UNIVERSITY OF CALIFORNIA,

IRVINE

Closing the loop on development of rehabilitation technologies: a Design for Uptake paradigm

DISSERTATION

submitted in partial satisfaction of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

in Mechanical and Aerospace Engineering

by

Veronica Ann Swanson

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DEDICATION

To Jacob, my partner in life, to my family, to my friends, and to the many teachers and mentors I have had, thank you. I am truly blessed and grateful for the support I have received.

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ABSTRACT OF THE DISSERTATION

Closing the Loop on Development of Rehabilitation Technologies: a Design for Uptake Paradigm

By

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Doctor of Philosophy in Mechanical and Aerospace Engineering

University of California, Irvine, 2023

Professor David J. Reinkensmeyer, Chair

Movement recovery after stroke is a long process requiring intensive rehabilitation. As an individual recovers, the setting of their care changes and the level of supervision decreases, from supervised clinic, to supervised home, to unsupervised home rehabilitation. Robotics and sensor-based technologies rehabilitation technologies (RTs) have been developed to support rehabilitation through these stages, but it is still unclear when and how they can be most useful. This dissertation leveraged systematic literature review, qualitative data analysis, and direct measurements from RTs themselves in the form of usage analytics to gain insight into these issues and improve RT design.

In Part 1 of the dissertation, use of RTs was studied in the three settings. To understand uptake in the supervised clinical setting, a systematic review of the existing literature on rehabilitation technology was used to generate a list of 17 constructs that influence uptake. Three occupational therapists (OTs) and two physical therapists (PTs) employed at a major, rehabilitation hospital that encourages the use of technology wrote vignettes from a written prompt describing their RT use decisions during treatment sessions with nine patients. Vignettes were coded using deductive qualitative analysis

from the 17 constructs. In the clinical setting early in rehabilitation, therapists rarely chose to use RT, characterizing candidate RT as having a relative disadvantage compared to conventional treatment in the clinic due to lack of relevance to functional training, the time required for training and setup, and poor adaptability to patient-specific attributes, such as cognitive limitations. RT was typically only used when specific devices provided a desirable function that conventional treatment could not.

In contrast, RT was seen as having a relative advantage during supervised use in the home setting. A Sensor Enhanced Activity Management (SEAM) system was developed to combine home exercise program (HEP) management software with a movement sensor for monitoring and motivating HEP adherence. Three therapists used the system in their regular practice during the first six months of the COVID-19 pandemic. Patients were active for a mean of 40% (26% SD) of prescribed days and completed a mean of 25% (25% SD) of prescribed exercises. The therapists reported that remote monitoring and the use of a physical movement sensor was motivating to their patients and increased adherence, highlighting a perceived advantage of RT in the home setting.

Given RT's potential in the home setting to motivate use, can changes in the design of RT modulate uptake and further increase its use? Motor learning research suggests that a key to motivation is optimizing challenge. This hypothesis was tested using long-term, self-determined exercise patterns of a large number of individuals (N = 2,581) engaging in home rehabilitation with a sensorized gaming exercise system (SGES) without formal supervision. The SGES is comprised of two puck-like sensors and a library of 40 gamified exercises for the hands, arms, trunk, and legs that are designed for people recovering from a stroke. Appropriate challenge level and regular initiation of exercise sessions were found

to maximize perseverance, while experiences of low challenge in the first week were associated with the lowest levels of overall perseverance.

In summary, Part 1 of the dissertation found that RT has a relative advantage in the home versus clinical setting if it can improve motivation. Further, a key factor of RT design – the challenge level it presents – was demonstrated to modulate perseverance. Part 2 of the dissertation then focused on measuring the actual effects of RT uptake in the home setting. First, a systematic review was conducted and the SGES was evaluated based on recommended design features. The SGES can be considered near optimal, except it does not have a recommended feature that allows a therapist to monitor and communicate with the user. Next, improved clinical outcomes resulting from use of the SGES compared to conventional home therapy were demonstrated based on analysis of results from a single-blind, randomized controlled trial with 27 participants in the subacute phase of stroke. Adherence in the context of the clinical trial was shown to be superior to adherence in an unsupervised context, suggesting that the missing design feature of therapist presence affected adherence. Finally, it was demonstrated that home RT has the potential to measure its own effect on the user, because it provides data that can be used to accurately estimate users impairment level using nonlinear modeling techniques. This opens the door for self-assessing RTs for the home setting.

In Part 3 of the dissertation, refinements to the design of the SEAM and SGES RTs for home exercise were implemented and evaluated. Changes to the SEAM system focused on automating the connections to the sensor via Bluetooth and improving the repetition counting algorithm. In a subsequent trial of the system, 63% (39% SD) of the exercises that patients completed in the system generated sensor data compared to 22.1% (29.7% SD) of

the completed exercises from the first trial, a three-fold increase in the uptake of the sensor component. A suite of changes to the SGES studied here aimed to ramp up the difficulty more quickly for less impaired users and give an option to manually lower the difficulty for more impaired users. However, examining a second set of user data (N = 1,251) 2.5 years after these changes were implemented showed a decrease in overall levels of perseverance relative to the previous versions of the system in the number of repetitions performed (median 2,047 vs 1,219 repetitions), time spent exercising (median 52 vs 48 minutes), and the number of days (median 6 vs 5 days) the system was used. Though the intent of the changes was to have users experience more challenging exercises more quickly, the actual result was that more users achieved 100% success during their first week of use, an experience which corresponds to low rates of perseverance in the system. The reasons for this unintended result are discussed, but, overall, this study illustrates at large scale how RT software design changes modulate user behavior in complex ways. Further, the self-monitoring capability of RT is proposed as a powerful new tool to guide RT design for the home rehabilitation environment, where measures of adherence have been historically difficult to obtain.

Chapter 1: Introduction – The Problem of Uptake in Rehabilitation Technology Design

1.1 Prevalence of Stroke

Approximately 80 million people a year experience a stroke around the world [1]. In the US, the American Heart Association projects that by 2030, an additional 3.4 million people over the age of 18 years old will have had a stroke, which will be a 20.5% increase in prevalence from 2012 [2], and approximately 795,000 people experience a stroke each year. On average, someone has a stroke every 40 seconds [2].

A stroke is a neurologic injury that can have a wide variety of impacts on an individual's life. A stroke usually occurs when a blood clot blocks the flow of blood in the brain – an ischemic stroke – or a blood vessel ruptures within the brain – a hemorrhagic stroke [3]. The effects of a stroke vary by the size and the location of the lesion within the brain [4], but symptoms can include hemiparesis, motor impairments, vision problems, memory loss, change in behavior, and speech and language problems [5] that can be acute or chronic, affecting the individual for the rest of their life. In fact, stroke is a leading cause of chronic disability in the United States [6], [7]. Most post-stroke care relies on rehabilitation interventions, and stroke mortality in the US continues to decline [2], [8], [9]. This suggests a growing need for rehabilitative services for stroke recovery.

1.2 Stroke Rehabilitation

Recovery from stroke is a long process requiring extended periods of neurologic rehabilitation, which includes cycles of assessment, goal setting, prescribed interventions, evaluation, and adjustment of interventions [10], [11]. Intensive upper extremity (UE)

rehabilitation can reduce long-term impairments after stroke [12]–[16]. This typically requires patients to perform many repetitions of specific exercise motions [17], and though exact dose-response relationships are unknown, recovery also appears to depend on the volume of movement practice [18]–[22].

Post-stroke care involves a progression through several stages of care with decreasing levels of supervision from professional health care providers. After onset of stroke, a patient typically receives treatment in an acute-care hospital. Between 24-48 hours after onset, once their condition is deemed stable, patients begin inpatient rehabilitation to prevent complications from inactivity [11]. Following a period of inpatient rehabilitation, patients may be discharged to their home or a skilled nursing facility and visit an outpatient treatment center regularly to continue receiving care from a professional healthcare provider. In the United States, health insurance typically pays for a limited number of outpatient visits. Once this allotment has been used, patients may need to continue pursuing their own recovery unsupervised at home.

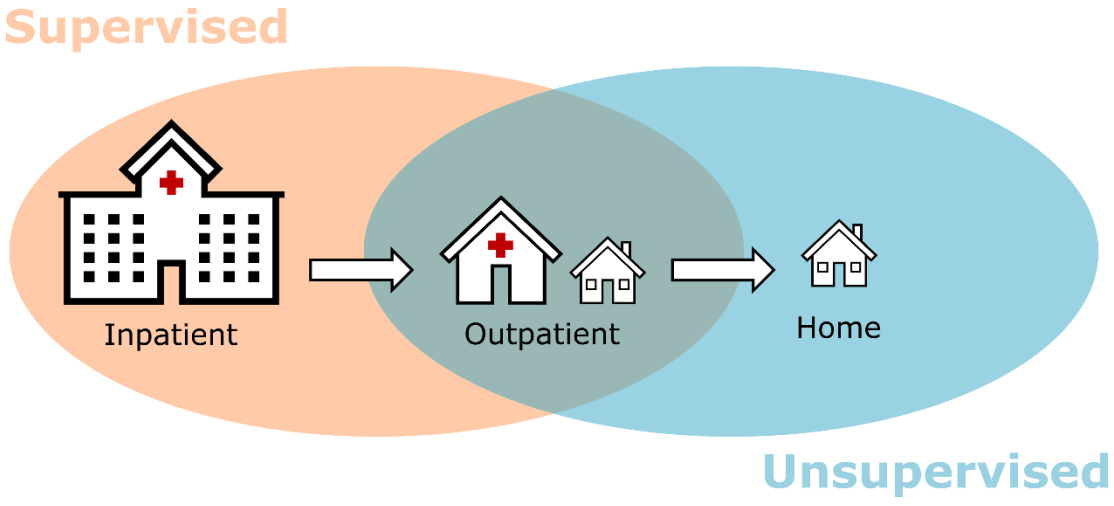

Figure 1: The typical stages of stroke care as patients progress their recovery. Once a patient is stabilized, care begins in an inpatient facility fully supervised by a healthcare professional. After patients are discharged from inpatient care, they will

receive supervised treatment at an outpatient facility, but most of their time will be unsupervised. Finally, they will discontinue organized care, and they may need to continue pursuing their recovery unsupervised.

Physical rehabilitation in a health care facility is commonly delivered through one-on-one supervised therapy sessions. In the inpatient setting, these sessions occur daily Monday-Friday, and in the outpatient setting, visits occur less frequently. However, these one-on-one session may not provide patients with a sufficient dose of exercise therapy to facilitate recovery [23]. One study found that patients receiving upper-limb rehabilitation therapy for stroke performed an average of 32 repetitions per session [24], where studies of motor recovery in animal models have shown that thousands of repetitions are needed to promote the neurologic reorganization that drives motor recovery following a neurological injury such as a stroke [19], [25]. Because of this, in the outpatient setting, clinicians will instruct patients to continue practicing selected movement exercises on their own at home, and successful outcomes for physical rehabilitation programs depend on patients' completion of these home exercise programs (HEPs) outside of the clinic [26], [27].

1.2.1 Home Rehabilitation

Home rehabilitation has multiple goals including reducing inpatient stays, continuing rehabilitation at home to replace institutional rehabilitation, and providing HEPs to help patients maintain or augment the gains made under supervision of a health care professional [28], [29]. The importance of continuing with therapeutic exercise at home has increased because of decades-long actions aimed at reducing inpatient rehabilitation stays [30]. The COVID-19 pandemic has caused further emphasis on carrying out rehabilitation at home [31]–[33], which may continue this trend toward expecting rehabilitation to occur outside of formal facilities in the longer-term [34].

1.2.2 Adherence to Home Exercise Programs

Though HEPs are prescribed to increase movement training dose, and successful outcomes for physical rehabilitation programs depend on patients' completion of therapeutic exercises prescribed to be completed outside of the clinic [26], [27], the current standard of care—following printed sheets of exercises—is associated with poor compliance, poorer outcomes, and high dropout rates [27], [35]–[39]. Between 30–50% of patients are nonadherent or only partially adherent to their HEPs for musculoskeletal programs [27], [39], though estimates vary across studies [40] in part due to difficulties accurately measuring adherence to HEPs [41]. Adherence is typically measured using patient diaries and self-reported questionnaires [27], [42]. Both methods have the potential to be biased by the patient's ability to recall their activity and social pressure to please their care provider. A comparison of patient-completed exercise diaries and data gathered from concealed sensors in exercise equipment found that patients over-reported their activity by 25% on average [43]. In a survey delivered to physical therapists, only 36% of therapists reported high levels of adherence to home exercises among their patients. Among the factors reported to affect adherence, 81% of therapists responded that forgetting to do their exercises was a barrier for their patients, and 64% of therapists reported that patients forgot how to do their exercises [44]. Nonadherence is a multidimensional process not easily solved including internal factors (such as patient's locus of control, depression, belief in importance of activities) and external factors (such as supportive environment and access to transportation) [26], [45], but digital delivery of HEPs through web-based [46] or app-based [47] systems have been shown to improve adherence relative to traditional delivery with paper handouts.

1.3 Rehabilitation Technologies

As defined by the Rehabilitation Act of 1973, rehabilitation technology (RT) is "the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of and address the barriers confronted by individuals with disabilities…" [48]. Technologies for physical rehabilitation range from measurement tools like blood pressure cuffs to exercise equipment like bodyweight supported treadmills. Rehabilitation robots, which may be end-effector-based or exoskeletons [49], are used for therapeutic exercise or as assistive devices [50]. Robotic devices, virtual reality systems, sensors, and tablets [51] are used for home rehabilitation. In remote rehabilitation, wearable activity trackers and web-based and mobile applications are used [52]. Figure 2 shows a sample of rehabilitation technologies [53].

Figure 2: Examples of rehabilitation technologies. (Top row, left to right) Lower extremity dynamometer, Functional Electrical Stimulation cycling system, ceiling mounted bodyweight support. (Middle row, left to right) soft ankle foot orthosis, dynamic hand splint, sensorized glove for therapeutic gaming, sensor-based therapy board. (Bottom row, left to right) balance and gait treadmill, robot-assisted gait training therapy, 3D motion capture virtual reality gait training.

1.3.1 Why Use Rehabilitation Technology?

There are several benefits of incorporating RT into therapy. In the clinic, RT can enable therapists to achieve tasks that are difficult or impossible to do without RT, such as lifting a heavy patient or measuring physiological variables [54]. It can reduce the need for providing continuous physical assistance or supervision to a patient, which could increase therapist productivity, enhance patient access to therapeutic training [55], and enable

patients to achieve larger volumes of movement practice repetitions [49], [56]–[58]. RT can increase motivation for therapy by providing physical assistance that allows patients to attempt and complete movements [59]–[61] or by incorporating gaming environments and quantitative feedback [62]. In a study on hand rehabilitation at home, participants who used a sensorized glove to encourage them to perform gripping motions as part of a video game similar to Guitar Hero completed a larger volume of movements than was required [63], [64]. RT can be used to provide telerehabilitation to increase capacity, improve access to rehabilitation [65], and by providing care entirely remotely [66], [67] or by augmenting on-going outpatient treatment sessions. Telerehabilitation can be performed through video conferencing, mobile apps and web apps, or remote sensing technologies.

1.3.2 What is Uptake and Who Drives It?

Uptake, in the context of technology use, is the act of making use of technology that is available. In supervised care settings, use of rehabilitation technology is dictated by the health care provider [68]. Clinicians will select a technology for patients to use, and help patients use the technology. So, unless a patient rejects a technology, uptake of technology is primarily driven by the clinician. In the outpatient setting, clinicians supervise patients during treatment sessions in a facility, but patient adherence to interventions prescribed for the patient to use or complete at home is generally unsupervised. Uptake at home is primarily driven by the patient, though it can be moderated by clinicians and care givers for example through education or encouragement. Even further, once patients are no longer participating in outpatient treatments, patient uptake of technology is solely driven

by the patient and the properties of the technology itself, unless they have help from a care giver.

1.3.3 Rehabilitation Technology Uptake in Supervised Settings

Despite observed benefits and efficacy trials, clinicians still encounter barriers to using RT in practice. Barriers in the clinic can come from the patient, the clinician, or the rehabilitation setting [69]. Patients can reject RT in favor of conventional therapy or have cognitive deficits which inhibit their participation [57]. Clinicians may question the effectiveness or necessity of the device [57]. Within the clinical setting, devices are sometimes too large and bulky to adapt use within an organization [50]. Clinician use is also influenced by institution facilitation of use, organizational culture and intention of use [54]. External barriers to clinical use also exist when a device is unavailable to the patient post-discharge [69].

1.3.4 Rehabilitation Technology Uptake in Unsupervised Settings

To help patients increase the amount of movement exercise they perform, either in addition to or as part of a supervised program or on their own without direction or supervision from a health care professional, there has been a surge in the development of technologies to enabling patients to exercise on their own at home. Patient uptake in the home can be limited by patients' technological literacy, cognitive impairments that result from their injury, motivation, poor usability of technology, and lack of availability of space in their home or living space.

1.3.5 How is rehabilitation technology uptake currently studied?

Studies of the uptake of technologies in healthcare settings typically employ survey, interview, and focus group methodologies [54], [69]–[72].[70] Participants span a range of stakeholders including patients, caregivers, and healthcare providers [70], [73]. These methods allow researchers to understand subjective experiences of key stakeholders, and open-ended methods allow for participants to share features of the experience that are important to them which the researchers may not have known about when designing measurement tools. However, self-reported data can be subject to recall and social desirability biases [74], limiting its value.

1.3.6 Goals of this Dissertation

As digital and advanced rehabilitation technologies become more prevalent, it is becoming increasingly possible to directly measure use through metrics captured by the technology itself [75]. The working hypothesis of this dissertation is that use of direct measurements of use as captured by a device can mitigate biases in self-reported data collected for the purpose of studying uptake of the given technology. Further, these direct interaction metrics can also provide more granular information regarding volume of use, patterns of timing of use, or rates of interactions with specific features of a device. Perhaps most excitingly, the availability of direct interaction metrics opens the possibility of doing in-the-field experiments to test how specific RT design features impact rehabilitation adherence. What is envisioned is a new era of RT design in which RT uptake is optimized through large data sets obtain by the devices themselves.

The goal of this dissertation is therefore to combine the conventional qualitative data sources with emerging, quantitative data sources to improve the design of RTs for uptake in rehabilitation. Data sources include surveys, written accounts, verbal interviews, and device usage data. Some of the device data used in this work comes from widely commercialized technologies, which gives us access to larger data sets than could be collected in traditional research settings as well as data produced naturally in the end-use setting by real users without therapist supervision.

1.4 Summary of Technologies Discussed in this Work

This work primarily focuses on devices that are commercially available and in use in clinical or home rehabilitation contexts. This emphasis on commercial technologies allows us to study barriers and facilitators to practical implementation and better understand the needs of stakeholders at the point of care. Through relationships with commercial technology developers, we have had the opportunity to suggest development changes based on our research, and then study the effects of those changes in practice. In Chapter **2**, the technologies mentioned are devices that are available in the research hospital where the study was conducted. Chapter **3** discusses the use of a system in development that is a combination of products from two separate companies: a patient management app and web portal developed by Pt Pal, and a sensor device for home rehabilitation developed by Flint Rehab. Chapters **4**, **5**, and **6** focus on a standalone sensorized home rehabilitation system developed by Flint Rehab.

1.4.1 Contributions from Commercial Entities

I declare that none of the commercial entities mentioned in this work have directly financially supported me, Veronica Swanson. Corporate entities have supported this work in the following ways. In Chapter **2**, Pt Pal donated licenses to use their patient management platform and Flint donated sensor pucks and clips for clinicians to use. Both companies modified their products based on discussions with the research teams and provided technical support to the research teams. Both Pt Pal and Flint Rehab have provided user data collected by their systems to the research teams.

1.5 Outline of Dissertation

The work in this dissertation aims to move beyond closed form surveys and use direct measurements of usage obtained from device usage data to understand rehabilitation technology uptake. Where possible, we enhance our investigation with qualitative methods that consider the usage context and provide a richer account of the user experience. When applicable, the insights gained will be used to make changes to the technologies studies, and the effectiveness of these changes will be determined through comparisons of usage data collected before and after changes are implemented.

Part I focuses on investigating facilitators and barriers to uptake of RT in the three main settings of rehabilitation. Chapter 1 uses vignettes written by three occupational therapists (OTs) and two physical therapists (PTs) describing their RT use decisions during treatment sessions with nine patients to understand use factors in an inpatient facility. The vignettes were coded using deductive qualitative analysis from 17 constructs derived from

the RT literature and the Consolidated Framework for Implementation Research (CFIR). Data were synthesized using summative content analysis.

Chapter 2 moved to the outpatient setting and asked therapists to use a specific sensor enhanced activity management (SEAM) system. In the current rehabilitation service paradigm, clinicians instruct patients to continue practicing selected movement exercises on their own at home, in the form of home exercise programs (HEPs), following periods of inpatient and/or outpatient treatment. Adherence to home exercise programs (HEPs) during physical rehabilitation is usually unmonitored and is thought to be low from self-reported data. The SEAM system combines HEP management software with a movement sensor for monitoring and motivating HEP adherence. In this trial, four therapists used the system in their regular practice during the first six months of the COVID-19 pandemic. Therapists filled out surveys, kept notes, and participated in interviews. Exercise data from the SEAM system were used to understand HEP adherence.

As in Chapter 2, Chapter 3 focused on a particular system. Chapter 3 studied the unsupervised use of a sensorized gamified exercise system (SGES) in the home setting. The relationship between challenge level and perseverance was studied using long-term, self-determined exercise patterns of a large number of individuals (N = 2,581) engaging in home rehabilitation with an SGES, FitMi, without formal supervision.

As will be seen, an important finding from the studies in Part I is that a key value of RT is its ability to motivate use in the unsupervised home context. Part II then focused on measuring the efficacy of home RT and estimating clinical outcomes from RT usage data. Chapter 5 described the results of a randomized controlled trial (RCT) of the SGES studied

in Chapter 4 that compared the effectiveness of the SGES with a paper-based approach. Participants were instructed to perform home exercises for 3 hours a week for 3 weeks. The interventional group used the SGES, and the conventional therapy group performed similar exercises delivered using printed sheets of paper.

Chapter 5 found that the SGES improved participants' UEFM scores. Still, it would be useful to know if the unsupervised users studied in Chapter 4 received a similar benefit. If so, are there particular usage patterns that lead to this benefit? Chapter 6 therefore tested whether the rate of repetitions performed in the SGES could be used to estimate Upper Extremity Fugl-Meyer (UEFM) score.

Part III describes design changes made to the systems studied during this work and the resulting changes in uptake as measured by usage data captured by the systems. Chapter 7 describes changes to the SEAM system which aimed to automate a large portion of the user workflow and improve the accuracy and transparency of the exercise data captured and reported to users. Chapter 8 describes the design changes made to the SGES studied here which aimed to ramp up the difficulty more quickly for less impaired users and give an option to manually lower the difficulty for more impaired users. Each chapter evaluates the changes based on usage data collected from the devices themselves.

Finally, Chapter 9 discusses factors influencing uptake which were found throughout the work completed as part of this dissertation and describes desirable design features which could be implemented accordingly. The role and importance of the usage data collected by the SEAM system and SGES are highlighted, leading to the proposal of

transitioning from the User-Centered Design paradigm to a Design for Uptake paradigm. Lastly, directions for future work are discussed.

Part I: Understanding Uptake in Physical Rehabilitation Contexts

The factors that drive or inhibit uptake are context specific. Stroke rehabilitation occurs in a progression of three stages, and each of these stages includes varying levels of involvement from different stakeholders. Therefore, to study the uptake of technologies designed to support stroke rehabilitation, we need to study that technology in its specific use context. The three stages of care are supervised care in an inpatient facility, semi-supervised care in an outpatient facility, and unsupervised care in the home. In the first stage, patients stay full-time in a facility, and a rehabilitation therapist visits them to perform one-on-one therapy with them. In the second stage, the patient has been discharged from the primary care facility, and then visits an outpatient treatment center to see a rehabilitation therapist. The schedule of visits is typically less frequent in the outpatient setting than in the in-patient setting. As such, therapists prescribe activities for patients to perform between visits to the outpatient center. In the third stage, patients stop their outpatient therapy, and may choose to use technology to help them continue pursuing their recovery on their own at home, unsupervised by a healthcare provider. The following three chapters each describe an investigation into the barriers and facilitators to use of technology available in one of the three stages.

Chapter 2: Supervised Uptake in the Clinic – Vignettes from Therapists Describing their Decision-Making Process when Choosing to Use Technology in Practice[1]

Summary

Neurorehabilitation engineering faces numerous challenges to translating new technologies, but it is unclear which of these challenges are most limiting. Our aim is to improve understanding of rehabilitation therapists' real-time decision-making processes on the use of rehabilitation technology (RT) in clinical treatment. We used a phenomenological qualitative approach, in which three OTs and two PTs employed at a major, technology-encouraging rehabilitation hospital wrote vignettes from a written prompt describing their RT use decisions during treatment sessions with nine patients (4 with stroke, 2 traumatic brain injury, 1 spinal cord injury, 1 with multiple sclerosis). We then coded the vignettes using deductive qualitative analysis from 17 constructs derived from the RT literature and the Consolidated Framework for Implementation Research (CFIR). Data were synthesized using summative content analysis. Of the constructs recorded, the five most prominent are from CFIR determinants of: (i) relative advantage, (ii) personal attributes of the patients, (iii) clinician knowledge and beliefs of the device/intervention, (iv) complexity of the devices including time and setup, and (v) organizational readiness to implement. Therapists characterized candidate RT as having a relative disadvantage compared to conventional treatment due to lack of relevance to

[1] This chapter is a slightly modified version of the paper titled "A day in the life: a qualitative study of clinical decision-making and uptake of neurorehabilitation technology" published in the Journal of NeuroEngineering and Rehabilitation in 2021 (Celian et al., 2021).

functional training. RT design also often failed to consider the multi-faceted personal attributes of the patients, including diagnoses, goals, and physical and cognitive limitations. Clinicians' comfort with RT was increased by their previous training but was decreased by the perceived complexity of RT. Finally, therapists have limited time to gather, setup, and use RT. Despite decades of design work aimed at creating clinically useful RT, many lack compatibility with clinical translation needs in inpatient neurologic rehabilitation. New RT continue to impede the immediacy, versatility, and functionality of hands-on therapy mediated treatment with simple everyday objects.

Statement of Contributions

This work is published as 'C. Celian et al., "A day in the life: a qualitative study of clinical decision-making and uptake of neurorehabilitation technology," Journal of Neuro Engineering and Rehabilitation, vol. 18, no. 1, p. 121, Jul. 2021.' As second author, my contributions included performing the literature review on which the codebook was based, performing analysis, writing sections of the manuscript, and editing the manuscript.

2.1 Background

Rehabilitation technology (RT) is "the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of and address the barriers confronted by individuals with disabilities…" [48]. Occupational and physical therapists (OTs and PTs) use a variety of measurement and therapeutic RTs to enable delivery of evidence-based rehabilitation. The field of neurorehabilitation engineering faces numerous challenges with translating new RT into everyday practice at all stages of development and

implementation. Successful application of therapeutic RT requires development, testing, validation, clinician uptake, and patient acceptance.

There are several benefits of incorporating RT into therapy. RT can enable therapists to achieve tasks that are difficult or impossible to do without RT, such as lifting a heavy patient or measuring physiological variables [54]. RT can enable patients to achieve a higher number of movement practice repetitions, a necessary element of neuroplasticity during recovery [56], [57]. RT can increase motivation for therapy by providing physical assistance that allows patients to attempt and complete movements [59]–[61] or by incorporating gaming environments and quantitative feedback [64]. Finally, it can also reduce the need for providing continuous physical assistance or supervision to a patient, which can increase productivity or can increase patient access to therapeutic training [55].

