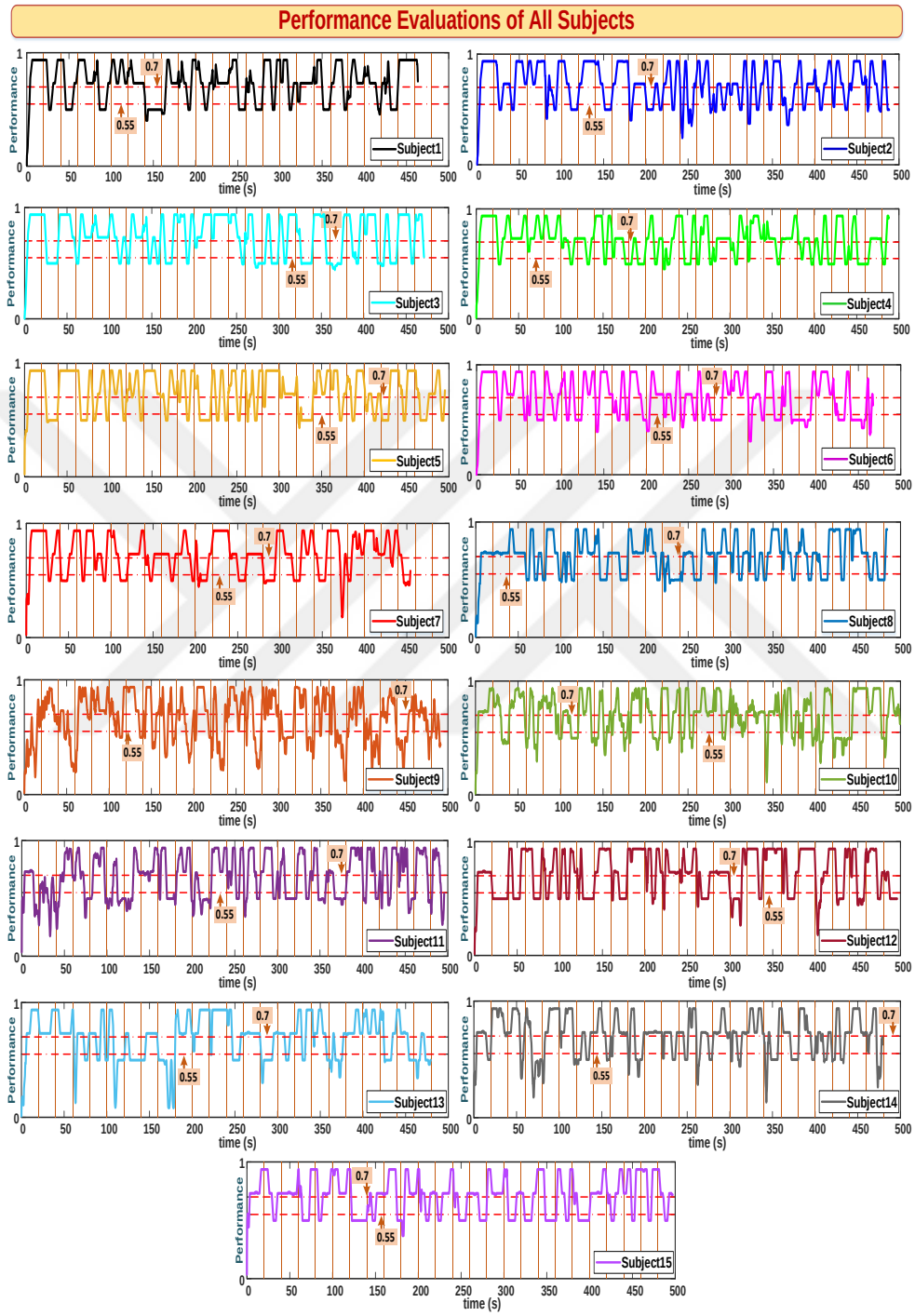

Figure 5.2. PRES performance assessment for all subjects

In Figure 5.2, vertical lines indicate the 20-second intervals in which subjects' performance was evaluated. In these intervals, if the mean performance of the subject was more than 0.7, the exercise level was increased; if the mean value was less than 0.55, the exercise level was decreased. The difficulty levels of the tasks were adjusted by changing the therapy task or speed level of the therapy target. The exercise level has not changed in the mean performance between these two values. In Figure 5.3, the variations in task difficulty levels for all the subjects are given.

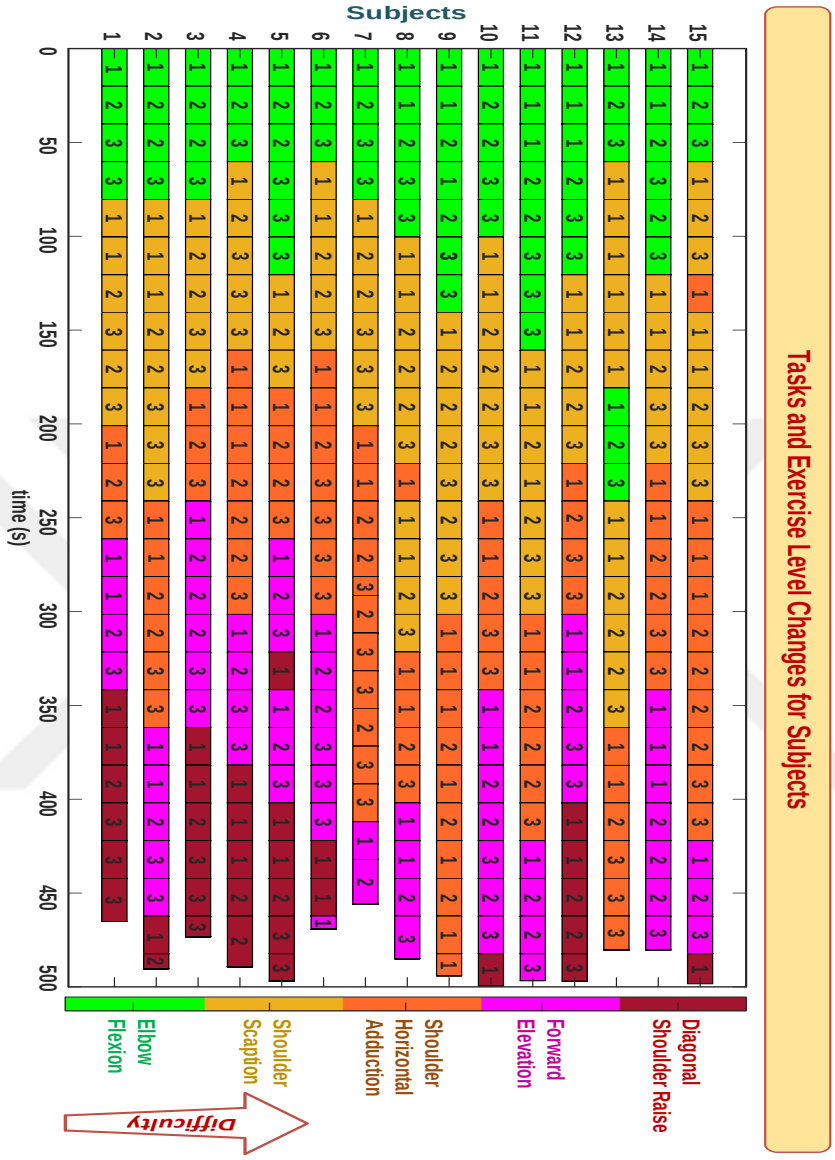

Figure 5.3. Tasks and exercise level changes for all subjects during the experiments

In Figure 5.3, each box indicates the intervals in which the subject's performances were evaluated. The numbers on the boxes show the exercise level of the therapy task. The four subjects completed the experiments at the last task and exercise level. Four subjects have reached the final task level but not the final exercise level, five subjects finished the experiments at the fourth task level, and two subjects finished the experiments at the third task level.

For evaluating the change in subject performance according to age, participants were separated into two groups. There are seven subjects (Subject 1 - Subject 7) in the first group. The mean age of these subjects is 29.8 years, and the standard deviation is 3.6 years. Three of the seven participants (%43) in the first group completed the experiments at the last task and exercise level. The second group comprises eight subjects (Subject 8 - Subject 15). The mean age of these subjects is 44 years, and the standard deviation is 13.3 years. Only one of the eight participants (%12) in the second group completed the experiments at the last task and exercise level. These results show that younger participants have higher performance as expected.

All subjects' HR, GSR, and trajectory tracking error signals during the experiments are given in Figures 5.4, 5.5, and 5.6.

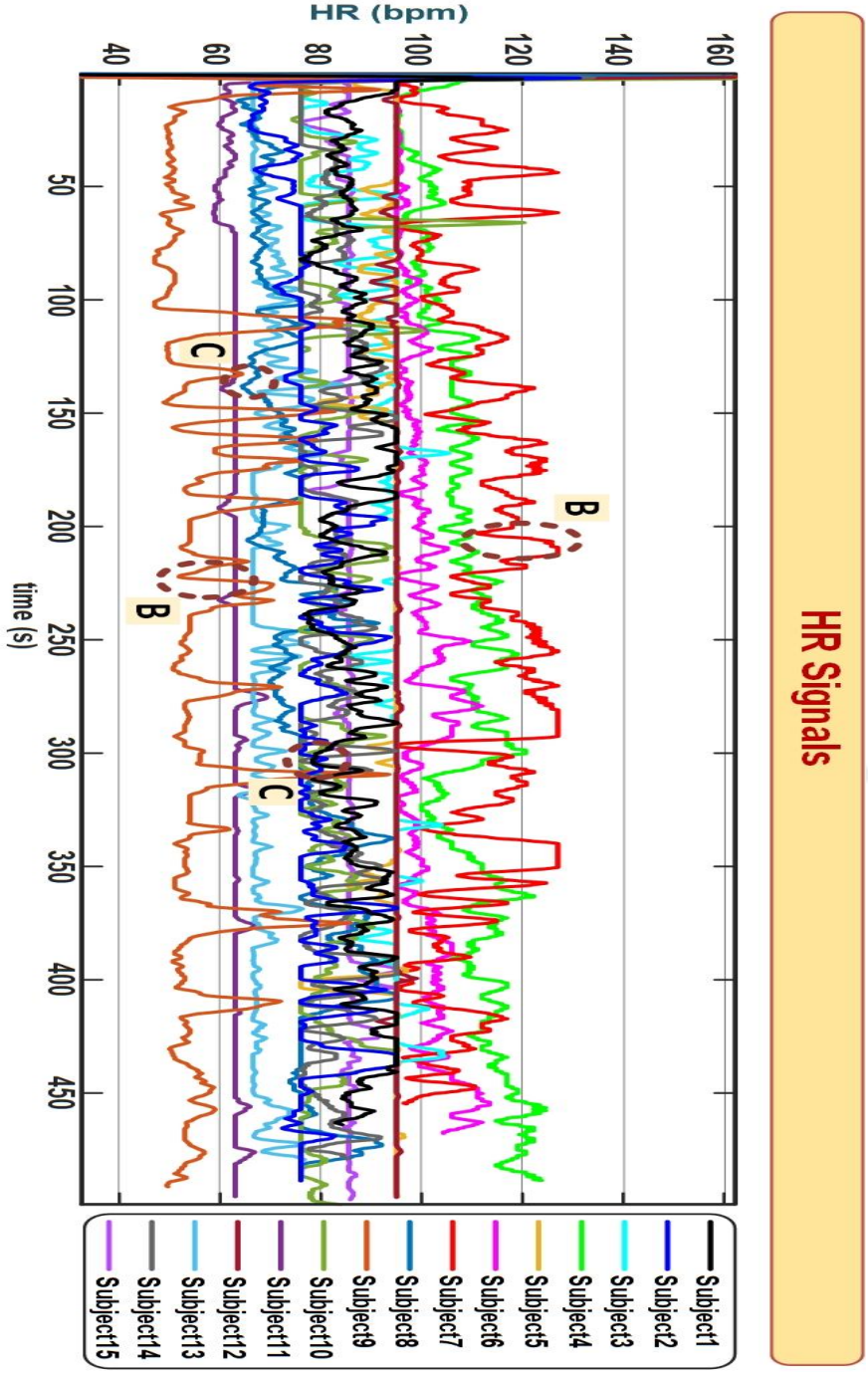

Figure 5.4. HR signals of all subjects during the experiments

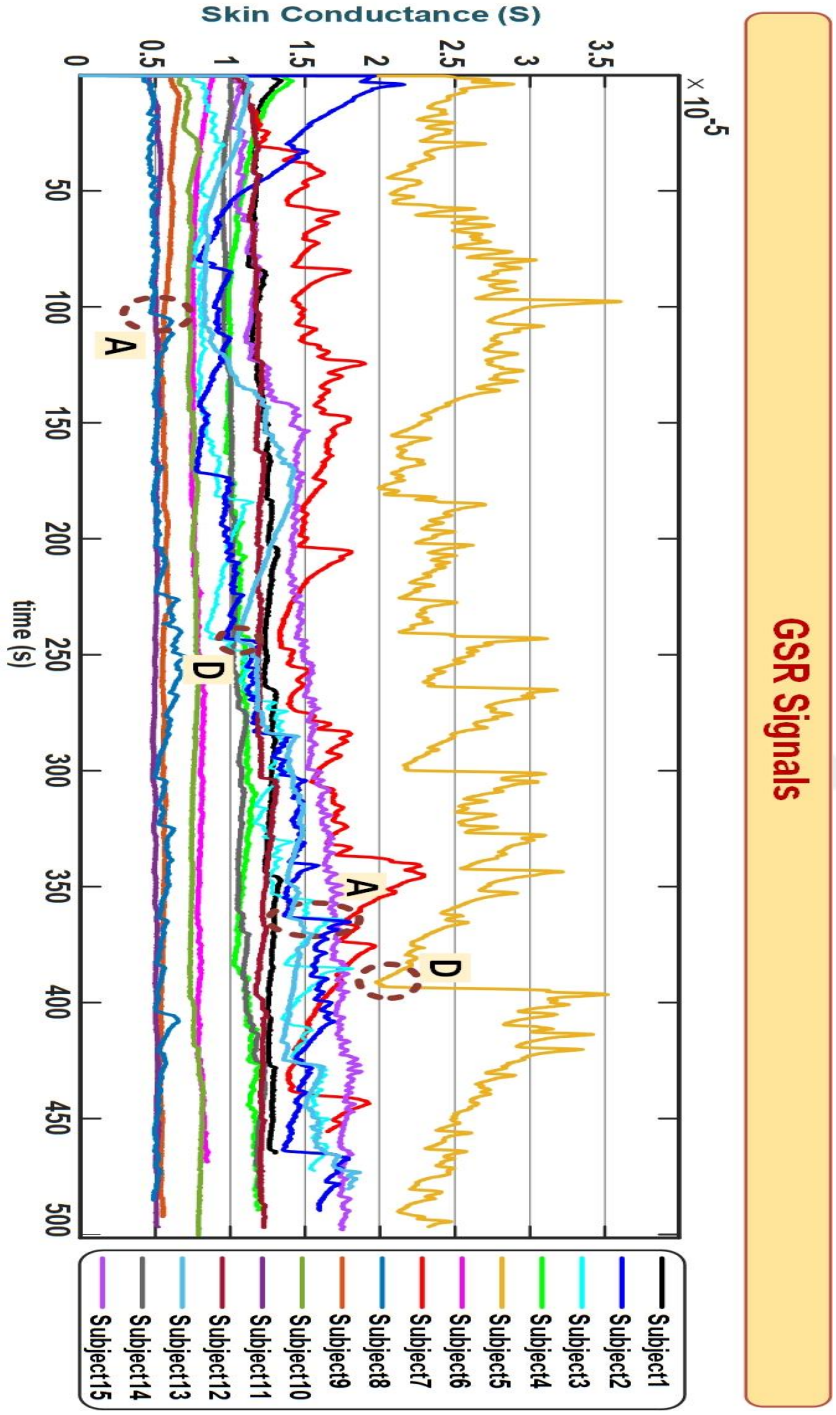

Figure 5.5. GSR signals of all subjects during the experiments

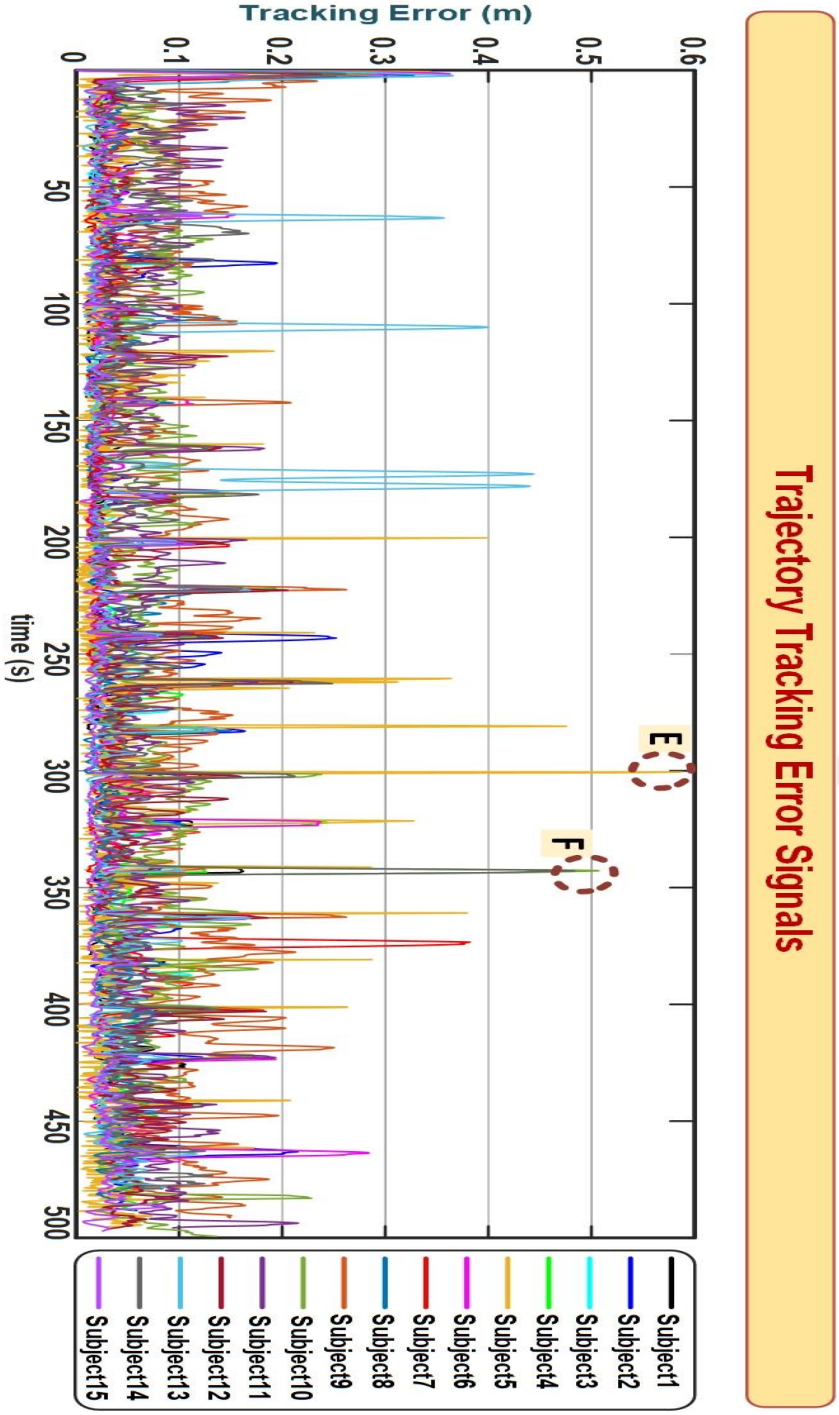

Figure 5.6. Trajectory tracking error signals of all subjects during the experiments