Despite the observed benefits of RT, clinicians report barriers to their practical application. Barriers can arise from multiple domains such as the patient, the clinician, or the rehabilitation context [69]. Patients themselves can reject RT in favor of conventional therapy or have cognitive deficits which inhibit their participation [57]. Clinicians question the effectiveness strength and clinical necessity of the device [57]. Within the clinical setting, devices sometimes are too large and bulky to adapt use within an organization [50]. Clinician use is also influenced by institution facilitation of use, organizational culture and intention of use [54]. Outside clinical setting barriers also exist when a device is unavailable to the patient post-discharge [69].

In supervised clinical settings, research suggests that clinicians function as gatekeepers to promote the implementation of new interventions [68]. The process for adopting RT into

the clinic must undergo intense scrutiny before uptake including the clinical applicability, cost–benefit analysis, and safety of the device [76]. Therefore, it is vital to determine the gaps between the theoretical benefits and the practical application of such RT that would enable clinician uptake. Several previous studies have used survey methods [69], [71] or focus groups [57] to identify these gaps, but such approaches may not fully capture the real-time, pragmatic decision making that therapists must engage in during treatment sessions. Our approach here combined implementation science methodology to help make research more generalizable. Our premise is that integrating implementation science with neurorehabilitation engineering can accelerate the future integration of novel RT.

Our purpose is to describe clinician decision-making around incorporating RT into treatment sessions to improve understanding of clinician uptake, the critical step to device implementation. To provide a window into a day-in-the-life of clinician and the decision-making during a typical treatment session, we had OTs and PTs write vignettes describing a treatment session, along with their thought processes. Then we synthesized the vignette data using an implementation science framework, the Consolidated Framework for Implementation Research (CFIR), a common implementation framework used to classify the determinants (barriers and facilitators) of successful implementation [77]. From our qualitative data analysis, we were able to pinpoint several constructs mentioned in the vignettes to highlight the hurdles encountered by therapists in treatment sessions. Presenting and synthesizing vignettes will help engineering audiences to understand the practical application of the devices they develop and how to improve the success of future RT.

2.2 Methods

2.2.1 Context

The Shirley Ryan AbilityLab research rehabilitation hospital includes interdisciplinary inpatient acute rehabilitation, outpatient rehabilitation, and research infrastructure. It differs from many interdisciplinary inpatient acute rehabilitation facilities in two key ways: (1) the facility was built with planned integration of state-of-the art RT in clinical areas and (2) research infrastructure is embedded in the clinical areas. The environment strives to be conducive to RT use through greater availability and integration of clinician researchers. Within this technology-encouraging context, we ask the questions of how RT is chosen for use, or if it's chosen at all.

2.2.2 Vignette development

We asked three OTs and two PTs to write vignettes sharing (1) their decision-making process related to RT use, (2) describe their comfort level with RT and (3) provide 1–2 examples of a recent clinical treatment session, focusing on their clinical reasoning behind their decision to use, or not use, RT. We provided the following vignette template:

> I am a PT/OT … I am a (describe yourself—technophile, technology early-adopter, skeptic, technophobe, or other) and normally use technology when… The barriers to my access to technology are… A patient with this diagnosis… and characteristics… Their goals were…. I had a ____ min session, I opted to do these interventions (tools/technologies) …. because…. It took me this much time to set up… I provided these instructions… The patient responded in this way… I chose not to use tools because… It worked/did not work because…

2.2.3 Analysis

We used deductive qualitative analysis to identify codes in the provided vignettes related to barriers to RT use and knowledge translation identified in literature [69], [71], [78]. We named these barriers using the CFIR framework, which explains 39 implementation constructs across 5 domains. These constructs can be barriers or facilitators, making implementation more or less difficult, respectively [77]. The codebook (Table 1) contained 15 original CFIR constructs identified in prior research [69], [71], [78]. Two constructs were added to distinguish between the attributes, knowledge and beliefs of clinicians compared to patients.

Three reviewers coded each vignette in their entirety, but the vignettes are presented in a summarized form to follow the template more concisely and provide novel information. Summative content analysis included used the total number of codes presented, and the proportion of times each code was used across clinicians and vignettes [79]. This qualitative analysis plan provided a systematic method to synthesize the vignette results.

2.3 Results

The constructs, their definitions, and results of summative content analysis are presented in Table 1. Nine vignettes provided by five therapists detail experiences with patients with the following diagnoses: traumatic brain injury (n = 2), SCI (n = 1), stroke (n = 4), and multiple sclerosis (n = 1). Six vignettes were provided by OTs. Three vignettes were provided by PTs. All therapists have at least 4 years of clinical experience and have assisted with research projects in the past. The 17 codes (listed in Table 1) were applied 174 times. Most statements were coded with one code (n = 91), but when all three coders agreed,

other statements were either double (n = 31), triple (n = 6) or quadruple (n = 3) coded. Each code is presented with exemplar quotes in Table 1, providing examples of the barriers and facilitators to implementation.

Content analysis of the 17 codes resulted in all five clinicians making statements coded as relative advantage, personal attributes of the patients, clinician knowledge and beliefs of the device/intervention, complexity of the devices, and overall implementation climate. Furthermore, all nine vignettes included statements coded as complexity, relative advantage, and personal attributes of the patient.

Occupational therapy vignette 1

> I would describe myself as a skeptic when it comes to consistent use of technology to treat the arm post neurologic injury. As an OT, we are taught "function, function, function!", and this sentiment is reinforced by our professional organizations and therapy leaders. Patient goals and function inform treatment plans as paid for by Medicare/Medicaid, and treatment must improve functional Quality Reporting Measures (i.e., the ability to complete toilet transfers, dressing, grooming, etc.). It is challenging to connect devices with functional improvement, so I sparingly choose technology.
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> The patient was a 56-year-old male with left-sided (dominant) weakness after stroke. He had little distal active movement, was unable to participate in electrical stimulation because of the presence of a cardiac event monitor. His goals were feeding, reaching to cabinets, and managing medications, and he wanted to return to living alone after discharge. He was a "good candidate"

Table 1 CFIR domains, definitions, and occurrences in vignettes

CFIR domain	Construct*	Definitions*	Number of clinicians (of 5) & number of vignettes (of 9) mentioning (%)	Total number of times mentioned (% of 174 total mentions)	Exemplar quotes**	
					Facilitators	Barriers
Intervention characteristics	Intervention evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes	2/5 (40%) 3/9 (33.3%)	4 (2.3%)	"[the device allows delivery of] evidence-based practice regarding intensity of treatment."	"One session would also not allow for achieving recommended frequency and duration to obtain the known benefits with use of the device"
	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs	1/5 (20%) 1/9 (11.1%)	2 (1.1%)	[none coded]	"I would have liked to use the device … but the device was … locked in a manager's office because it is expensive" (clinician stage of change)
	Complexity	Perceived difficulty of the intervention, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement	5/5 (100%) 9/9 (100%)	16 (9.2%)	"I typically use devices or technology when it is easy to set up, requires less steps, time or burden of down time for my patients or burden of time outside of my clinical treatment	"Using … 1-h of physical therapy and taking at least 20 min … to set up 4–6 electrodes on each leg before testing and trialing for one 30 min
	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs	3/5 (60%) 4/9 (44.4%)	7 (4.0%)	"I can modify the speed …, body weight support, … [and] aspects of the set up … for those requiring a significant amount of assistance …" (design quality and packaging)	"Technology does not fit well in a small galley kitchen or in a tight spaced bathroom where my patient needed to practice"
	Design quality and packaging	Perceived excellence in how the intervention is bundled, presented, and assembled	2/5 (40%) 2/9 (22.2%)	7 (4.0%)	"…it is easy to operate with its portable remote to allow me to change parameters in real time and not have to stop if I am changing speed or inclines. It has built in safety/back up options if the portable remote did not work, but also for emergency stops, which also are adjustable …"	"In design, … It is not user friendly. As clinicians, we believe in being objective when we record treatment. Due to no easy, clear, objective ability to measure weight bearing … we cannot objectively document how much weight we are using …."
	Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution	5/5 (100%) 9/9 (100%)	32 (18.4%)	"…and if not for technology, [patients] would not be able to otherwise get up and perform this specific treatment."	"It is easier to setup a treatment using task-specific training with functional, everyday objects than try to make an unfamiliar device work." (complexity)

Table 1 (Continued)

CFIR domain	Construct*	Definitions*	Number of clinicians (of 5) & number of vignettes (of 9) mentioning (%)	Total number of times mentioned (% of 174 total mentions)	Exemplar quotes**	
					Facilitators	Barriers
Outer setting	Clinician knowledge and beliefs about the intervention	Clinician's attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention	5/5 (100%) 7/9 (77.8%)	18 (10.3%)	"It's always easier to try new/ unfamiliar interventions with patients who you have built a rapport with over time, and who you know would benefit from trying something new" (patient needs/resources)	"…we were hesitant to use it during a normal treatment time with patients since the device involved games when most of our patient's goals revolved around function (dressing, handwriting, etc.)."
	Clinician stage of change—readiness	Characterization of the phase a clinician is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the	4/5 (80%) 5/9 (55.6%)	10 (5.7%)	"I was lucky enough to learn how to set up a patient for [the device] while I was a student…" (clinician knowledge and	"The device lived on our floor for a while, a daily reminder of the guilt of never finding time to improve familiarity."
	Other personal attributes of the clinician	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning stylet	4/5 (80%) 4/9 (44.4%)	4 (2.3%)	"After …residency early in my career, … I would consider myself an early adopter and enthusiast to learn new approaches for best patient outcomes…" (clinician	Despite being involved with technology in all roles, I would describe myself as a skeptic when it comes to consistent use of technology to treat the arm post neurologic injury
	Patient knowledge and beliefs about the intervention	Patient's attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention	2/5 (40%) 3/9 (33.3%)	4 (2.3%)	"He ended up loving this intervention, because to him it was the closest he was able to get to lifting weights (something that was really important to him prior to his injury." (relative	"I also find that when meeting a patient for the first time, doing something that they can understand will help them get back home is pretty helpful in gaining rapport"
	Other personal attributes of the patient	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style	5/5 (100%) 9/9 (100%)	27 (15.5%)	"Below is an example of a patient who checks all the boxes as being a "good candidate" for technology use- young, motivated, and willing to try anything."	"However, I did not have many patients who would be appropriate for this equipment because they have cognitive deficits that limit attention, initiation, or comprehension of such games. Or they had extremely limited ovement on their affected side."

Table 1 (continued) * see https://cfirguide.org/constructs/ for full definitions of each code
** where applicable, quotes that were double coded are noted in parentheses

CFIR domain	Construct*	Definitions*	Number of clinicians (of 5) & number of vignettes (of 9) mentioning (%)	Total number of times mentioned (% of 174 total mentions)	Exemplar quotes**	
					Facilitators	Barriers
Inner setting (organization)	Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization	4/5 (80%) 6/9 (66.7%)	14 (8.0%)	"When it was time for him to leave, I provided him with information to get a cycle for home through the vendor that we had worked with, as she mentioned that she may be able to get him a cycle for a discounted rate since he was in the military.	"Finally, the patient's wife is present and is very anxious, providing too many cues to the patient, overwhelming him and expressing disappointment with his performance."
	External policy	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting	3/5 (60%) 3/9 (33.3%)	5 (2.9%)	[none coded]	"…how do I balance what is required vs what is ideal (required insurance tasks, progress updates, outcome measures, what has the patient already done for the day, what is recommended best available evidence for the interventions that address their goals)." (relative advantage, intervention evidence, patient attributes)
	Readiness to implement	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention	4/5 (80%) 5/9 (55.6%)	12 (6.9%)	"[the vendor] was able to come to a co-treatment with the patient and I to help me with optimal setup."	"It had been a while since the 2-h training session that I went to …"
	Overall implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization	5/5 (100%) 5/9 (55.6%)	6 (3.4%)	"…is integrated as part of the new hiring system …. In my experience, learning to correctly use the machine has not been any issues after initial training/mentoring." (readiness to implement)	"My colleague and I both lacked confidence and did not want to use normal therapy time to test out the device, but we decided to treat patient pro bono after clinical hours to setup and run through with the device to improve familiarity." (external policy, clinician attributes. clinician stage of
	Culture	Norms, values, and basic assumptions of a given organization	2/5 (40%) 2/9 (22.2%)	3 (1.7%)	"… appeal for "sexy" technology …"	"As an OT, we are taught 'function, function, function!', and this sentiment is reinforced by our professional organizations, and therapy leaders, that patient goals, daily interventions and treatment plans should address improved function.
Process of implementation	Executing	Carrying out or accomplishing the implementation according to plan	2/5 (40%) 2/9 (22.2%)	4 (2.3%)	"…we were assured that although the initial use would be confusing, consecutive uses become efficient."	"My confederate therapist and I could not coordinate another time to practice on the new device…"

for technology because young, motivated, and willing to try. However, the goal areas and need to be independent upon discharge swayed my decisions to use a mirror therapy protocol. The patient quickly progressed within 2 weeks to participate in a high repetition training. At this point technology such as an exoskeleton or smart glove could have been selected, but patient goals pushed me towards functional repetitive practice. We used forks, spoons, cups, coins, and standing to reach in our therapy kitchen and bathroom, areas where technology does not fit well. I hesitated to use technology because it could not have the patient working within 3 min of the start of the OT session, nor could it go home with him.

Occupational therapy vignette 2

The hospital acquired a high-tech upper extremity exoskeleton that provided proximal support while a patient plays games on a screen. The hospital provided a half-day course for training; we were instructed that although the initial use would be confusing, consecutive uses become efficient. My colleague and I both lacked confidence and did not want to use normal therapy time to test out the device, but we decided to treat a patient pro bono after clinical hours to setup and run through with the device to improve familiarity.

The patient was a 50-year-old male who recently suffered a stroke resulting in left hemiparesis. We asked this patient to help primarily because he was able to verbally consent to extra treatment and had some movement in his left arm, which is rare in acute stroke. During the treatment session, we noticed that when the patient

fatigued his flexor tone became worse, requiring removal of his arm from the exoskeleton for stretching.

We did three rounds of 1–2 min of exercises, followed by a stretching break. This process repeated, resulting in a total of 9 min of treatment in a 40-min session, including setup. Then, the patient informed us of the need for the restroom, resulting in us ending the session earlier than anticipated. My colleague and I could not coordinate another time to practice on the new device, and we were hesitant to use it during a normal treatment time with patients since the device involved games when most of our patient's goals revolved around function (dressing, grooming, etc.). It is easier to setup a treatment using task-specific training with functional, everyday objects than try to make an unfamiliar device work. The device lived on our floor for a while, a daily reminder of the guilt of never finding time to improve familiarity. However, I did not have many patients who would be appropriate for this equipment because they have physical deficits with extremely limited movement on their affected side or they have cognitive deficits that limit attention, initiation, or comprehension of such games. The device was eventually removed from the floor since it was unused by the therapy team.

Occupational therapy vignette 3

A 75-year-old male with a prior medical history of atrial fibrillation, aortic valve repair, hypertension, epilepsy, and a prolonged (4 months) stay in a long-term acute care facility. He then had a subdural hematoma near the right frontal lobe resulting in a traumatic brain injury (TBI). His hospitalization was complicated by

pneumonia, seizures, acute ischemic infarcts, and a tracheostomy placement. Impairments included bilateral upper extremity weakness (Action Research Arm Test: 0 left, 10 right), intention tremors in the right arm, decreased trunk control, decreased cervical control, and general malaise. Patient was unable to stand, walk, and hold himself upright in his wheelchair. He identified goals of "walking" and becoming more independent with brushing his teeth and getting dressed.

This was a 1-h session with a focus on grooming (oral hygiene and shaving) to improve arm control with both his upper extremities, strength, and upright head control. Since the patient had a low ARAT score on his left arm compared to his right, I decided to use a mobile arm support (MAS) to assist the patient with unweighting his left arm to engage bilaterally in the task. Setup took about 15 min, which involved retrieving the MAS from the gym, setting it up in the patient's bathroom, wheeling the patient to the bathroom, and padding the device with towels to prevent his arm from slipping out. The patient had a lot of difficulty with incorporating his left arm into the task since he did not have effective grip strength, and overall, he required > 50% assistance with brushing his teeth due to difficulties reaching his face. The forward tilted wheelchair frequently led to his chin resting on his chest requiring the right arm to be propped on the sink. We then focused on task-oriented mass practice (retrieving toothbrush from the sink, moving it to the face, then placing it on a nearby table) assisted by the MAS, accomplishing only 15 repetitions because of frequent stops to readjust posture and the tension of the MAS system. This was difficult as I was simultaneously preventing falls out of the wheelchair, readjusting the MAS, cueing, and answering questions from the patient's

wife. The wife cued the patient but also expressed disappointment, which overwhelmed the patient. This took 35 min after the setup, with another 15 min for cleaning, moving the patient back, educating, and answering questions. Running 5 min late I excused myself, offering to check in again at the end of the day.

Occupational therapy vignette 4

A young female in her twenties with no prior medical history presented 2 months after TBI resulting in multiple brain hemorrhages, diffuse axonal injury of the corpus callosum, splenium, and midbrain. She presented in a minimally conscious state (Rancho Los Amigos 3). She was non-verbal, restless, and moved her arm and right leg around non-purposefully with limited movement on her right side. She stared in the direction of sound cues most times and would follow some commands, but responses were inconsistent, delayed, and fleeting.

For this treatment, there were three areas of focus: functional communication, functional object use, and command follow. The communication device used in the session was a large button the patient was asked to hit with either her hand or foot. The patient successfully hit the device with her left foot in 4/20 trials. She also fatigued quickly from the activity, only able to try about 30 s at a time. She was unable to hit the device using her arm, and she repeatedly rubs her face and hair when cued to hit the target requiring hand-over-hand assistance. This process took about 25 min. We next tried brushing teeth with the left hand with cuing. The patient repeatedly brought the toothbrush to her mouth and chewed it in 3 instances after 20 min of engagement in the activity. During this time, the attending

physician and students entered to watch and speak to the mother and the patient becomes fatigued and falls asleep in her wheelchair. I leave the session 5 min early.

Occupational therapy vignette 5

As a float occupational therapist who sees patients on all different units, I am often seeing new patients each day that I have never met. I am a techno-phobe in my treatments because I feel strongly that using familiar objects/tasks are more motivating and patients understand how the intervention will be helpful to reach their goals. Consistent use of technology can be difficult because chart reviews may not paint the picture of how the patient is going to look when you finally see them.

A recent patient who suffered a stroke had visual deficits, left hemiparesis, was motivated, and wanted to work on visual scanning. I considered an interactive light board designed to train visual scanning and reaction timing, but it had been a while since the 2-h training session. When I am seeing patients more consistently and have built a rapport, I will know who will benefit from something new and I will brush up on my skills with such equipment. In this case, I chose to stick to familiar functional tasks and use time wisely, opting to use a visual scanning kit to organize a tackle box as shown in a picture. The patient had some difficulty completing it and needed some cueing, however, ultimately was able to complete the task with some support.

Occupational therapy vignette 6

As an occupational therapist working with the Spinal Cord Injury population, I am always looking for ways to adapt every self-care task to allow them to be more

independent. I worked with a young patient who was in a motor vehicle accident and sustained a C2 fracture, was on a ventilator, and had no movement in his upper or lower extremities other than the ability to shrug his shoulders. He was 19 years old and was in the US Army at the time of his accident. He did not have any surgical intervention, and when he was admitted he was classified as an ASIA B (sensory function preserved, motor function is not, below the level of injury).

Since he was active prior to injury, I thought he might enjoy the functional electrical stimulation (FES) bike as he became more stable. However, I was not as comfortable with setting up this piece of equipment at the time, so I contacted the vendor who is also an OT. The vendor attended, co-treated, and helped me with optimal setup. It was also helpful to have a second person since we added scapula and arm electrodes that took a long time. The patient loved this intervention because it was the closest to lifting weights, an activity that was important to him. Also, electrical stimulation below his injury level can see if he might regain strength in those muscles. When it was time for him to discharge, I provided him with information to get a cycle for home at a discounted military rate. This is one of my favorite interventions with SCI patients because of high repetitions and endurance, although it can take a while to set up.

Physical therapy vignette 1

I am a PT working almost exclusively with traumatic and acquired brain injuries in an acute inpatient setting, and I am neutral to technology. There have been times when I frivolously support it, times I am skeptic, and times, I believe some devices

will gather dust. The determining factor for my technology use is its adaptability, and if it's quick to learn (~ 2 practice trials under supervision after formal training session). One of the pieces of technology I unequivocally support is Body Weight Supported Treadmill Training (BWSTMT). BWSTMT allows for earlier ambulation interventions, while assisting patient needs and high-intensity when appropriate. Speed can be modified to focus on aspects of gait that need more fine-tune control, such as step length or terminal knee extension. Other adaptations can be made to encourage upright trunk through use of strapping, additional inclines and allowance for backwards and lateral stepping. If not for such technology, I would be unable to perform this treatment. This also frees my hands, so I can assist with a specific target area (by positioning limbs in a specific phase in gait or adding bolsters for a patient to step over) or stand back and see the bigger picture of gait mechanics. The portable remote allows me to change parameters such as speed and incline in real time, making the treadmill efficient to operate. Additionally, there are built-in safety/backup measures available and can be adjusted by the treating clinician.

As a student, I was lucky to work in a hospital that taught me how to set up and frequently use BWSTMT. Now as a Clinical Instructor for PT students, performing BWSTMT is an integral part of my daily practice. Thus, most students learn this as a part of their clinical experiences. For those who are unfamiliar with the BWSTMT, it takes practice, with variable patient assist levels, before using it independently. Often, practice is needed to learn more challenging set ups of the harness system on someone who requires 100% assist to don/doff a treadmill harness from a seated

position and without a second hand to make the set-up smoother. Any sort of learning needed for this machine is integrated as part of the new hiring system.

While I am in full support of using BWSTMT for ambulation interventions, I have identified some drawbacks both in design and in application. Limitations in documenting body weight supported objectively or fitting the equipment to all patient sizes and shapes do not outweigh the positives. However, scheduling problems and patient cognition do limit my ability to use BWSTMT in a session. It can take about 15 min to set up someone and about 5 min to remove/clean up (less if the patient is higher level and the clinician is experienced and/or there is an extra assistor like a tech/aide). This amounts 20 min of therapy time. If a patient is scheduled for a 30-min session, or has an incontinent episode, a delay in medication, eating, or in bed at the beginning of therapy, it may be more effective and efficient to choose another treatment. Additionally, cognitive characteristics that accompany brain injury can decrease a patient's tolerance for BWSTMT. A lack of insight into deficits in conjunction with a low frustration tolerance with high verbal and physical outbursts can impact safety of clinicians and patients, can reduce buy-in, or lead to treatment resistance. These limitations can present ethical implications. As a clinician, understanding how to modify the treatment parameters to the individual is just as important as knowing how to operate the technology itself.

Physical therapy vignette 2

I am a PT with 9 years of experience in a large hospital, primarily inpatient. Because of my neurologic physical therapy residency, I am an early adopter, enthusiast, and

proponent of novel technology, and have even participated in some efficacy and feasibility trials. My organization has many advanced devices available, but this does not equate to regular use unless it is easy to set up, does not cause patient downtime, or extensive personal time. Limits to technology use are: (1) is the device unready; (2) the patient is unready for treatment; (3) the patient goals do not match; (4) imbalance between organization or insurance requirements and ideal (evidence-based practice).

The patient was a 70-year-old female with right sided hemiparesis due to a left pare median pontine perforator infarct. Her goals were to improve walking speed and distance without assistance at home. I had a 60-min session and recognized the need for intense task-specific training. In previous sessions, she had difficulty reaching target heart rate due to poor right foot clearance, but more recently demonstrated improvement in proximal leg strength with remaining difficulty with knee control and foot clearance.

I chose to use BWSTMT to strengthen proximal leg muscles because we had equipment ready and I am extensively trained. To improve foot clearance, I had difficulty deciding whether to use a traditional ankle foot orthosis (AFO) or an FES orthosis. Although trained in FES, the barriers were (1) the device was four floors away; (2) the device was locked in a manager's office because it is expensive; (3) I am required to send an email to the manager to check it out; (4) the device may not be charged; (5) I was unsure of where the electrodes were, and (6) if I delegate to a rehab aide, they might grab the incorrect one. Instead, I chose traditional AFO in the

nearby cabinet, which worked okay but required more verbal cues more hands-on assistance for timing of step initiation and step lengths to maximize intensity.

The next day, I considered finding 20 min of personal time to locate and setup the FES device, but had an insurance progress note due, which meant I needed to assess the patient's mobility skills and had limited time for gait training. The progress notes also led to extra documentation requirements, limiting my available time during lunch to track down the device. Additionally, I have some concerns with using this device in inpatient rehabilitation, for fear that it may not be covered by the patient's insurance when they are discharged.

Physical therapy vignette 3

A 48-year-old female with secondary progressive MS had goals to stand and make stepping actions. She had severe lower extremity weakness, already wore custom AFOs, and wanted to get stronger. Her parents were aging and were dependently lifting her in and out of bed. At the time, she required maximum assistance to stand, and we only had her for a short length of stay to get her home safely with less assistance since she already had good support at home. I considered the FES bike at one point but ultimately determined it would not have been beneficial time investment during inpatient rehabilitation as she was also seeing 1 h of speech therapy, 1 h of occupational therapy, and 1 h of physical therapy 5 of 7 days a week. Using her 1-h of physical therapy and taking at least 20 min or more to set up 4–6 electrodes on each leg before testing and trialing for one 30 min training session is not ideal for the time frame of her length of stay, and not supportive of her over all

goals of transferring independently. Also, using the FES bike one time would not achieve the recommended frequency and duration to obtain the known benefits of the device. I chose to focus on slide-board transfers to reduce burden of care on her aging parents. Ultimately, her transfers improved significantly, and she was able to transfer herself using the slide-board.

2.4 Discussion

Applying therapeutic RT for individuals with neurological impairments requires successful progression through a long and fragile chain of events: development, testing, validation, clinician uptake, and patient acceptance. Although each step presents its own set of challenges, we focused on the often overlooked but critical step of clinician uptake [68]. This study moved beyond surveys or focus groups to a vignette methodology that allowed us to understand clinicians' real-time decision-making process in the moments when they are with their patients. We found that the five most common themes fell within the CFIR constructs of relative advantage, personal attributes of the patients, clinician knowledge/beliefs, device complexity (including time and setup), and organizational readiness to implement.

2.4.1 Relative advantage

The most discussed barrier to using RT was its perceived relative disadvantage due to lack of relevance to everyday functional activities. Priority in this setting was task specific practice of day-to-day functional activities. In contrast, many therapeutic RT enable repetitive practice, but usually in the form of games and simple strength and range of motion impairment-focused activities. Therapy outcomes are evaluated and reimbursed based on functional outcomes (e.g. bed mobility, transfers, walking, and self-care skills such

as dressing, toileting, eating, and bathing) [80], rather than impairments or assessment scores (e.g. Action Research Arm Test, Fugl Meyer Assessment of Motor Recovery, Berg Balance Scale). Research has shown the biggest predictor of intention to use a RT is performance expectancy, or the degree to which an individual believes in the potential benefit of that RT [54], [81]. Thus, if therapists are unable to connect the impairment-focused task or game to a functional benefit they are less likely to use the device. RT endorsed in our vignettes increased repetitions of functional tasks and enabled patients to complete an action they could not otherwise complete, such as BWSTM and MAS systems. One possible solution to improve clinician uptake in inpatient rehabilitation, is for RT development to demonstrate the efficacy of RT in addressing functional outcomes. It may be of interest to developers to include functional metrics used by payer sources in the validation process and demonstration of efficacy of their devices. Researchers could also investigate the relationship between changes in impairment and assessment scores and corresponding changes in functional outcomes to motivate the use of technologies whose value is demonstrated by changes in impairment scores.

2.4.2 Patient attributes

Attributes of the patients and adaptability of the device determine clinician uptake and use of RT. Understanding the attributes of patients, as well as their needs and resources were common themes in the vignettes. In other studies, patient acceptance was a highly important factor for RT adoption [69]. Patient diagnoses, goals, and physical and cognitive abilities play a large role in guiding treatment decisions. Many engineering development studies exclude patients with cognitive deficits and can have very tight inclusion criteria related to physical function and sensation. Although necessary in the development phase,

these restrictions limit generalizability in inpatient rehabilitation. It has been proposed that developers should clearly identify the appropriate patient population for their devices [57]. However, another solution that would be more valuable to clinicians is for developers to design devices that are adaptable to a variety of diagnoses, patient needs, and environments.