The physiological responses of all the subjects, given in Figure 5.4 and Figure 5.5, show that these signals increase due to physical workload as therapy tasks get difficult. The examples of the increases are remarked on the GSR signals of 2nd, 3rd and 8th subjects as point A and the HR signal of 7th and 9th subjects as point B in Figures 5.4 and 5.5. The increase in these signals indicates that using HR and GSR signals for evaluating patients' participation and physical effort in therapy exercises is a suitable method. However, as a result of subjects getting used to therapy tasks over time and performance increases, these signals decrease until a new therapy exercise. These decreases could be seen in the 1st and 8th subjects' HR signals and the 5th and 13th subjects' GSR signals, as stated in C and D points in Figures 5.4 and 5.5. Therefore, using changes in the physiological responses instead of their levels in evaluating patient performance occurs as a much more convenient method.

The participants' instant high trajectory tracking error signals (as specified by E and F points in Figure 5.6) usually arise from the adaptation period to the new therapy task or exercise level. During therapy, patients' performance can change momentarily, as seen in performance assessments of all the subjects (see Figure 5.2). Hence, carrying out patient performance evaluations during a certain exercise period provides a more accurate assessment. The experimental results in Figures 5.2 to 5.6 demonstrated that the proposed method successfully evaluates the subjects' performances.

During the exercises of the seventh subject, the system detected tiredness. Tiredness evaluation of this subject is also given in Figure 5.7 (a). Vertical lines indicate the 10-second intervals in which the tiredness of the subject was evaluated. The intervals at which the tiredness was detected are remarked in the figure. Due to tiredness detection, the exercise level was reduced twice during this subject's experiment. This decrease in exercise level is indicated as A and B intervals in Figure 5.7 (b). When the seventh subject's physiological signals are analyzed, it is seen that the GSR and especially the HR signal increase significantly during the

exercises. The main reason for these increases is the excessive effort exerted by the subject to perform the tasks; therefore, tiredness detection has occurred.

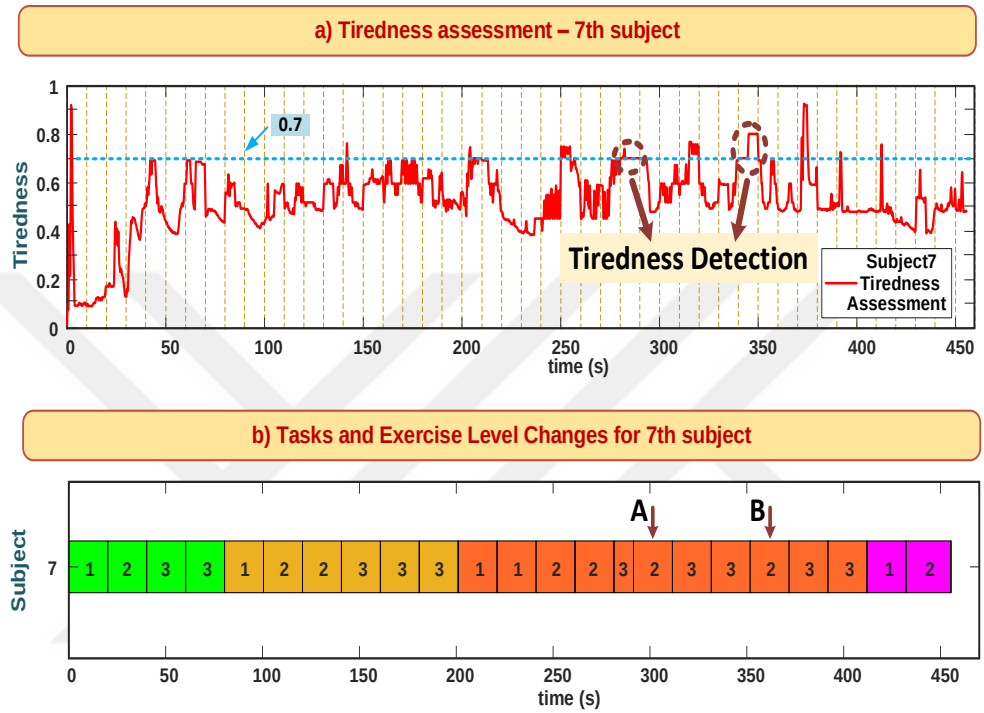

Figure 5.7. (a) Tiredness assessment and (b) task level changes of the 7. subject

The fifth subject's GSR signal exceeded the medium level (20 µS) during the experiment. However, this subject's HR signal remained stable throughout the experiment (see Figure 5.4). Therefore, no tiredness determination has been performed for this subject.

5.2.1. Experiments Related to Effect of Therapy Task Order on System Performance

In addition to experiments to assess system performance, experiments were also carried out to study the effect of the order of therapy tasks on system performance. The application order of the five selected therapy tasks was modified

to assess the impact of the therapy tasks order on system performance, and three subjects were asked to perform the experiments with the new task order. The performance assessment of these participants is shown in Figure 5.8.

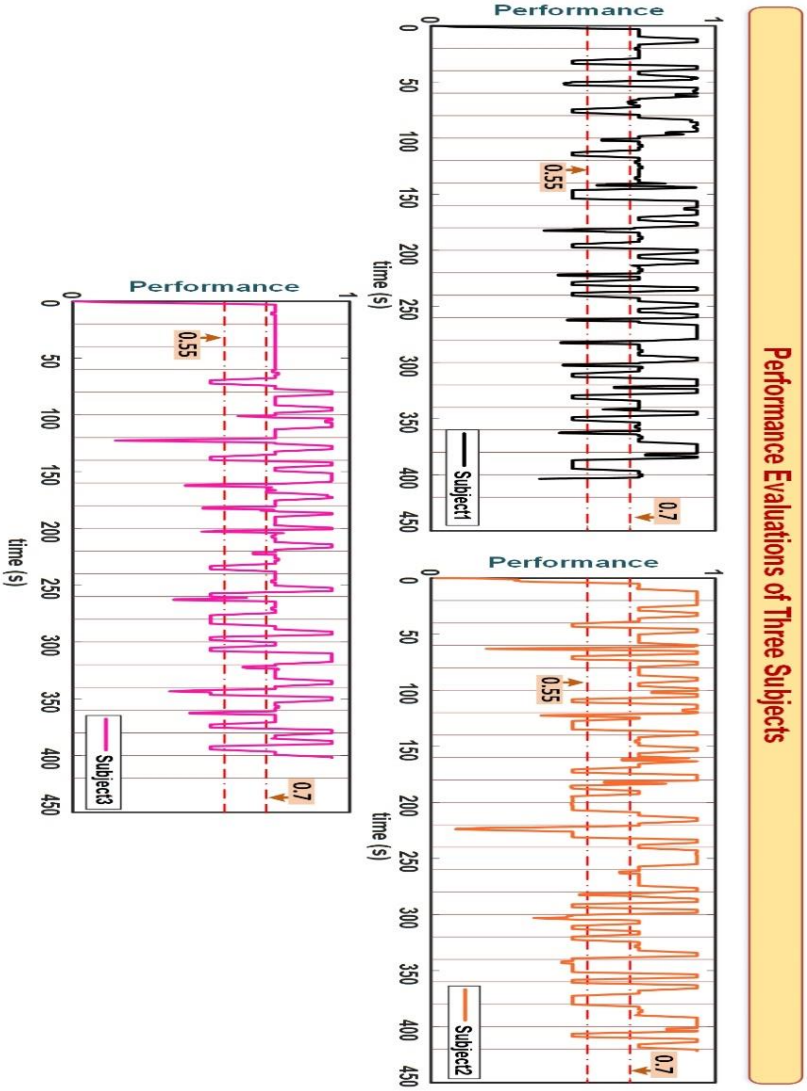

Figure 5.8. Performance evaluations of three subjects during the experiments with modified therapy tasks order

As in the previous experiments, if the subject's mean performance was more than 0.7, the system increased the exercise level; if the mean value was under 0.55, the exercise level decreased. The exercise level stayed unchanged for the mean performance between these two values. The changes in task difficulty level for the subjects are given in Figure 5.9.

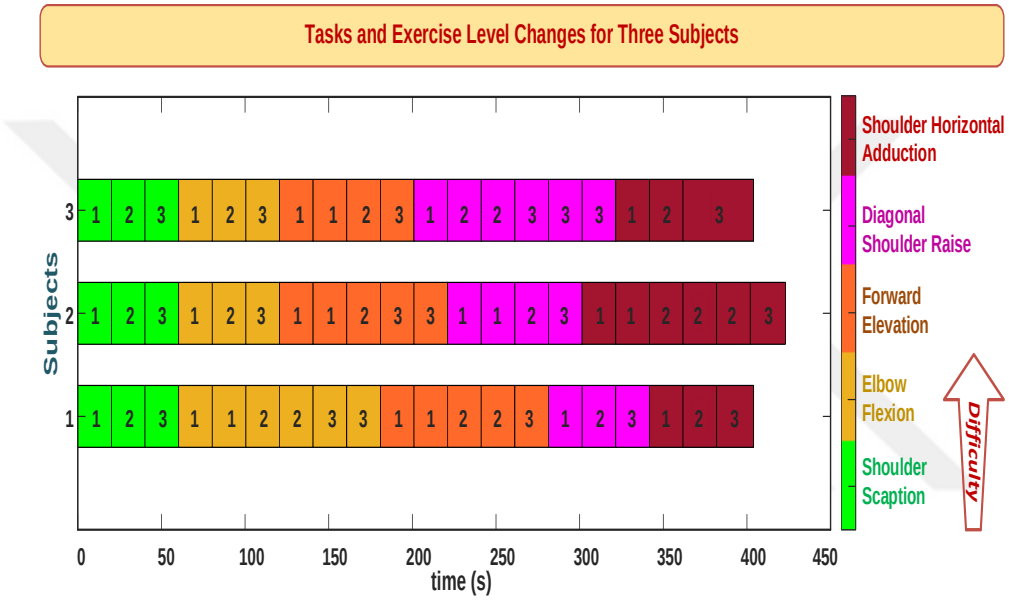

Figure 5.9. Tasks and exercise level changes for three subjects during the experiments with modified therapy tasks order

In Figure 5.9, each box shows the intervals during which the subjects' performance was evaluated, and therapy tasks are illustrated with colors. All the subjects have completed the experiments at the last task and exercise level with the modified therapy task order. The HR, GSR, and trajectory tracking error signals of three subjects during the experiments are given in Figure 5.10.

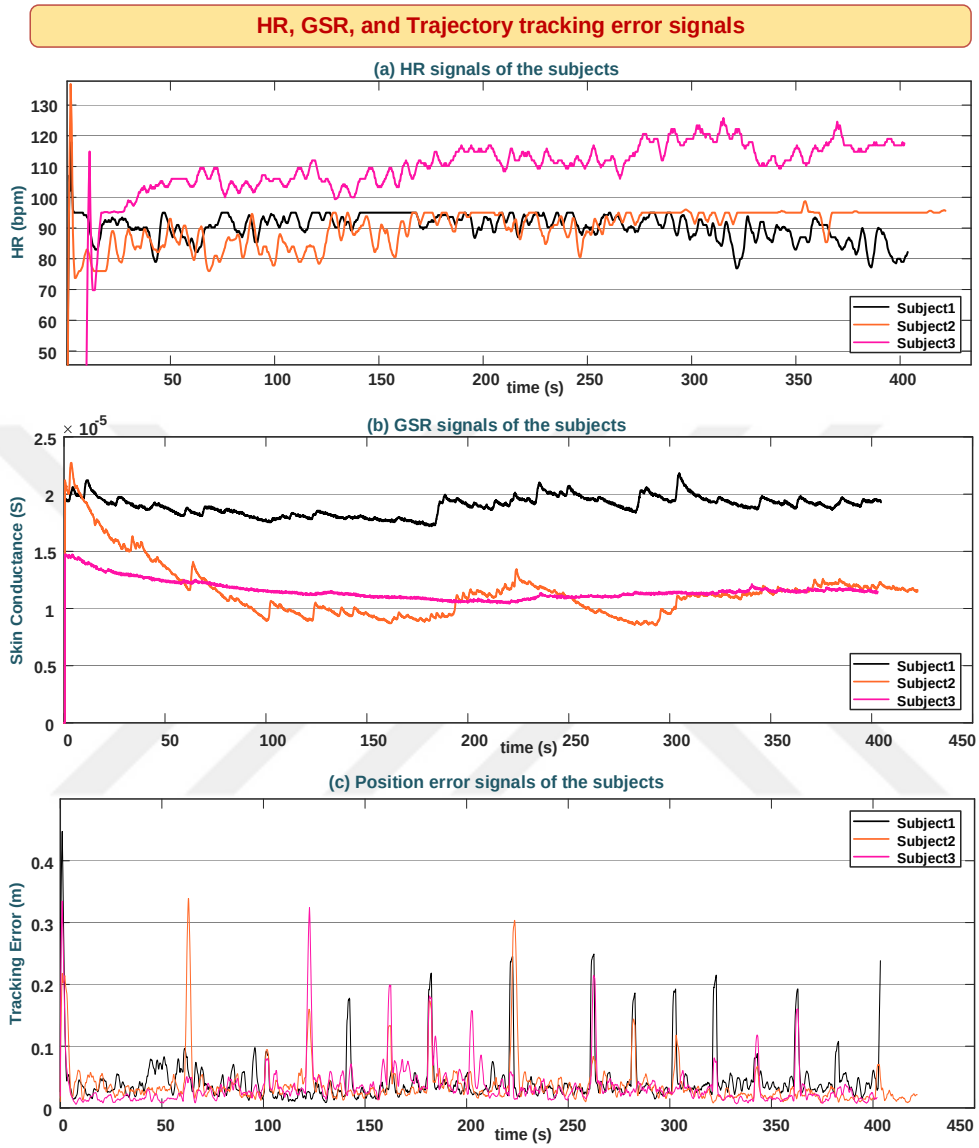

Figure 5.10. (a) HR, (b) skin conductance, and (c) trajectory tracking error signals of the subjects during the experiments with modified therapy tasks order

The subjects' physiological signals increased as the tasks got difficult, despite the changing order of the therapy tasks. These results showed that the proposed method could adequately evaluate patients' performance, regardless of the therapy tasks or order of these tasks.

5.2.2. Validation of Participation Assessment Method by Measuring sEMG Signals

For evaluation of the proposed method's effectiveness, experiments were performed for two different cases. In the first case, one subject performed the therapy exercises with healthy behavior until reaching the last exercise level of the first therapy task (Elbow Flexion). Then, the subject completed the experiment with atypical behavior. As the atypical behavior, subjects intentionally failed to perform the tasks by going in the wrong direction or repeatedly stopping during the exercises. During this experiment, the sEMG signals of the subject's Biceps and Brachioradialis muscles, which are the muscles associated with the Elbow Flexion task, were measured.

The EMG signals reflect the electrical activity produced by muscles during the contraction or relaxation periods and can be measured using electrodes on the surface of the skin or inserted in the muscle (Phinyomark et al., 2020). The sEMG signals have been measured with the BIOPAC® system at a sampling rate of 1 kHz by using BIOPAC® SSL2B transducers and Ag/AgCl surface electrodes.

The subject’s HR, GSR, and trajectory tracking error signals during the experiment of evaluating the proposed method's effectiveness are given in Figure 5.11.

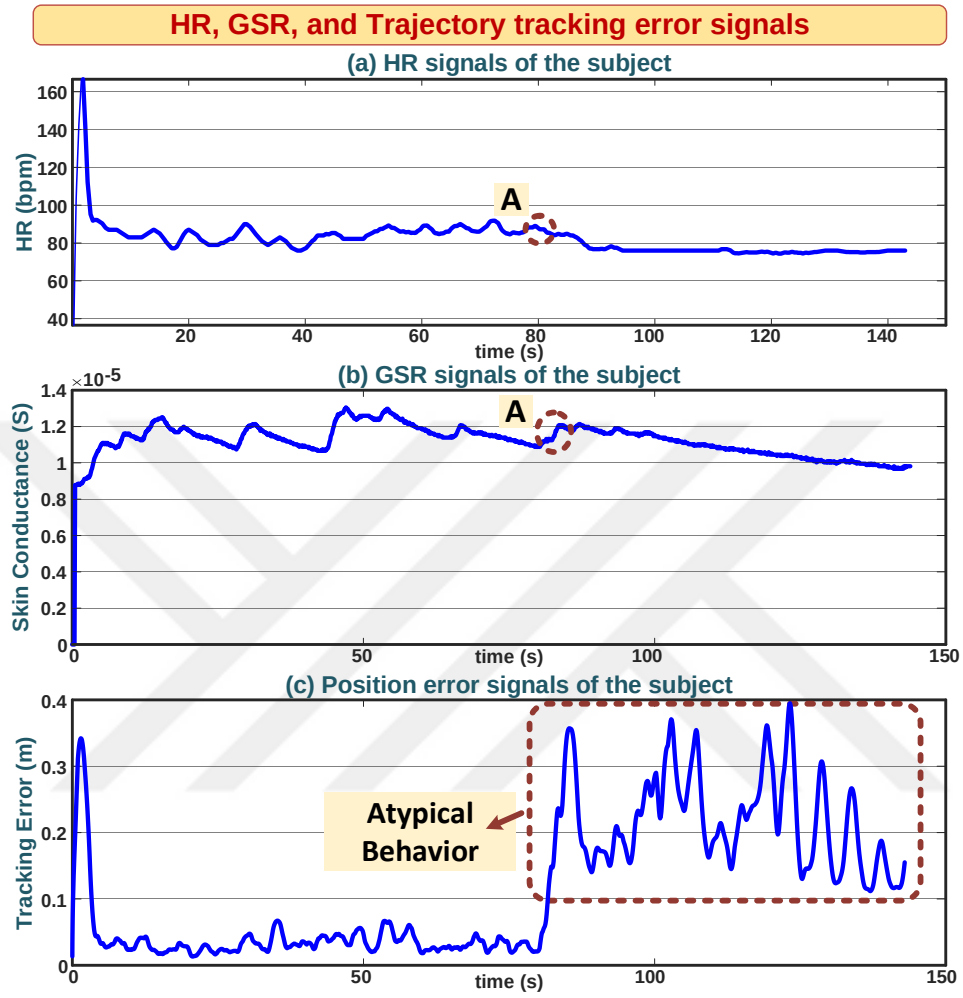

Figure 5.11. (a) HR, (b) skin conductance, and (c) trajectory tracking error signals of the subject during the experiment of evaluating the proposed method's effectiveness

In this figure, A indicates the point where the subject begins exercising atypical behavior. Starting at this point, it is seen that while the physiological signals decrease, the trajectory tracking error signal increases. These changes show that physiological signals are indicators of the patient's physical activity level and therapy participation. The performance, slacking assessment, and variations in task difficulty levels of the subject during this experiment are given in Figure 5.12.

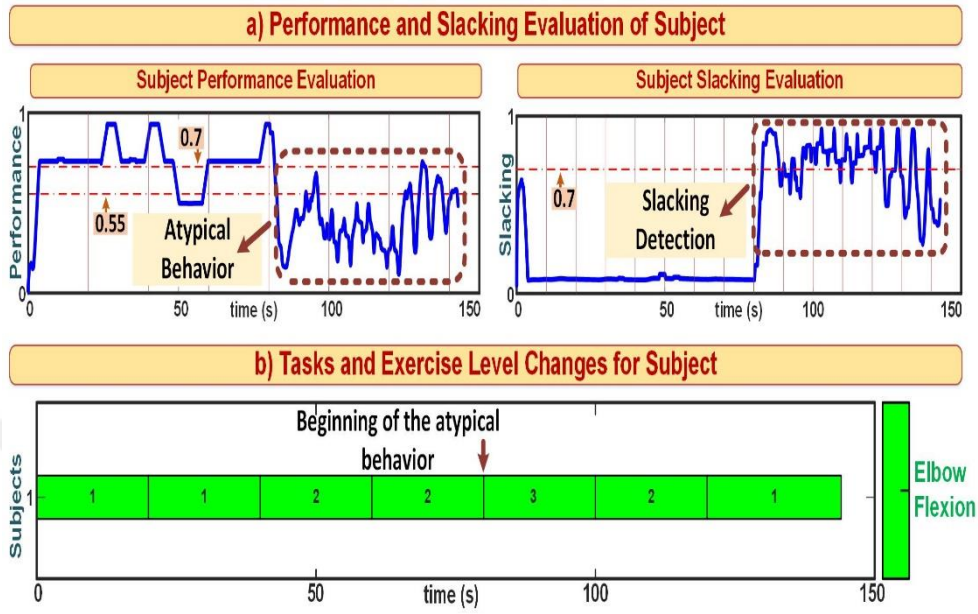

Figure 5.12. (a) Performance and slacking evaluation of the subject, and (b) exercise level changes for the subject during the experiment of evaluating the proposed method's effectiveness

While the subject performs the exercises with healthy behavior, the subject's performance has been evaluated as high, and the PRES has increased the exercise level, as seen in Figure 5.12 (a). However, after the onset of the atypical behavior, the performance has been evaluated as low due to the alterations in the physiological responses and trajectory tracking error signal, and the therapy task management module reduced the exercise level because of the low-performance evaluation, as seen in Figure 5.12 (b). Also, during the atypical behavior, due to the decrease in physiological responses and the increase in the trajectory tracking error signal, the atypical behavior has been evaluated as slacking by the developed system (see Figure 5.12 (a)). In Figure 5.13, the Raw and Root Mean Square (RMS) value of the sEMG signals of the subject's Biceps and Brachioradialis muscles during this experiment is given.

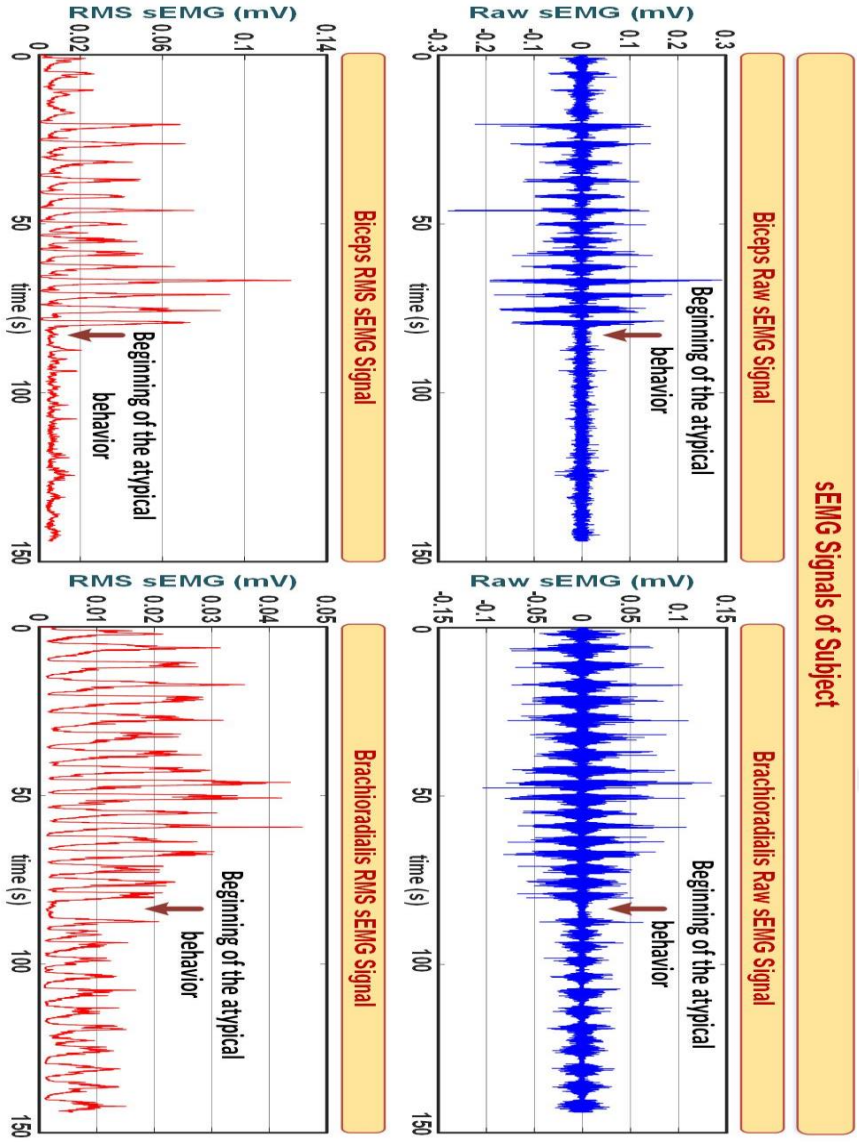

Figure 5.13. Raw and RMS values of the sEMG signals of the subject's Biceps and Brachioradialis muscles during the experiment of evaluating the proposed method's effectiveness

High EMG signal amplitudes during the period when the subject performs the exercises with healthy behavior indicate the voluntary and active participation of the subject in the exercises. During this voluntary participation period, the subject's performance has also been evaluated as “high” by the proposed system. However, after the beginning of atypical behavior, the EMG signals of the Biceps and Brachioradialis muscles have decreased. As indicated earlier, the subject's performance was also evaluated as “low” by the PRES during this period. Besides, the trajectory tracking error signal increased during the atypical behavior period (see Figure 5.11 (c)). Decreased EMG signals and increasing trajectory tracking error indicate that the subject was slacking, and the subject's behavior during this period has also been evaluated as slacking by the PRES. This experiment shows that the subject's EMG signals measured during the exercises coincide with the developed system's participation assessment.

The selected tasks in the proposed method could be challenging for patients but not challenging enough to cause any fatigue for healthy participants. Therefore in the second case, two subjects (Subject1 and Subject3) who had completed the experiments at the last task and exercise level were asked to repeat the experiments while holding a 2 kg weight to induce subjects' fatigue and evaluate the proposed method's tiredness assessment.

Two selected subjects' HR, GSR, and trajectory tracking error signals during the normal and weighted exercises are presented together in Figure 5.14 for comparison.

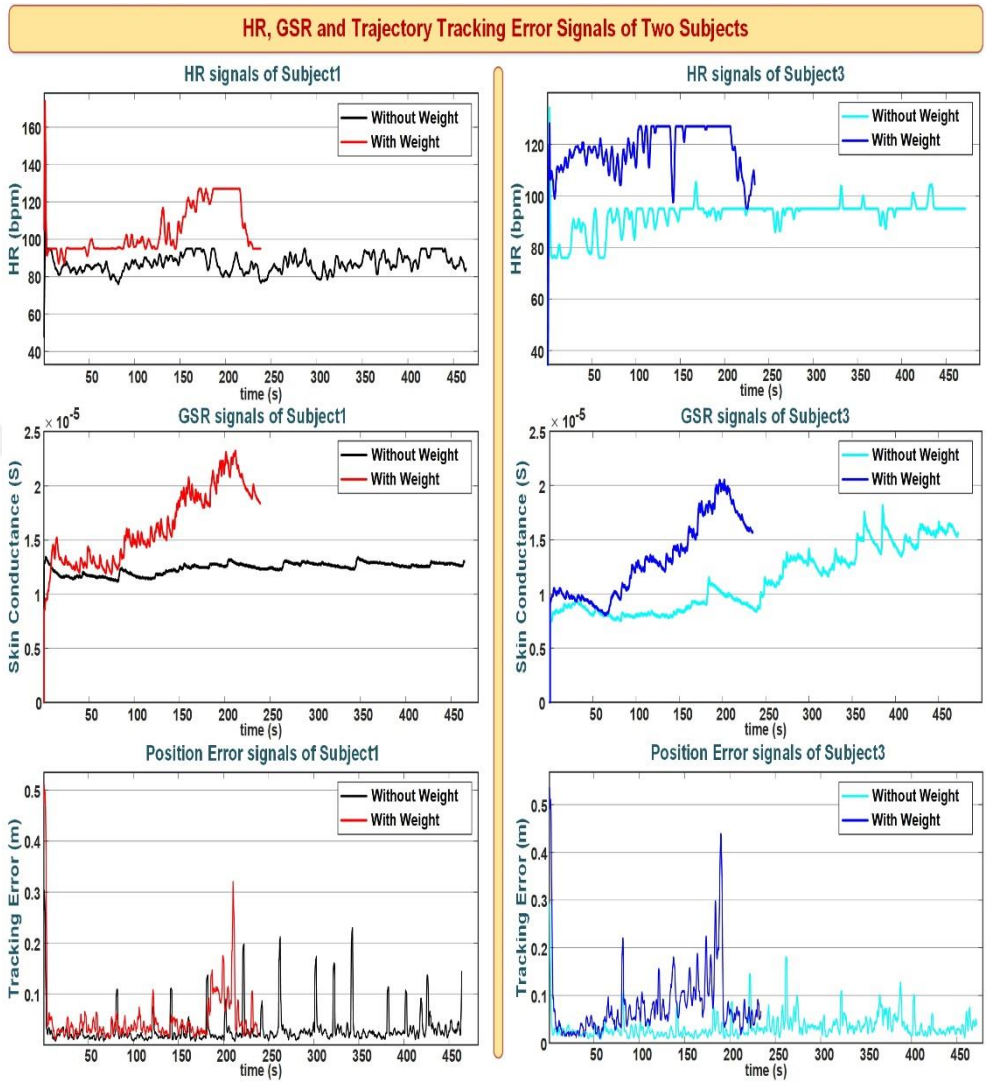

Figure 5.14. The HR, GSR, and trajectory tracking error signals of two selected subjects during the normal and weighted exercises

Physiological signals of both subjects have risen more during the weight exercises compared to the standard experiments. These changes in physiological signals show that these signals are directly proportional to physical effort. The performance and tiredness evaluations of the subjects during the tiredness assessment experiments are given in Figure 5.15.

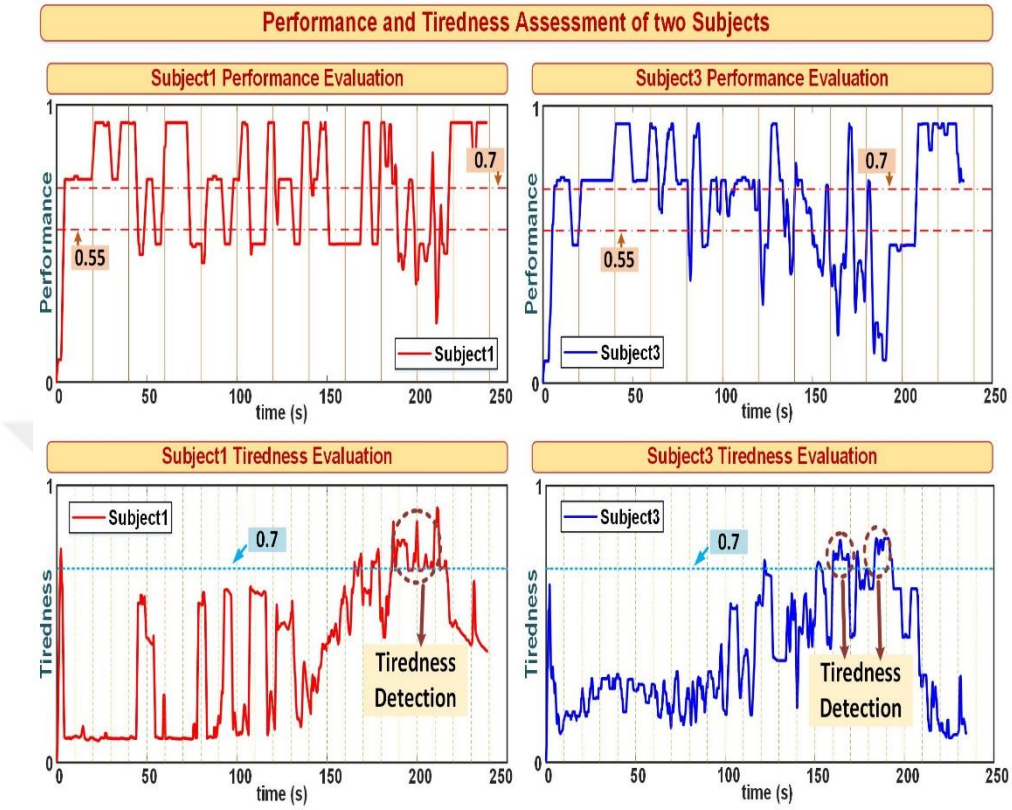

Figure 5.15. The performance and tiredness evaluations of selected two selected subjects during the tiredness assessment experiments

During these experiments, tiredness was detected by the proposed system for both subjects due to the increase in their physiological responses and the trajectory tracking error signals. The intervals at which the tiredness was detected are indicated in Figure 5.15. The changes in task difficulty level for the subjects during the tiredness assessment experiments are given in Figure 5.16.