2.4.3 Clinician knowledge and beliefs

A third CFIR construct endorsed by all five therapists was clinician knowledge and beliefs about the intervention. Clinicians' individual experiences and comfort with RT, as well as their readiness to change, greatly influenced their decision to use RT in treatment. We found that clinicians appeared to value RT more when it is incorporated into their academic training, onboarding, or a part of their regular clinical practice. Providing only a single training session for complex RT may result in lower mastery or clinician self-efficacy, which are required for use with real patients. Interestingly, prior studies did not link RT uptake or barriers to therapists' employment status, age, discipline, educational level, experience, or technology acceptance [54], [69], [71]. This suggests that clinician experience and training with specific RT may dictate RT uptake more than general clinician experience. One solution to improve clinician knowledge and beliefs about the intervention would be increase training duration or frequency to improve mastery or to incorporate technology training in schools.

2.4.4 Device complexity and time

One of the most striking issues described narratively in the vignettes was that therapists have extraordinarily little time to use complex RT. Studies frequently mention the importance of simplicity, ease of set up, and convenient availability of RT [69], [71]. One

limitation of the CFIR framework is that it does not include a specific construct for time. Instead, comments related to time barriers fell under several other constructs, including complexity, relative advantage, clinician stage of change, clinician knowledge and beliefs, implementation climate, and external policy. RT developers cannot create more time for therapists, and it is difficult for them to influence implementation climate and external policy. However, RT developers can create devices that are quick, intuitive, present a clear advantage over traditional interventions, and optimize clinical workflow. Additionally, training protocols should target moving the clinician through readiness to change into adoption of novel RT by addressing their knowledge and beliefs about the benefits of RT to support the amount of time it takes to use RT, particularly if the RT is perceived as complex.

2.4.5 Organizational readiness to implement

Although RT developers may have low influence on organizational readiness, our vignettes support the importance of the organizational implementation climate for clinician uptake of RT. Implementation climate is defined as the "absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization" [77]. Further organizational investments in the implementation process are helpful to improve clinician uptake of devices. Examples of investments include time for practice and reflection, organizational incentives to increase motivation to use RT, as well as assistance with RT setup from rehabilitation technicians. Organizational implementation factors in the literature include support from the institution to facilitate use [54] and making RT use mandatory and seamless in clinical treatment [57]. Despite a goal of RT to supplement and

assist therapists with treatment, it can place an unintentional burden on therapists when it comes to uptake and use in the clinic. Adding expectations for therapists to be trained on different RT oftentimes is an investment from therapist's personal time, which in turn might contribute to burnout [68]. RT developers should consider how their devices fit into the overall organizational priorities and workflow to address the clinician uptake barrier related to organizational readiness to implement.

2.4.6 Other constructs

Our interdisciplinary research team was surprised with infrequent mentions of evidence strength and cost compared to previously reported barriers to device implementation. Others have reported that clinicians rated cost as a very important acquisition factor [69], [71] or indicate cost as a barrier due to limited cost-effectiveness compared to intensive therapy evidence to warrant use [57], [82]. Our vignettes mentioned cost in the context of inconvenient procedural controls put in place to protect an expensive device or costs relative to a patient's ability to acquire the device after discharge through insurance or other discounts. Other studies have shown that OTs and PTs rate evidence as the most important factor behind device use [71]. These vignettes dichotomously presented evidence strength as both allowing therapists to administer the number of repetitions recommended for significant clinical change; but also deterred another therapist due to inability to provide repeated use of RT to reach clinically significant gains due to short patient length of stay. The clinic already acquired and made the RT available to the clinicians in the vignettes, which suggests that the RT available to the therapists had enough evidence and were believed to be cost-effective to support the organization

acquiring the device. These constructs suggest the importance of studying clinician uptake of RT after addressing the initial development and acquisition barriers.

2.5 Limitations and directions for future research

Limitations are present in this analysis related to generalizability and the qualitative research methods. We acquired vignettes from one inpatient rehabilitation hospital with state-of-the-art RT, which may hold entrenched biases that are not reflective of the wider community of practitioners. A larger qualitative study exploring the barriers and facilitators in multiple organizations and therapists working in different rehabilitation setting would improve the generalizability. Additionally, we only look at the clinician perspective of RT uptake, when a more comprehensive approach would look at the perspectives of the patient and institution via administrators and management team. Technology use is a co-decision between the therapist and patient, and developers should consider both perspectives. Our report here should only be understood as a single snapshot of beliefs of rehabilitation therapists that still may be important for developers to understand as they prepare for the design or development process in this field. Related to the qualitative methods, our vignette prompt may have led to increased mentions of certain topics, such as the time taken to setup. A different vignette prompt could explore greater consideration of impairment-focused treatment and measurement RT. Additionally, we limited our coding to the 17 CFIR constructs that were already present in the literature, rather than inductive analysis to allow themes to emerge. However, using established implementation frameworks have demonstrated generalizability of findings in the presence of limited number of settings [83]. Future research and development should attend to determinants of successful clinical uptake supported in these vignettes. New RT

should address relative advantage of functional task practice over impairment-focused interventions, the adaptability required to address varied patient populations, and the complexity of the RT. Developers also need to consider the importance of clinicians' knowledge and beliefs about the intervention and support from the institution to facilitate a positive implementation climate.

2.6 Conclusion

Considering clinician experiences will help developers to understand the complex clinical decision-making processes of the end users. The implementation science framework identifies actionable areas to improve RT development related to the intervention itself (advantages compared to traditional techniques and simplicity of design), the people involved in the intervention (attributes of patients, clinician knowledge/beliefs), as well as the organizations' implementation climate. Future research addressing these areas can aide in development and clinical integration of innovative RT.

Chapter 3: Semi-Supervised Uptake in the Home – A Pilot Study using a Sensor Enhanced Activity Management (SEAM) System in an Outpatient Clinic[2]

Summary

In the current rehabilitation service paradigm, clinicians instruct patients to continue practicing selected movement exercises on their own at home, in the form of home exercise programs (HEPs), following periods of inpatient and/or outpatient treatment. Adherence to home exercise programs (HEPs) during physical rehabilitation is usually unmonitored and is thought to be low from self-reported data. This chapter describes the exploratory implementation of a Sensor Enhanced Activity Management (SEAM) system that combines HEP management software with a movement sensor for monitoring and motivating HEP adherence. The chapter also presents results from attempting to gain reimbursement for home use of the system with therapist oversight using Remote Physiologic Monitoring (RPM) codes, as the ability to bill for services may be a key factor in practical clinical implementation. In this trial, four therapists used the system in their regular practice during the first six months of the COVID-19 pandemic. Therapists filled out surveys, kept notes, and participated in interviews. Billing and reimbursement data were obtained from the treatment facility. Exercise data from the SEAM system were used to understand HEP adherence. Patients were active for a mean of 40% (26% SD) of prescribed days and completed a mean of 25% (25% SD) of prescribed exercises. The therapists billed 23 RPM codes ($2,353), and payers reimbursed 8 of those instances ($649.21). The therapists reported that remote monitoring and the use of a physical movement sensor was motivating to their patients and increased adherence. Sustained technical support for therapists will

[2] This chapter is a slightly modified version of the paper titled "A Pilot Study of a Sensor Enhanced Activity Management System for Promoting Home Rehabilitation Exercise Performed during the COVID-19 Pandemic: Therapist Experience, Reimbursement, and Recommendations for Implementation" published in the International Journal of Environmental Research and Public Health in 2021 (Swanson et al., 2021).

likely improve implementation of new remote monitoring and treatment systems. RPM codes may enable reimbursement for review and program management activities, but, despite COVID-19 CMS waivers, organizations may have more success if these services are billed under supervision of a physician.

3.1 Introduction

Successful outcomes for physical rehabilitation programs depend on patients' completion of therapeutic exercises prescribed to be completed outside of the clinic [26] [27]. However up to 65% of patients are nonadherent or only partially adherent to their home exercise programs (HEPs) [27], with estimates varying across studies [26], [40]. Patient diaries and self-reported questionnaires are largely used to measure adherence, making it difficult to obtain accurate information [42] [27]. A comparison of patient-completed exercise diaries and data gathered from concealed sensors in exercise equipment found that patients over reported their activity by 25% on average [43]. In a study of patient adherence to exercise programs for chronic low back pain (n=61), 39% self-reported as being completely adherent, but therapists perceived that only 16% of participants were completely adherent, and only 15% of participants were able to recall all of the exercises contained within their program and demonstrate them accurately [45]. In a survey delivered to physical therapists, only 36% of therapists reported high levels of adherence to home exercises among their patients. Among the factors reported to affect adherence, 81% of therapists responded that forgetting to do their exercises was a barrier for their patients, and 64% of therapists reported that patients forgot how to do their exercises. 82% of the physical therapists that responded provided verbal education about patients' HEPs, and of those therapists, 45% used verbal instructions exclusively [44].

Nonadherence is a multidimensional process not easily solved including internal factors (such as patient's locus of control, depression, belief in importance of activities) and external factors (such

as supportive environment and access to transportation) [26], [45]. Digital delivery of HEPs has already been shown to enhance patient adherence [46], [67], [84], [85] and with the relatively high rate of smartphone ownership [86] there is a growing body of work investigating the use of smartphones, apps, and sensing technologies to facilitate rehabilitation and remote care [87]–[90]. However there has been limited study of implementation of mobile health applications in routine care settings [87], [90], and most efforts have focused on specific medical conditions [89] or have a limited set of exercises which can be performed using the system [90]–[92]. We therefore aim to contribute exploratory findings from a clinical setting of a system designed for general use with narratives from participating therapists and adherence data from patients.

This preliminary study was initiated in response to the COVID-19 pandemic. Rehabilitation is an essential service for patients [93]–[96] that needs to be continued during the COVID-19 pandemic [97]. However, the practice of physical rehabilitation itself can pose a risk of exposure to the virus for patients and healthcare practitioners alike, and investigation is needed for methods to continue provision of care while mitigating risks. If adherence was problematic before the pandemic, the issue has likely been further compounded with reduced face-to-face contract and group organized rehabilitation. Telerehabilitation services may provide a partial solution [98], [99]. What is learned and developed now during the pandemic can potentially provide a basis for expanding use of telerehabilitation in the future.

The goal of this study was to investigate the feasibility and implementation of a novel Sensor-Enhanced Activity Management (SEAM) system [100] for physical rehabilitation and explore its use during the COVID-19 crisis. This effort is part of the Rehabilitation Engineering Research Center for Mobile Rehabilitation (mRehab) RERC, the purpose of which is to "ensure ICT (Information and Communication Technology) access by people with disabilities in order to advance the development and use of mobile rehabilitation technologies that will improve adherence, engagement, and outcomes of home- based therapeutic interventions" [101]. The interest in applying mobile

technologies to adherence with HEPs was motivated by survey work investigating use cases for mRehab in which 73.9% of physical therapists who responded identified supporting patient adherence to prescribed exercises and activities as a desired use case [102].

The pilot investigation of reimbursement feasibility was made possible because of expanded guidelines for Remote Physiologic Monitoring, sometimes referred to as Remote Patient Monitoring, (RPM) codes (see Table 2) set by the Centers for Medicare and Medicaid Services (CMS) during the COVID-19 pandemic. Specifically, CMS expanded the type of healthcare professionals who were allowed to furnish and bill for remote monitoring services to include physical therapists and occupational therapists, making it possible to implement a remote monitoring and treatment system that might provide return on investment for a physical therapy clinic [103]. CMS first introduced a separately payable RPM code in 2018, and then created three new RPM codes (99453, 99454, 99457) in 2019 to more accurately reflect how RPM services are furnished using current technology and staffing models [104] [105]. Finally in 2020, CMS added a fourth RPM code, 99458, which allowed for additional monitoring time (past the first 20 minutes of service billed with 99457) to be billed in a single month. At this time, it was clarified that RPM services could be furnished "incident to" under general supervision of a physician [106]. Further details on the use of RPM codes can be found in Text S1. There is limited existing research on the use of RPM codes [107].

Table 2: List of RPM codes and their descriptions. See Text S1 for further details.

Code	Description
99453	Initial set up and patient education
99454	Supply of devices and collection, transmission, and summary of services each 30 days
99457	First 20 minutes of remote physiologic

	monitoring by clinical staff, physician, or qualified healthcare provider in a calendar month
99458	For additional 20 minutes of remote physiologic monitoring by clinical staff, physician, or qualified healthcare provider in the same calendar month as 99457

The SEAM system we investigated is the combination of two existing commercial products: Pt Pal [108] and FitMi [109] (Figure 3). Neither company compensated members of the study team, but they donated devices, subscriptions, and provided technical consulting.

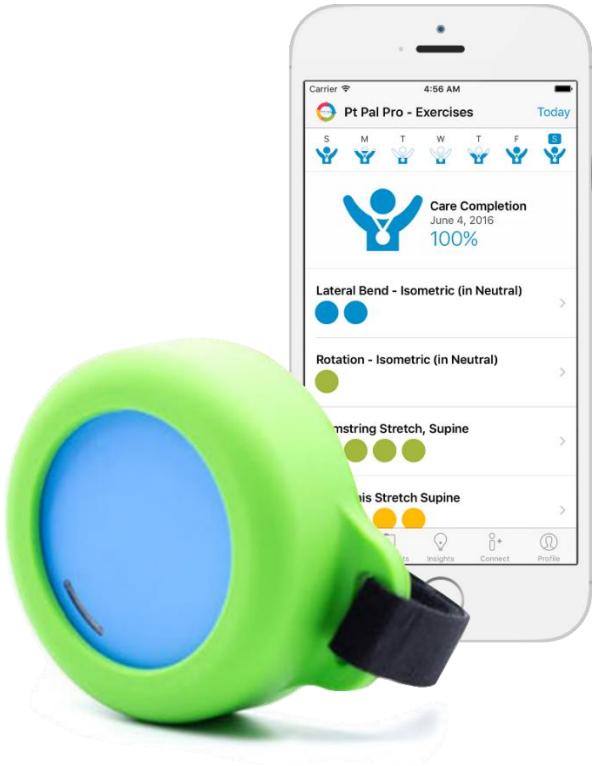

Figure 3: FitMi sensorized puck (blue) and silicone-velcro strap (green) and Pt Pal patient app. The puck can be held and moved, squeezed, placed on a table or the floor and pressed, or strapped to a limb.

Pt Pal is a cloud-based clinical patient engagement platform that assists healthcare providers in managing patient care via patients' mobile devices and web-based portals. FitMi is an interactive

exercise tool designed for stroke rehabilitation that interfaces two puck-like sensors with software that guides users through 40 therapeutic, gamified, exercises, interactively recording and responding to movement activity via an embedded accelerometer, gyroscope, and load cell. Through the integration of these two products, the SEAM system offers a method of remotely delivering HEPs for physical therapy and collecting objective data about patient adherence. Through a web interface, therapists can use Pt Pal to prescribe HEPs choosing from a large library of exercises, monitor patient adherence, and manage HEP progression. Patients use the Pt Pal app to access and complete exercises. The app tracks patient initiation of exercises and the amount of time the patient interacted with the exercise up to completing the full prescribed exercise time. The FitMi pucks can be used during exercises to track activity accomplished during exercise. Thus, we designed the SEAM system to combine the benefits of a robust HEP management and patient engagement platform in Pt Pal with objective movement data from the FitMi pucks to assess adherence with prescribed exercises.

The aims of this pilot study were the following: to investigate usefulness of a remote patient monitoring system during the Covid-19 pandemic from the perspective of rehabilitation therapists, in particular with respect to objective compliance data; to identify areas of improvement in the integration of these two existing systems; to investigate important aspects of implementation as identified by treating therapists and study team members; and to test the use of remote patient monitoring codes for reimbursement.

3.2 Materials and Methods

Participants: Three therapists from outpatient services of University of California, Irvine Medical Center participated in the pilot study, two Physical Therapists (PT) and one Occupational Therapist (OT). UCI Medical Center is situated in an urban setting and has 411 licensed beds. It is the principal clinical facility for the teaching and research programs of the UC Irvine School of Medicine and is designated as Orange County's only Level I Trauma Center.

This study focused on implementation issues experienced by therapists using existing healthcare technologies to perform their normal treatment activities, and we did not acquire protected health information. Therefore, this study was determined exempt from full review following the UCI IRB's exempt self-determination tool. The study was confirmed by the UCI IRB, participants provided informed consent, and study staff followed all relevant Human Research Protection Program policies and procedures.

3.2.1 Study Design

Therapists were provided two initial training sessions by the product development teams, Pt Pal and Flint Rehab: an initial 3.5-hour training session followed by a 2-hour training session two weeks later. The first session consisted of an overview of the study by the study team, an overview of the technical system by the product development team, a hands-on walkthrough of several key features, and a demonstration of the typical set-up process for a patient. Therapists were instructed to explore the system and practice in between sessions. On returning for the second session, the study team addressed questions from the therapists and reviewed the set-up procedure. Therapists were given user manuals for reference and encouraged to reach out to the study team if they had questions or technical difficulties. The study team provided on-site troubleshooting and offered assistance adding exercises to the system if the therapists chose to. Training on the RPM billing codes was also delivered in the initial training sessions given by the study team. Therapists' time spent on study-related activities (training, practice, documentation of study activity) was funded by the study.

Patients were invited to use the technology according to their therapists' judgement of candidates' suitability across factors such as diagnosis, cognition, patient interest, and patient acceptance of the technology. No restrictions were made on patient diagnoses or demographics and no mandates were given on the types of activities that should be performed with the patients. The only restriction was that participants must have a smartphone, and we asked the therapists to enroll

patients with a variety of health insurance payer sources if possible. Treatment decisions such as duration of care or specific rehabilitation activities were left to the discretion of the treating therapist. Therapists were encouraged to use videoconferencing technologies such as Zoom to conduct treatment sessions if they felt it was appropriate.

3.2.2 System Description

The SEAM system integrates two existing systems: Pt Pal and FitMi. Pt Pal provides a web-based portal that allows therapists to prescribe exercises to patients, which are then viewed on the patient's phone in an app. There is an extensive library of existing exercises or therapists can choose to upload their own exercises. The library of existing exercises included 40 gamified exercises designed explicitly for use with the FitMi pucks, which were based on the RehabStudio PC software that normally comes with FitMi. Patients open the app and connect to their FitMi puck via Bluetooth. In the app, they are presented with a list of exercises that their therapist has prescribed for them on that day. When patients select an exercise by pressing the exercise icon, they are first presented with written instructions describing how to perform the exercise. Exercises also include a picture of the exercise or a video showing the exercise being performed. This video can be a link to an existing video, or a recording made using the patient's phone. Patients then tap a button presented on the app screen to begin the exercise which (depending on the style of exercise prescribed) will play a visual and auditory sequence cuing when patients should perform movement repetitions and when they should rest. While performing the exercise, patients hold the FitMi puck as they move, or squeeze the puck, or strap the puck to their leg or arm as directed by their therapist for each exercise. The accelerometer and gyroscope within the puck are used to count distinct movements of the puck and the force sensor detects when the puck is pressed or squeezed during the activity. The web-portal records if the patient initiates the exercise, completes the exercise, and the number of movements or squeezes experienced by the puck during that exercise. If a patient stops an exercise early, or the

therapist has indicated they should receive this survey, they are prompted with a feedback survey asking about the patient's pain and difficulty performing the activity. Feedback is reported numerically in a table format as well as graphically in the web-portal and can be used to help track a patient's experience over time. Secure messaging within the app enables patients and therapists to communicate as desired.

3.2.3. Data Collection and Statistical Analysis

Several data sources were used. Therapists filled out surveys after technology training sessions and after patient treatment sessions. The Post Therapy Session survey focused on perceived ease of using the system with their patient and their perception of their patient's satisfaction with the SEAM system. Patients were not asked to fill out a survey about their satisfaction during treatment sessions to avoid additional time burdens on treatment sessions. Paired sample, two-tailed t-tests were used to compare therapist's perceived ease of use and perceived patient satisfaction on the first day of use with a patient and the last recorded day of use with that patient. Each therapist kept a diary to record observations or notes that they felt were not captured by the surveys, and therapists kept logs tracking time spent towards study-specific activities (training, practice, documentation) and tracking the RPM codes billed for SEAM use.

The study team also conducted mid-study discussions with therapists to collect information and answer questions, and end-of-study interviews with each therapist. End-of-study interviews were recorded, transcribed using Otter.ai, and checked against recordings for correctness. Transcripts of interviews with therapists in the outpatient setting were qualitatively analyzed using summative content analysis. Qualitative analysis codes were inductively generated. Frequency of codes was used to highlight repeated comments and identify larger themes related to therapists' experiences and guide understanding of relative importance between codes and themes. Discussions with members

of the management teams and the inpatient therapist were used to inform material presented in the discussion.

Finally, therapists administered discharge surveys to participating patients when they were discharged from their care. This survey contained items from the Intrinsic Motivational Inventory (IMI) [110], [111], questions related to the patient's experience with the SEAM system, and questions to the therapist regarding their experience with the SEAM system and this particular patient. The survey contained four IMI categories: Value or Usefulness, Interest or Enjoyment, Effort or Importance, and Perceived Competence. Surveys used in this study can be found in Text S2.

3.3 Results

After the initial training session, the therapists rated how comfortable they felt using the SEAM system on a scale from 1 (Very Uncomfortable) to 5 (Very Comfortable; see Table 3).

Table 3: Survey results and time spent training by each therapist outside of training session delivered by study team.

Therapist	Self-Rating After Initial Training	Time Spent Training After Session I (Hrs)	Time Spent Training After Session II (Hrs)
Therapist 1	3	6	1
Therapist 2	3	1	1.5
Therapist 3	4	0	0.25

Self-Ratings were reported in response to the question: "Now that the training session is complete, how comfortable do you feel using the SEAM system?" on a scale from 1 (Very Uncomfortable) to 5 (Very Comfortable).

Therapist 1 and 2 gave lower self-ratings after the initial training than Therapist 3 and subsequently spent more time on training activities outside of the sessions delivered by the study

team. Therapist 3 later reported they would like more practice activities to be built into the training sessions, as they personally prefer structured to unstructured training styles. Only one therapist requested assistance creating new exercises to include in PT Pal. To aid in this, a member of the study team reformatted images the therapist had such that they met the dimension requirements of the system. Ten patient participants were recruited (Table 4). One patient, SEAM 02, was enrolled but dropped out after discovering their insurance would not pay for the total of their treatment costs. One patient, SEAM 06, was enrolled in the inpatient setting where RPM codes could not be billed. These patients are not included in the results.

Table 4: Participants' (n=9) payer sources, care setting, and care domain.

Patient ID	Payer Source	Care Setting	Care Domain (PT/OT)
SEAM 01	Aetna MC PPO	Outpatient	PT
SEAM 03	Medicare	Outpatient	OT
SEAM 04	Cigna PPO	Outpatient	OT
SEAM 05	Blue Cross	Outpatient	PT
SEAM 06	Blue Cross HMO	Inpatient	PT
SEAM 07	Blue Cross Blue Shield PPO	Outpatient	PT
SEAM 08	Blue Shield PPO	Outpatient	OT
SEAM 09	Healthy HMO	Outpatient	OT
SEAM 10	Blue Cross PPO	Outpatient	PT

3.3.1 Adherence

Deidentified Pt Pal activity records were analyzed to summarize prescriptions patients were given (Table 5) and quantify their adherence (Table 6).

Table 5: Patient prescriptions quantified as the average number of activities prescribed per day, the total number of days the system was in use, and the total number of activities prescribed over usage of the system. Therapists prescribed exercises to their patients every day except for SEAM 07 who was not prescribed exercises on Sundays.

Study ID	Average Activities per Day	Total Number of Days	Total Number of Activities
SEAM 01	40	49	1,973
SEAM 03	4	150	639
SEAM 04	14	16	218
SEAM 05	20	71	1,437
SEAM 07	12	46	549
SEAM 08	11	135	1,515
SEAM 09	12	116	1,419
SEAM 10	11	74	823

SEAM 01 was prescribed an aerobic sequence of short exercises, giving them a higher average of activities per day than other patients. Patients were prescribed a broad variety of activities including strengthening, motor control, flexibility, and pain control activities.

Table 6: Adherence statistics per patient. Percent Active Days indicates the percent of days, on which exercises were prescribed, that any level of activity was performed. Percent of Exercises Completed reports the percent of prescribed exercises that were completed in full, as determined by the Pt Pal software running through the full exercise sequence. Percent of Exercises with Device Data indicates the percent of prescribed exercises that were initiated for which data from the puck was recorded. Puck data was not collected for some exercises because of Bluetooth connectivity issues.

Study ID	Percent Active Days	Percent of Exercises Completed	Percent of Attempted Exercises with Puck Data
SEAM 01	24%	6%	35%
SEAM 03	24%	16%	0%

SEAM 04	6%	5%	0%
SEAM 05	54%	37%	76%
SEAM 07	35%	13%	36%
SEAM 08	52%	36%	16%
SEAM 09	34%	11%	0%
SEAM 10	92%	78%	0%

SEAM 04 self-discharged from care early and had minimal interaction with the system. On average, patients were active for M = 40 (26 SD) percent of prescribed days of exercise. Patients completed M = 25 (25 SD) percent of their prescribed exercises. Of the exercises that patients attempted (i.e. started and completed or started and ended before prescribed duration), M = 20 (27 SD) percent of these exercises had associated device data reported as the number of movements or squeezes captured by the puck sensors during the exercise.

3.3.2 Survey Responses

From therapists' responses to the Post Therapy Session surveys, on average, therapists rated their patients' initial satisfaction (1 Very Dissatisfied, 5 Very Satisfied) as M = 3.9 (0.69 SD) and final satisfaction (or their last reported value) with a rating of M = 4 (1 SD). Therapists rated their initial ease of use in using the system with a patient during a visit (1 Very Difficult, 5 Very Easy) as M = 3.3 (0.49 SD) and their final (or their last reported value) ease of use with a patient as M = 4.1 (0.69 SD). The change in patient satisfaction rating between the start and end of treatment for all patients was not significant (t-test, $p>0.05$); however, the change in therapists' reported ease of use between start and end of treatment for patients was significant (t-test, $p<0.05$).

At the time of writing, four of eight patients were discharged from care, and three of the four patients were administered the discharge survey by their therapists. On a 1-7 scale, with 7 showing agreement, their average response is as follows: Value or Usefulness M = 6.33 (0.58 SD), Interest or Enjoyment M = 6.50 (0.50 SD), Effort or Importance M = 6.67 (0.58 SD), and Perceived Competence M = 5.17 (1.61 SD). Thus, these three patients found working with the SEAM system interesting, enjoyable, and of importance to them.

In open-ended questions, patients expressed appreciation for the structure and progress the system provided, and patients noted that the videos of exercises embedded in the system were particularly helpful. Patients expressed dissatisfaction with the physical movement sensor used to capture data, primarily because of its bulkiness (Table 7). All three responding patients expressed they were "Likely" or "Very Likely" to continue using the system after discharge. SEAM 05 and SEAM 07 participated in some telerehabilitation using video conferencing. These patients agreed that the SEAM system made telerehabilitation easier to perform. When asked if using the SEAM system made them more comfortable getting physical therapy during the COVID19 pandemic, SEAM 05 responded "Strongly Agree," SEAM 07 responded "Agree." Therapists noted that the ability to embed videos of prescribed exercises into the app was useful and that the system was useful for promoting motivation and adherence. On average, therapists responded that the system was moderately easy to use with their patient M = 3.25 (0.5 SD) (1 Very Difficult, 5 Very Easy), and their patients appeared satisfied with the SEAM system, M = 4.25 (0.96 SD) (1 Very Dissatisfied, 5 Very Satisfied).

Table 7: Patient and Therapist responses to questions at discharge. SEAM 04 self-discharged before the discharge survey could be delivered and thus the survey response only includes the parts from their therapist, Therapist 03.