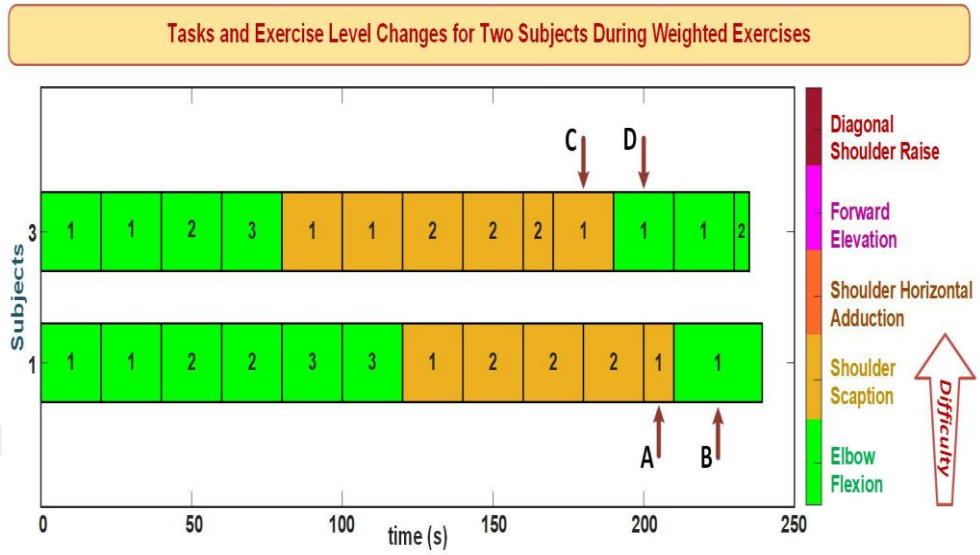

Figure 5.16. Tasks and exercise level changes for two selected subjects during the tiredness assessment experiments

The exercise level was reduced twice for both subjects, depending on tiredness detection. These decreases in exercise levels correspond to A - B intervals for Subject1 and C - D intervals for Subject3 in Figure 5.16. A while after tiredness was detected, the experiments were terminated at the request of the subjects.

To determine muscle fatigue, the use of EMG signals is a widely preferred method (Karthick et al., 2016; Keshavarz Panahi and Cho, 2016; Liu et al., 2019). During muscular fatigue, the amplitude of the EMG signals increases, and the frequency decreases (Keshavarz Panahi and Cho, 2016; Liu et al., 2019). Therefore in these experiments, Subject1's affected muscles' EMG signals were measured to observe any possible change with fatigue. In the tiredness assessment experiment of the Subject1, tiredness was detected during the Shoulder Scaption exercise. Raw and RMS values of the sEMG signals of Subject1's Deltoid Anterior and Middle Head muscles, which are the affected ones of the Shoulder Scaption exercise, are given in Figure 5.17. Also, the mean frequency (MNF) value of these signals, which is one of the most commonly used frequency variables in fatigue detection using EMG signals, is given in Figure 5.17 to analyze the frequency changes of the

signals during the exercises (Liu et al., 2019). The MNF is the average frequency of the power spectrum and is defined as

$$MNF = \sum_{j=0}^{M} f_j P_j / \sum_{j=0}^{M} P_j \tag{5.1}$$

where f_j is the frequency value at data sampling j, P_j is the EMG power spectrum at data sampling j, and M is the length of data sampling j (Phinyomark et al., 2012).

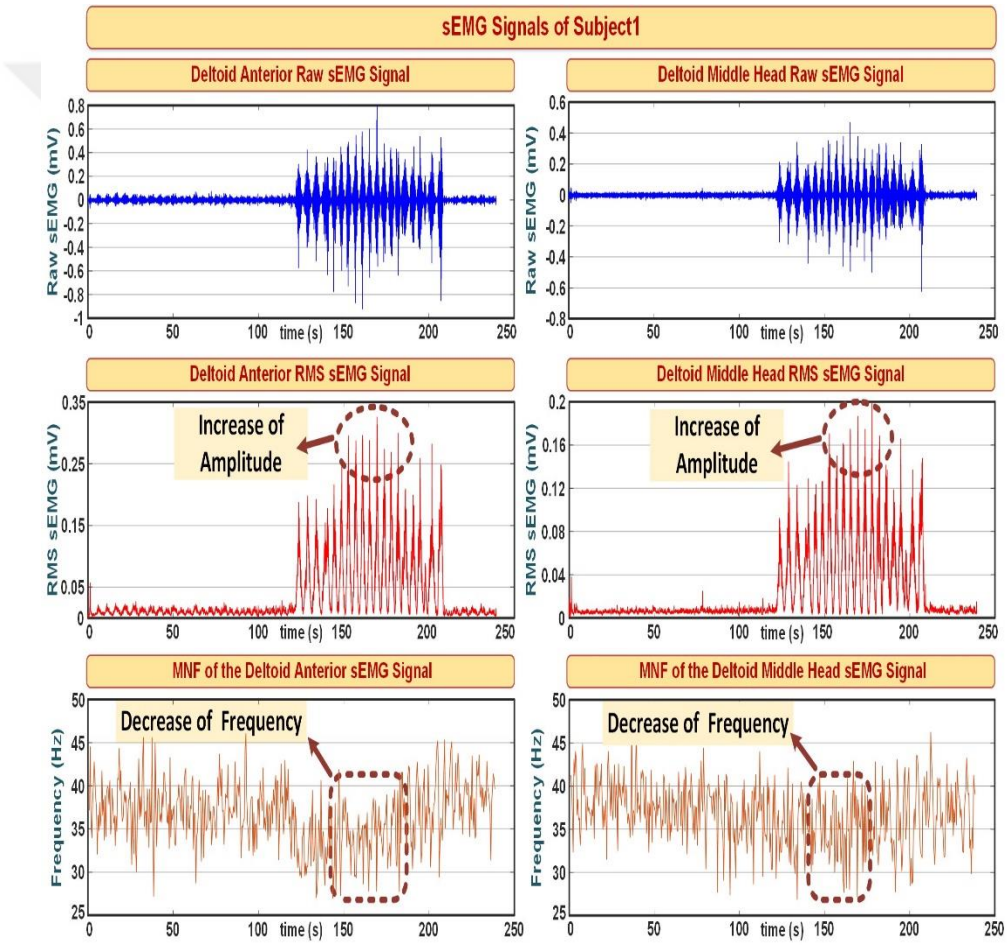

Figure 5.17. Raw, RMS, and MNF values of the sEMG signals of subject1's Deltoid Anterior and Middle Head muscles during the tiredness assessment experiment

After a while during the experiment, the amplitude of the EMG signals of the Deltoid Anterior and Middle Head muscles increased, and the MNF values decreased (Figure 5.17). The increase in the amplitude of the EMG signals and the decrease in the MNF values indicate muscle fatigue in these muscles. As a result of the muscle fatigue, the trajectory tracking performance of the subject decreased, and the error signal was increased (Figure 5.14). The physiological responses also increased due to the excessive effort exerted by the subject. Based on these changes in physiological responses and trajectory tracking error signals, tiredness was detected by the PRES, and the exercise level was reduced. It is also seen in Figure 5.17 that after the subject's effort decreased due to fatigue, the amplitude of the EMG signals decreased, and the MNF values increased. These experimental results indicate that the proposed method successfully evaluates the tiredness of the subjects.

To summarize, all experimental results obtained from healthy subjects demonstrated that the proposed method successfully estimates the subject's changing capabilities and therapy participation regardless of any therapy device or therapy tasks and adjusts the therapy tasks and task difficulty levels based on the subjects’ performance and tiredness.

6. CLINICAL TRIALS WITH PATIENTS

In this section, details of clinical trials conducted with patients who have frozen shoulder syndrome and the related results are presented. The limitations of the proposed system observed after clinical experiments are also mentioned.

6.1. Details of Clinical Study Performed with Patients

The clinical study was carried out in the private Fizica medical center in Adana/Turkey. This center consists of doctor examination rooms, a waiting hall, a special-purpose exercise hall, an exercise hall for neurological and orthopedic rehabilitation, and a fully equipped hand rehabilitation unit in accordance with the standards specified by the regulations. The study is approved by the clinical trials ethics committee of the Çukurova University (Appendix A). The clinical trial environment is shown in Figure 6.1.

Figure 6.1. Clinical trial environment

The clinical study has been carried out with patients who have been diagnosed with frozen shoulder syndrome by physiotherapy and rehabilitation specialists. Patients with frozen shoulder syndrome were preferred because they were the largest patient group in the clinic where the study was performed.

As mentioned earlier, the developed system is therapy participation and patient performance evaluation system. The purpose of the clinical trial process is to compare the patient performance evaluation data of the proposed system with the patients' progress in the treatment process and thus to assess the performance and participation evaluation effectiveness of the developed method. To achieve that, various scales and measurements were implemented to evaluate the patients' progress during the therapy period and their status during the use of the proposed system. The measurement of the sEMG signals (Section 5.2.2) was used to demonstrate the effectiveness of the proposed method and is not a part of the developed system. Therefore, sEMG signal measurement was not included in clinical studies.

The developed system implementation, used scales, and performed clinical measurements are explained in detail in the next sections.

6.2. Profile of Recruited Patients

The participants of the clinical study carried out were patients diagnosed with frozen shoulder syndrome by a specialist physician. A total of ten patients (two male and eight female) were included in the clinical trials. The recruited patients were aged between 42 and 65; the mean age is 54.7 years, and the standard deviation is 7.9 years. Baseline characteristics of patients are given in Table 6.1.

Table 6.1. Baseline characteristics of the patients

	Frequency (n)	Percentage (%)
Gender		
Female	8	80,0
Male	2	20,0
	Mean±SD	**Med (Min-Max)**
Age (year)	54,7±7,9	53,5 (42-65)
Length (cm)	165,2±8,1	161,5 (159-183)
Weight (kg)	78,2±10,7	76,5 (63-96)
Body Mass Index (BMI)	28,6±2,2	28,1 (24,6-31,3)

In order to not affect the physiological signal measurements (heart rate and skin conductance) and to evaluate the system performance correctly, patients with the following medical conditions were not included in the clinical study.

- Patients with upper extremity circulation problems
- Patients with pacemakers
- Pregnant patients
- Patients with a history of upper extremity orthopedic surgery in the last six months
- Patients with a chronic disease that may affect balance and coordination

6.2.1. Frozen Shoulder Syndrome

Frozen shoulder syndrome (FSS) is a condition of uncertain etiology that causes progressive loss of both active and passive shoulder motion (Mertens et al., 2020). Codman (1934), first used the term "frozen shoulder" for this disease, which was first described by Duplay in 1872 and named "scapulohumeral periarthritis". In

frozen shoulder syndrome, which is characterized by pain and limitation in joint range of motion, the complaints usually regress spontaneously within 1-3 years, however, it has been reported that this period may be prolonged up to 10 years for some patients (Mertens et al., 2020). This syndrome is mainly seen in individuals between the ages of 40-60 who are active and have the working ability, and it severely restricts ADL (de la Serna et al., 2021). The recovery period can take up to 3-10 years, which diminishes patient comfort and comes with a high socioeconomic cost.

Frozen shoulder patients can be divided into two subgroups those with primary frozen shoulder and secondary frozen shoulder (Grubbs, 1993). Primary frozen shoulder is a condition seen with a frequency of approximately 2–5% and manifestation with progressive limitation of active and passive shoulder motion. Although it is common in women, it is more frequent between the ages of 35-70 and on the non-dominant side (Bhargav and Murrell, 2011). Besides, its etiology is not known precisely; it has been associated with diabetes mellitus, thyroid dysfunction, autoimmune diseases, and breast cancer (T. S. Lynch and Edwards, 2013). Secondary frozen shoulder occurs due to intrinsic, extrinsic, and systemic effects, and its possible causes can be trauma and post-surgical process (Grubbs, 1993). In this clinical study, all the recruited participants were patients with primary frozen shoulder syndrome.

6.2.1.1. Frozen Shoulder Syndrome Diagnosis

The diagnosis of frozen shoulder is based mainly on the patient's medical history and clinical examination (Grubbs, 1993). Clinically, pain and limitation of movement are the main complaints. Patients usually complain of severe pain that concentrates around the deltoid insertion and radiates downward. The FSS pain becomes more severe at night and prevents the patient from performing ADL.

6.2.1.2. Treatment of Frozen Shoulder Syndrome

FSS treatment aims to reduce pain, restore shoulder movement RoM, and maintain that motion capability (Mertens et al., 2020). Although different methods have been applied for therapy, treatments can be divided into two main headings non-surgical and surgical (de la Serna et al., 2021). Non-surgical treatment comprises drug use, physical therapy exercises, and steroid injections. Surgical treatments involve manipulation under anesthesia, shoulder arthroscopy, and botulinum toxin application. Especially in treating primary frozen shoulder patients, rehabilitation exercises related to ADL have an important place (Alptekin et al., 2016).

6.3. Therapy Procedure of Patients and Implementation of Designed System

In the clinical trials, the patients followed the treatment protocols recommended by the physician. This therapy protocol includes methods such as joint mobilization, Transcutaneous Electrical Nerve Stimulation (TENS) applications, warm modalities, and manipulation that are used in the treatment of primary FSS. The therapy process of the patients contains a total of 20 sessions, four weeks and five days a week.

During their four-week treatment period, the participants were asked to perform the RoM exercises using the developed system once a week. RoM exercises are preferred as they are used in the treatment of primary FSS, as mentioned in section 6.2.1.2. The selected tasks and their exercise patterns are illustrated in Figure 6.2. Each of the selected therapy tasks for clinical study has two different speed levels for the trajectory target. Thereby, a total of six difficulty levels have been defined for three tasks, with two levels for each task.

Figure 6.2. Implemented therapy tasks and their exercise patterns in the clinical study

Before the clinical trials, informed consent was obtained from the patients participating in the study using the Informed Consent Form (Appendix B).

Patients were briefed about the system's structure, the purpose of the study, and the therapy tasks before the clinical trials. At the beginning of the first experiments, the patient was given a few minutes of adaptation time without performing any exercises. After the adaptation period, the patient was given a 5-minute break.

The patients performed the exercises with the developed system before the therapy procedures prescribed by the doctor so that the applied treatment methods would not affect the performance evaluation of the system. The applied scales and performed measurements were carried out after the patients completed the exercises with the developed system.

The patients performed the experiments by sitting on a chair in front of the GUI screen. The IMU sensor was placed on the participants' right arm. The HR and GSR sensors were attached to the patient's left hand. As in the experiments with healthy subjects, the patients were asked not to move their left hands during the exercises so as not to affect the measurements. The clinical trial implementation of the designed system is shown in Figure 6.3.

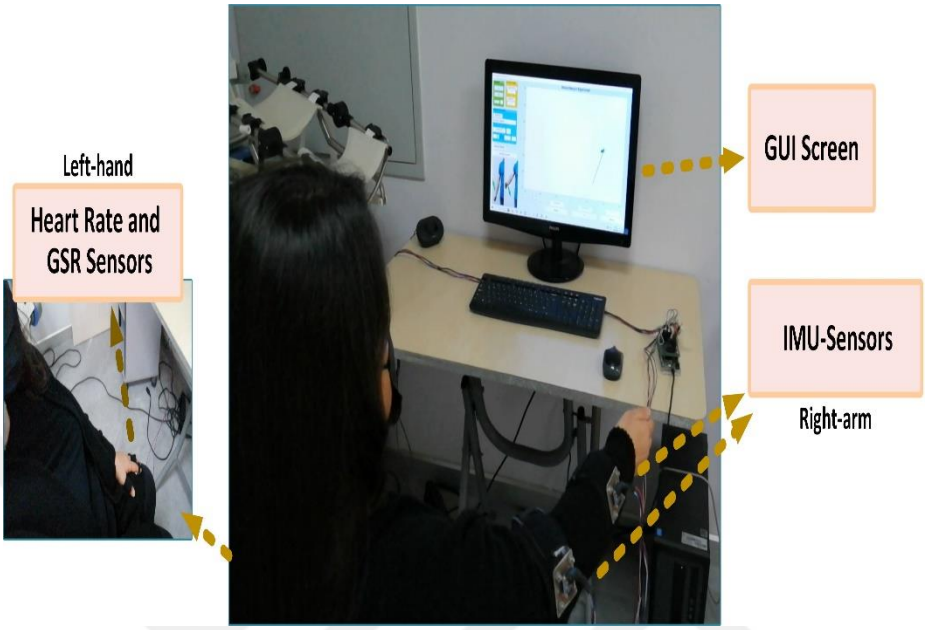

Figure 6.3. Implementation of the developed system in the clinical environment

6.4. Clinical Measurements and Implemented Scales

Although the system developed within the scope of this thesis can be used for performing rehabilitation exercises or movement analysis, the system's primary focus is evaluating patient participation and performance during therapy exercises. Therefore, the clinical study was planned based on comparing the participation and performance assessment data of the designed system with the patient's progress during the treatment process. In this context, various scales and clinical measurements were carried out to evaluate patients' improvements during the therapy process and their status during the use of the designed system. Implemented scales and clinical measurements are explained below and also given in Appendix C.

6.4.1. Personal Information Form

Participants' demographic information, such as age, height, body weight, and dominant extremity, was collected using the personal information form.

6.4.2. Patient Self-Assessment Scale

The Self-Assessment Scale was applied to make patients evaluate their exercise performance. The patients were asked to rate their performance between 0 and 10 after the experiments every week, and the scores given by the patients were recorded.

6.4.3. Joint Range of Motion (RoM) Measurement

RoM measurements assist physicians in making diagnoses, determining functional limitations, monitoring therapy improvements, or demonstrating treatment outcomes. Therefore, in clinical and scientific research, RoM measurements are performed using many methods, from simple tapes to electrical goniometers and kinematic analysis systems that evaluate patient kinematic data (Kolber and Hanney, 2012). In this study, the patients' shoulder joint RoM angles were measured by a clinician after weekly experiments and recorded. A digital inclinometer/goniometer was used for RoM measurements.

6.4.4. Visual Analog Scale for Physical Fatigue and Pain

Visual Analog Scale (VAS) is used to convert some values that cannot be measured numerically into quantitative. This scale consists of a 10 cm horizontally or vertically positioned line. At both ends of the line, there are two contrary statements about the situation to be evaluated. In the scales used in this study, these conditions are "extreme tiredness", "not feeling tired" for the fatigue scale, "having no pain", and "unbearable pain" for the pain assessment. During clinical trials, participants were asked to mark the point on the VAS line that best reflected their fatigue and physical pain level. The point marked by the patient is measured from the lower end of the line with the help of a ruler in cm to determine the patient's fatigue and pain score. VAS is a valid and reliable method for fatigue and pain assessment (Hewlett et al., 2011; Waterfield and Sim, 2013).

6.5. Results of Clinical Trials

The participants exercised for between five and seven minutes with the developed system during the clinical study, depending on their performance. All experiments were carried out under the supervision of a physiotherapist. The initial exercise level is always Shoulder Scaption – 1st speed level of the therapy target. The task levels at which the patients completed the exercises in the four-week experiments are given in Figure 6.4.

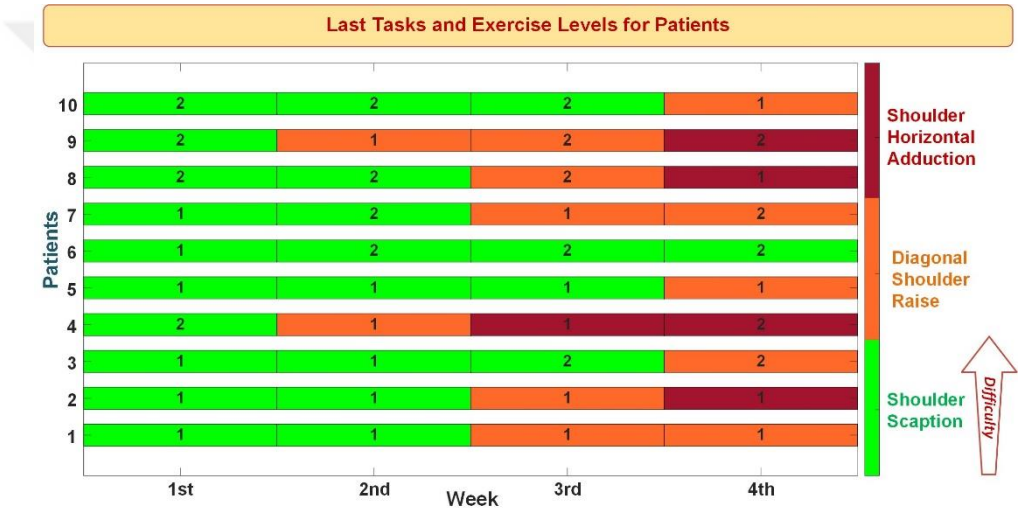

Figure 6.4. Patients' last tasks and exercise levels during the four-week experiments

The boxes in the figure show at which task level the patients completed the experiments that week. The numbers on the boxes represent the exercise level of the therapy task. During the four-week experiments, two patients reached the last task and exercise level. Two participants reached the final task level but not the final exercise level. Five patients completed the experiments at the second task level, and one patient finished the experiments at the first task level.

6.5.1. Statistical Evaluation

Statistical analysis was performed to examine the data obtained from the clinical study. In the statistical evaluation, the patients' measured shoulder joint RoM angles, the VAS for fatigue, and pain scales, the patient self-assessment scale, and the average weekly performance of the patients evaluated by the developed system were included. In addition, the task levels at which the patients completed the weekly exercises were included in the statistical analysis by enumerating the therapy tasks specified in Section 6.3. This enumeration was performed by evaluating the first therapy task and exercise level (Shoulder Scaption - 1st speed level of the therapy target) as one and the last task and exercise level (Shoulder Horizontal Adduction - 2nd speed level of the therapy target) as six.

For the statistical analysis of the data, SPSS (Statistical Package for the Social Sciences) 25.0 software was used. Categorical measurements were summarized as numbers and percentages, and continuous measurements as mean and standard deviation (median and minimum-maximum where appropriate). Shapiro-Wilk test was used to determine whether the parameters in the study showed a normal distribution. The Repeated Measures test was used to examine the difference between the patients' joint RoM angles (PJA), VAS for fatigue (VASF), and pain (VASP) scores, patient self-assessment scores (PSA), therapy performance of patients evaluated by the designed system (SPE), and patients' last task and exercise levels (PEL) according to weeks. Wilcoxon rank test was used to analyze the difference between weekly variations. For examining the relationship between continuous measurement parameters, the Spearman correlation test was implemented. The statistical significance level was taken as 0.05 in all tests.

6.5.1.1. Examination of the Shoulder Joint RoM Measurements

Table 6.2 shows the weekly changes in the shoulder joint RoM angles of the patients. When the findings were examined, it was determined that the weekly changes in shoulder flexion ($p<0.001$), shoulder extension ($p<0.001$), shoulder

abduction (p<0.001), shoulder adduction (p<0.001), shoulder internal rotation (p<0.001) and shoulder external rotation (p<0.001) were statistically significant (p<0.05).

Table 6.2. Examining the weekly changes in the shoulder joint angles

	1. Week	**2. Week**	**3. Week**	**4. Week**	**p**
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**	
Shoulder Flexion	120,8±19,5	130,3±18,8	139,1±5,9	147,1±13,6	**<0,001****
Shoulder Extension	22,4±4,7	29,8±6,8	35,7±5,9	40,6±5,9	**<0,001****
Shoulder Abduction	103,0±18,1	119,0±21,2	131,2±19,1	139,9±14,5	**<0,001****
Shoulder Adduction	11,0±3,8	18,0±3,9	23,5±3,7	27,2±2,7	**<0,001****
Shoulder Internal Rotation	51,3±15,2	57,8±16,9	68,3±14,4	74,0±14,2	**<0,001****
Shoulder External Rotation	40,5±18,3	47,0±19,1	58,4±17,4	63,8±15,9	**<0,001****

** p<0,05, **p<0,001, Repeated measures test*

In Table 6.3, the differences between the weekly changes in the shoulder joint angles were examined. In addition, the weekly variations of the shoulder joint angles are given in Figures 6.5 to 6.10.

Table 6.3. Differences between weekly changes in shoulder joint angles

	p1	p2	p3	p4	p5	p6
Shoulder Flexion	**0,005****	**0,005****	**0,005****	**0,005****	**0,005****	**0,005****
Shoulder Extension	**0,005****	**0,004****	**0,005****	**0,005****	**0,005****	**0,007****
Shoulder Abduction	**0,008****	**0,005****	**0,005****	**0,005****	**0,005****	**0,005****
Shoulder Adduction	**0,007****	**0,005****	**0,005****	**0,005****	**0,005****	**0,007****
Shoulder Internal Rotation	**0,007****	**0,005****	**0,005****	**0,011***	**0,008****	**0,007****
Shoulder External Rotation	**0,007****	**0,005****	**0,005****	**0,005****	**0,005****	**0,007****

** p<0,05, **p<0,001, Wilcoxon rank test, p1: 1. week - 2. week, p2: 1. week -3. week, p3: 1. week - 4. week, p4: 2. week - 3. week, p5: 2. week - 4. week, p6: 3. week - 4. week*

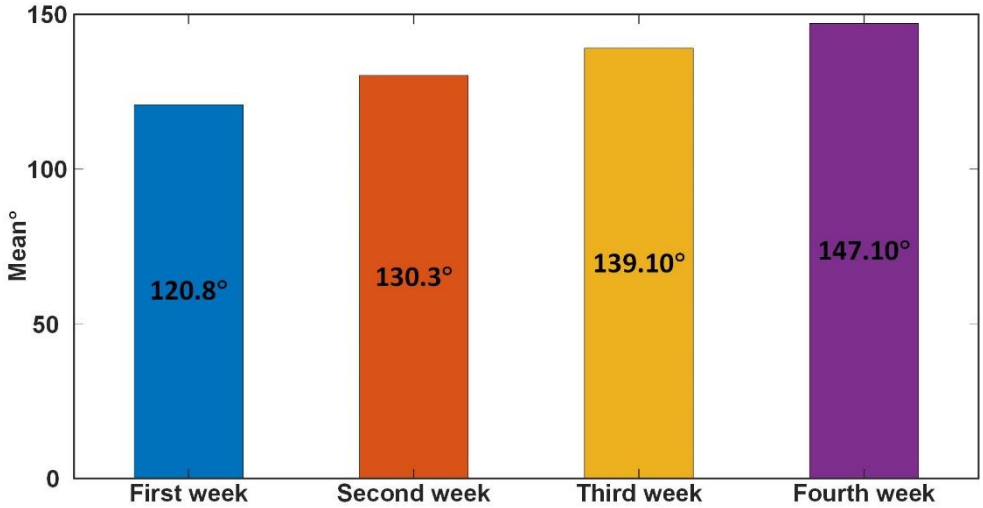

Figure 6.5. Weekly changes in the shoulder flexion angles of the patients

When the findings of the weekly change of patients' shoulder flexion angles are analyzed, there is a significant difference among weekly variations. The findings reveal that;

- 1st-week shoulder flexion angles are lower than 2nd week (p=0,005), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week shoulder flexion angles are lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week shoulder flexion angles are lower than the 4th-week shoulder flexion angles (p=0,005; p<0,05) (Table 6.3; Figure 6.5).

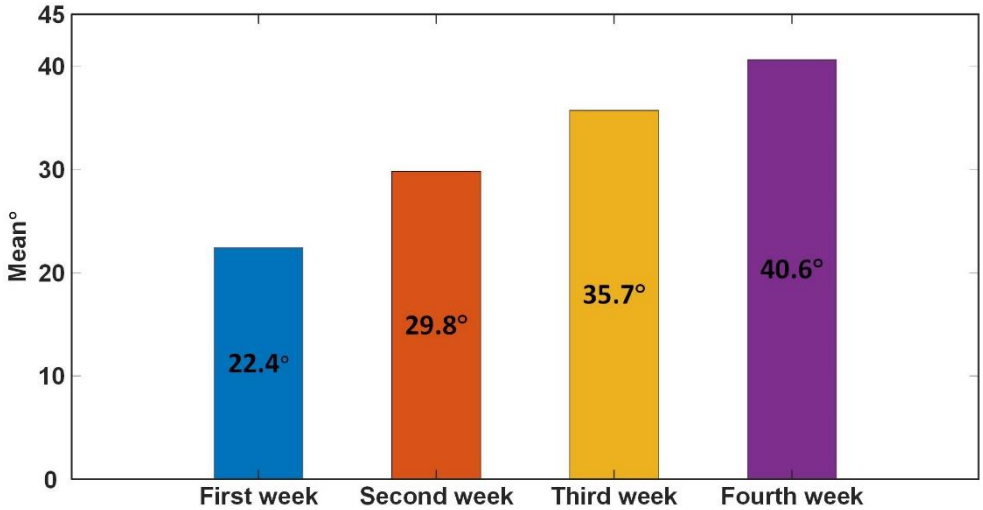

Figure 6.6. Weekly changes in the shoulder extension angles of the patients

Examination of the weekly change of patients' shoulder extension angles reveals that;

- 1st-week shoulder extension angles are significantly lower than 2nd week (p=0,005), 3rd week (p=0,004), and 4th week (p=0,005),

- 2nd-week shoulder extension angles are significantly lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week shoulder extension angles are significantly lower than the 4th-week shoulder extension angles (p=0,007; p<0,05) (Table 6.3; Figure 6.6).

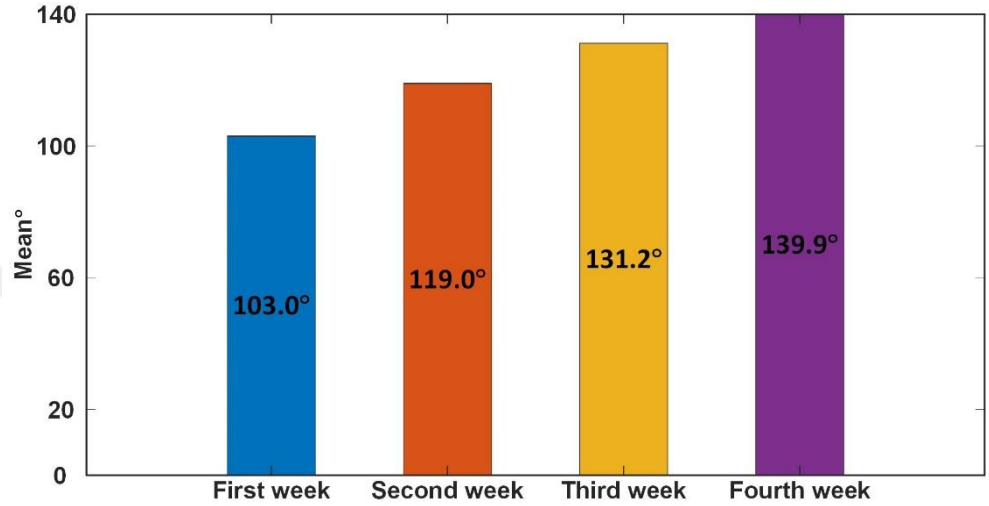

Figure 6.7. Weekly changes in the shoulder abduction angles of the patients

The findings obtained from the analyses of the weekly change in patients' shoulder abduction angles show that;

- 1st-week shoulder abduction angles are significantly lower than 2nd week (p=0,008), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week shoulder abduction angles are significantly lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week shoulder abduction angles are significantly lower than the 4th-week shoulder abduction angles (p=0,005; p<0,05) (Table 6.3; Figure 6.7).

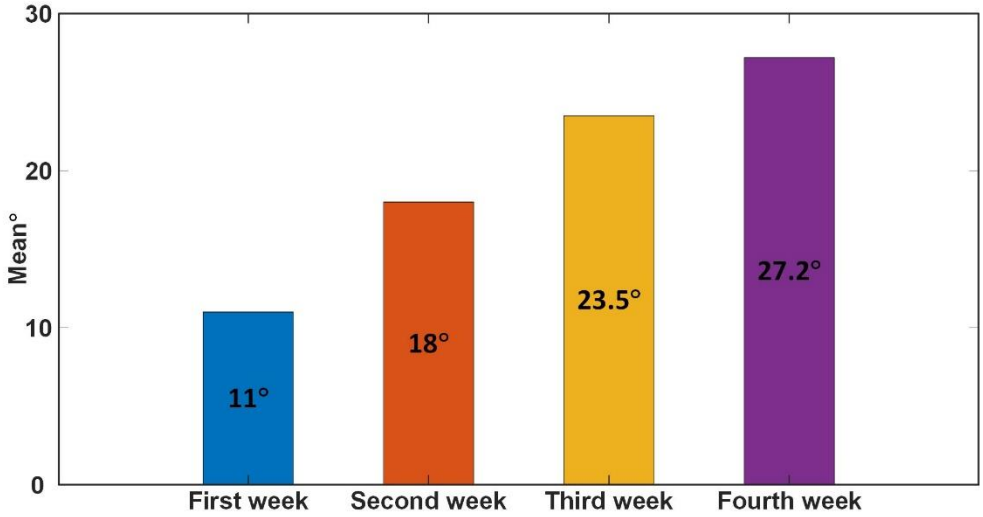

Figure 6.8. Weekly changes in the shoulder horizontal adduction angles of the patients

When the findings of the weekly change of patients' shoulder horizontal adduction angles are analyzed, there is a significant difference among weekly variations. The findings reveal that;

- 1st-week shoulder horizontal adduction angles are lower than 2nd week (p=0,007), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week shoulder horizontal adduction angles are lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week shoulder horizontal adduction angles are lower than the 4th-week shoulder horizontal adduction angles (p=0,007; p<0,05) (Table 6.3; Figure 6.8).