Patient	Therapist	Patient Question: What did you like most about the system?
SEAM 01	Therapist 1	'It took me along progressively and I was able to watch the videos we recorded which helped. But the videos got accidentally deleted.'
SEAM 05	Therapist 2	'It kept me on task'
SEAM 07	Therapist 2	'I liked having the exercises organized by day and having the videos'
SEAM 04	Therapist 3	
		Patient Question: What did you like least about the system?
SEAM 01	Therapist 1	'It was hard and uncomfortable to put the puck on my arm.'
SEAM 05	Therapist 2	'The puck was a hassle, large and bulky and did not always capture the repetitions and hard to understand '
SEAM 07	Therapist 2	'The puck did not provide specific feedback so it didn't seem beneficial'
SEAM 04	Therapist 3	
		Therapist Question: What did you find most useful about the SEAM system for treating this patient?
SEAM 01	Therapist 1	'The ability to record videos'
SEAM 05	Therapist 2	'Patient was motivated to use the system because they knew I was monitoring their completion of their exercises'
SEAM 07	Therapist 2	'Pt Pal'
SEAM 04	Therapist 3	'Being able to monitor compliance'
		Therapist Question: What was the most difficult or frustrating part of using the SEAM system with this patient?
SEAM 01	Therapist 1	'The multiple steps to use the system each time I saw the patient.'

SEAM 05	Therapist 2	'The puck was not useful for most of the exercises.'
SEAM 07	Therapist 2	'The puck was not very useful and the patient decided not to do Zoom after the 3rd visit and switched to in clinic visits for the remainder of the therapy'
SEAM 04	Therapist 3	'Time constraints for reviewing progress'

3.3.3 End of Study Interviews

Summative content analysis was used to codify end-of-study interviews to distill repeated comments and identify larger themes related to their experiences using the system during the study period. A summary of this analysis is shown in Table 8. Response concepts coded were organized by positive or negative sentiment, and then further organized into thematic categories and subcategories. Positive themes related to the value the system provided to patients, and ways in which the system facilitated providing care to patients. Negative themes were stratified into themes related to implementation, potential system improvements identified by therapists, and technical issues. The number of mentions of each code by each therapist is given to highlight the diversity of experiences and opinions. Though there were 30 different codes identified in this analysis, 6 codes (3 positive and 3 negative) were mentioned frequently enough that they each represented 5% or more of the total distinct mentions found in this analysis (n = 104). These highlighted codes were adherence, patient satisfaction, and patient motivation within the positive sentiment codes, and patient attributes, pucks not recording/performing as expected, and Bluetooth problems within the negative sentiment codes.

Table 8: Summary of content analysis results from end of study interviews with outpatient therapists.

Themes			Code: Descriptions or Examples	Number of Mentions by Therapist (T#)		
				T1	T2	T3
Positive	Value to Patients		**adherence:** compliance, adherence, accountability	0	2	4
			patient satisfaction: patients find the system interesting and engaging	3	2	2
			game mode: gamification aspects, mentions of engagement relative to gamified exercises	0	1	1
			patient motivation: motivation, excitement, having a physical device was motivating, motivation as a result of being monitored	4	1	1
			feedback to patients: system provides feedback to patients	1	0	0
	Facilitating Care		**facilitate telerehab:** communication with patients, remote monitoring	1	2	0
			billing: making non-productive time productive, difficulties related to billing	1	3	0
			order sets: convenience of creating order sets for prescribing	0	1	0
			adding exercises: ability to create custom exercises	0	1	0
			useful features: automatic Bluetooth connection, activity tracking, "copy to all exercises"	4	0	0
			monitoring: ability to monitor patient activity even when they are not in the clinic	1	1	3
			future and potential uses: to bridge gaps between evaluation and treatments	1	0	0
			feedback from patients: feedback allows modification of programs or preventing injury	0	0	2
Negative	Implementation Issues	Patient Selection	**patient attributes:** consistency in following instructions, diagnosis, cognition, fear of technology, preference for paper instructions, state their phone or data plan could not support the intervention	3	2	4
			patient unable to operate alone	4	0	0
			lack of caregiver support: patients have no one to assist them with the system in the home setting	2	0	0
		System Suitability	**puck suitability for diagnoses:** device does not capture data relevant to balance and stability exercises, patients have difficulty grasping puck	0	4	0
			game mode: exercises that therapists wanted were not available, suitability for diagnosis	2	1	0
		Training/ Education	**survey:** patients did not complete or selected answers straight down the middle, therapists were not trained how to optimally assign surveys	1	1	2
			billing: confusion, missed billing opportunities, improper sequence, no preauthorization	0	1	1
			exercise library: dissatisfaction with uniformity, not finding desired exercises, organization not what was expected, experience with other HEP software	2	1	0
			portal interface: difficulties navigating and using interface	2	0	1
	Potential System Improvements		**reasons for non-complete:** the reasons for non-complete did not line up with patients' reasons	0	1	0
			number of steps: patient forgot app access code, Bluetooth workflow	5	0	0
	Technical Issues		**app/software:** software instability, number of steps required	1	2	0
			pucks not recording/performing as expected: reported counts are different than expected, difficulties connecting to Bluetooth	2	1	3
			Bluetooth problems: problems regarding making the Bluetooth connection	6	0	1
			facility internet	1	0	0
			patient frustration: patient frustration due to system not operating properly or as the patient believes it should	0	2	2

3.3.4 Billing and Reimbursement

The therapists billed 23 RPM codes for a total of $2,353 and payers reimbursed 8 of those codes for a total of $649.21 (see Table S3 for full reimbursement data). The main items that were denied

were codes 99457 and 99458, which are for the first 20 minutes of remote physiologic monitoring performed in a month and an additional 20 minutes of services furnished in that same calendar month. Of the 23 codes billed, 14 of them were for 99457 and 99458, and 85% of those charges were denied, primarily because payer sources reported they were not covered (see Table 9). However, both Cigna and the United Healthcare Medicare Managed Care plan denied one unit of 99457 and reimbursed one unit of 99457. Blue Cross denied all the RPM codes billed but cited that these patients' contracts for PT had already reached the maximum reimbursable amount for a given day before these RPM services were billed.

SEAM 05's insurance, Blue Cross, rejected the RPM billing codes. These codes were not listed as approved under physical therapy in their insurance policy, however the codes the facility regularly used for in-person therapy were approved. As such, the care team only billed SEAM 05's insurance for in-person therapy.

Table 9: List of reasons why specific RPM codes were denied by payers.

Payer	Code	Reason
AETNA MEDICARE MANAGED CARE	99457	Non-Covered
	99458	Non-Covered
MEDICARE	99457	Non-Covered
	99458	Non-Covered
CIGNA	99454	No Reason Given (one count of 99457 was reimbursed and one was not)
BLUE CROSS	99453	Contract for PT maxes at $317 per day
	99454	Contract for PT maxes at $317 per day
	99457	Contract for PT maxes at $317 per day
BLUE SHIELD	99457	Non-Covered
	99458	Non-Covered
UNITED HEALTHCARE MEDICARE MANAGED CARE	99457	Non-Covered (one count of 99457 was reimbursed and one was not)

Several codes that were eligible to be billed were missed as seen in the missing 99453 and 99454 values under Blue Shield and the United Healthcare Medicare Managed Care rows of Figure 4. Billing opportunities were missed due to confusion related to how to use the codes and forgetting to bill as part of a new workflow.

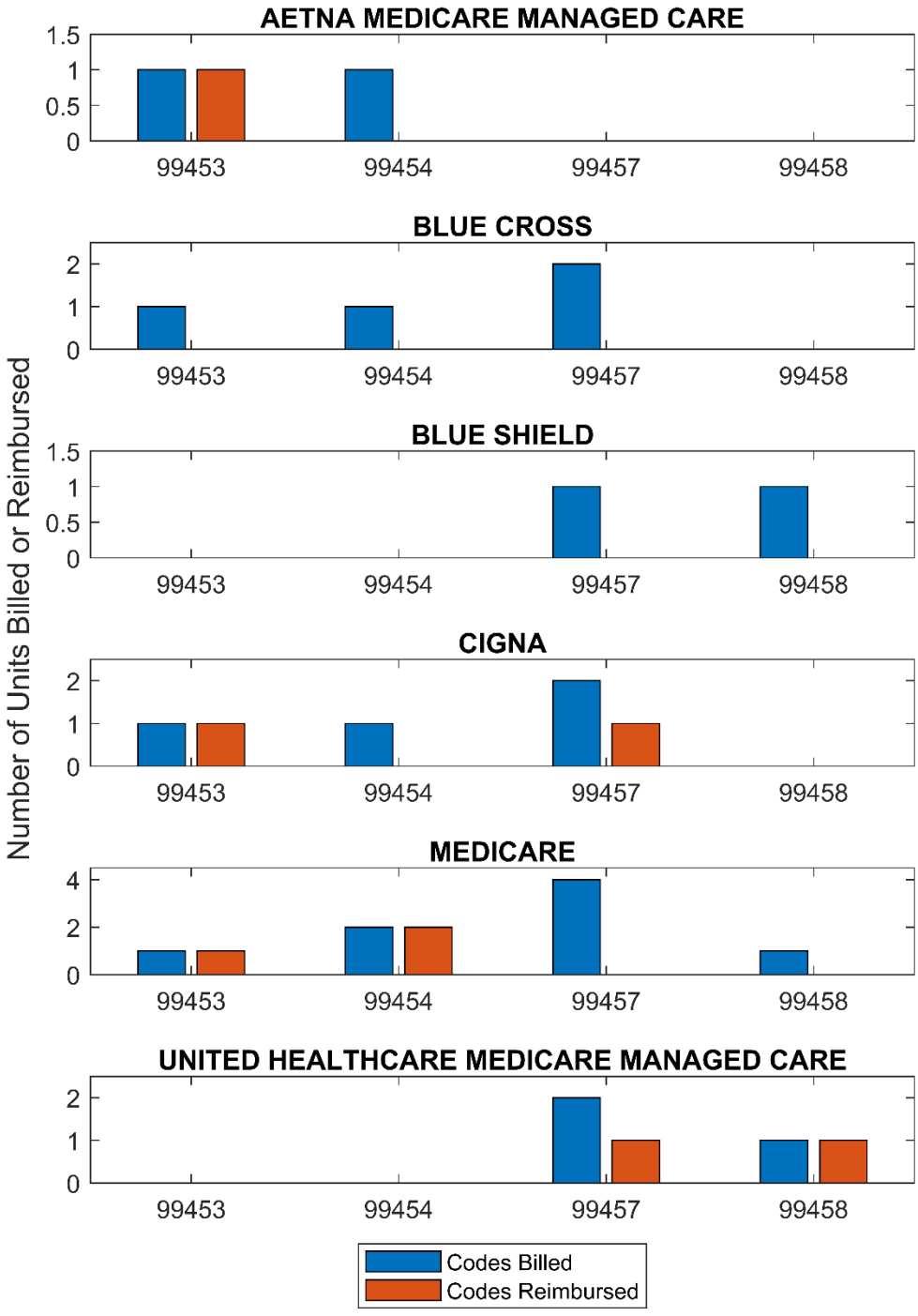

Figure 4: Chart of codes billed (blue) and codes reimbursed (orange) organized by payer.

3.4 Discussion

We developed and tested a Sensor Enhanced Activity Management (SEAM) system that combines HEP management software with a movement sensor. The SEAM system remotely captured objective data regarding HEP adherence, demonstrating that patients' adherence was partial (patients completed 25% of prescribed exercises on average). Nonetheless, therapists expressed the opinion that remote monitoring with the physical movement sensor was motivating to their patients and appeared to improve patient adherence compared to their experience with conventional HEPs. Reimbursement was partial as well, with 8 of 23 codes being reimbursed, but therapists still expressed the desirability of even partial reimbursement. We now discuss these findings, elaborating on them by sharing brief quotes obtained during interviews with the study therapists. We will focus first on the results concerning adherence and motivation, then on our findings on reimbursement for remote patient monitoring, then conclude with study limitations and recommendations for future research.

3.4.1 Adherence and Motivation

In our coding analysis of the therapists' comments, codes related to adherence/accountability, patient motivation, and patient satisfaction were the most frequently mentioned codes that expressed positive sentiment. Therapists felt that the addition of a physical device with which to perform their exercises was beneficial to patients because it conveyed to patients that their therapist was monitoring their activity. Therapists conveyed these sentiments in interview quotes such as these:

> **Therapist 1:** One thing I learned, is how motivating the use of the technology was. Before, my patient wasn't really doing much of anything, and now they were doing their homework and they were going for walks.

Therapist 2: It really helped keep my patients on task with their home exercise program. Because they knew that they were being monitored, I think that helps them to be more compliant with their home exercises.

Therapist 3: Very beneficial, even just having the puck there, believe it or not. I felt just having that there, even if it wasn't necessarily capturing all of their repetitions, it was just something that reminded them "this is something that I'm doing." Versus just sitting there and you're stretching your hand or your arm, here you're given something that's visual or tangible that helps keep you on track.

Therapist 3: Overall, it did help compliance and accountability. When they walked in, if they didn't do their exercises that week, they already came in with the "I'm so sorry, this is the reason why I didn't get it done." For me, I felt like it was always in there, in the back of their mind. They knew I had a way of seeing that they did or did not complete their exercises.

What is clear from these quotes is that the therapists viewed the incorporation of sensors into home exercise programs in a positive light, particularly insofar as the sensors served as a motivational aid to their patients. This is consistent with existing literature examining the effect on exercise adherence of remote monitoring programs [67], [84]. The primary body of literature discussing home exercise literature for rehabilitation reports adherence by percent of participants that report complete adherence to their prescribed programs. Here we find that none of our participants were completely adherent (Table 6), but the system produced objective data on participation at the level of the specific exercise prescribed. Such methods will facilitate further study on patient adherence and potential factors which influence it.

3.4.2 Reimbursement for remote patient monitoring

Therapists also appreciated that use of the SEAM system allowed them to at least partially bill for services similar to what they were already providing, but could not previously bill for. As an example, consider the following quote:

> **Therapist 2:** Having the ability to bill the insurance for some remote patient monitoring really helped make my time more productive, from a billing perspective. When the pandemic first started, and the clinic was closed, I was making a lot of phone calls to patients and asking them questions and giving them advice, but I wasn't able to bill for any of that. But with this system, that could be very useful.

However, some billing attempts were not reimbursed. We identified three main reasons. First, confusion related to the billing codes may also have led to missed billing opportunities. Therapist 2 stated that they thought they may have underbilled for their services at the start of the study, but that they became more confident in the use of the codes as the study progressed. Therapist 3 stated that at one point during the study they billed a code out of order. This was corrected after a member of the facility's billing department reached out to them. Evidence of missed codes can be seen in the full reimbursement table (Table S3) and Figure 4. SEAM 07, SEAM 08, and SEAM 09 have codes 99457 and 99458 codes billed, but not 99453 or 99454, which are meant to be billed at the start of service. Missed billing opportunities further emphasize the need for investment in initial training.

Second, Blue Cross denied all the RPM codes billed during this study. They reported that these patients' contracts for PT had already reached the maximum reimbursable amount for a given day before these RPM services were billed. Third, most of the 99457 and 99458 codes billed were denied and payers stated that these codes were not covered. Billing for these codes appear to have been rejected because of confusion related to who can bill for and furnish RPM services. SEAM 05's insurance denied the claim, specifically citing that pre-authorization from a physician was required.

The current CMS clarifications for 2021 state that RPM codes are listed under Evaluation and Management (E/M), and therefore can only be billed by physicians or NPPs who are eligible to bill Medicare for E/M services [112], where an NPP is defined as Non-Physician Practitioner, defined separately from a qualified therapist such as a PT or an OT [113].

However, we note that the "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers" states:

> This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services [103].

Furthermore, the declaration stated that the blanket waivers are in effect, with a retroactive effective date of March 1, 2020, through the end of the emergency declaration, which at the time of writing, has not ended. Following these clarifications, it is the opinion of the research team that RPM services should have been reimbursed under the COVID-19 waiver. For further explanations of billing RPM codes, as well as Chronic Care Management Codes, in the context of Medicare, the reader is referred to another recent paper [107], which presents the design of a "Safe at Home" program and includes theoretical projections for how it can be reimbursed.

3.4.3 Limitations, Recommendations, and Future Directions

The most consistently cited technical issue during this pilot study was that repetitions captured by the sensors did not quantify patient activity with enough accuracy. Developing a robust algorithm for accurately counting exercise repetitions was a key design goal in our efforts to improve the system following this study. Patients found the sensor puck was bulky to wear on a limb and difficult to grasp if they had limited hand function or strength. In improving the system, we replaced the puck with a smaller "clip"-like sensor that is less than a quarter of the size and roughly 18 times lighter in

response to this finding. Finally, therapists and patients also reported issues connecting to the pucks from the app via Bluetooth. In response to these reported issues, on the recommendation of the study team, the development teams have redesigned the system workflow such that the app prompts the user to initiate the Bluetooth connection when applicable and will also notify users if the relevant settings are not enabled, reducing the number of steps a patient must initiate on their own. Key system usability improvements were completed, and a second feasibility study was completed at Shepherd Center in Atlanta, Georgia in April of 2022 (Detailed in Chapter 7).

We did not track patient eligibility in this study, but, given their experience with the system, we asked therapists to estimate the percent of their patient population that could be eligible to use the system and would benefit from the system (Table 10).

Table 10: Estimated percent of eligible patient population that could benefit from the SEAM system, including descriptions of the general population and reasons they might not be eligible.

Therapist	Domain	%	General patient diagnoses	Reasons patients might not be eligible
1	PT	22%	Movement disorders, neurologic conditions	Age, technological fluency, lack of smart phone, cognitive deficits from diagnosis
2	PT	75%	Lymphedema	Technological fluency, lack of smart phone, diagnosis related barriers
3	OT	100%	Neurologic conditions	

Therapist 1 reviewed their current case load and estimated the smallest eligibility citing barriers of technological fluency, lack of a smart phone, and diagnosis related complications were cited as potential barriers. Therapist 3 reported that all their patients would likely benefit from the portability and accountability provided by the system even if their patients experienced difficulties with the system. Clearly, there is substantially variability in therapists' estimates of eligibility, in part due to the specific features of the patient populations they treat. Future studies should rigorously track eligibility and patient experience with such technology for different patient populations.

As suggested by therapists in this study, future directions of study for the SEAM system could involve the use of the remote monitoring and treatment system to provide HEPs to patients between gaps of care. Depending on demand and capacity, patients can wait for months between discharge from an inpatient facility and evaluation at an outpatient facility and wait further time still between their evaluation at the outpatient facility and the start of their treatment. Whether it will be possible to bill for such a service during gaps of care is unclear, yet the therapists we interviewed believed it would be an effective strategy to prevent patient health decline and loss of motivation.

Another important direction for future research is to study how patterns of HEP prescriptions, such as number of exercises or types of exercises, influence patient adherence [114]. Incorporation of systems like SEAM into routine practice will make this sort of analysis possible using large scale data. This in turn will usher in a new era of evidence-based guidelines for optimizing HEP prescriptions.

Finally, In the authors' opinion, training with the therapist care team is crucial for implementing new technologies such as SEAM. Therapists are the access point to the system for patients, and if they are not comfortable with the system, they will use alternative methods with which they are more familiar [102] [68]. However, working against sufficient training is the fact that therapists have little time in the clinic outside of patient visits and some allotted documentation time [115]:

Therapist 3: Overall, the biggest challenge is time. And it's not the study or the program, it's just time. Being able to incorporate something new and novel into your program takes a little bit more time and effort to be proficient with it. And with some of the constraints that we have, you're always pressed. I think it's just the nature of the beast of how healthcare is right now. Everything is just maximize time, maximize productivity, and then everything else kind of falls in wherever it can.

Troubleshooting the system, navigating the software interface, and creating exercise programs for patients were the most cited time concerns.

To minimize these time demands, we suggest three approaches. First, we drafted a recommended training schedule that builds on the training delivered at the start of this study (see Text S4). The schedule recognizes initial training sessions alone are not sufficient, because not all issues can be foreseen, since they vary by therapist and patient.

Second, we suggest that it will be helpful to have a technical assistant to assist with troubleshooting patient setups and perform initial system installation for patients. Such an assistant could have "office hours" or a technical assistance hotline for patients to contact to preserve treatment time for therapy and relieve therapists from the role of troubleshooting. An assistant in this role could be a member of the facility's IT support staff, or, perhaps, a volunteer who has learned to use the technology.

Third, although the system is designed to be used with a wide variety of patient types and diagnoses, careful selection of initial patients may increase therapists' success when they are new to the system. Indeed, patient attributes were one of the most frequently mentioned codes in our coding analysis, as exemplified by the following quote:

Therapist 3: There are definitely diagnoses that I feel it would work really well with, higher level patients that basically you give your home exercise program to, you're able to monitor it,

you check in with them a couple times a week, just to make sure that they're doing it safely, that they're doing them correctly, or if they have any questions. Some of the other patients, with more moderate to severe impairments, it's definitely challenging because, one of the big things that we do as therapists is putting our hands on the patients to help facilitate movements or inhibit movements and you just can't do that via telerehab.

Therapist 1 enrolled only a single patient during the study due to the complexity of their patients' conditions. Selecting patients with intact cognition, available caregiver support, and at least moderate technology fluency will facilitate implementation.

This work represents preliminary investigation of feasibility and implementation of a remote patient monitoring system in an outpatient physical therapy setting and provided unique insight under the conditions of the Covid-19 pandemic. To our knowledge, existing literature on use and implementation of RPM codes is quite small and this is the first study performed in the domain of physical rehabilitation. The numbers of therapists and patients studied were small. In addition, the focus was on therapists' experience, and future work should analyze the user experience from the patient perspective in a larger population of patients. Future studies should also closely track patient eligibility statistics as well as formal clinical outcomes achieved by using the system.

However, despite these limitations, the study provides a proof of concept that can inform future work. For example, the observations and findings presented here should help inform designers of mRehab interventions for clinical and home use about therapist perspectives and some of the relevant contextual and implementation considerations. The study team will use the findings to inform future implementation work following improvements to the system and a subsequent multi-site efficacy randomized controlled trial.

3.5 Conclusion

SEAM provided a remote monitoring platform for therapists to provide treatment remotely or in-person. RPM codes allowed therapists and organizations to bill for their HEP review and management activities, but despite CMS waivers during the COVID-19 pandemic, organizations may have the most success billing for these services if they are billed incident to and furnished under general supervision of a physician. Further, the newly introduced Remote Therapeutic Monitoring (RTM) codes introduced in (YEAR) may be more suited to this application. Analysis of patient interaction in the system indicates relatively low adherence but offers a new avenue of objective data collection regarding adherence to HEP's. If facilities are interested in investing in new systems of remote monitoring and treatment, we highly recommend designing a structured program for training and technical support throughout the initial implementation period. Though work needs to be done on identifying the optimal sensor information to report to therapists, therapists found the monitoring aspects of the system and the physical device to be motivating to their patients and reported increased adherence to prescribed HEP's.

Chapter 4: Unsupervised Uptake in the Home – A Large Dataset of In-the-wild Use of a Sensorized Gamified Exercise System (SGES)[3]

Summary

Persevering with home rehabilitation exercise is a struggle for millions of people in the US each year. A key factor that may influence motivation to engage with rehabilitation exercise is the challenge level of the assigned exercises, but this hypothesis is currently supported only by subjective, self-report. Here, we studied the relationship between challenge level and perseverance using long-term, self-determined exercise patterns of a large number of individuals (N = 2,581) engaging in home rehabilitation with a sensor-based exercise system without formal supervision. FitMi is comprised of two puck-like sensors and a library of 40 gamified exercises for the hands, arms, trunk, and legs that are designed for people recovering from a stroke. We found that individuals showed the greatest perseverance with the system over a two-month period if they had 1) a moderate level of motor impairment and 2) high but not perfect success during the first week at completing the exercise game. Further, a steady usage pattern (versus accelerating or decelerating use) was associated with more overall exercise, and declines in exercise amount over time were associated with exponentially declining session initiation probability rather than decreasing amounts of exercise once a session was initiated. These findings confirm that an optimized challenge level and regular initiation of exercise sessions predict achievement of

[3] This chapter is a slightly modified version of the paper titled "Using Large-Scale Sensor Data to Test Factors Predictive of Perseverance in Home Movement Rehabilitation: Optimal Challenge and Steady Engagement" published in Frontiers in Neurology in 2022 (Ramos Muñoz et al., 2022).

a greater amount of overall rehabilitation exercise in a group of users of commercial home rehabilitation technology and suggest how home rehabilitation programs and exercise technologies can be optimized to promote perseverance.

Statement of Contributions

This work was published as 'E. D. J. Ramos Muñoz et al., "Using Large-Scale Sensor Data to Test Factors Predictive of Perseverance in Home Movement Rehabilitation: Optimal Challenge and Steady Engagement," Frontiers in Neurology, vol. 13, 2022.' As second author, my contributions to the work included conception of analysis strategies, performing analysis, writing sections of the manuscript, and editing the manuscript.

4.1 Introduction

The World Health Organization estimated that one in three individuals worldwide have conditions that would benefit from rehabilitation [116]. Movement-related conditions, such as low back pain (~568M people per year) and stroke (~80M people per year) account for over 80% of these conditions [116]. For stroke patients in the US, the total estimated cost for rehabilitation services is greater than $9B each year [117].

In the current rehabilitation service paradigm, clinicians instruct patients to continue practicing selected movement exercises on their own at home following periods of inpatient and/or outpatient treatment. Clinicians usually provide patients with printed descriptions of the exercises. The importance of continuing with therapeutic exercise at home has increased because of decades-long actions aimed at reducing inpatient rehabilitation stays [118]. However, there have been few innovations that have helped

ensure that discharged patients complete home rehabilitation exercise programs. The COVID-19 pandemic caused an even greater emphasis on carrying out rehabilitation at home [119],[120],[121], potentially furthering this trend toward expecting rehabilitation to occur outside of formal facilities in the longer-term [122].

Studies examining home exercise programs have found that compliance is partial across a variety of health conditions. While estimates vary, most reports indicate the majority of patients do not fully adhere to prescribed home exercise routines. One estimate suggested that up to 65% of patients are nonadherent to their home exercise programs [27]. Therapist estimates of their patients' adherence tend to be lower than patients' reports. For example, only 36% of physical therapists reported high levels of adherence to home exercises [44]. In a study of home exercise for low back pain, 39% of patients reported adherence, while therapists estimated 16% were adherent. Low adherence is also implied by patients' poor memory of their prescribed exercises: only 15% of participants were able to recall all of the exercises contained within their program and demonstrate them accurately [45].

Most home rehabilitation adherence studies have relied on subjective and self-reported methods, primarily surveys [42],[27]. The introduction of sensor and computer gaming technologies for home rehabilitation – or mRehab (mobile rehabilitation) systems [123],[124] – has made it possible to objectively quantify adherence. Studies with sensor systems have reinforced the concept that adherence is partial and highly variable. A recent systematic review of home-based, upper limb practice after stroke examined 42 studies that used a variety of technologies to facilitate movement practice, ranging from the Wii, to

the iPad, to custom-designed sensor or robotic devices [125]. These studies were typically small: only three enrolled more than 30 participants, and the largest study, which used Nintendo Wii Sports for arm rehabilitation after stroke, enrolled 235 individuals [126]. The studies also varied substantially on whether and how they prescribed a dose of practice. The seven studies that allowed participants to self-select their dose of practice found that stroke survivors chose to train for approximately 24 min/day, 4–5 days/week. For studies where practice amounts were prescribed, participants were asked to complete between 9.5 and 161 h of practice over four to 24 weeks. Adherence varied widely, being ≤ 50% in five studies, 51% to 74% in nine studies, 75% to 100% in 13 studies, ≥ 101% in six. Considering this variability, determining how to help patient populations consistently persevere with home exercise is an important goal for promoting health and function.

Maintaining motivation to adhere to home exercise programs is difficult for many stroke survivors [28], with rates of apathy in stroke survivors above 30% [127] and evidence that apathy has a strong effect on limiting participation in meaningful activity [128]. A key factor that has been hypothesized to influence the motivation to engage with rehabilitation exercise is the challenge presented by the assigned exercises [129]. For example, if an individual is severely impaired, exercises can quickly become overly challenging, requiring large amounts of effort to complete [130],[131]. On the other hand, exercises that are too easy to complete may be viewed as non-beneficial by the person exercising. In a study of repetitive finger movement training after stroke in which the exercise was gamified, success at playing the game predicted the level of self-reported motivation for engaging in the exercise, as well as self-efficacy in achieving functional gains [132].

Here, we leveraged a unique opportunity to analyze anonymous usage logs from a commercial, sensorized, home rehabilitation technology, called FitMi, to study what predicts perseverance in rehabilitation. FitMi is comprised of two puck-like sensors and software that visually guides the user through 40 therapeutic exercises for the hands, arms, legs, and torso in a game-like setting (Figure 5). This game format allows users to "level-up" if they perform a target number of repetitions for a given exercise, providing a quantitative measure of successful exercise completion. Users typically buy the system out-of-pocket and use it freely on their own without direct supervision from a rehabilitation therapist. We are therefore studying a group of people who have taken concrete steps to continue their rehabilitation by acquiring a home rehabilitation technology. Individuals with enhanced autonomy and self-efficacy have better health outcomes, including in stroke rehabilitation [133]–[136]. However, we hypothesize that even among this motivated subpopulation, there will be variance in their perseverance which is influenced by challenge level and steadiness of use. To test whether challenge levels are associated with perseverance in unsupervised, home rehabilitation exercise, we studied whether the impairment level of the user, measured with the device itself, as well as the user's success in leveling up in the first week of use, predicted total amount of use of the system. Therapists sometimes warn patients not to "overdo" their exercises when they begin a new program lest they become too fatigued or sore. Further, people who engage with new consumer technologies are known to sometimes experience a novelty effect in which engagement is initially high but rapidly tapers [137], [138]. We therefore also quantified steadiness of FitMi use and tested for a potential association with perseverance.

Figure 5 FitMi (produced by the company Flint Rehab Devices) consists of two force and motion sensing pucks and a software application called RehabStudio. Top row: Hardware required for FitMi. Bottom row: Graphical user interface for FitMi

4.2 Methods

We analyzed usage data from 2,581 users of the FitMi movement rehabilitation system acquired over a three-year period. We required users to have had the system for at least eight weeks to be included in the analysis. Data were anonymous, having been automatically uploaded to a server managed by Flint Rehabilitation Devices, the company that manufactures and sells FitMi, without any identifying information after each exercise session. The study was confirmed by the UC Irvine Institutional Review Board.

4.2.1 FitMi Overview

FitMi is an FDA-listed medical device marketed to individuals who have experienced a stroke to help them perform movement exercise. The system consists of two sensorized "pucks" and companion software which uses data from the pucks' sensor arrays to detect completion of the exercises available in the system. FitMi provides user-selectable, therapist-designed exercises for the arms, hands, core, and legs. Users initiate a session by selecting a body region and an amount of time to exercise. FitMi then presents the unlocked exercises for that body area and the user chooses which exercises to perform during the session. If they achieve the target number of repetitions for a specific exercise in a set amount of time, they "level up" and the software will increase the target number of repetitions for the exercise. The three easiest exercises (as judged to be the easiest by an experienced occupational therapist) in each body region are unlocked at the beginning of use. The software will unlock more difficult exercises if the cumulative level (of the currently unlocked exercises in the region) exceeds a threshold (5, then 10, 15, 20, 25, 30, 40, 50). During an exercise, the user has a set amount of time to complete the target number of repetitions.

Users typically acquire the system directly and use it on their own without supervision from a therapist. As such, they are recommended to "take a tour" of the software when they first interact with the system. In this tour, the system presents a sequence of messages explaining the graphical interface to perform their first exercise. The system also comes with a written user's guide and online resources (e.g. setup videos hosted on YouTube). For each exercise available in the system, there are written instructions and an embedded

video users can access in which an occupational therapist explains the exercise and provides tips to properly complete the exercise. During the exercise, the interface presents a visual of the desired start and stop state for each repetition with a slider prompting the user to move between the two states (Figure 5, Bottom row, right).

4.2.2 Data acquisition and cleaning

We used FitMi user data acquired between June 20th, 2016 and December 15th, 2019. We removed data from test users, clinic users, and users whose first exercise was less than eight weeks prior to the end of our data collection (as described in the **Error! Reference source not found.**), resulting in data for 2,581 users. We assigned the start time of each user's first day to be 12:00 am, counting days of use as 24-hour periods after this start time.

We found that the total number of repetitions performed by each user during their first eight weeks had a lognormal distribution (see 4.3 Results). Thus, we filtered outliers from the data using the log transform of total repetitions performed, excluding users with log transformed data more than two standard deviations from the mean. This filter resulted in the exclusion of 117 (4.5 %) users with total repetition counts that were less than or equal to 16 or greater than or equal to 79,380. A total of 2,464 users remained after this outlier removal process.

4.4.3 Data analysis

Estimating Upper Extremity Impairment: The large data set was anonymous and contained no clinical information about the users' impairment. We hypothesized that the rate of repetition of an exercise would reflect the user's motor impairment level. To test this hypothesis, we used data from a randomized controlled trial (RCT) using the FitMi

system (ClinicalTrials.gov Identifier: NCT03503617) for which a rehabilitation therapist monitored 41 persons with a chronic stroke as they played three (out of the ten total) exercises in each of the four FitMi regions [**paper ref**] (See section **#.#** for details on the Trial). The therapist also evaluated each participant with the Upper Extremity Fugl-Meyer (UEFM) assessment, a widely-used and validated measurement of upper extremity impairment after stroke that varies from 0 (meaning complete paralysis) to 66 (normal arm movement) [139]. As described below, we studied the relationship between the subject's initial repetition rate for various FitMi exercises and their UEFM score.

Success Rate: A FitMi user "levels up" when they complete the target number of repetitions for a given exercise in the allotted time. We defined each user's "Success Rate" as the percentage of exercises in which the user leveled up during the first week of use, divided by the number of exercises they attempted during that first week, excluding Level 10 exercises because leveling up was not possible at Level 10.

Lifetime: To compare trends between users over the entirety of their interaction with FitMi (i.e., beyond the eight-week window), we calculated various outcomes measures as a function of "lifetime". We defined each user's lifetime as the period of time between their first (assigned value 0%) and final day of interaction (assigned value 100%). Data for all other days in the user's lifetime were proportionally distributed throughout the percent lifetime into 100 bins, each representing an increment of 1% (Figure 6). If a user had more than 100 days of activity, neighboring day data were summed and placed into the nearest 1% bin. When we calculated ensemble statistics across percent lifetime, we considered only bins corresponding to days on which the user could have used the system. We

excluded users who used the system for only one day from the lifetime analysis, leaving 2,033 users for these analyses.

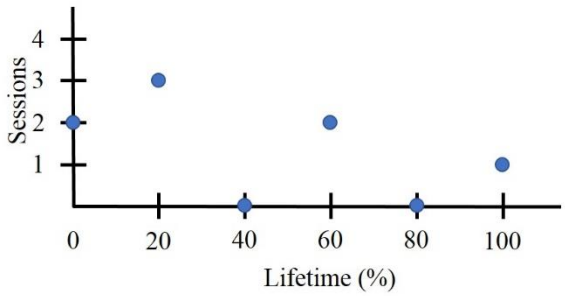

Figure 6 Sample lifetime data for a user who quit using FitMi after six days and initiated an exercise session only on four days.

Steadiness of Use: To quantify steadiness of use of the system, we first plotted the cumulative percentage of total exercises initiated versus the percent lifetime (Figure 7A). We found that the curvature of the progress lines between users varied from concave to convex. We fit a function based on the smooth approximation from [140] with a single parameter μ (which we will refer to as the "steadiness curvature") that specifies concavity, using the fmincon solver on MATLAB R2019b (Figure 7B). See Supplemental Material for function and details. We did not include the values of the first and last exercise session because these were always 0 and 100% and the fit curve also was constrained to have these values. We only included users with five or more active days in this analysis, to ensure there was sufficient data to estimate a curvature, resulting in 1,385 users.

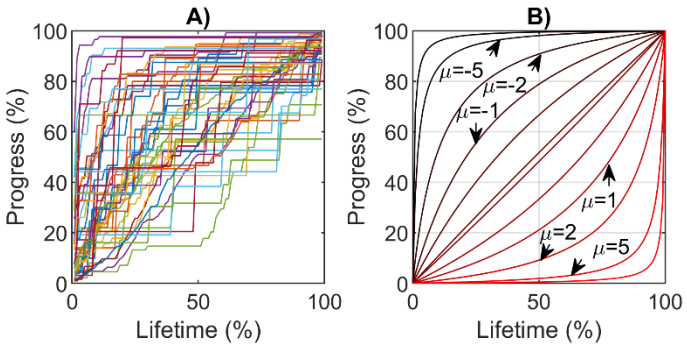

Figure 7 Estimating steadiness of use. A) % Progress in exercises achieved versus % lifetime. B) We fit curves of this form, identifying the parameter μ as the "steadiness curvature". A curve with m = 0 indicates perfectly steady use over the lifetime, while a curve with μ = -5 indicates high initial use tapering rapidly off (deceleration), and a μ = 5 indicates light initial use, rapidly increasing (acceleration).

Probability of Perseverance: We quantified perseverance as the probability that individuals would achieve low, medium, or high levels of usage. We defined the thresholds for low, medium, and high levels to be the 25th, 50th, and 75th percentiles of various measures of usage – total repetitions, total usage time, and total active days. We estimated the probability of perseverance for a given range of three factors (estimated impairment, success level, and steadiness of use) by finding all individuals within that range for that factor, then calculating the fraction of those individuals who exceeded the level of usage.

Statistical Tests for a Maximum in Perseverance: For the three factors we analyzed, measures of perseverance often had a maximum at an intermediate value of the factor and fell off in either direction from that value. To test whether this maximum was significant,

we compared the maximum to the value immediately next to it (Phi test) or, if there were at least four neighboring values, we tested for a relationship in the descending region using regression analysis. For brevity, we will refer to this statistical methodology as the "sweet spot test" below, providing the two p values needed to assess whether there was a significant declining trend on the left and right side of the peak, respectively.

4.3 Results

4.3.1 Usage Statistics

To provide context for the ensuing analysis of factors that predicted perseverance, we first provide summary statistics for usage of the system over the entire 3.5 year data snapshot window. The 2,464 users performed a mean of 245 ± 617 (SD) exercises per user, which they achieved over 16 ± 35 days of use. Users focused more on performing upper extremity exercise (39.9% of exercises were for the arms and 27.8% for the hands) versus the core (15.8%) or leg (16.5%) exercises (see Figure S-1). The average time spent on each exercise was 58.2 ± 52.7 seconds, resulting in a mean total exercise time of 237 ± 682 minutes (3.9 hours), during which users achieved 13,033 ± 42,789 repetitions.

Total repetitions and total exercise minutes (but not total # of active days) were distributed in log-normal fashion (Figure 8). Thus, while there were a large number of users who used the system only lightly and relatively fewer heavy users, there was no clear demarcation between them. The top 1% of users completed a mean of 332,189 repetitions, a ~25-fold increase in perseverance compared to the average user.

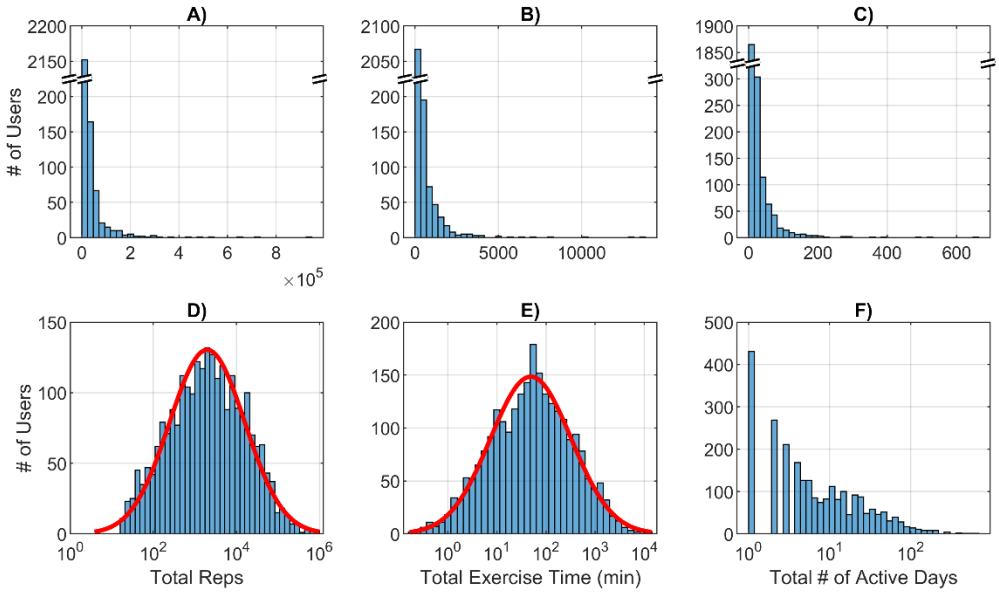

Figure 8 Histograms across 2464 FitMi users for (A) total repetitions (B) total exercise time and (C) total active days. (D), (E), and (F) show the same data plotted on a log scale for the x-axis. Red lines are best-fit normal distributions.

4.3.2 Factors Associated with Perseverance

Impairment Level: To determine a sensor-based measurement that we could associate with impairment, we first analyzed the data acquired from 41 individuals with hemiparesis after stroke who used FitMi in a clinic under the supervision of a rehabilitation therapist. Among the six upper-extremity FitMi exercises tested, the initial repetition rate of the "Reach to Target #2" exercise was most strongly correlated with UEFM score (adjusted R^2 = 0.75, $p < 0.001$), a common clinical measure of upper extremity impairment. The relationship was well-fit by an exponential function (Figure 9).

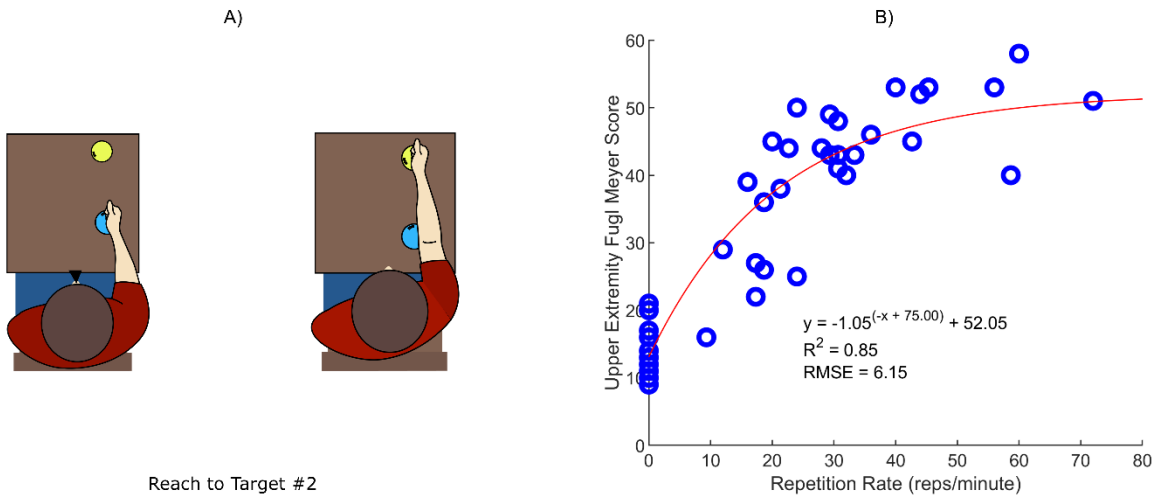

Figure 9: Identifying a system measurement that relates to clinically-measured, upper extremity impairment. (A) "Reach to Target #2" exercise diagram (B) Relationship between the Upper Extremity Fugl-Meyer (UEFM) score, assessed by a rehabilitation therapist, and repetition rate of the "Reach to Target #2" exercise. Shown is an exponential curve fit with the associated statistics.

This repetition rate measured in the first week predicted perseverance, measured as the probability of achieving various levels of either total repetitions, exercise time, or active days during Weeks #1-8 (Figure 10). Users with lower repetition rate (i.e., greater estimated impairment) exhibited a perseverance probability that was decreased by 7-64% compared to users with the maximum probabilities, although this trend was not always significant. Users with higher repetition rate (i.e. lower impairment) also exhibited probabilities decreased by 27-64%, but this trend was significant only for the active days measure. The optimal range of 40-50 reps/min indicated that people with generally less

impairment tended to persevere more, however, and corresponded to a relatively mild UEFM score (Figure 9B).

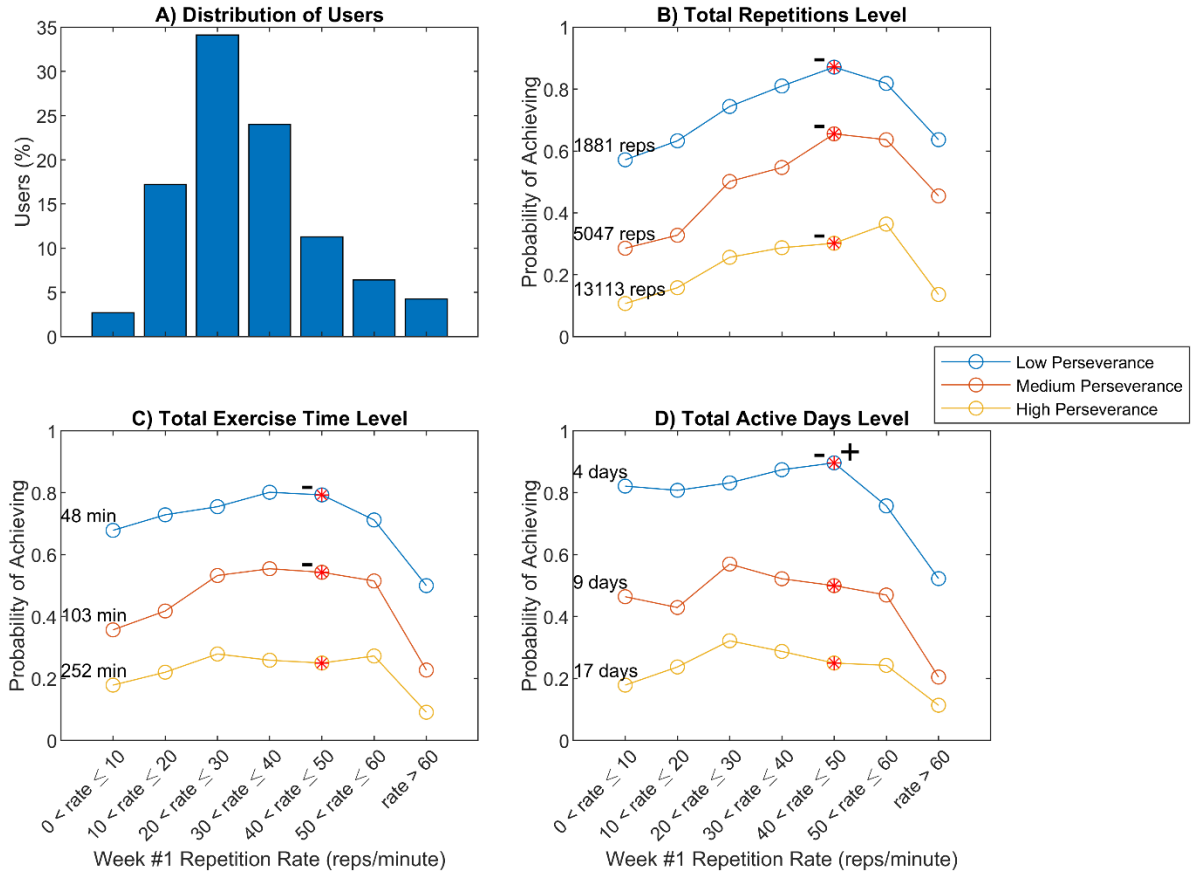

Figure 10: Relationship repetition rate of the Reach to Target # 2 exercise in Week 1 and perseverance. A) Distribution of users with various repetition rates B-D) Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across eight weeks of use. The – symbol indicates a significant decline from the peak value moving to the left, and + sign indicates a significant decline from the peak value moving to the right, using the "sweet spot" test described in the methods ($p < 0.05$).

Success Level: People who experienced lower levels of success in the first week of use exhibited decreased probabilities of achieving the different levels of use in the eight-week window, as did people who experienced 100% success (Figure 11). Thus, there was an

optimal range of initial success associated with perseverance, which was above 90% but not 100%. Notably, only 45% of users who achieved 100% success rates initiated another exercise after the first week, while 72% of users who achieved lower success rates initiated an exercise after the first week, a significant difference (Phi Test, Coeff = 0.2, p-value < 0.001). About 85% of users who obtained 0% success rates went on to initiate another exercise after the first week.

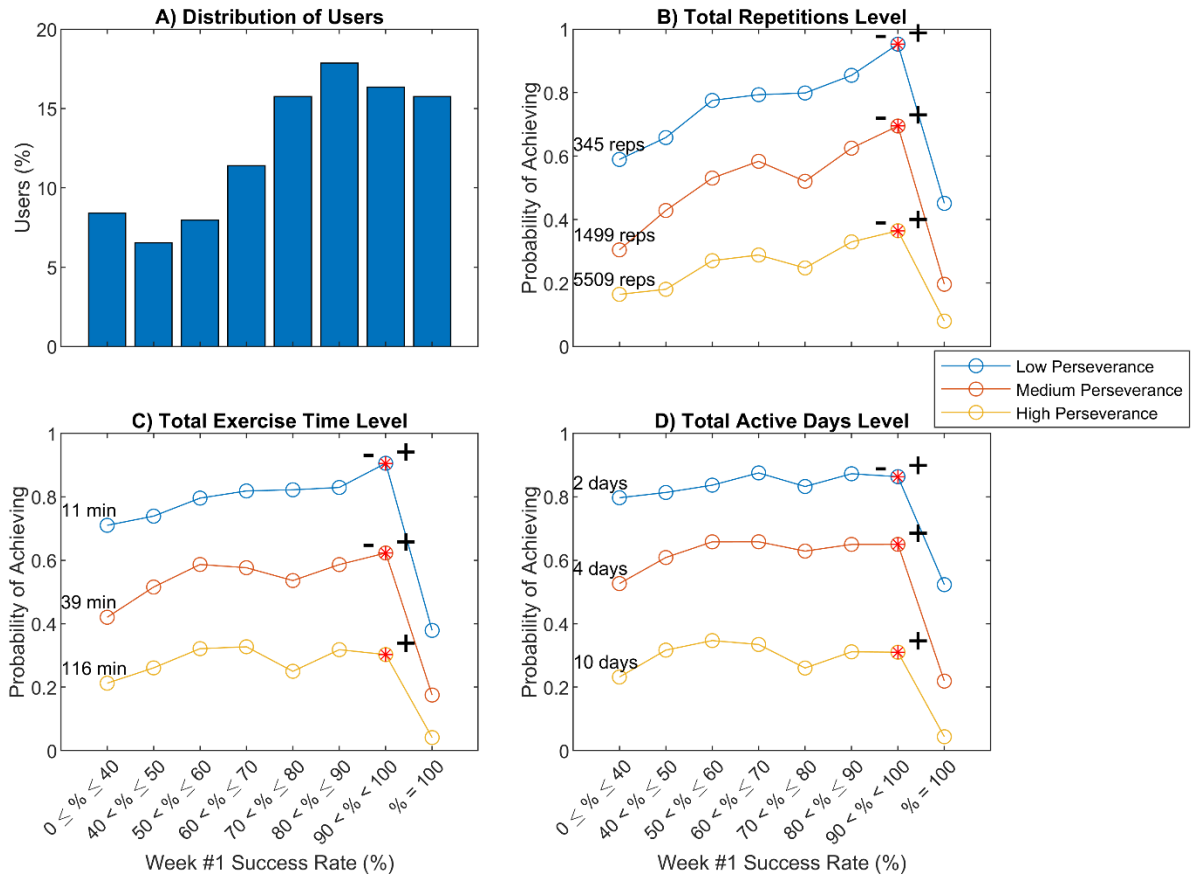

Figure 11: Relationship of initial success and perseverance. A) Distribution of users with various success levels in leveling up during Week #1 B-D) Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across eight weeks of use. The – and + symbols indicated significant declines to left and right, respectively, from the peak value using the "sweet spot" test described in the methods (p < 0.05).

Steadiness of Use: Some users initiated exercises at a steady rate over time, while others exercised at a high-then-low rate (decelerating), or a low-then-high rate (accelerating). The steadiness curvature (m from Figure 7) had a mean curvature value of -1.1, which was significantly less than zero (t-test, $p < 0.01$) (Figure 12A). Users with greater steadiness curvature (either decelerating or accelerating) tended to use the system less (Figure 12). Thus, there was an optimal range for steadiness of exercise initiation associated with the probability of perseverance, although the relationship was relatively flat in the intermediate range.

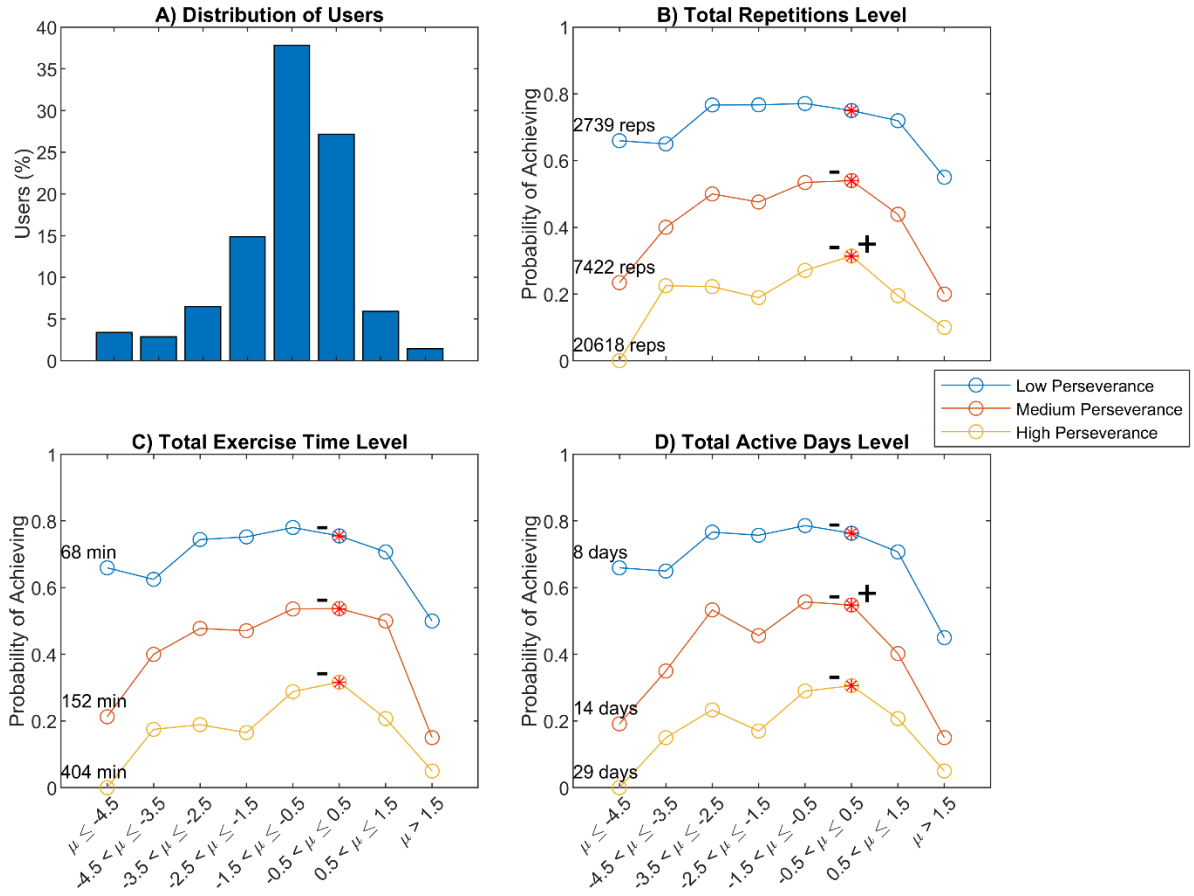

Figure 12: Relationship of steadiness curvature and perseverance. A) Distribution of users with various steadiness curvatures. Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of

three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across eight weeks of use. The – and + symbols indicated significant declines from the peak value to the left and right, respectively, using the "sweet spot" test described in the methods ($p < 0.05$).