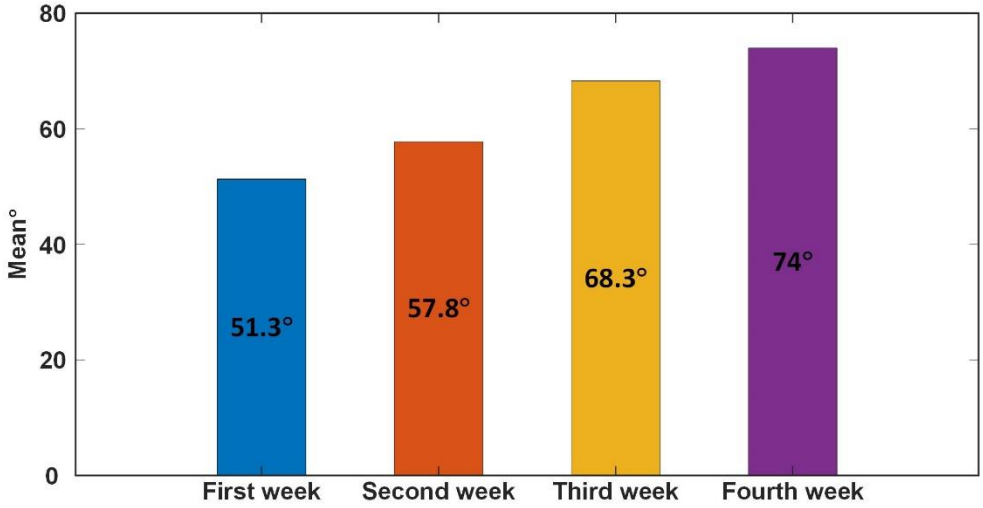

Figure 6.9. Weekly changes in the shoulder internal rotation angles of the patients

Examination of the weekly change of patients' shoulder internal rotation angles reveals that;

- 1st-week shoulder internal rotation angles are significantly lower than 2nd week (p=0,007), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week shoulder internal rotation angles are significantly lower than 3rd week (p=0,011) and 4th week (p=0,008),

- 3rd-week shoulder internal rotation angles are significantly lower than the 4th-week shoulder internal rotation angles (p=0,007; p<0,05) (Table 6.3; Figure 6.9).

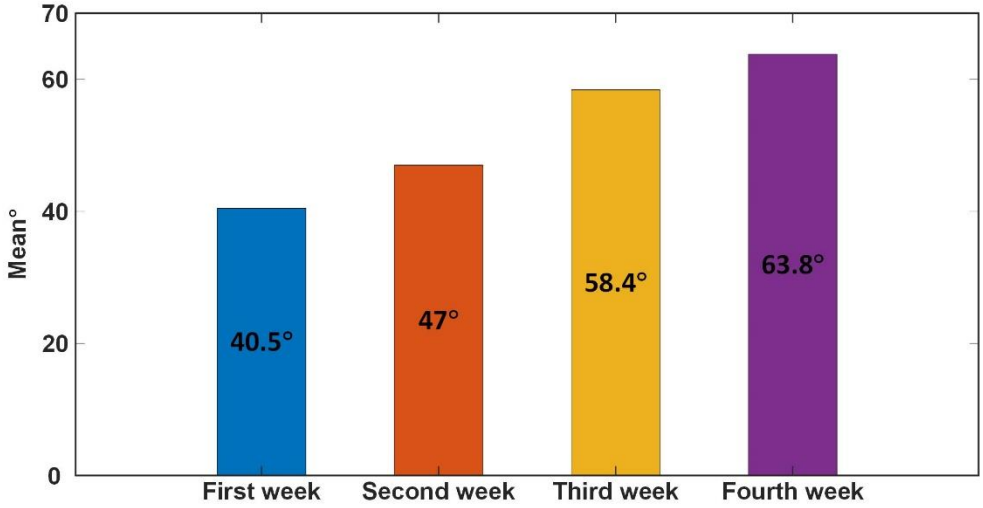

Figure 6.10. Weekly changes in the shoulder external rotation angles of the patients

When the findings of the weekly change of patients' shoulder external rotation angles are analyzed, there is a significant difference among weekly variations. The findings reveal that;

- 1st-week shoulder external rotation angles are lower than 2nd week (p=0,007), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week shoulder external rotation angles are lower than 3rd week (p=0,011) and 4th week (p=0,008),

- 3rd-week shoulder external rotation angles are lower than the 4th-week shoulder external rotation angles (p=0,007; p<0,05) (Table 6.3; Figure 6.10).

6.5.1.2. Examination of Patients' VAS Findings

In Table 6.4, the weekly changes in the VAS fatigue and VAS pain scores of the patients were examined. In the analysis, weekly changes in VAS pain (p=0.026) and VAS fatigue (p<0.001) scores were found to be statistically significant (p<0.05).

Table 6.4. Examination of weekly changes in patients' VAS fatigue and pain scores

VAS	1. Week	2. Week	3. Week	4. Week	p
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Fatigue (VASF)	1,10±0,2	1,58±1,7	0,96±,3	0,91±0,2	**0,026***
Pain (VASP)	5,87±0,9	4,84±0,9	3,54±1,2	2,19±0,6	**<0,001****

** p<0,05, **p<0,001, Repeated measures test*

In Table 6.5, the differences between the weekly changes in VAS fatigue and VAS pain scores of the patients were examined. The weekly variations of the Vas fatigue and pain scores of the patients are also given in Figures 6.11 and 6.12.

Table 6.5. Differences between patients' weekly changes in VAS fatigue and pain scores

VAS	p1	p2	p3	p4	p5	p6
Fatigue	0,325	0,137	**0,032***	0,091	**0,049***	0,343
Pain	**0,005****	**0,005****	**0,005****	**0,007****	**0,005****	**0,005****

** p<0,05, **p<0,001, Wilcoxon rank test, p1: 1. week - 2. week, p2: 1. week -3. week, p3: 1. week - 4. week, p4: 2. week - 3. week, p5: 2. week - 4. week, p6: 3. week - 4. week*

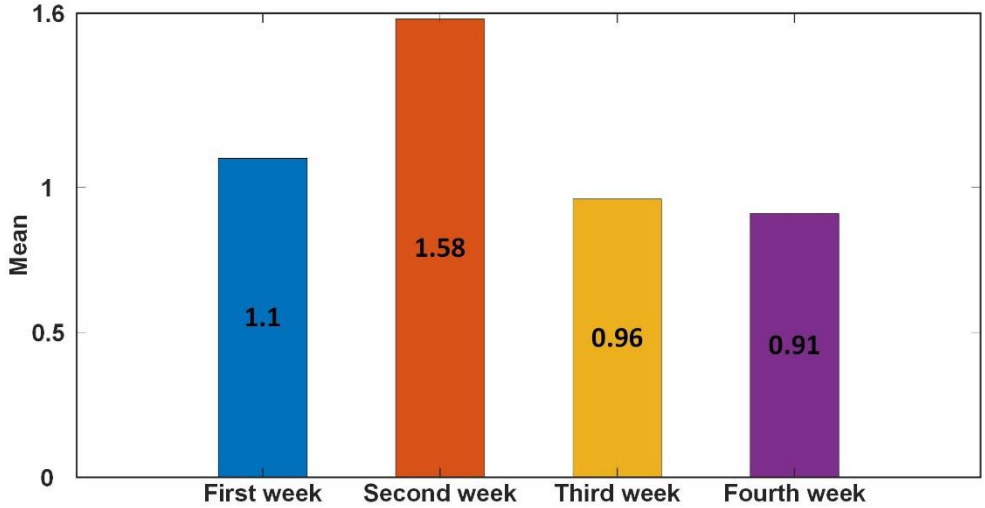

Figure 6.11. Weekly changes in patients' VAS fatigue scores

Analyzing the weekly change of patients' VAS fatigue scores, it was found that;

- 1st week's VAS fatigue score of patients was significantly higher than 4th week's score (p=0,032),

- 2nd week's VAS fatigue score of patients was also significantly higher than 4th week's score (p=0,049).

There was no significant difference between the VAS fatigue score for the other weeks (Table 6.5; Figure 6.11).

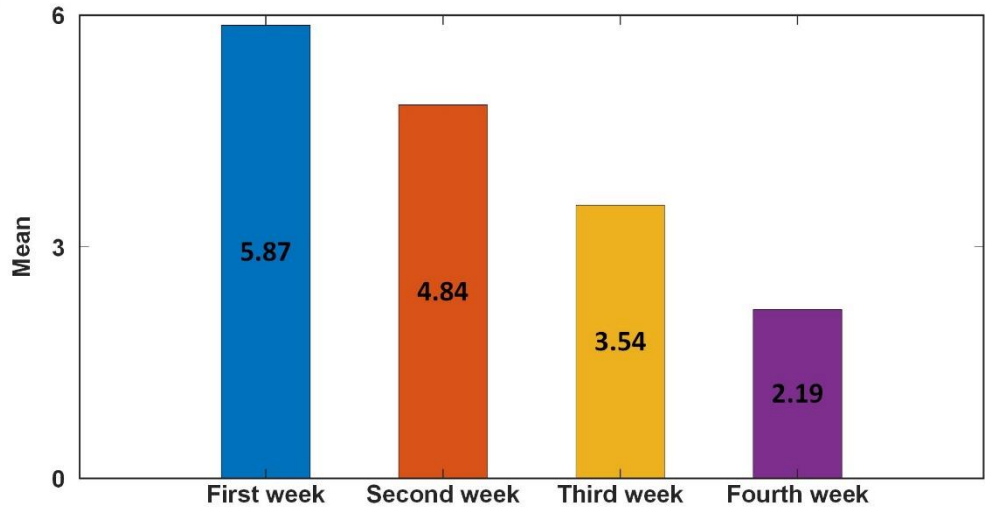

Figure 6.12. Weekly changes in patients' VAS pain scores

As seen in Table 6.5, the findings from the weekly change of patients' VAS pain scores analyses show that;

- 1st week's VAS pain score of patients was significantly higher than 2nd week (p=0,005), 3rd week (p=0,005), and 4th week (p=0,005),

-2nd week's VAS pain score of patients was significantly higher than 3rd week (p=0,007) and 4th week (p=0,005),

-3rd week's VAS pain score of patients was significantly higher than the 4th week's score (p=0,005; p<0,05) (Figure 6.12).

When the weekly VASF scores of the patients given in Figure 6.11 are examined, an increase is observed in the average of the second week's VASF score. The main reason for this increase is that the VASF score of the second patient this week is higher than the values in the other weeks. The second patient's weekly VASF scores are given in Figure 6.13.

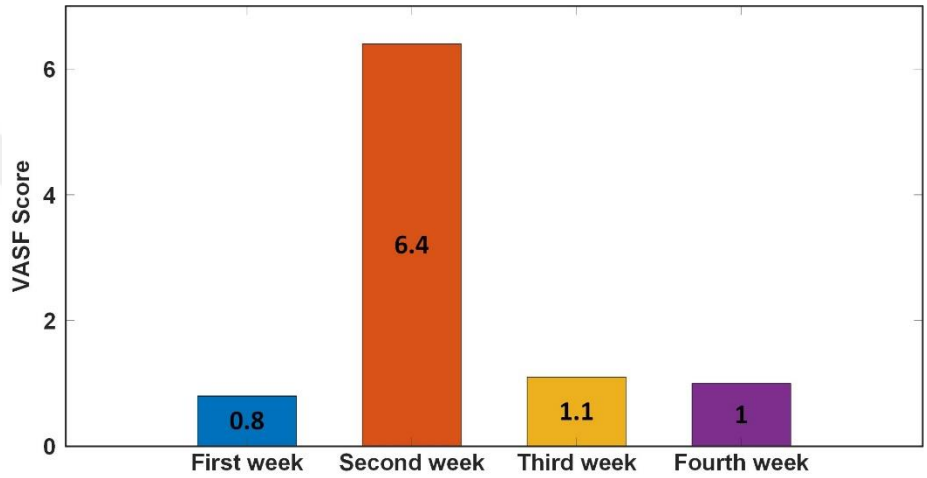

Figure 6.13. Weekly VAS fatigue scores of the second patient

In addition, tiredness was detected by the developed participation evaluation system during this patient's 2nd week of experiments. HR, GSR, and trajectory tracking error signals of this patient during the exercises in the 2nd week in which tiredness was detected and the signals in the 3rd week when there was no tiredness detection are given together in Figure 6.14 for comparison.

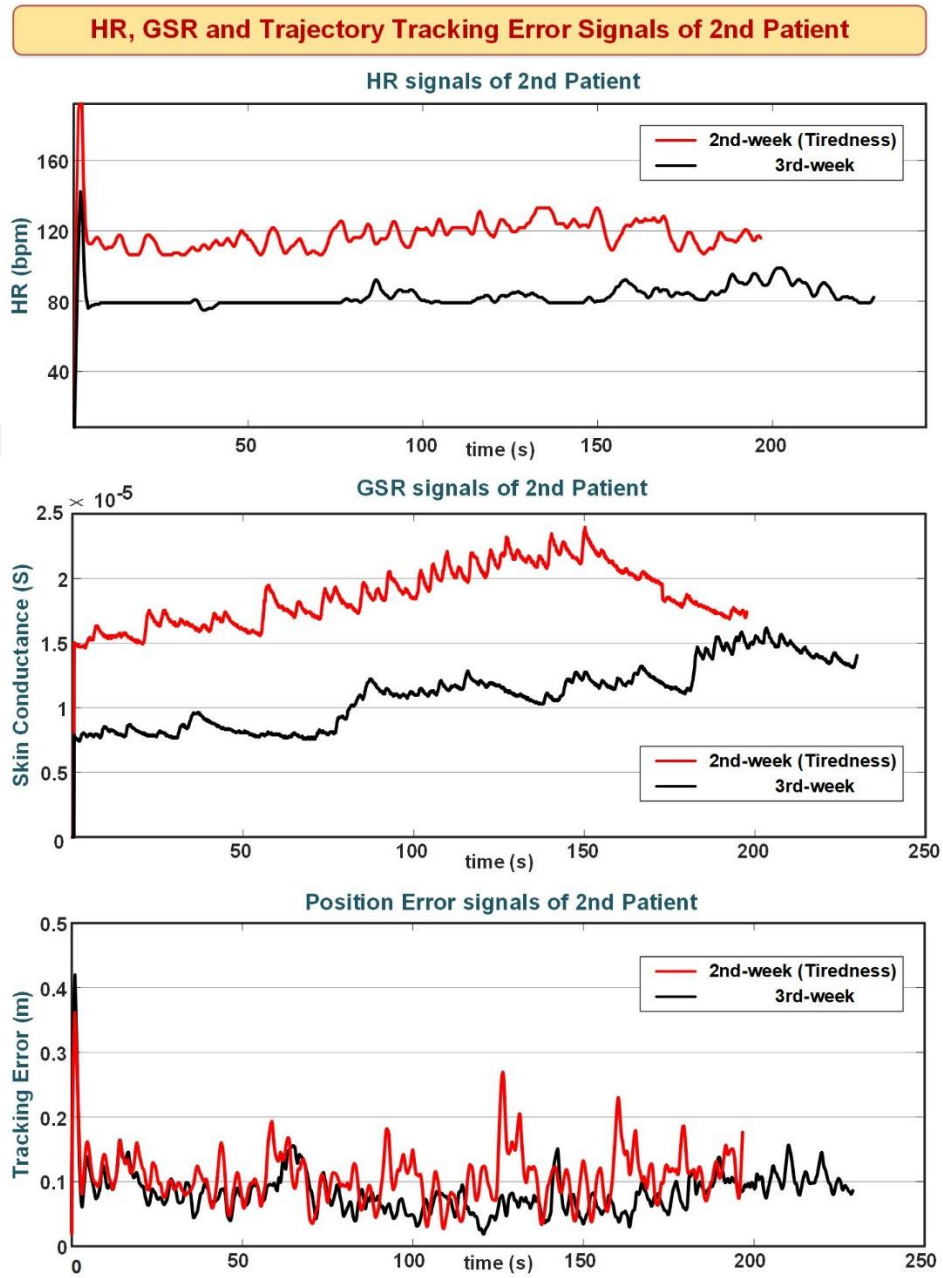

Figure 6.14. Second patient's (a) HR, (b) skin conductance, and (c) trajectory tracking error signals during the 2nd-week and 3rd-week experiments

When the physiological signals of this patient were examined, it was seen that the physiological signals in the second week when tiredness was detected were higher than the signals in the third week. Also, the trajectory tracking error signal in the second week was higher than in the third week. The performance, tiredness assessments, and variations in task difficulty levels of the patient during the 2nd-week experiment are given in Figure 6.15.

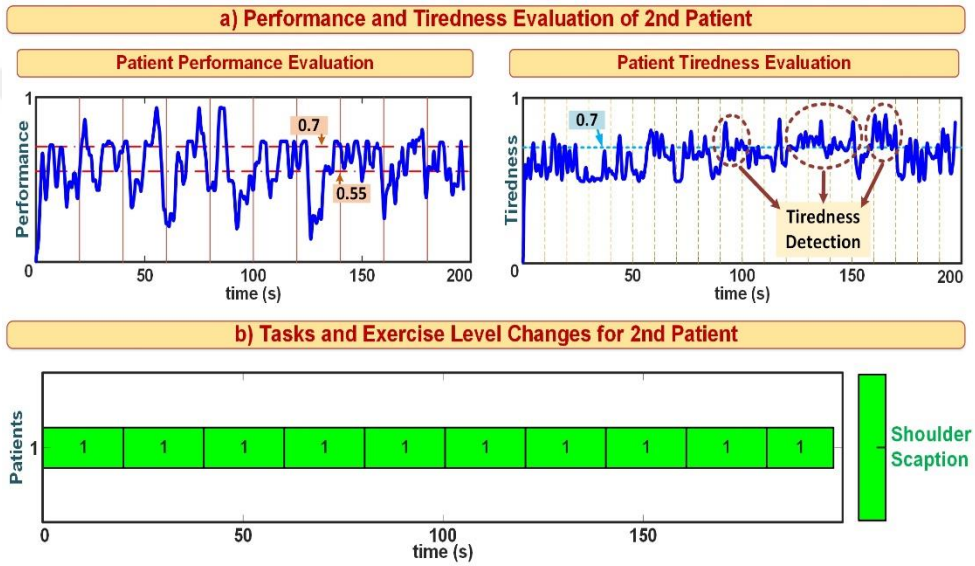

Figure 6.15. Second patient's (a) performance and tiredness evaluation and (b) exercise level changes during the 2nd-week experiment

When the VASF score and physiological signals of the patient in the second week were examined, it was seen that the developed system successfully evaluated the patient's tiredness.

6.5.1.3. Examining the Findings of Patient's Self-Assessment Scale

Weekly changes in the self-assessment scores of the patients were examined in Table 6.6. In the analysis, the weekly change in patient self-assessment scores was found to be statistically significant ($p<0.001$; $p<0.05$).

Table 6.6. Examination of weekly changes in patient self-assessment scores

	1. Week	2. Week	3. Week	4. Week	p
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Patient Self-Assessment (PSA)	7,10±1,3	7,35±1,1	8,15±0,9	9,4±0,7	**<0,001****

** p<0,05, **p<0,001, Repeated measures test*

In Table 6.7, the differences between the weekly changes in the patient self-assessment scores were examined. The weekly variations of the self-assessment scores of the patients are also given in Figure 6.16.

Table 6.7. Differences between weekly changes in patient self-assessment scores

	p1	p2	p3	p4	p5	p6
Patient Self-Assessment	0,595	**0,010***	**0,004****	**0,042***	**0,004****	**0,006****

** p<0,05, **p<0,001, Wilcoxon rank test, p1: 1. week - 2. week, p2: 1. week -3. week, p3: 1. week - 4. week, p4: 2. week - 3. week, p5: 2. week - 4. week, p6: 3. week - 4. week*

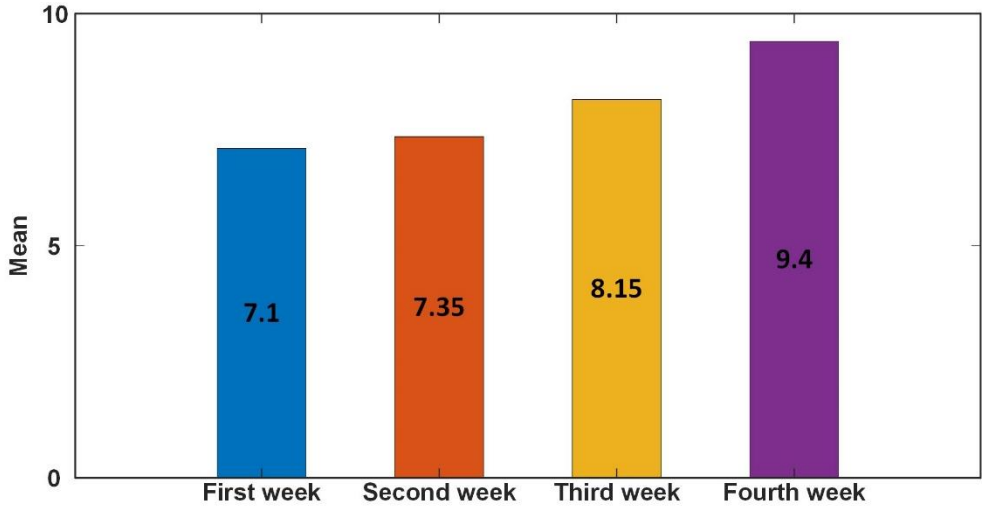

Figure 6.16. Weekly changes in the patient self-assessment scores

The findings obtained from the analyses of the weekly change in the patient self-assessment scores it was found that;

- 1st-week patient self-assessment scores are significantly lower than 3rd week (p=0,010) and 4th week (p=0,004),

- 2nd-week patient self-assessment scores are significantly lower than 3rd week (p=0,042) and 4th week (p=0,004),

- 3rd-week patient self-assessment scores significantly are lower than the 4th-week patient self-assessment scores (p=0,006; p<0,05) (Table 6.7; Figure 6.16).

6.5.1.4. Examining the Findings of Proposed System Patient Performance Evaluation

In Table 6.8, the weekly changes in the mean system performance assessment findings of the patients were examined. In the analysis, it was determined that the weekly change in the mean performances of the patients evaluated by the system was statistically significant (p<0.001; p<0.05).

Table 6.8. Examining the weekly changes in the mean performances of the patients evaluated by the developed system

	1. Week	**2. Week**	**3. Week**	**4. Week**	**p**
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**	
System Performance Evaluation (SPE)	0,58±0,03	0,60±0,03	0,63±0,03	0,66±0,03	**<0,001****

** p<0,05, **p<0,001, Repeated measures test*

In Table 6.9, the differences between the weekly change findings of the patients' mean performance assessed by the designed system were examined. Also,

the weekly variations of the average system performance evaluation values of the patients are given in Figure 6.17.

Table 6.9. Differences between weekly changes in the mean performance of patients assessed by the system

	p1	p2	p3	p4	p5	p6
System Performance Assessment	**0,005****	**0,005****	**0,005****	**0,005****	**0,005****	**0,005****

** p<0,05, **p<0,001, Wilcoxon rank test, p1: 1. week - 2. week, p2: 1. week -3. week, p3: 1. week - 4. week, p4: 2. week - 3. week, p5: 2. week - 4. week, p6: 3. week - 4. week*

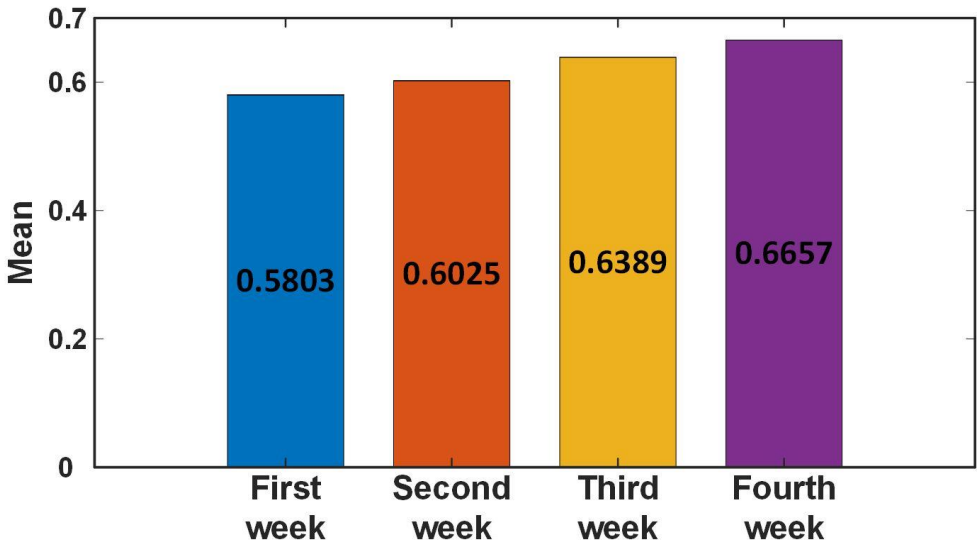

Figure 6.17. Weekly changes in patients' mean system performance evaluation values

When the weekly changes in the mean system performance assessment findings of the patients are analyzed, there is a significant difference among weekly variations. The findings reveal that;

- 1st-week patient performance evaluation values are lower than 2nd week (p=0,005), 3rd week (p=0,005), and 4th week (p=0,005),

- 2nd-week patient performance evaluation values are lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week patient performance evaluation values are lower than the 4th-week patient performance evaluation values (p=0,005; p<0,05) (Table 6.9; Figure 6.17).

6.5.1.5. Examining the Findings of Patient Exercise Levels

In Table 6.10, the weekly changes in the exercise levels that the patients completed the experiments were examined. In the examination, the weekly change in exercise levels was found to be statistically significant (p<0.001; p<0.05).

Table 6.10. Examining the weekly changes in patient exercise levels

	1. Week	**2. Week**	**3. Week**	**4. Week**	**p**
	Mean±SD	**Mean±SD**	**Mean±SD**	**Mean±SD**	
Patients Exercise Levels (PEL)	1,40±0,5	1,80±0,8	2,90±1,2	4,10±1,4	**<0,001****

** p<0,05, **p<0,001, Repeated measures test*

The differences between the weekly changes in the exercise levels of the patients were examined in Table 6.11. Also, the weekly variations of the patients' exercise levels are given in Figure 6.18.

Table 6.11. Differences between weekly changes in patient exercise levels

	p1	**p2**	**p3**	**p4**	**p5**	**p6**
Patients Exercise Levels	**0,046***	**0,010***	**0,005****	**0,015***	**0,007****	**0,010***

** p<0,05, **p<0,001, Wilcoxon rank test, p1: 1. week - 2. week, p2: 1. week -3. week, p3: 1. week - 4. week, p4: 2. week - 3. week, p5: 2. week - 4. week, p6: 3. week - 4. week*

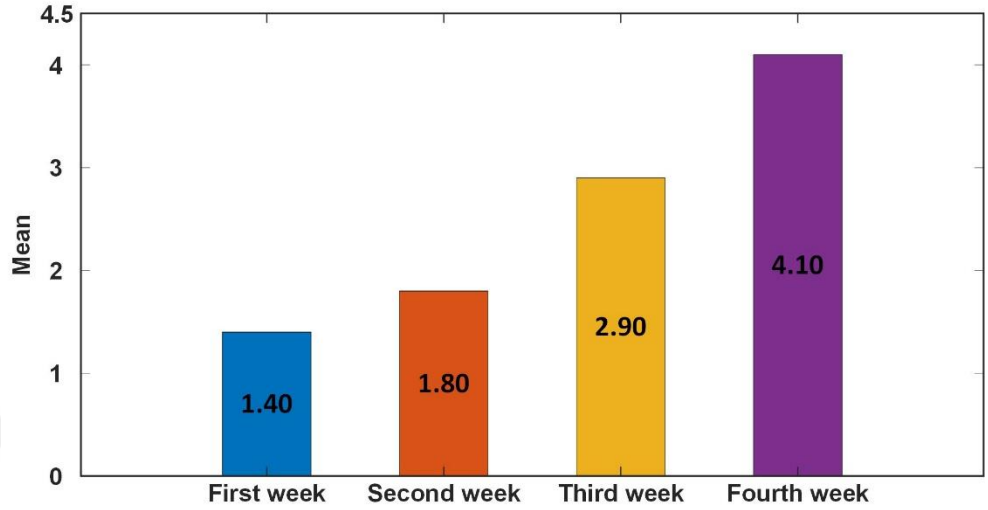

Figure 6.18.Examination of the weekly changes in the exercise levels of the patients

Examination of the weekly change of patients' levels reveals that;

- 1st-week exercise levels of the patients are significantly lower than 2nd week (p=0,005), 3rd week (p=0,004), and 4th week (p=0,005),

- 2nd-week exercise levels of the patients are significantly lower than 3rd week (p=0,005) and 4th week (p=0,005),

- 3rd-week exercise levels of the patients are significantly lower than the 4th-week exercise levels (p=0,007; p<0,05) (Table 6.11; Figure 6.18).

6.5.1.6. Examining the Changes in Patient Findings during the Therapy Period

The difference between the 4th-week and the 1st-week values of the findings evaluated statistically in the previous sections constitutes the delta (Δ) values of those findings. The delta shoulder joint angles of the patients are given in Figure 6.19. The figure reveals that the patients' shoulder joint delta angles are 36.9° delta shoulder abduction, 26.3° delta shoulder flexion, 22.7° delta shoulder internal rotation, 23.3° delta shoulder external rotation, 18.2° delta shoulder

extension, and 16.2° delta shoulder adduction from the largest to the smallest, respectively.

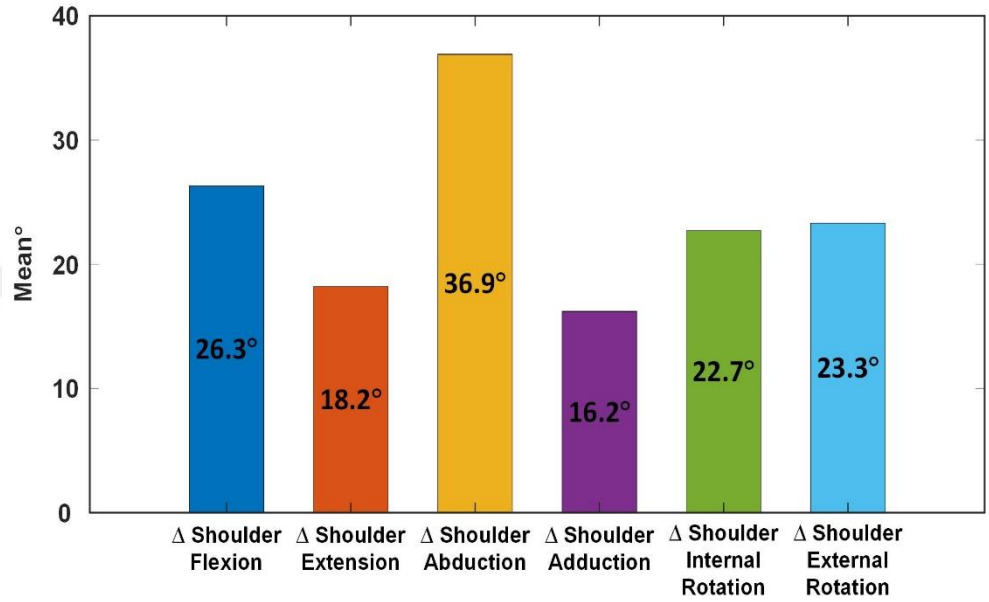

Figure 6.19. Examination of delta joint angles

In Figure 6.20, the changes in ΔVASF, ΔVASP, ΔPSA, ΔSPE, and ΔPEL values were examined. According to the examination, it was seen that there was an increase in ΔPEL with an average of 2.70, ΔPSA with an average of 2.30, and ΔSPE with an average of 0.09. Besides, It was observed that the patients' ΔVASP score decreased by an average of -3.68, and the ΔVASF score by an average of -0.19.

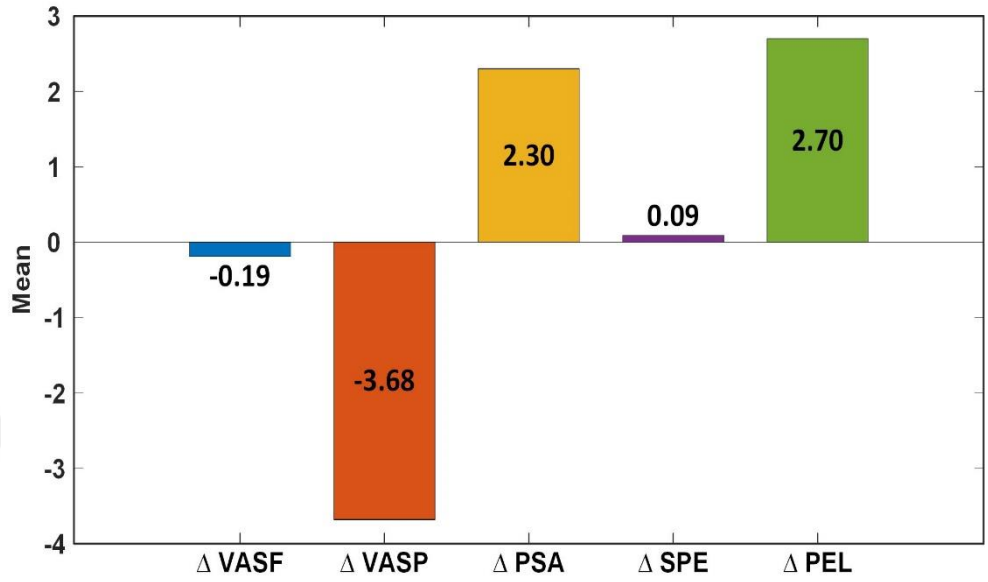

Figure 6.20.Examination of the changes in the ΔVASF, ΔVASP, ΔPSA, ΔSPE, and ΔPEL findings of the patients

6.5.1.7. Examining the Relationship between Delta Values of Patient Findings

In Table 6.12, the relationship between Δjoint angles, ΔPSA, ΔSPE, and ΔPEL values was examined. According to the analysis, no significant relationship was observed between ΔShoulder Flexion, ΔShoulder Extension, ΔShoulder Abduction, ΔShoulder Adduction, ΔShoulder Internal Rotation, and ΔShoulder External Rotation angles and ΔPSA, ΔSPE, and ΔPEL values ($p>0.05$).