In the above analysis, user's initial repetition rates, success rates, and steadiness curvature included data from Week #1, and we used them to predict overall perseverance, which also included data from Week #1. To test if including data from Week #1 biased the patterns we observed, we repeated the above analyses with measures of perseverance calculated over Weeks #2-8. The results of these analyses were similar to the results presented above.

4.3.3 Session Initiation Probability

The results of the analysis of steadiness of use indicated that users on average had a decelerating pattern of use (since the mean steadiness curvature was -1.1). We studied this decelerating pattern further by calculating the probability of initiating a session across the population as a function of lifetime. On average across the population, session initiation probability decreased in an exponential-like fashion over the lifetime of use (Figure 13A). However, when users initiated an exercise, on average they achieved increasingly more exercise repetitions over time (Figure 13B). The amount of time spent exercising per session stayed roughly constant (around 20 minutes, Figure 13C), so the increase in repetitions was attributable to doing more repetitions per minute, a demand the game software automatically imposed on users as they "leveled up". As a result of this demand, users had less success leveling up over time (Figure 13D).

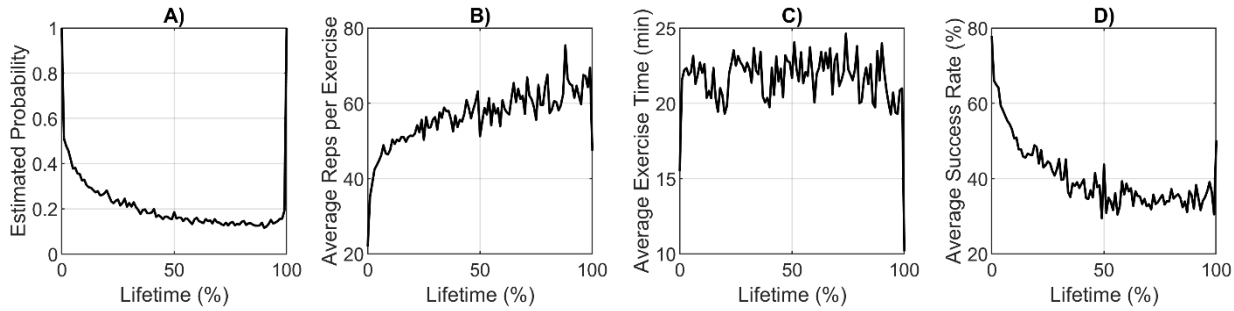

Figure 13: A) Estimated probability of initiating at least one session, and B-D) Average activity metrics plotted against percent lifetime for active users only. By our definition of percent lifetimes, all users are active on the first and last ticks of the normalized lifetimes.

We observed an exponential-like decrease in session initiation probability on average across the user population. To determine if individuals also tended to follow exponential-like decreases in session initiation probability, we tested the ability of various decay functions (the sum of two exponential functions, a single power function, and a double power function) to fit individual users' session initiation probability curves plotted over their lifetime. For individual users, we estimated session initiation probability (for one or more sessions in a day) using a moving average with a window of size 19% of lifetime, padding the start and end of the data with ones and zeros, respectively. The value of 19% was chosen to give a smooth curve; smaller or larger windows did not alter the main results. Only users with more than one day of activity were fit. The sum of two exponential functions fit users significantly better than the other two with an average adjusted R2 of 0.84 (0.19 SD) vs. 0.50 (0.13 SD) and 0.70 (0.19 SD) for the single and double power functions, respectively. Fit statistics for different functions were significantly different (Kruskal Wallis $p < 0.001$). Thus, session initiation was best characterized by the sum of

two exponential decay processes (Figure 14). The decay constants, λ, were on average 16.7 (9.3 SD) and 6 (8.7 SD). Converting the decay constants to time constants, τ (where $\tau = 1/\lambda$), shows these processes had an average mean time constant of 8.8% (2.9 SD) and 51.6% (17.3 SD) of normalized lifetime respectively.

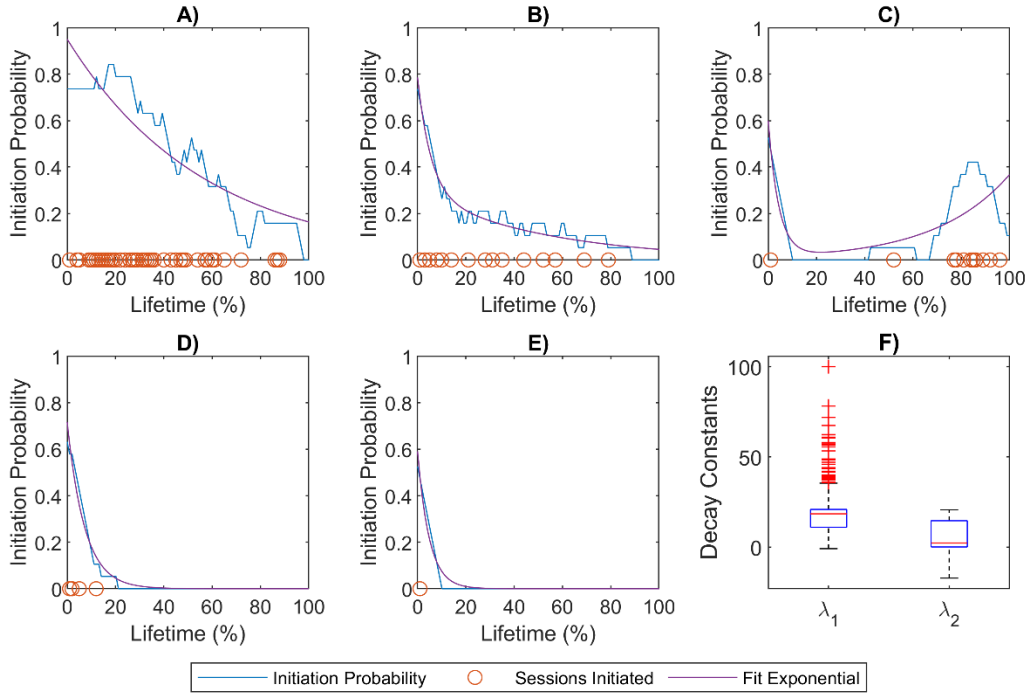

Figure 14: Pattern of individual users' session initiation probabilities. A-E: Examples of five users' session initiation probability demonstrating a variety of the usage patterns. Orange circles mark initiation of at least one exercise session at that lifetime %. The blue line is the probability of initiating at least one session calculated with a sliding window average (window size = 19). The purple line is the sum of two exponential functions fit to each user's probability of session initiation curve. F: Decay constants of the two exponentials. For the model fit, $f(x) = ae^{-\lambda_1 x} + be^{-\lambda_2 x}$*, the average coefficients of the population were* $a = 0.42 \pm 0.17$, $\lambda_1 = 16.7 \pm 9.3$, $b = 0.43 \pm 0.17$, $\lambda_2 = 6 \pm 8.7$.

4.4 Discussion

The data set studied here represents the self-determined exercise patterns of a large number of individuals continuing their rehabilitation at home without formal supervision

following purchase of a commercial exercise technology. We tested whether three factors – impairment level, initial success, and steadiness of use – were associated with persevering at home rehabilitation exercise over an eight-week window. For each factor there was an optimal range associated with higher perseverance: mild impairment (but not too mild), high levels of success (but not perfect success), and steady, regular use, respectively. We also observed that the amount of exercise being achieved decelerated over time. This deceleration was attributable to an exponentially decreasing probability of initiating sessions, rather than a declining amount of exercise within a session. We first discuss the relevance of these findings for home rehabilitation exercise programs and then limitations and directions for future research.

4.4.1 Perseverance and Motor Impairment

Severity of motor impairment would be expected to predict perseverance because people who are weaker and less coordinated perceive exercise as more effortful and difficult [141]. Since we did not have any clinical information about the users, we identified a sensor-based measure of impairment level – repetition rate of the Reach to Target #2 exercise. This rate strongly correlated with a widely used clinical measure of upper extremity impairment (the UEFM score), as measured in a separate, clinically-monitored study (ClinicalTrials.gov Identifier: NCT03503617; Chapter 5).

There was a downward trend in probability of achieving various levels of total repetitions, minutes of use, and active days of exercise as repetition rate decreased; this trend was significant in 6 of the 9 curves considered (Figure 10). This trend is expected when the total number of repetitions is the perseverance measure (since exercising at a slower repetition rate should produce lower total number of reps), but it was also at least partially true when

total minutes of use and total days of exercise were the measures, which are behavioral decisions rather than performance related. This finding supports the concept that people who are more severely impaired have marginally greater difficulty persevering with home rehabilitation exercise.

However, this was not a strong effect, as not all curves examined had a statistically significant maximum despite the large sample size. This may be due in part to the fact that the FitMi system was designed to accommodate people with a wide range of impairment levels by including exercises with a broad range of difficulties, including exercises with simple movements and low requirements for hand dexterity.

4.4.2 Perseverance and Optimal Challenge

A striking observation about both the impairment and initial success factors was that perseverance increased steadily as capability increased, but then fell off dramatically near the highest level of capability. This finding is consistent with the idea that training should be "not so hard that we are discouraged, but not so easy that we get bored" [142].

The Challenge Point Hypothesis is influential in motor learning theory and posits that the amount of learning will be maximized when the challenge presented during practice is optimized [143],[129]. Several studies suggest, however, that the self-selected amount of practice is also maximized when the challenge is optimized. For example, rats who were given a running wheel to run on in their cage at night ran less when the wheel incorporated more resistance [144]. Reducing success at playing a video game during robotic hand rehabilitation exercise after stroke lowered motivation and self-efficacy [132]. Persons with a stroke engaging in technology-aided home rehabilitation seem to intuit this principle. In a recent study of a wearable sensing glove for practicing finger dexterity, home

users tended to select difficulty parameters so that they practiced the game at a high success rate (near 90%) [145]. To achieve this, they adjusted difficulty up and down based on their recent experience of success or failure. Success rates of ~80-90% have been found to optimize learning for a broad class of learning algorithms that are useful in describing human and animal perceptual, motor, and reinforcement learning [142]. The results of this study contribute to the principle that 80%-90% success is desirable for promoting learning-related activity in terms of practice dosage.

This notion is also consistent with Csikszentmihalyi's concept of flow—an enjoyable psychological state that occurs when individuals are engaged in optimal challenges [146]. Flow theory posits that an activity becomes intrinsically rewarding (hence, more likely to be initiated and sustained) when the individual's skillset is appropriate for the task but continues to develop, and the level of challenge is gradually increased. Our findings support what others have proposed—incorporating elements that optimize flow into design games for rehabilitative therapy could be helpful for promoting adherence and optimizing outcomes [147], [148].

4.4.3 Perseverance and Steadiness of Use:

Steadiness of use was also associated with perseverance. Users with heavily accelerating steadiness curvatures often had substantial periods of inactivity shortly after they first started using FitMi, followed then by periods of increased use. On the other hand, heavily decelerating users tended to exhibit less usage as well. They may have experienced burnout from exercising too much too quickly, becoming fatigued or sore from exerting themselves, or become bored with the system, consistent with a novelty effect. Factors unique to FitMi might have contributed to decreasing session initiation probability as well.

For example, after leveling up, users could not practice at previously experienced levels of an exercise. Thus, users eventually reached levels where they could no longer achieve high success rates. While this design choice forced users to perform exercises at higher repetition rates over time, the increasing game failure rates may have decreased session initiation probability.

We highlight the finding that it was the decreased session probability, rather than the decreased amount of exercise within a session, that was associated with reduced perseverance. That is, it was the act of "getting started again" rather than "finishing a session" that users struggled with. Indeed, the smaller and larger time constants found in the analysis of individuals' initiation decrease may reflect two processes, a brief period of higher use due to a novelty effect [138] and a lower use period with slower decay due to the individual's intrinsic motivation, an important clue for rehabilitation technology developers we discuss further below.

4.4.4 Information Contained in the Distribution of Usage

Total repetitions and exercise time were distributed log-normally. Thus, a large portion of users had low perseverance, while a small portion of users performed substantially more than their peers (recall that the top 1% of users used the system ~25 times more than the average user). It is important to notice, however, that the data were distributed smoothly, preventing clear clustering of users into low, moderate, or high performing users. Log-normal distributions arise in many branches of science, including analyses of human behavior [149] and characterizations of neurophysiological parameters [150], because they occur in samples where the mean value is low, the variance is large, and the data cannot take negative values [149], conditions met in the present study. Mechanistically, log-normal

distributions arise as the result of a multiplicative effect of small independent factors, such as repeated choices [149],[151]. For the population we studied, it may be that the multiplicative effect of the daily choices the users made on whether or not to initiate a session caused a log-normal distribution of perseverance to arise [145]. If so, another important clue for rehabilitation technology developers provided by this analysis is to consider various means to influence daily choices that users make to exercise or not.

4.5 Limitations and Future Work

There are several potential limitations of this work. The data in this study are anonymous, and we did not have access to any demographic or clinical data about users beyond their direct interactions with the system. For example, our measure of impairment was inferred from exercise rates and only partially characterized impairment. Biological, psychological, and socio-environmental measures are key predictors of health outcomes [152], as well as rehabilitation outcomes for people who have had a stroke [153]–[155]. Due to the anonymity of the data, our analysis did not include any biopsychosocial measures, and this limits our ability to compare results with other work on stroke. It is also important to note that our results are likely biased towards a specific type of person, limiting their generalizability. Namely, we studied people who: (a) could afford the technology and had internet access (which allowed the anonymous data collection); (b) had a profile of disabilities that did not inhibit them from engaging with the system (e.g. sufficient visual and cognitive capabilities); and (c) were motivated enough to seek out a technology to continue rehabilitation. As FitMi is marketed for stroke rehabilitation, we assume that most users have experienced a stroke. but, other types of users undergoing rehabilitation

were possible (e.g. people with spinal cord injury or cerebral palsy), and this may have introduced further variability. An important direction for future research is to understand the psychological, demographic, and clinical characteristics of FitMi users that also modulate perseverance [156], potentially through surveys sent to FitMi users. A small fraction of data entries for a given user may have been generated by other people with access to the device playing with the system, or by a clinical facility purchasing the home version of FitMi and using a single user ID with multiple patients. We filtered potentially anomalous users to limit their impact. Despite these limitations, we believe the present study provides a first-of-its-kind demonstration that inferences about perseverance with rehabilitation exercise can be drawn even from anonymous patterns of sensor usage. Of note, analyses drawn from anonymous usage patterns maintain privacy while also providing insights into how to optimize home rehabilitation systems.

A key principle supported by our analysis is that providers of home rehabilitation exercises should design programs that appropriately challenge the participant. High levels of success are desirable, but 100% success rates should be avoided. The company that produces FitMi has already implemented software changes based on these findings. The changes allow less successful users to increase their success, and highly successful users to increase their challenge more quickly. Another approach could be to incorporate an initial assessment of user capability into the home exercise system, and then to titrate challenge based on the assessment results.

Our findings also suggest that providers of home rehabilitation exercises should incorporate methods to sustain session initiation. Beyond factors intrinsic to the exercises

such as challenge, extrinsic factors, such as providing reminders to exercise [157], having a therapist monitor achieved amounts of exercise [158], encouraging the involvement of caregivers [159], promoting self-efficacy through actions plans or goal setting [160], or embedding the exercise program in a supportive community [161] will also likely play a critical role in making home rehabilitation effective and could be examined in future studies with FitMi.

Other important directions for future research include the following. It is feasible to conduct large-scale experiments to test factors that influence perseverance – such as challenge level or other factors – by releasing modified versions of the software to subgroups of users; indeed, as mentioned above, the company that produces FitMi has implemented a new version of the FitMi software based on the findings of this study (See Chapter 8 for an analysis of the effects of these changes), and as users accumulate, it will be possible to test whether these changes improved perseverance. It is also feasible to quantify the exact amount of exercise associated with generating a therapeutic benefit on movement capability, which would help settle an open, fundamental question in rehabilitation practice [162], [163]. Using artificial intelligence to predict dropout and to automatically send encouragements or adapt system parameters is an interesting possibility [164]. Finally, an important direction for future research is to study the "super-users" who persevered the most to try to determine what factors contributed to their extreme behavior. Perhaps by understanding the motivational characteristics of super-users, strategies could be developed to help other users better persevere in their rehabilitation.

Part I Summary

The factors that drive or inhibit uptake are context specific. Therefore, Part I aimed to study uptake in the three main stages in which stroke rehabilitation occurs: supervised care in an in-patient facility, semi-supervised care in an outpatient facility, and unsupervised care in the home.

To understand uptake in the supervised inpatient setting, three occupational therapists (OTs) and two physical therapists (PTs) wrote vignettes describing their rehabilitation use decisions during treatment sessions with nine patients. Vignettes were coded using deductive qualitative analysis from a list of 17 constructs from a systematic review of the existing literature on rehabilitation technology uptake. The therapists rarely chose to use RT and characterized candidate RT as having a relative disadvantage compared to conventional treatment in the clinic due to lack of relevance to functional training, the time required for training and setup, and poor adaptability to patient-specific attributes, such as cognitive limitations. RT was typically only used when specific devices provided a desirable function conventional treatment could not.

In contrast, RT was seen as having a relative advantage during semi-supervised use in the outpatient setting due to its ability to motivate and monitor activity in the otherwise unsupervised home setting. A Sensor Enhanced Activity Management (SEAM) system was developed to combine home exercise program (HEP) management software with a movement sensor for monitoring and motivating HEP adherence. Three therapists used the system in their regular practice during the first six months of the COVID-19 pandemic. The therapists reported that remote monitoring and the use of a physical movement sensor was

motivating to their patients and increased adherence, highlighting a perceived advantage of RT in the home setting. During this study, therapists billed for services delivered using remote physiologic monitoring (RPM) codes. Relatively few of these billing instances were reimbursed, and this might be improved by using the newly introduced remote therapeutic monitoring codes (RTM).

Finally, factors affecting use unsupervised in the home setting were investigate in a dataset of self-determined exercise patterns for a large number of individuals (N = 2,581) engaging in home rehabilitation with a sensorized gaming exercise system (SGES) without formal supervision. The SGES is comprised of two puck-like sensors and a library of 40 gamified exercises for the hands, arms, trunk, and legs that are designed for people recovering from a stroke. Appropriate challenge level and regular initiation of exercise sessions were found to maximize perseverance, while experiences of low challenge in the first week were associated with the lowest levels of overall perseverance.

In summary, Part 1 of the dissertation found that RT has a relative advantage in the home versus clinical setting if it can improve motivation. Further, a key factor of RT design – the challenge level it presents – was demonstrated to modulate perseverance.

Part II: Measuring the Effects of Unsupervised Uptake in the Home

Improving uptake of a technology is only valuable if using the technology provides benefit. In the inpatient and outpatient stages, a healthcare provider monitors a patient's status to assess if current treatment plans are effective and alter treatment plans if necessary. In this way, the healthcare provider can determine if a given technology is providing benefit for a particular patient. In the unsupervised stage at home, individuals are pursuing their pursuing their own recovery without the guidance of a healthcare professional. Therefore, it is important to determine if technologies used in this context are safe to use and effective at improving recovery. Additionally, it would be beneficial for systems to provide estimates of a user's impairment either as information for the user or to facilitate the system's use in remote treatment of a patient by a healthcare provider. The following two chapters describe the results of a study investigating the efficacy of a home rehabilitation system and an investigation into the feasibility of using interactions with that system to estimate clinical measures for users.

Chapter 5: A Clinical Study of the Effect of an SGES[4]

Summary

Upper extremity (UE) stroke rehabilitation requires patients to perform exercises at home, yet patients show limited benefit from paper-based home exercise programs. The goal of this study was to compare the effectiveness of a sensorized gamified exercise system (SGES) that incorporates recommended design features with a paper-based approach for reducing UE impairment. In this single-blind, randomized controlled trial, 27 participants in the subacute phase of stroke were assigned to the SGES (n=14) or conventional therapy group (n=13), though 2 participants in the conventional therapy group were lost to follow-up. Participants were instructed to perform self-guided movement training at home for at least three hours/week for three consecutive weeks. The SGES group used FitMi, a computer game with two puck-like sensors that encourages movement intensity and auto-progresses users through 40 exercises. The conventional group used a paper book of exercises. The primary outcome measure was the change in Upper Extremity Fugl-Meyer (UEFM) score from baseline to follow-up. Secondary measures included the Modified Ashworth Scale for spasticity (MAS) and the Visual Analog Pain (VAP) scale. The participants who used the SGES improved by an average of 8.0 ± 4.6 points on the UEFM scale compared to 3.0 ± 6.1 points for the conventional participants, a significant difference (t-test, $p = 0.029$). SGES participants exhibited no significant changes in UE MAS or VAP

[4] This chapter is a slightly modified version of the paper titled "Optimized Home Rehabilitation Technology Reduces Upper Extremity Impairment Compared to a Conventional Home Exercise Program: A Randomized, Controlled, Single-Blind Trial in Subacute Stroke" published in Neurorehabilitation and Neural Repair in 2023 (Swanson et al., 2023).

scores. This shows that an SGES incorporating a suite of recommended design features significantly and safely reduced UE impairment compared to a paper-based, home exercise program.

5.1 Introduction

Stroke is a leading cause of chronic disability in the United States.[2], [6], [7] Intensive upper extremity (UE) rehabilitation can reduce long-term impairment after stroke[12]–[16], [165] and is more effective when delivered in the subacute phase following stroke.[166] Though exact dose-response relationships are unknown, recovery also appears to depend on the volume of movement practice. [18]–[22] One-on-one supervised therapy sessions are likely insufficient to achieve the required dose.[23], [24] Home exercise programs are prescribed to increase movement training dose, but the current standard of care—following printed sheets of exercises—is associated with poor compliance, poorer outcomes, and high dropout rates.[27], [35]–[39]

Recognizing the need for sustainably increasing the amount of movement practice that individuals undertake, there has been a surge in the development of technologies for enabling individuals to practice on their own at home.[36], [167]–[175] Home-based technologies for stroke rehabilitation include sensors, games, telerehabilitation, robotic devices, virtual reality, apps, and tablets.[51] As technologies have been developed and tested, a set of recommended design features has emerged (Table 11). However, the net effect of optimizing home rehabilitation technology by implementing these features is still unclear.

Table 11: Summary of recommended design features for home rehabilitation technology. FitMi was designed to incorporate most of these features, except for the four that are highlighted, which can be grouped into two categories: ensuring that high-quality movements are practiced and facilitating collaboration with a therapist or caregiver. We generated this table based on a systematic review of recommendations [62], but also incorporated suggestions from other studies of home rehabilitation technology that were not included in that review, as indicated by the referencing.

Domain	**Recommendation**
Hardware Design	System is small, lightweight, easy to store, portable [51], [62], [176]–[179]
	Hardware is adjustable for different body sizes and different grip types or movements [62]
	Sensors are reliable and validated sensor accuracy [51], [62], [176], [177]
	System can be interfaced with the user's existing TV, computer, or mobile device [180]
	System is robust and not easily damaged [178], [179]
	Hardware promotes quality movements and helps prevent compensatory motions [178], [180]
Software Interface Design	Software is easy to navigate, with clear and simple operating instructions [62], [176], [180]
	Software provides a tutorial or introduction to use [62]
	Software contains clear text displayed in a large font size [176]
Operation	System requires simple installation, setup, shut down, and charging procedures [51], [62], [178]
	System is simple enough to be used with minimal external support [62], [178], [179], [181]
Therapeutic Activity Design	Activities are physically challenging but also achievable [62], [178], [180], [182]
	Activities incorporate games or gamification to enhance motivation [51]
	Activities are tailored to personal goals, needs, and interests [51], [183]
	System includes a variety of activities that accommodate different ability levels [51], [62], [178], [180]
	Difficulty and duration adapt as user improves, both over time and in the moment [51], [181]
	Movements practiced relate to functional movements or activities of daily living (ADL) [62], [180]

Performance Feedback	Feedback is multi-modal (e.g. numerical, graphical, and auditory) [62], [180], [181]
	Feedback on performance is provided during the activity [176], [180]
	Summary feedback is presented immediately after the activity is complete [62], [176], [178], [180]
	A history of the user's performance over time is available [51], [62], [176], [180]
	System enables goal tracking [176]
	System encourages periods of rest when applicable [178]
	System provides positive feedback with a partial reinforcement schedule [178]
	A healthcare professional can monitor the user remotely and provide feedback [62], [180], [181]
Support	Technical support is available, especially at start of use [51]
	Support is offered using multiple communication methods (e.g. text, voice, and video) [180]
	Support is available in different languages [180]
	System enables healthcare providers to communicate with user [180]
Safety	An emergency stop button and/or warning messages are provided when appropriate [62]
	Hardware design avoids sharp edges, possible finger traps, and protects the users' skin [62]
Cost	System is relatively low cost [178], [179], [182]
User's Social Context	System is attractive and acceptable to the user and their family members [51]
	System does not create additional burden on family members or caregivers [178]
	System can be used cooperatively with a family member or friend [180]

FitMi (Figure 15) is a commercial home rehabilitation technology designed to put into practice many of these features (see Table 11). This randomized controlled trial aimed

to evaluate the effectiveness of FitMi in reducing UE impairment compared to conventional paper-based home exercises in the subacute phase following a stroke. We hypothesized that the participants in the FitMi group would improve their Upper Extremity Fugl-Meyer (UEFM) score significantly more than the conventional therapy group, as assessed at the follow-up assessment.

Figure 15: FitMi (produced by Flint Rehab, LLC) consists of two force and motion sensing pucks and a companion 'mixed-reality gym' software application. Top row: FitMi hardware. Bottom row: FitMi software. Note, FitMi can be used with an individual's existing computing hardware (Top Right) or with a custom 10" touchscreen tablet in a kiosk mode that only requires users to turn the tablet on and touch an icon to access the application (Top Left).

5.2 Methods

5.2.1 Device Design

The FitMi hardware consists of two wireless input devices (called pucks), a USB receiver, a docking station for one-handed charging, and a silicone strap for users who have difficulty grasping the pucks (see Figure 15). Each puck contains an accelerometer, gyroscope, magnetometer, load cell, onboard LED, and vibration motor. The top half of the puck is coupled to the bottom half through the load cell, allowing the device to detect either pressing forces or grip forces. Data from each puck's sensor array is wirelessly transmitted to the USB receiver, which can be plugged into any computer and used without configuring the devices. Using this data and custom software algorithms, FitMi detects the completion of forty different exercises for the hands, arms, trunk, and legs that were designed with the input of experienced stroke therapists (Supplemental Text 1). For each exercise, the FitMi software presents users with a repetition goal for a bout of exercise, progress towards that goal, and real-time feedback each time a repetition is completed. Before exercising, users are shown written instructions and images of the starting and ending position for each repetition of the given exercise. They can also watch a video of an experienced therapist demonstrating the exercise and providing tips to prevent compensatory movement patterns. Once users begin an exercise, the screen indicates the exercise position they need to move towards (Figure 15), and the system provides a game-like environment with music that encourages movement intensity. Users are provided with audio, visual, and haptic feedback as they repetitively move between the starting and ending positions for each exercise. The height of an exercise intensity bar indicates their exercise rate, and if the rate

slows too much, the bar hits a "bomb," and the exercise session ends. After an exercise is completed, the software displays the user's performance history over time, both within an exercise session and across days of use. To optimize the system's challenge level, the software progressively unlocks new exercises and adapts the goal number of repetitions for each exercise based on the user's past performance. At any time, users can access an interactive tutorial on how to use the software. The FitMi software can run on a personal computer or a custom 10" touchscreen tablet in a kiosk mode (i.e. the tablet runs no other software besides the FitMi software).