Table 6.12. The relationship between patients' Δ joint angles and ΔPSA, ΔSPE, and ΔPEL findings

Delta Joint Angles	**Δ PSA**		**Δ SPE**		**Δ PEL**	
	r	**p**	**r**	**p**	**r**	**p**
ΔShoulder Flexion	0,222	0,538	-0,387	0,270	0,000	1,000
ΔShoulder Extension	-0,190	0,599	0,089	0,807	-0,095	0,795
ΔShoulder Abduction	-0,362	0,304	0,086	0,813	0,270	0,451
ΔShoulder Adduction	-0,211	0,558	0,251	0,485	-0,385	0,272
ΔShoulder Internal Rotation	-0,162	0,656	0,116	0,751	0,110	0,763
ΔShoulder External Rotation	-0,578	0,080	0,603	0,065	0,445	0,198

*Δ: Delta, * p<0,05, **p<0,001, r: Spearman correlation test*

The relationship between Δ joint angles and BMI and age values was examined in Table 6.13. According to the examination, no significant relationship was found between ΔShoulder Flexion, ΔShoulder Extension, ΔShoulder Abduction, ΔShoulder Adduction, ΔShoulder Internal Rotation, ΔShoulder External Rotation angles, and BMI and age values (p>0.05).

Table 6.13.The relationship between patients' Δ joint angles, BMI, and age findings

Delta Joint Angles	**BMI**		**Age**	
	r	**p**	**r**	**p**
ΔShoulder Flexion	-0,546	0,102	0,276	0,440
ΔShoulder Extension	-0,196	0,587	0,241	0,503
ΔShoulder Abduction	-0,228	0,527	0,295	0,407
ΔShoulder Adduction	0,226	0,530	0,428	0,217
ΔShoulder Internal Rotation	-0,407	0,243	-0,219	0,544
ΔShoulder External Rotation	0,098	0,787	-0,111	0,761

Δ*: Delta, * p<0,05, **p<0,001, r: Spearman correlation test*

Table 6.14 examines the relationship between Δ joint angles, ΔSPA, ΔSPE, ΔPEL data, and ΔVASF and ΔVASP scores. According to the analysis, no significant correlation was found between ΔShoulder Flexion, ΔShoulder Extension, ΔShoulder Abduction, ΔShoulder Adduction, ΔShoulder Internal Rotation and ΔShoulder External Rotation angles, and ΔVASF and ΔVASP scores (p>0.05). In addition, there was no significant relationship between ΔSPE, ΔPEL values, and ΔVASF and ΔVASP scores (p>0.05).

As the ΔVASF level of the patients decreased, it was determined that the ΔPSA value showed a moderate increase in the positive direction (r=-0.673; p=0.033; p<0.05).

Table 6.14. The relationship between patients' Δ joint angles, ΔSPA, ΔSPE, ΔPEL data, and ΔVASF and ΔVASP findings

Delta Joint Angles	**ΔVASF**		**ΔVASP**	
	r	**p**	**r**	**p**
ΔShoulder Flexion	-0,478	0,162	0,195	0,589
ΔShoulder Extension	0,019	0,958	-0,240	0,504
ΔShoulder Abduction	-0,106	0,771	-0,019	0,959
ΔShoulder Adduction	0,037	0,919	-0,608	0,062
ΔShoulder Internal Rotation	-0,222	0,538	-0,343	0,332
ΔShoulder External Rotation	0,137	0,706	-0,309	0,385
ΔPSA	-0,673	**0,033***	0,450	0,192
ΔSPE	0,239	0,506	-0,118	0,745
ΔPEL	-0,057	0,876	0,308	0,387

Δ*: Delta, * p<0,05, **p<0,001, r: Spearman correlation test*

6.6. Discussion

The effectiveness of the developed method was tested in clinical studies with patients with frozen shoulder syndrome, and the results were analyzed statistically. Later in this section, a detailed evaluation of the statistical findings was carried out.

Frozen shoulder is a syndrome that causes pain in patients and makes ADL difficult by restricting shoulder joint movements (Kelley et al., 2009). Although this syndrome can be seen in all age groups, it is more common between the ages of 40-60 and in females (Bhargav and Murrell, 2011; de la Serna et al., 2021).

These findings are consistent with the mean age of the patients participating in the study and the proportion of females among the patients.

When the shoulder joint angles and VASP scores of the patients were examined with the Repeated Measures test, it was observed that the shoulder joint angles increased each week significantly during the treatment, while the VASP scores decreased significantly (Table 6.3 and Table 6.5).

The majority of patients' VASF scores during the experiments were low and did not show overall significant change over weeks (Table 6.4 and Table 6.5). However, as seen in Figure 6.13, the second patient had a high VASF score during the 2nd-week experiments. In addition, the developed system detected tiredness during the patient's exercises this week (Figure 6.15). This tiredness detection is consistent with the patient's VASF score and reveals that the system can successfully evaluate the patient’s fatigue.

The weekly performances of the patients evaluated by the system and the levels at which they completed the exercises were statistically examined. Statistical results show that patient performances and exercise levels significantly increase each week (Table 6.9 and Table 6.11). In addition, as seen in Table 6.7, PSA scores generally increase significantly. When PSA scores are evaluated together with patient performance evaluations and exercise levels, it can be considered that patients can accurately evaluate their progress but give high scores when assessing their therapy performance.

In the correlation tests, no significant relationship was found between the changes in the shoulder joint angles and VASP scores of the patients, and the changes in the patient's performance evaluations and exercise levels (Table 6.12 and Table 6.14). It is considered that these results are due to the differences in the weekly rate of change of the findings. However, in the treatment of frozen shoulder, the main criteria for recovery are reduction in pain and increased joint angles (Challoumas et al., 2020). When the findings are examined clinically, it is consistent with the weekly increase in the joint angles of the patients and the

decrease in VASP scores, and the weekly increases in the patient performance evaluations and exercise levels. While joint angles increased and VASP scores decreased as an indicator of patient improvement and progress, patients' performance evaluation values and exercise levels increased in parallel. These findings reveal that the developed system can successfully evaluate patient performance clinically.

No slacking was detected for any patient during the experiments. This finding can be interpreted as patients who come to a private clinic by paying a fee to be treated actively participate in therapy exercises. In addition, in the correlation tests, no significant correlation was found between the changes in the joint angles of the patients and the BMI and age data (Table 6.13).

6.7. Limitations

Despite the successful results obtained from the experiments with healthy subjects and clinical trials, the number of patients limits the generalizability of the results. It is considered that the reluctance of patients to go to medical institutions during the COVID-19 pandemic is also effective in the low number of participants in the clinical trials (Chang, 2020). Also, fatigue during physical exercise depends on many different factors such as age, gender, exercise history, and type of exercise (Wan et al., 2017). Therefore, clinical studies with a larger patient population may provide a more comprehensive evaluation of the developed system's effectiveness. In the proposed method, the fuzzy membership functions and the ruleset have been determined experimentally. Even though the experimental results show that the designed FIS works successfully, this approach could affect the performance estimation of the system. Also, implementing wireless communication between sensors and data acquisition boards will increase the applicability of the system.

7. CONCLUSION

In the treatment of patients with neuromuscular disorders, active and voluntary participation in rehabilitation exercises is a critical factor for improving the functional outputs gained from therapy. When performing the rehabilitation exercises with robotic devices, for enhancing the active engagement of the patients, therapy tasks and device assistance are adjusted based on the patient's therapy performance. However, some of the existing performance evaluation approaches in the literature are based on certain device designs. Also, some methods are suitable for only specific therapy tasks or neglect the patient's changing capabilities during the exercises.

In this thesis, a new method is proposed that assesses the patient's changing capacities and therapy performance during rehabilitation exercises based on a multimodal sensor fusion form by the trajectory tracking error signal and the patient's physiological data (heart rate and skin conductance). The proposed method evaluates the therapy performances of patients independently from any therapy tasks or device designs. Patients' status like fatigue and slacking are substantial factors that should be assessed during therapy exercises. The developed system also evaluates the tiredness and slacking of the patients. In the proposed structure, upper limb joint angles are measured by IMU sensors, and the patient’s upper limb movements are estimated by the upper limb kinematic module. The performance, tiredness, and slacking are evaluated using a fuzzy inference system based on the patient’s physiological responses and exercise profile. Therapy tasks and difficulty levels of these tasks are adjusted by the therapy task management module according to the patient's performance and tiredness.

For performance assessment, the proposed method firstly has been tested experimentally on healthy subjects. Also, additional experiments have been performed for different cases while measuring the sEMG signals of the subjects to demonstrate the proposed method's effectiveness. Experimental results have shown

that the system evaluates subject performance successfully and adjusts the difficulty levels of therapy tasks according to the subjects' performance & voluntary engagement. The developed system has also thoroughly assessed the tiredness and slacking of the subjects during the rehabilitation exercises. After completing the experiments with healthy subjects, the efficacy of the proposed system was tested on patients with frozen shoulder symptoms in a clinical environment. The findings from the clinical study revealed that patients' progress and recovery during the therapy coincided with the weekly changes in the system's performance evaluation and the patients' exercise levels. In addition, the developed system successfully detected patient tiredness during the clinical trials. Moreover, the overall success of the proposed system was validated by the statistical analysis using clinical findings of the experiments.

The proposed method offers a low-cost solution for the performance assessments of the patients during the rehabilitation exercises, and it is suitable for use in-home, clinical treatment environments, and tele-rehabilitation applications. The proposed system also could be implemented for performance evaluation in conventional therapy and sports exercises.

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BIOGRAPHY

Erkan ÖDEMİŞ received his BSc. and MSc. from the Electrical and Electronics Engineering Department of Çukurova University in 2012 and 2015, respectively. He has been working as a Research Assistant in the Biomedical Engineering Department of Çukurova University since 2012. His research areas are robotics, rehabilitation robotics, and sensor fusion.

SCI/SCI-Expanded Publications

Ödemiş, E., and Baysal, C. V., "Development of a participation assessment system based on multimodal evaluation of user responses for upper limb rehabilitation", Biomedical Signal Processing and Control, vol. 70, 2021.

National and International Patents

A Participation Assessment System Based on Multimodal Evaluation of User Responses for Upper Limb Rehabilitation, **Erkan ÖDEMİŞ**, Cabbar Veysel BAYSAL (In Progress)

APPENDICES

APPENDIX A:

ETHICS COMMITTEE APPROVAL

T.C. ÇUKUROVA ÜNİVERSİTESİ TIP FAKÜLTESİ GİRİŞİMSEL OLMAYAN KLİNİK ARAŞTIRMALAR ETİK KURULU

Toplantı Sayısı		Tarih
113		9 Temmuz 2021

KARAR NO 22- Çukurova Üniversitesi Fen Bilimleri Enstitüsü Elektrik-Elektronik Mühendisliği Anabilim Dalı'nda, Doktor Öğretim Üyesi Cabbar Veysel Baysal yönetiminde, Çukurova Üniversitesi Spor Bilimleri Fakültesi Doktora Öğrencisi Mustafa Alhaddad'ın katkılarıyla, Araş. Gör. Erkan Ödemiş tarafından yürütülmesi öngörülen, "Rehabilitasyon Amaçlı Akıllı Robotik Kol Ortezinin Tasarımı ve Değerlendirilmesi" başlıklı doktora tez projesi araştırma etiği yönünden değerlendirildi. Toplantıya katılan üyelerin oybirliğiyle uygun olduğuna karar verildi.

BAŞKAN	**Prof Dr Selim Kadıoğlu** Tıp Tarihi ve Etik Anabilim Dalı	
ÜYELER	**Prof Dr Davut Alptekin** Tıbbi Biyoloji Anabilim Dalı	
	Prof Dr Dinçer Yıldızdaş Çocuk Sağlığı ve Hastalıkları Anabilim Dalı	
	Prof Dr Gülşah Seydaoğlu Biyoistatistik Anabilim Dalı	
	Prof Dr Gürhan Sakman Genel Cerrahi Anabilim Dalı	
	Doç Dr Zehra Hatipoğlu Anesteziyoloji ve Reanimasyon Anabilim Dalı	
	Doktor Öğretim Üyesi Yasemin Saygıdeğer Göğüs Hastalıkları Anabilim Dalı	
	Av Simay Sönmezateş Hukukçu Üye	
	Dr Neşe Kayrın Kurum Dışı Üye	

Çukurova Üniversitesi Tıp Fakültesi Dekanlık Binası, Balcalı 01330 Adana
Telefon: 0322 338 60 60 dahili 3465, Faks: 0322 338 67 22

(Signatures were shaded in accordance with personal data protection principles.)

APPENDIX B:

THE INFORMED CONSENT FORM

AYDINLATILMIŞ ONAM FORMU

REHABİLİTASYON AMAÇLI AKILLI ROBOTİK KOL ORTEZİNİN TASARIMI VE DEĞERLENDİRİLMESİ

BİLGİLENDİRME ve RIZA FORMU

Dr. Öğr. Üyesi Cabbar Veysel BAYSAL yönetiminde, Çukurova Üniversitesi Fen Bilimleri enstitüsü Elektrik Elektronik Mühendisliği anabilim dalı doktora öğrencisi Ar. Gör. Erkan ÖDEMİŞ tarafından doktora tez çalışması olarak sürdürülen araştırmamız çerçevesinde yetişkin bireylerde ile ilgili ölçümler yapılacaktır.

Bu çalışmanın amacı, "Design and Evaluation of an Intelligent Robotic Arm Orthosis for Rehabilitation Use (Rehabilitasyon Amaçlı Akıllı Robotik Kol Ortezinin Tasarımı Ve Değerlendirilmesi)" başlıklı doktora tezi kapsamında geliştirilen, rehabilitasyon egzersizleri sırasında hasta katılımını değerlendirme yönteminin etkinliğinin incelenmesidir.

Çalışmaya katılan gönüllülere sadece hekim tarafından önerilen tedavi modaliteleri uygulanacak, bunlardan başka herhangi bir girişim olmayacaktır.

Sonuçlar öncelikle bilimsel amaçla kullanılacak, kişisel bilgileriniz gizli tutulacak, sorun saptanması halinde durum size bildirilecek ve alınması gereken önlemler konusunda ayrıntılı bilgilendirme yapılacaktır. Parasal bir bedel ödemenizi gerektirmeyen ve size de bir ödeme yapılması söz konusu olmayan bu çalışmaya katılmama ve katıldıktan sonra çekilme hakkınız bulunmaktadır. Ek bilgi talebiniz olursa sözlü olarak karşılanacaktır.

Araştırmamıza katılmayı kabul ediyorsanız, lütfen aşağıdaki bölüme adınızı-soyadınızı yazıp tarih ve imza atınız. Teşekkür ederiz.

Katılımcı ile görüşen Doktora öğrencisi
Ar. Gör. Erkan ÖDEMİŞ

SÖZ KONUSU ARAŞTIRMAYA, YUKARIDA BELİRTİLEN KOŞULLAR ÇERÇEVESİNDE HİÇBİR BASKI VE ZORLAMA OLMAKSIZIN KENDİ RIZAMLA KATILMAYI KABUL EDİYORUM.

Katılımcı
Adı, soyadı:
Adres:
Tel.
İmza

Görüşme tanığı
Adı, soyadı:
Adres:
Tel.
İmza:

Katılımcı ile görüşen fizyoterapist
Adı soyadı, unvanı:
Adres:
Tel.
İmza

APPENDIX C:

CLINICAL MEASUREMENTS AND IMPLEMENTED SCALES

Personal Information Form

KİŞİSEL BİLGİ FORMU Tarih:

Anket No: GSM/Tel no:

1.Ad ,Soyadı; 2.Yaş: 3.Boy (m):

4.Ağırlık (kg): 5:Dominant Ekstremite:

Patient Self-Assessment Scale

HASTA SELF DEĞERLENDİRME ÖLÇEĞİ

Ad, Soyadı: Tarih:

Deney sırasındaki performansınızı 0 ile 10 arasında puanlayınız.

Hasta Puanı:…….

Joint Range of Motion (RoM) Measurement

Hasta Adı: *Tarih:*

Eklem Açıklığı Ölçümleri

Omuz Fleksiyon:	
Omuz Ekstensiyon:	
Omuz Abdüksiyon:	
Omuz Hor. Addüksiyon:	
Omuz İç Dönme:	
Omuz Dış Dönme:	

Visual Analog Scale for Physical Fatigue

FİZİKSEL YORGUNLUK İÇİN GÖRSEL ANALOG ÖLÇEK (GAÖ)

Ad, Soyadı: **Tarih:**

Şuan ki genel fiziksel yorgunluk şiddetinizi aşağıdaki 10 cm'lik çizgi üzerinde işaretleyiniz.

Kendimi fiziksel olarak dayanılmaz şiddette yorgun hissettim

10

0

Kendimi fiziksel olarak hiç yorgun hissetmedim

Visual Analog Scale for Pain

AĞRI İÇİN GÖRSEL ANALOG ÖLÇEK (GAÖ)

Ad, Soyadı: **Tarih:**

Omzunuzdaki ağrı şiddetini aşağıdaki 10 cm'lik çizgi üzerinde işaretleyiniz.

Hiç ağrı olmaması — En dayanılmaz ağrı