5.2.2 Trial Design

This study was a single-site, single-blind randomized controlled trial comparing home-based therapy with FitMi to conventional therapy for individuals in the subacute phase of stroke. The study was performed at Rancho Los Amigos National Rehabilitation Center in Downey, CA. Participants were invited for an initial assessment to confirm they met the inclusion criteria and to establish baseline measures. Participants provided informed written consent. Qualifying participants were randomly assigned to either the FitMi group or the conventional group. Participants in both groups were instructed to perform self-guided therapy for at least three hours/week for three consecutive weeks. All participants received weekly phone calls from a supervising therapist. After the three-week exercise period, participants returned for an end-of-therapy assessment and to return study materials. Participants returned one month later for a follow-up assessment. The trial was pre-registered on ClinicalTrials.gov (NCT03503617) and approved by the Rancho

Research Institute, Inc. Institutional Review Board at Rancho Los Amigos National Rehabilitation Center (IRB #263).

5.2.3 Participants

Inclusion criteria were: experienced one or more strokes between 2 weeks and 4 months prior; baseline UEFM Score >5 and ≤55 out of 66; absence of moderate to severe pain defined as a score of 4 or lower on the 10-point visual-analog pain scale; ability to understand the instructions to operate FitMi; and aged 18 to 85 years old, to limit potential confounds due to naturally diminished physical mobility and cognitive function associated with older age.[184] Exclusion criteria were: concurrent severe medical problems that precluded the individual from participating in routine rehabilitation; visual deficits defined as a score >1 on question 3 of the NIH Stroke Scale (NIHSS); severe cognitive deficits or apraxia defined as a score >0 on questions 1a and 1c of the NIHSS; severe neglect defined as a score >1 on question 11 of the NIHSS; severe aphasia defined as a score >1 on question 9 of the NIHSS; and enrollment in other therapy studies. Recruitment aimed to balance the age, ethnicity, and gender of the study participants to be representative of Los Angeles County in California, USA. All participants provided informed consent.

Using an estimated Cohen's d[185] effect size of 1.05 based on long-term follow-up data from a previous arm training study during subacute stroke,[186] power analysis established that 21 participants in each group would provide a 90% chance of detecting a significant difference between FitMi and conventional therapy at the 0.05 significance level (two-tailed t-test). To account for 20% dropout, the target sample size was n = 25 participants in each group.

Adaptive randomization was used to ensure matched levels of impairment between the FitMi and conventional therapy groups. Specifically, subjects were stratified by their UEFM Score into three levels (i.e. 5-22, 23-39, 40-55) and then randomized by alternating block allocation.[187]

5.2.4 Intervention

Participants randomized to the FitMi group were given a FitMi system with a custom 10" touchscreen tablet. They received 30 minutes of training on how to set up and use the FitMi system. They were instructed to spend most of their time performing upper extremity exercises, but access to the trunk and leg exercises in the FitMi software was not disabled. Participants randomized to the conventional therapy group were given a booklet of paper exercises that were selected from the same library of 40 exercises available in the FitMi software. The booklet was placed in a sensorized folder which included an accelerometer to detect movement events and a magnetometer and magnet on opposite sleeves to detect when the folder was opened or closed. These events were recorded to a memory card by an embedded microcontroller.

For both groups, a supervising rehabilitation therapist selected the exercises for each participant based on their specific impairments. All participants received 30 minutes of training from the therapist on how to perform the selected exercises correctly. After the 3-week exercise period, participants returned for an end-of-therapy assessment. At this assessment, participants returned the FitMi system or the sensorized booklet of exercises for data collection. Participants returned one month later for a follow-up assessment.

5.2.5 Outcomes

The primary outcome measure was the change in Upper Extremity Fugl-Meyer (UEFM) score[188] from baseline assessment to follow-up. UEFM was assessed at baseline, end-of-therapy, and follow-up. Secondary measures included the Box and Blocks Test,[189] the 10 Meter Walk Test,[190] the Modified Ashworth Spasticity (MAS) scale[191] for the elbow, wrist, and fingers, and the Visual Analog Pain (VAP) scale for the upper extremity, all of which were assessed at baseline, end-of-therapy, and follow-up. Motor Activity Log (MAL) was measured at end-of-therapy and follow-up to assess self-reported quantity and quality of movement.[192] The European Quality of Life five dimensions, three levels (EQ-5D-3L) and its companion Visual Analog Scale (EQ-VAS) were measured at end-of-therapy and at follow-up to assess overall perceived health state,[193], [194] and the Intrinsic Motivation Inventory (IMI)[110] categories of Interest/Enjoyment, Value/Usefulness, and Effort/Importance were measured at end-of-therapy to assess participants' perceived motivation. These measures are widely used in stroke rehabilitation research and have good sensitivity and reliability. All assessments were performed by a blinded, trained evaluator.

To assess adherence, the FitMi software recorded the date, time, and number of repetitions completed for each exercise, and the sensorized folder used in the conventional therapy measured the times at which the participants opened the booklet.

5.2.6 Statistical Methods

Statistical analyses were performed using Matlab R2020 software. For measures taken at baseline and follow-up, the change from baseline to follow-up was calculated. Then the changes were compared between groups using an unpaired two-tailed t-test. This was the analysis specified for the primary outcome in the statistical analysis protocol established before the project started. For the UEFM, we also assessed within-group changes between timepoints using paired t-tests. We corrected for multiple comparisons for secondary outcomes using a Holm-Bonferroni correction. Cohen's d, using pooled standard deviation, was used to assess the effect size of the difference in changes between groups. As a post-hoc, supplemental analysis, mixed model ANOVAs were used to analyze outcomes taken at all three time points, using the mixed procedure in SPSS 28.0, to further account for variance over time. If a significant time and group interaction was found, pairwise comparisons were then used to find differences within or between groups at any time point by using Sidak adjustments to correct for multiple comparisons.

MAS scores were grouped by flexion or extension items and summed to obtain lumped MAS extension and flexion values. We quantified items marked with a '+,' with an additional 0.5 points for calculations. EQ-5D-L3 was analyzed following.[193], [194] Responses to questions in IMI categories were averaged within the category for each participant and compared across groups using Wilcoxon rank sum tests.

Several participants dropped out of the study (see Figure 16). Subjects who did not return for an end-of-therapy assessment were not considered for analysis. Missing data

was imputed to keep the same number of participants across timepoints for analysis using the MissForest random forest imputation algorithm.[195]

To assess the ability of FitMi to motivate an appropriately high dose of home therapy, we performed a post-hoc exploratory analysis comparing the total number of repetitions that FitMi participants completed to a theoretical target dose of 2,700 repetitions. A dose of 2,700 repetitions of UE exercise corresponds to 300 repetitions/hour (5 reps/minute) over 9 hours of exercise, an intensity and duration sufficient to provoke a forelimb rehabilitative effect in a rodent model of stroke.[25]

5.2.7 Interim Analysis

Due to the unexpected additional risks to participating in this study due to the COVID-19 pandemic, an unplanned interim futility/efficacy analysis of the primary outcome measure was conducted after recruitment was halted in March 2020. Group labels were removed, and the analysis was reviewed by an independent investigator. For the futility analysis, a conditional power of 20% was selected. For the efficacy analysis, a P-value of 0.033 was selected using the Lan-DeMets alpha spending function for the Pocock boundary (n=27 out of a planned 50 at interim analysis).[196]

5.3 Results

5.3.1 Recruitment and Participant Flow

Participants were recruited from November 20, 2018, until March 12, 2020, when the study was halted due to the COVID-19 pandemic. In the interim analysis, a significant difference in the primary outcome measure was observed between groups (two-tailed t-

test, $p<0.033$). Thus, recruitment was halted early based on detected efficacy at 27 out of a planned 50 participants.

Participant enrollment and allocation details are shown following CONSORT guidelines in Figure 16. Out of 300 individuals screened for eligibility, twenty-seven were randomized (

Table 12). Two participants from the conventional therapy group did not complete the end-of-therapy or follow-up assessment due to a second stroke for one and COVID-19 restrictions for the other. An additional conventional therapy participant could not return for the follow-up due to COVID-19 restrictions.

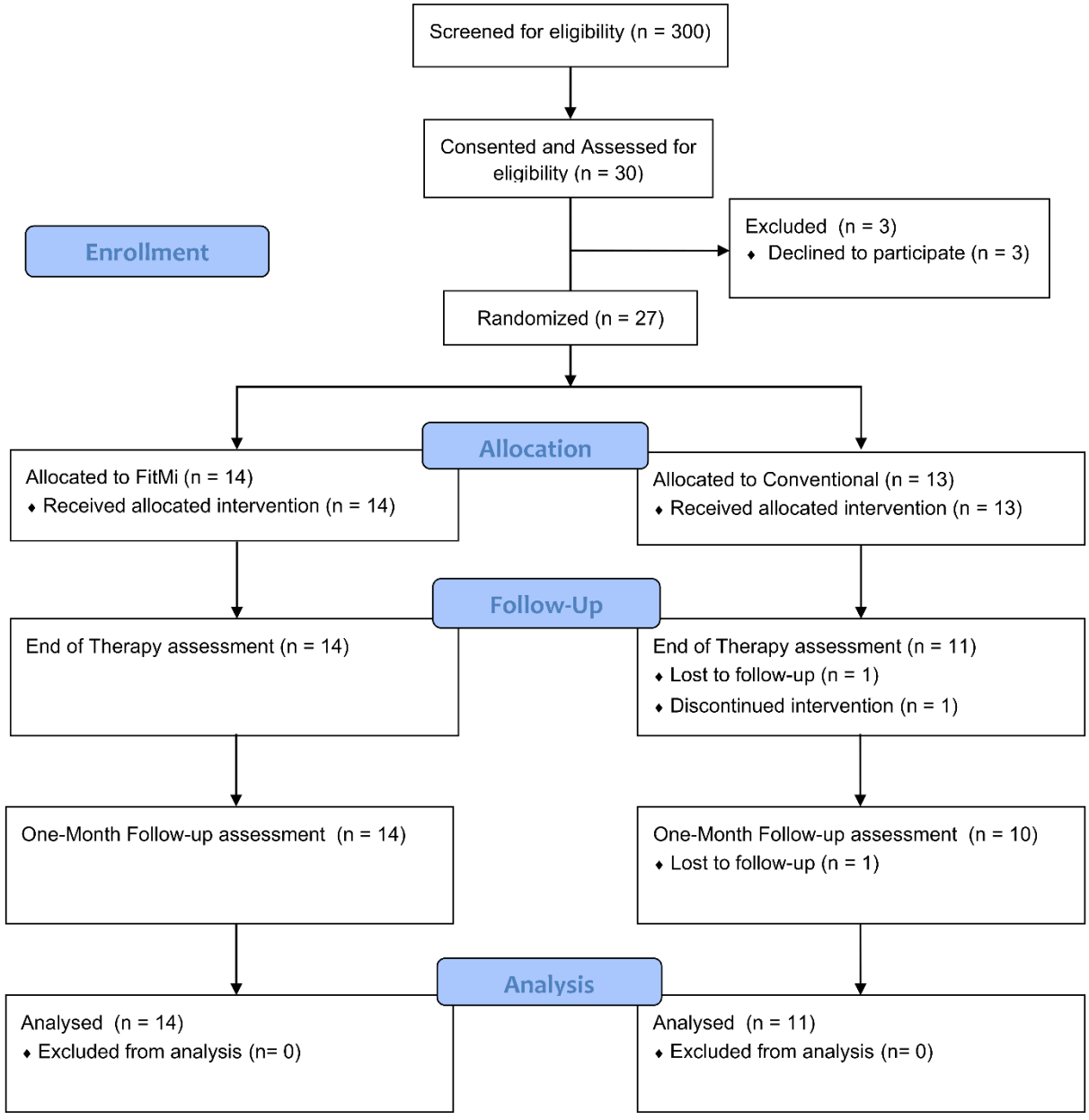

Figure 16: Participant flow diagram. Subjects who did not return for an end-of-therapy assessment were not considered for analysis. Missing data was imputed as described in the statistical methods to maintain group sizes across all analyses.

Table 12: Demographics of recruited participants at baseline aggregated by group. Where applicable, values are reported as Mean ± SD, [minimum, maximum]. Weeks Post Stroke indicates the number of weeks between the participant's stroke and the date of their baseline evaluation. ***H – Hispanic/Latino, N – Not Hispanic/Latino. **I – Ischemic, H – Hemorrhagic, B – Both Ischemic and Hemorrhagic.***

	Control	**FitMi**
Number of Participants	13	14
Age (years)	52 ± 8.7	50.3 ± 10.9
Sex (M/F)	9/4	14/0
Ethnicity (H/N)	10 H, 3 N	8 H, 6 N
Stroke Type (I, H, B)*	9 I, 3 H, 1 B	11 I, 3 H
Impaired Side (L/R)	8 L, 5 R	10 L, 4 R
Number Dominant Side Impaired	5	4
Weeks Post Stroke	10.1 ± 5.1, [4.6, 17.6]	9.7 ± 4.5, [4.3, 17.9]

5.3.2 Efficacy

All measures recorded at baseline, end-of-therapy, and follow-up assessments are reported in Table 13. All measures not recorded at baseline but recorded at end-of-therapy and follow-up are reported at the bottom of Table 13. UEFM scores at baseline ranged from 12 to 53 for the FitMi group and 9 to 50 for the conventional therapy group, indicating enrollment across a broad range of motor impairments (Supplemental Figure 1). There was no significant difference in the UEFM score, or any other outcomes, between groups at baseline ($p>0.3$).

For the primary outcome measure, the average change in UEFM from baseline to follow-up for participants in the FitMi group ($n=14$) was 8.0 ± 4.6 compared to an average change of 3.0 ± 6.1 for participants in the conventional therapy group ($n=11$), a significant difference with a large effect size ($p=0.029$, $d=0.925$; Table 13). A significant within-group increase in UEFM score was found for the FitMi group when comparing baseline to end-of-therapy and follow-up ($p<0.001$ for both intervals), but not for the conventional therapy group at either assessment (Figure 17).

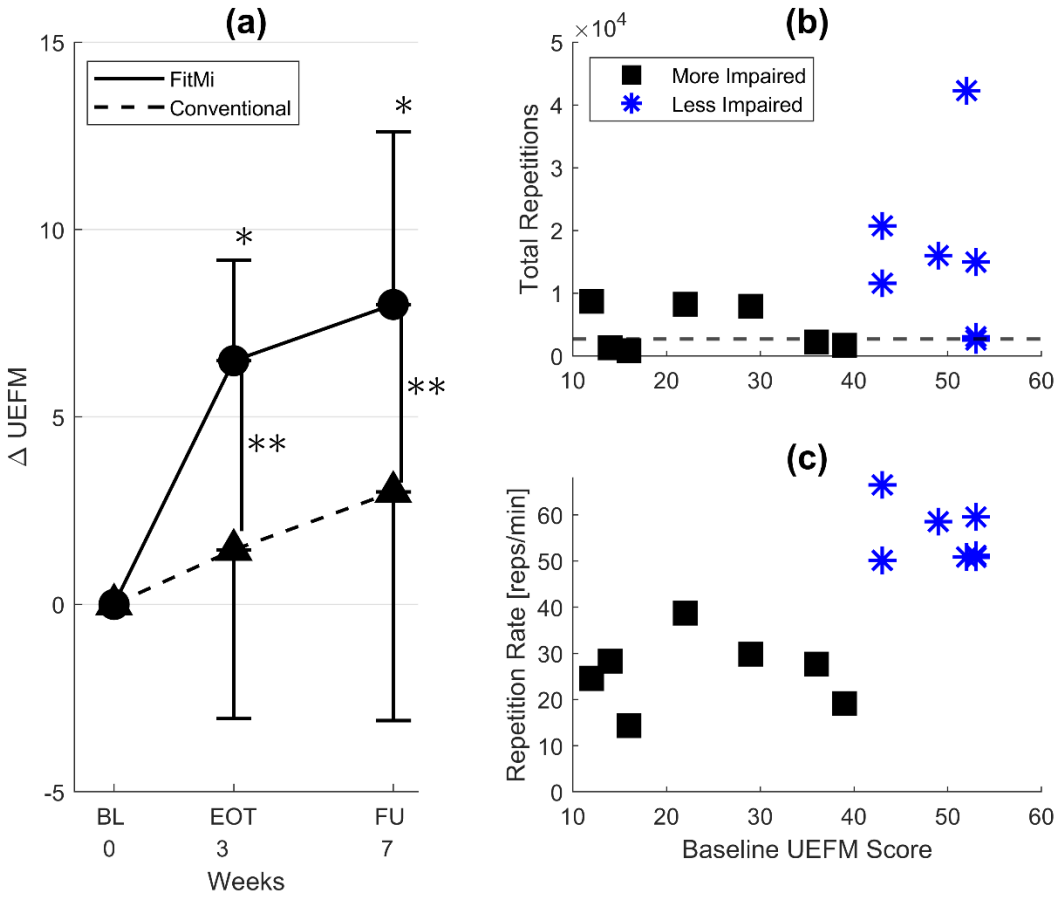

*Figure 17: a) Average change in Upper Extremity Fugl-Meyer score for FitMi group and conventional therapy group at each assessment. The error bars represent 1 SD. (BL = Baseline) FitMi participants improved significantly more than the conventional therapy group. *Indicates a significant within-group difference between UEFM scores at each time point compared to baseline ($p<0.01$). **Indicates a significant difference between the change in UEFM between groups at each time point ($p<0.033$). b) FitMi participants' total number of repetitions plotted as a function of their baseline UEFM score. The horizontal dashed line indicates a theoretical target dose of 2,700 repetitions. Note, there are two overlapping participants at baseline UEFM score 53, one who exceeded the threshold and one who did not. B) FitMi participants' average repetition rate, in repetitions per minute, plotted as a function of their baseline UEFM score. 3b and 3b are discussed in section 3.3 of the text.*

The two groups' scores did not change significantly differently for any of the secondary outcomes.

*Table 13: Results for outcome measures for FitMi and Conventional therapy groups. For measures with a baseline assessment, the change from baseline to follow-up was calculated. For each measure, the change was compared between groups using unpaired, two-tailed t-tests. T-tests for secondary outcomes were corrected for multiple comparisons using a Holm-Bonferroni correction. The difference between groups was quantified using Cohen's d effect size. The absolute value of the effect size is shown here. *Indicates a significant difference using the corrected α-value for that assessment.*

	BL	EOT	FU	Δ from BL to FU	p-value Between-group Comparisons of Δ	Effect Size
UEFM						
FitMi Therapy	36.7 ± 15.4	43.2 ± 16.3	44.7 ± 16.2	8.0 ± 4.6	*0.029	0.925
Conventional Therapy	35.18± 14.5	36.64 ± 14.8	38.18 ± 16.2	3.0 ± 6.1		
Box and Blocks						
FitMi Therapy	25.4 ± 17.6	28.9 ± 17.6	30.2 ± 19.7	4.8 ± 6.3	0.701	0.156
Conventional Therapy	23.5 ± 14.8	24.5 ± 15.8	27.2 ± 16.1	3.7 ± 7.2		
10 Meter Walk Test (m/s)						
FitMi Therapy	0.98 ± 0.37	1.02 ± 0.40	1.06 ± 0.41	0.08±0.020	0.857	0.071
Conventional Therapy	0.86 ± 0.28	0.87 ± 0.40	0.92± 0.48	0.06 ± 0.33		
MAS (Extension)						
FitMi Therapy	0.57 ± 0.87	0.50 ± 0.71	0.46 ± 0.69	-0.11 ± 0.59	0.944	0.029
Conventional Therapy	0.55 ± 1.04	0.18 ± 0.40	0.45 ± 0.82	-0.09 ± 0.54		
MAS (Flexion)						
FitMi Therapy	2.8 ± 1.9	2.4 ± 2.2	2.5 ± 2.0	-0.29 ± 1.59	0.828	0.091
Conventional Therapy	2.4 ± 2.1	1.6 ± 1.5	2.0 ± 2.2	-0.41 ± 1.10		
VAP						
FitMi Therapy	1.3 ± 1.7	2.1 ± 2.4	2.6 ± 2.1	1.4 ±2.3	0.176	0.555

Conventional Therapy	1.5 ± 1.5	4.0± 3.4	4.3 ± 2.8	2.8 ± 2.9		
		EOT	**FU**			
MAL (AS)						
FitMi Therapy		2.81 ± 0.74	3.11 ± 1.14			
Conventional Therapy		2.52 ± 1.74	2.41 ± 1.82			
MAL (HW)						
FitMi Therapy		2.78 ± 1.01	3.01 ± 1.26			
Conventional Therapy		2.22 ± 1.58	2.26 ± 1.71			
EQ-5D-3L						
FitMi Therapy		0.77 ± 0.10	0.74 ± 0.06			
Conventional Therapy		0.84 ± 0.09	0.82 ± 0.11			
EQ-VAS						
FitMi Therapy		63.93 ± 17.24	74.2 ± 15.6			
Conventional Therapy		71.36 ± 14.16	70.27 ± 10.90			

Mixed model ANOVA analysis for UFEM scores found a significant time effect ($F(1.771,40.725) = 21.119$, $p < 0.001$, $\eta p2 = 0.479$), and a significant time*group interaction ($F(1.771,40.725) = 5.506$, $p = 0.010$, $\eta p2 = 0.193$), but not a significant group effect. Pairwise comparisons show the FitMi group's UEFM scores increased significantly between baseline and end-of-therapy ($p<0.001$), and between baseline and follow-up ($p<0.001$) but did not significantly change between end-of-therapy and follow-up. Significant time effects were found for the Box and Blocks assessment ($F(1.718,39.511) = 7.376$, $p < 0.002$, $\eta p2 = 0.243$) and the VAP ($F(2,46) = 9.175$, $p < 0.001$, $\eta p2 = 0.285$), but neither of these assessments showed significant time*group interactions or group effects. No significant

effects were found for the 10m walk test, MAS Extension, or MAS Flexion. Sphericity was violated for the UEFM and Box and Blocks scores, so the Huynh-Feldt corrected results are reported for these assessments.

5.3.3 Safety and Motivation

No significant harms related to the study were reported or observed over the course of the study. For participants in the FitMi therapy group, no significant change was found between baseline and end-of-therapy for MAS or VAP scores (paired t-test $p>0.05$). No significant difference was found between the FitMi therapy and conventional therapy participants in their responses to IMI questions related to Interest/Enjoyment (FitMi 5.1 ± 1.1, Conventional 5.4 ± 1.1), Value/Usefulness (FitMi 6.5 ± 0.7, Conventional 6.3 ± 0.6), and Effort/Importance (FitMi 6.4 ± 1.5, Conventional 6.7 ± 0.6). All items are rated on a scale from 0 to 7.

Participants interacted with the FitMi software for a median of 47% of the 21 days of the intervention period (range = 23% to 100%). FitMi participants interacted with the system for 5.4 ± 4.1 hours. Only two participants completed or exceeded the recommended 9 hours of interaction time. Due to technical issues with battery life, only 4 out of 13 sensorized folders provided to participants in the conventional therapy group were returned with recoverable data. These four participants interacted with their folders for 41%, 73%, 45%, and 100% of the 21 days of the intervention.

Of the 14 participants in the FitMi group, 9 out of 14 (64%) completed the theoretical target dose of at least 2,700 repetitions (as defined in the Methods) over three weeks of exercise, with 7 participants completing more than 3 times this amount (Figure

17b). Across the four exercise categories available in the FitMi software (hand, arm, trunk, and leg exercises), the participants completed 4,051 ± 4,986 [130, 18,617], 2,744 ± 3,076 [186, 11,262], 1,550 ± 1,439 [176, 5,469], 1,813 ± 2,029 [0, 6,908] repetitions, respectively (reported as mean ± standard deviation [minimum, maximum]).

We tested whether less impaired participants achieved more repetitions with FitMi. To do this, we ranked participants by baseline UEFM score and then split them into evenly sized groups (n=7) thus creating lower and higher UEFM groups defined by a UEFM cutoff of 40. Comparing total repetitions between groups (4,427 ± 3,648 [832, 8694] vs 15,890 ± 13,412 [2565 42256], respectively) revealed a significantly greater amount of exercise in the higher UEFM group (unpaired t-test, $p=0.0497$). In terms of exercise rate, the lower UEFM group exercised more slowly (26 ± 8 reps/minute) than the higher UEFM group (55 ± 6 reps/minute) (unpaired t-test, $p<0.001$) (Figure 17c). The change in UEFM score from baseline to end-of-therapy was moderately correlated with the total number of arm and hand repetitions each participant achieved ($p=0.005$, $r^2=0.52$, Supplemental Figure 2); the correlation was not significant at follow-up ($p=0.11$, $r^2=0.22$, Supplemental Figure 3). The participant with the highest number of repetitions was omitted as an outlier for these correlation analyses.

Comparison to Unsupervised Users

The FitMi group's system use was recorded similarly to the unsupervised use reported in Chapter **4**. This provides an opportunity for a comparison of the perseverance metrics between these groups. Using Wilcoxon rank-sum tests, the distributions of activity were

found to be significantly different (Figure 18). For all three metrics, the medians of the FitMi group from this RCT were higher than the medians from the unsupervised users (Reps: Unsupervised = 1,036, RCT = 8,093; Time: Unsupervised = 28, RCT = 187 minutes; Days: Unsupervised = 3, RCT = 7).

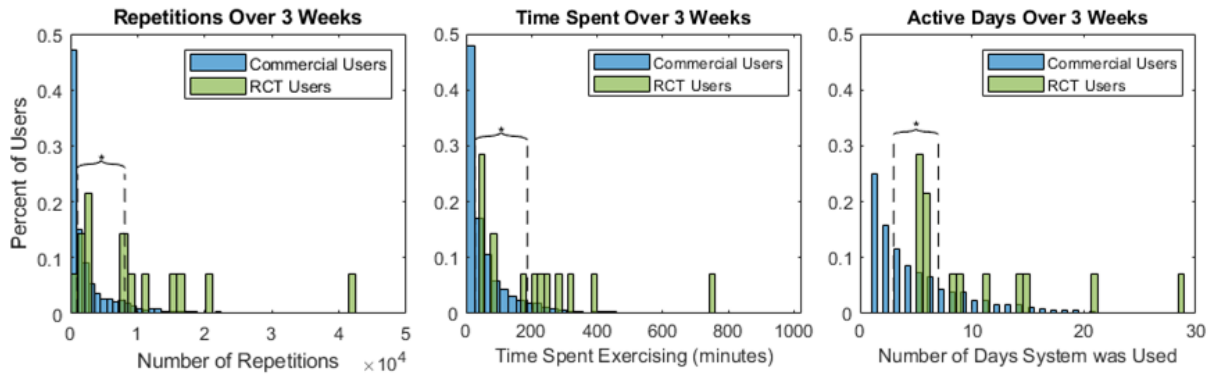

Figure 18: Histogram of the percentage of users achieving varying levels of engagement in the categories of repetitions, time, and days.

Given that the system used by both of these groups were the same, the increase in use by the FitMi group from this RCT may be due to the added presence of a healthcare provider. Connection to a healthcare professional was noted as an important home RT design feature in Table 11, and it is not embedded in the FitMi system. There are limitations to this comparison though, as the unsupervised data is anonymous. So the data may not be matched by impairment level, age, diagnosis or other biopsychosocial measures.

5.4 Discussion

We compared the effectiveness of a sensorized exercise system, FitMi, with a conventional exercise program specified using a paper booklet for at-home movement

training in subacute stroke. Participants who exercised with FitMi improved significantly more on the primary outcome, the change in the UEFM scale from baseline to follow-up, compared to the participants in the conventional therapy group without increasing UE spasticity or pain. We first discuss the significance of these results, followed by limitations and directions for future research.

5.4.1 Toward optimizing home rehabilitation technology

As reviewed in Table 1, FitMi was designed in a way consistent with previous research that recommended desirable features for home rehabilitation technology. The current study provides evidence that these features, when bundled together, make home movement training more effective at reducing UE impairment compared to the conventional, paper-based prescription of exercise in subacute stroke. Although the core mechanisms remain unclear, we speculate that this result relates to two causes. We hypothesize that the FitMi participants achieved more movement repetitions than the conventional therapy group because FitMi participants likely exercised at a higher intensity. Specifically, the FitMi technology encouraged rapid repetition of exercise and adaptively progressed the goal number of repetitions for each exercise based on each user's past performance—something that paper exercises cannot do. Indeed, the average exercise rates were quite high compared to what might be expected with paper-based exercise, being 26 reps/minute for the lower UEFM group and 55 reps/minute for the higher UEFM group. Interestingly, the IMI scores did not indicate that subjective self-report of motivation was significantly higher for the FitMi group. This may be because both groups had high motivation to achieve recovery at this early stage regardless of

intervention type. Future studies could focus on understanding the motivation to recover versus the motivation to exercise at a high intensity.

An important question is whether the system was usable by more severely impaired individuals, as there are fewer options available for such persons for continuing movement practice. The lower half of participants with more severe impairments (UEFM < 40) still achieved on average 4,427 repetitions, an amount that exceeded the theoretical target dose of 2,700 repetitions. Notably, most participants were able to exceed the 2,700-repetition target in a shorter amount of time than was prescribed, because they achieved an average rate of exercise of 41 ± 17 reps/minutes, which was greater than the 5 reps/minute we estimated a priori. This indicates that FitMi was accessible and motivating for individuals with a range of impairment levels, which is a key requirement for optimizing home rehabilitation technology as it allows a single solution to be used across a broad population.

As shown in Table 11, FitMi does not currently incorporate design features to 1) ensure that only high-quality movements can be practiced, or 2) facilitate collaboration with a therapist or caregiver. A key reason these features were previously recommended was to ensure that patients do not practice unsafe or compensatory movement patterns during unsupervised at-home therapy. However, in the present study, we found no significant increase in spasticity or pain in the FitMi group. Further, the observed reduction in UE impairment in the FitMi group cannot be explained by the learning of compensatory movements, since compensatory movements are discounted in the UEFM scoring process. Thus, foregoing these features in FitMi's design did not appear to reduce safety or

encourage abnormal movement execution in the present study. Nonetheless, incorporating these features into FitMi's design might improve future results.

While home training with FitMi led to a significantly greater reduction in UE impairment than paper-based exercise, an important question is whether the amount of improvement was clinically significant. The Minimal Clinically Important Difference (MCID) for the UEFM has been reported to be 4 points for subacute patients,[197] although another study with younger patients (average age 52) closer to the mean age of the participants in our study estimated it to be 9 points in the first few weeks (4-24 weeks) after stroke.[198] The MCID was reported to be ~5 points in the chronic stage of stroke for older patients.[199] Six out of 14 (43%) of participants in the FitMi group achieved a 9-point change in UEFM (with two additional participants achieving 8-point changes) compared to two out of 10 (20%) of participants in the conventional therapy group (with none achieving 8-point changes). Thus, exercise with FitMi appears to have a clinically meaningful impact for more individuals than paper-based exercise.

5.4.2 Limitations and Future Directions

No female participants were recruited into the FitMi therapy group, which limits the generalizability of the reported results. A smaller percentage of FitMi participants were impaired on their dominant side than in the conventional group (29% vs 38%). Alternating allocation has been shown to be prone to selection bias[200] and does not allow for naïve allocation. The randomization procedure used was peer-reviewed and approved before the study began, and analysis of group characteristics at baseline did not reveal any statistically significant differences between group characteristics. However,

future protocols could be improved by using different randomization methods. While the FitMi and conventional therapy group's clinical assessment scores were matched at baseline, we did not evaluate possible differences in their potential for recovery using biomarkers such as motor-evoked potentials.[201], [202] Recruitment was also stopped early due to the COVID-19 pandemic, reducing statistical power. Several participants who were recruited dropped out of the study (most due to COVID-19 restrictions, and all from the conventional therapy group) and required multiple imputation for analysis. Finally, while the number of days participants in the FitMi group exercised had a similar distribution to the 4 participants in the conventional therapy group for whom we collected data from their sensorized folders, we did not quantify the number of exercise repetitions participants in the conventional therapy group achieved. This limits our ability to determine if the observed benefits of FitMi are simply due to a higher number of movements performed or a specific benefit of the FitMi device.

Future research could study how exercise technologies such as FitMi can best be integrated into routine clinical practice. Providing stroke survivors with FitMi in any waiting period between the end of their inpatient treatment and the start of their outpatient treatment, or after they have used all the outpatient therapy visits allotted by their health insurance, could improve outcomes. We recently studied the use of the FitMi sensors in conjunction with an activity-management app to assist in home rehabilitation.[158] Therapists reported that remote monitoring and the use of a physical movement sensor were motivating to their patients and increased adherence. We also recently studied the long-term, self-determined exercise patterns of a large number of individuals (N = 2,581) who engaged in home rehabilitation with FitMi. We found that an

optimized challenge level and regular initiation of exercise sessions predicted the achievement of a greater amount of overall rehabilitation exercise.[203] Going forward, the fine-grained data collection facilitated by an accessible, commercially available, sensorized home exercise system such as FitMi opens interesting avenues of analysis to investigate the effects of the amount and type of exercise on rehabilitation outcomes in the real world.

Chapter 6: Methods to Estimate Outcomes for Unsupervised Use of an SGES[5]

Summary

It would be valuable if home-based rehabilitation training technologies could automatically assess arm impairment after stroke. Here, we tested whether a simple measure – the repetition rate (or "rep rate") when performing specific exercises as measured with simple sensors – can be used to estimate Upper Extremity Fugl-Meyer (UEFM) score. In a first experiment, 41 individuals with arm impairment after stroke performed 12 sensor-guided exercises under therapist supervision using a commercial sensor system comprised of two pucks that use force and motion sensing to measure the start and end of each exercise repetition. Using linear regression, UEFM score was well estimated using the rep rate of one forward-reaching exercise from the set of 12 exercises ($r^2 = 0.75$); this exercise required participants to alternately tap pucks spaced about 20 cm apart (one proximal, one distal) on a table in front of them. UEFM score was even better predicted using an exponential model and forward-reaching rep rate (Leave One Out Cross Validation (LOOCV), $r^2 = 0.83$). We also tested the ability of a nonlinear, multivariate model (a regression tree) to predict UEFM, but such a model did not improve prediction (LOOCV $r^2 = 0.72$). However, the optimal decision tree also used the forward-reaching task along with a pinch grip task to subdivide more and less impaired patients in a way consistent with clinical intuition. A subset of participants used the system at home for three weeks. Rep

[5] This chapter is a slightly modified version of the paper titled "Exercise Repetition Rate Measured with Simple Sensors at Home can be used to Estimate Upper Extremity Fugl-Meyer Score after Stroke" published in Frontiers in Rehabilitation Sciences in 2023 (Swanson et al., 2023).

rate for the forward-reaching exercise performed at home again well predicted UEFM score using an exponential model (LOOCV, $r^2 = 0.69$), but only after we re-estimated coefficients using the home data. These results show how a simple measure – exercise rep rate measured with simple sensors – can be used to infer an arm impairment score and suggest that prediction models should be tuned separately for the clinic and home environments.

6.1 Introduction

Recovery from stroke is a long process requiring extended periods of neurologic rehabilitation, which includes cycles of assessment, prescribed interventions, evaluation, and adjustment of interventions [10], [65]. The assessment stage is crucial to determine a patient's treatment plan and to evaluate the effectiveness of that plan after its execution. There are a variety of standardized assessments for stroke rehabilitation in practice and research [204], [205] that span the domains of impairments, functional limitations, and barriers to participation a stroke survivor might face.

Any assessment used must have appropriate psychometric properties [205]–[207], including validity, reliability, and responsiveness. A particularly important goal is that the assessment works well when evaluators change, i.e. assessments should have good inter-rater reliability [208]. Common motor impairment assessments with good psychometric properties used in stroke rehabilitation for the upper extremity include the Upper Extremity Fugl-Meyer (UEFM) Test, the Box and Block (BB) test, the Action Research Arm Test, the Nine Hole Peg Test, and the Wolf Motor Function Test [206].

A growing goal in rehabilitation research and development is to automate clinical assessments to reduce the burden on clinicians' time [209], eliminate the potential influence of evaluator subjectivity, improve the quality and access to effective remote care [210], [211] and support self-directed continuation of rehabilitation at home [10].

Home rehabilitation has multiple goals including reducing inpatient stays through early supported discharge, continuing rehabilitation at home to replace institutional rehabilitation, and providing home exercise programs to help patients maintain or augment the gains made under supervision of a health care professional [28]. Studies on home rehabilitation have shown comparable outcomes for patients pursuing rehabilitation at home and patients in institutional care. In some cases, early supported discharge promoted community reintegration and reduced costs of care more than institutionalized patients [212]. For people living at home continuing their care, a systematic review found significant effects in favor of home-based rehabilitation on functional independence measures, and some studies found cost benefits and increased caregiver satisfaction for individuals receiving home-based rehabilitation [213].

Exercise is important for improving functional capacity, performance of activities of daily living, and quality of life for post-stroke individuals [214] and may reduce the risk of stroke recurrence [215]. Achieving the American Heart Association's recommendations of performing aerobic exercises 3 to 7 days per week and strengthening, flexibility, and neuromuscular exercise 2 to 3 days a week is difficult to achieve in institutionalized care and could be better realized through home exercise programs. However, maintaining motivation to adhere to home exercise programs is difficult for many stroke survivors [28],

with rates of apathy in stroke survivors above 30% [127] and evidence that apathy has a strong effect on limiting participation in meaningful activity [128]. Successfully administering assessments in the home environment could support patient motivation by tracking recovery progression and could be used by healthcare providers to adjust aspects of treatment plans, such as the specific tasks being used, without or in between in-person encounters. The assessments previously mentioned are performance measures, in which a patient performs specific motions or activities, and the assessment is designed to analyze the body function or evaluate the execution of the activity [204], [208]. These assessments are therefore prime candidates for automation, as a patient could perform the assessment activity independently, a sensorized system could record data during performance of the activity, and an algorithm could generate a score for the activities similar to the score that a trained clinical evaluator would give the patient as part of the assessment. This is preferable to creating new assessments designed specifically for technical automation due to the aforementioned psychometric requirements, which involves an extensive process of design and clinical validation [208]. This work focuses on the Upper Extremity Fugl-Meyer (UEFM) [216] because it is a widely used measure in stroke rehabilitation research showing both high reliability and validity [217]. The assessment was developed to consider classically defined patterns of stroke recovery where motor function first returns in proximal muscles before distal muscles, and flexor synergistic movements return before extensor synergies in the arms [217]–[219].

Previous efforts to objectively measure and automate the UEFM (see Table 14) have used Image Processing Systems such as the Microsoft Kinect [220], Inertial Measurement Units

(IMUs) [221], and mechanical systems such as flex sensors, or a combination of these technologies [222]. However, image-based systems can suffer from variability due to environmental lighting and visual clutter. IMUs and mechanical systems are frequently used in wearable configurations, often requiring precise placement of multiple sensing units, which is difficult to do independently for patients with impairments. Two strategies commonly employed are to instrument the assessment, whereby patients perform the assessment or a subset of the assessment's items and data is recorded during the performance, or estimate an assessment score from data taken during representative motions or functional tasks [208]. Calculating a total, continuous value rather than estimating individual line items of an assessment could provide an advantage over conventional calculation methods which frequently rely on ordinal measures, which are less sensitive to smaller changes and potentially less precise than a continuous-valued output [223]. Using these methods, prediction strength has ranged from r^2 of 0.21 to 0.97 (see Table 14).

Table 14: A short survey of the various methods used by previous efforts to estimate or predict Fugl-Meyer assessment scores using sensors. Abbreviations following [208], IMU – Inertial Measurement Units, EEG – Electroencephalogram, MMS – Mechanical Systems, IMS – Image Processing Systems, OMS – Optoelectronic Systems. N in the table is the number of participants in each study.

Reference	Sensors	N	Task	Evaluation Features	Prediction/Estimation Strength
[224]	4 IMUs and EMG	34	Voluntary Upward Reaching	Max Shoulder Joint Angle, Peak and Average Arm Speed, Torso Balance Muscle Synergy	All Features were significant ($p < 0.001$, $r^2 > 0.34$
[225]	4 IMUs	37	Finger-To-Nose	movement time (MT), mean velocity (VM), peak velocity (VP), percentage of time to peak velocity (TVP%), number of movement units (NMU), and normalized integrated jerk (NIJ)	VP,VM,NMU ($p < 0.05$, $r^2 > 0.42$)
[209]	IMS	10	26 UEFM items	Joint Angle, Segment Rotation, Landmark Position	$r^2 = 0.985$
[221]	6 IMUs	24	Selected tasks from WFMT	20 speed, smoothness and coordination features	$r^2 > 0.44$
[226]	OMS	34	Reaching Task	ROM, Movement Smoothness, Trunk displacement, Trunk forward inclination	All Features were significant except Shoulder ROM ($p < 0.001$, $r^2 > 0.21$)
[227]	9 IMU	26	isolated shoulder flexion, pointing, reach-to-grasp a glass, and key insertion	joint ranges of shoulder abduction/adduction, shoulder flexion/extension, and elbow flexion/extension; trunk displacement; shoulder–elbow correlation coefficient; median slope; and curve efficiency	$r^2 > 0.24$
[228]	MMS	82	4 shoulder-elbow tasks, 3 wrist and forearm tasks	24 kinematic metrics for the shoulder-elbow, 35 metrics for wrist and forearm	$r^2 = 0.67$ ($p < 0.001$) for the linear model and $r^2 = 0.77$ ($p < 0.001$) for the nonlinear model

Using the rate of task performance to estimate impairment is not unique. For example, it is the strategy used by the Box and Blocks assessment. However, it is a strategy not often explored in attempts to sensorize and automate clinical assessments. This strategy potentially allows for a simple sensor array to be used, since it need only count reps, and a small number of test items (i.e. the task(s) whose rep rate is assessed). These are desirable features for an assessment procedure intended for patients to autonomously execute in the home.

The goal of this work was to determine how well we could estimate the UEFM score for individuals who have experienced a stroke based on their exercise rep rate as they interacted with a sensorized home-rehabilitation system. We used the rep rates of tasks completed with the system, rather than raw sensor data, which is a method that could be easily implemented with other systems. The data we used included data from a recently published randomized controlled trial (RCT) of the sensor system [229].

6.2 Methods

FitMi Overview

The FitMi system (Flint Rehab, LLC) consists of two wireless pucks that each contain an accelerometer, gyroscope, magnetometer, load cell, light emitting diode (LED), and a vibration motor (Figure 19). Custom software, run on a personal computer or tablet, presents a set of exercises for users to complete (Supplemental Text 1). A total of 40 exercises are available in the system, with 10 each designed for the legs, core, arms, and

hands. During the exercises, a universal serial bus (USB) receiver collects sensor data from the pucks and the software shows how to move the pucks or move between each puck to start and finish a repetition of the activity, reacting to the changing position or state of the pucks indicated by the sensors. For each exercise, users are presented a target number of repetitions and a limited amount of time to complete them. A small amount of time is added for each repetition completed, encouraging users to perform repetitions at a desired rate. As users complete the target number of repetitions presented, the challenge of the experience is increased by increasing the target number of repetitions and making more difficult exercises available.

Figure 19: FitMi (produced by Flint Rehab, LLC) consists of two force and motion sensing pucks and a companion software application. Left: FitMi hardware. Right: An example of the FitMi software interface during an exercise. Note, FitMi can be used with a custom 10" touchscreen tablet in a kiosk mode (shown) or with an individual's existing computing hardware using a Bluetooth receiver.

Experiment Description

An RCT comparing home-based therapy with FitMi to conventional therapy for individuals in the subacute phase of stroke was performed at Rancho Los Amigos National

Rehabilitation Center in Downey, CA from November of 2018 to March of 2020 (ClinicalTrials.gov #NCT03503617) [229]. Prior to the RCT, participants were invited for a separate in-clinic experiment to screen candidates for inclusion in the RCT and to collect data from a broad range of participants to facilitate general exploratory data analysis. As such, the in-clinic experiment participants represented individuals in the chronic phase and sub-acute phase of stroke recovery, while the RCT that followed contained only sub-acute participants who met the following inclusion criteria: aged 18 to 85 who experienced one or more strokes between 2 weeks and 4 months prior with a baseline Upper Extremity Fugl-Meyer (UEFM) Score >5 and ≤55 out of 66. For individuals who continued on to participate in the RCT following the in-clinic experiment, the in-clinic experiment served as their baseline assessment.

Individuals who participated in the in-clinic experiment were first guided through a set of 12 exercises (A4: Reach to Target #2, A6: Wrist Supination, A7: Bicep Curls, C4: Twists, C7: Oblique Crunch, C8: Standard Crunch, H3: Gripping, H5: Key Pinch Grip, H10: Object Flipping, L1: Stomps, L5 Marching, L9: Ankle Rotation; See Supplemental Text 1) in the FitMi system by a rehabilitation therapist. A single therapist conducted the in-clinic assessment for each participant. For each exercise, the therapist ensured a standard placement of the pucks across all participants according to the instructions presented in the system. The therapist also instructed participants how to perform the exercise correctly. They then verified that the participant could perform the exercise without undesired compensation patterns (i.e., any movement patterns that could risk injury or maladaptive plasticity if performed several times in succession). If a participant was unable

to complete an exercise or unable to perform the exercise without compensation, the therapist recorded that the participant performed zero repetitions of that exercise and moved on to the next exercise. Otherwise, the therapist instructed them to complete as many repetitions of the exercise as they could in 45 seconds and recorded the number of repetitions performed. Participants were given up to 2 minutes to rest between exercises.

Of the 41 participants of the in-clinic experiment, 27 participants, who met the inclusion criteria and agreed to participate, received therapy as part of the RCT. In the RCT, they were randomized into a FitMi group or a Conventional Therapy group using adaptive randomization to ensure matched levels of impairment between the groups. To accomplish this, subjects were classified by their UEFM Score into 3 levels (i.e., 5-22, 23-39, 40-55) and then randomized by alternating block allocation [187]. Participants in both groups were instructed to perform self-guided therapy at home for at least three hours/week for three consecutive weeks. The FitMi group performed their therapy using the FitMi system, and the Conventional Therapy group used a paper booklet of exercises. During the at-home phase of the study, exercise instructions and recommended puck placements were provided for each exercise in written instructions and in a video that participants could view before the exercise. However, beyond these instructions, standardization of the puck placement was left to the participant. Participants' activity in the FitMi system was recorded, including the date and time an exercise was performed, the type of exercise, the number of repetitions completed, the amount of time spent performing the exercise, and the difficulty level at which the exercise was performed. At the start of the trial, the three easiest exercises from each body region were available at the lowest difficulty level. After

three weeks, each participant returned for an end-of-therapy assessment, and then again after one month for a follow-up assessment. The Conventional Therapy Group's data (n=13) from the end-of-therapy and follow-up assessments are not used in the present study as they did not use the FitMi system during the home-therapy they performed during the RCT.

Therapists performed a battery of clinical assessments during the in-clinic experiment including the Upper Extremity Fugl-Meyer (UEFM) [188], Box and Blocks Test [189], the 10 Meter Walk Test [190], the Modified Ashworth Spasticity (MAS) scale [191] for the elbow, wrist, and fingers, the Visual Analog Pain (VAP) scale [230] for the upper extremity, Trunk Impairment Scale [231], Shoulder Subluxation, and Mini Mental Status [232]. Several measures were taken during the end-of-therapy and follow-up assessments of the subsequent RCT. From the end-of-therapy and follow-up assessments, only the UEFM scores of the FitMi group taken during their end-of-therapy assessment are used in this study.

Statistical Analysis

In the introductory session, all participants performed each exercise for 45 seconds, if they were able to perform the exercise. We converted the number of repetitions completed to the rate at which repetitions were completed. For analysis, the MAS was split between the different categories measured (elbow extension, elbow flexion, wrist extension, wrist flexion, finger extension, and finger flexion), and items scored with a '+' were transformed

to a numerical quantity by adding 0.5 to facilitate analysis. Unless otherwise mentioned, all analyses were performed in Matlab 2020b.

Clinic Data Analysis

As an exploratory analysis, linear regression was used to model the relationship between each exercise performed and each assessment taken during the in-clinic experiment (n=41). Several nonlinear functions were fit to the rate and outcome data for the pair which presented the strongest relationship from the previous step. The goodness of the fit for each candidate function was evaluated by comparing the resulting root mean squared error (RMSE), r-squared, and appropriateness of the function for the data as determined by the study team. Finally, the best fitting model was validated using a leave one out cross validation (LOOCV) procedure.

Home Data Analysis

The subset of participants who were randomized to the FitMi treatment group of the RCT (n=14) took the system home for 3 weeks to use without supervision. To test the suitability of the selected model for estimating clinical scores using exercise data from participants' home-activity, exercise data from these participants were used to estimate their clinical scores using the strongest model identified by the curve fitting process described above. The model was then refit to the home exercise data and participants' UEFM scores from the end-of-therapy assessment of the RCT to improve performance and validated following

LOOCV. Due to one participant not performing the "A4: Reach to Target 2" exercise at home, analyses for home data were performed without this participant (n=13).

Decision Tree

To incorporate multiple exercises into a single explanatory, nonlinear model, regression trees were fit to the data taken during the in-clinic experiment (n=41) using the Decision Tree Regressor from Scikit Learn in Python. As the data set is smaller than typical for machine learning applications, and the goal of this model was explanatory rather than predictive, the entire data set was used for training models, and models were evaluated using metrics from the training data. Decision tree models can be prone to overfitting, where the generated model might describe noise of the training set more than any underlying generalizable phenomena present. To prevent overfitting, multiple models were fit with varying maximum allowable depths and minimum samples per leaf (i.e., prediction node), where increasing the depth and reducing the minimum samples per leaf results in models with increasing accuracy but also increasing potential for overfitting. Models were compared by the research team considering the complexity of the resulting model, the depth and leaf design criteria, the RMSE, and the r^2. The results of this process are shown in Supplemental Figure 1. The final selected model was validated following LOOCV.

6.3 Results

Participants

Participants were recruited from November 20, 2018 to March 12, 2020. 41 individuals participated in the in-clinic experiment, and 27 of the participants from the in-clinic experiment moved on to the clinical trial, during which 14 participants were randomized to the FitMi group (Figure 20). Participants' clinical characteristics are shown in Table 15.

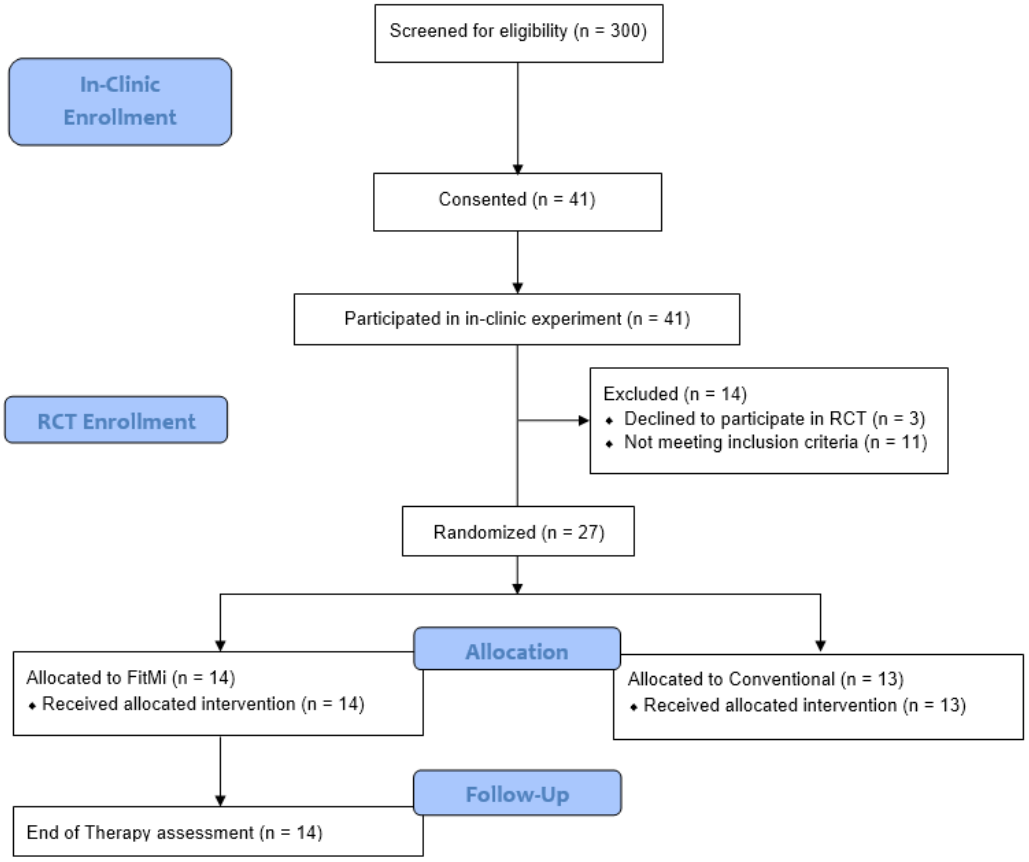

Figure 20: Participant flow diagram detailing screening, allocation, and assessments for individuals in the in-clinic experiment and the RCT. Follow-up data for individuals allocated to the conventional therapy group of the RCT was not used in this study.

*Table 15: Demographics of recruited participants at the time of the in-clinic experiment. All participants are included in the "Clinic Data" column, and only the subset of participants who continued on to the FitMi group are included in the "Subset of Participants with Home Data" column. All participants were right hand dominant. Values are reported as Mean ± SD, [minimum, maximum]. Weeks Post Stroke indicates the number of weeks between the participant's stroke and the date of their evaluation. *I – Ischemic, H – Hemorrhagic, B – Both Ischemic and Hemorrhagic.*

	Clinic Data	Subset of Participants with Home Data
Number of Participants	41	14
Age (years)	52.3 ± 10.1	50.3 ± 10.9
Sex (M/F)	3/8	14/0
Stroke Type (I, H, B)*	30 I, 10 H, 1 B	11 I, 3 H
Impaired Side (L/R)	27 L, 14 R	10 L, 4 R
Weeks Post Stroke	66 ± 114, [4.3, 456.7]	9.7 ± 4.5, [4.3, 17.9]
Mini Mental Status	29.56±0.71, [27, 30]	29.36±0.63, [28, 30]
Shoulder Subluxation	0.14±0.34, [0, 1]	0.14±0.36, [0, 1]
UEFM	33.4± 15.4, [9, 58]	36.7± 15.4, [12, 53]
Trunk Impairment	17.61±2.68, [13, 23]	18.36±2.27, [15, 23]
10 Meter Walk	0.87±0.32, [0.21, 1.50]	0.98±0.37, [0.23, 1.50]
VAP	1.17±1.61, [0, 5]	1.17±1.64, [0, 4]
MAS Extension		
Elbow	0.52±0.71, [0, 2.0]	0.54±0.74, [0, 2]
Wrist	0.10±0.30, [0, 1]	0.08±0.28, [0, 1]

Fingers	0.02±0.16, [0, 1]	0±0, [0, 0]
MAS Flexion		
Elbow	0.96±0.85, [0, 3]	1.04±0.60, [0, 2]
Wrist	1.02±0.82, [0, 3]	0.96±0.83, [0, 2]
Fingers	0.90±0.90, [0, 3]	0.88±0.79, [0, 2]
Box and Blocks	19.1±17.2, [0, 50]	25.4±17.6, [0, 50]

Heatmap

Figure 21 shows the results of the regression analyses exploring the relationship between each exercise performed and each outcome measured. Only regressions with an F-statistic p value ≤ 0.05 are shown, and regressions with a p value below the Bonferroni adjusted alpha value ($\alpha = 0.00032$) are indicated with an asterisk. The UEFM and Box and Blocks Test scores were strongly correlated with the rep rates from three of the exercises.

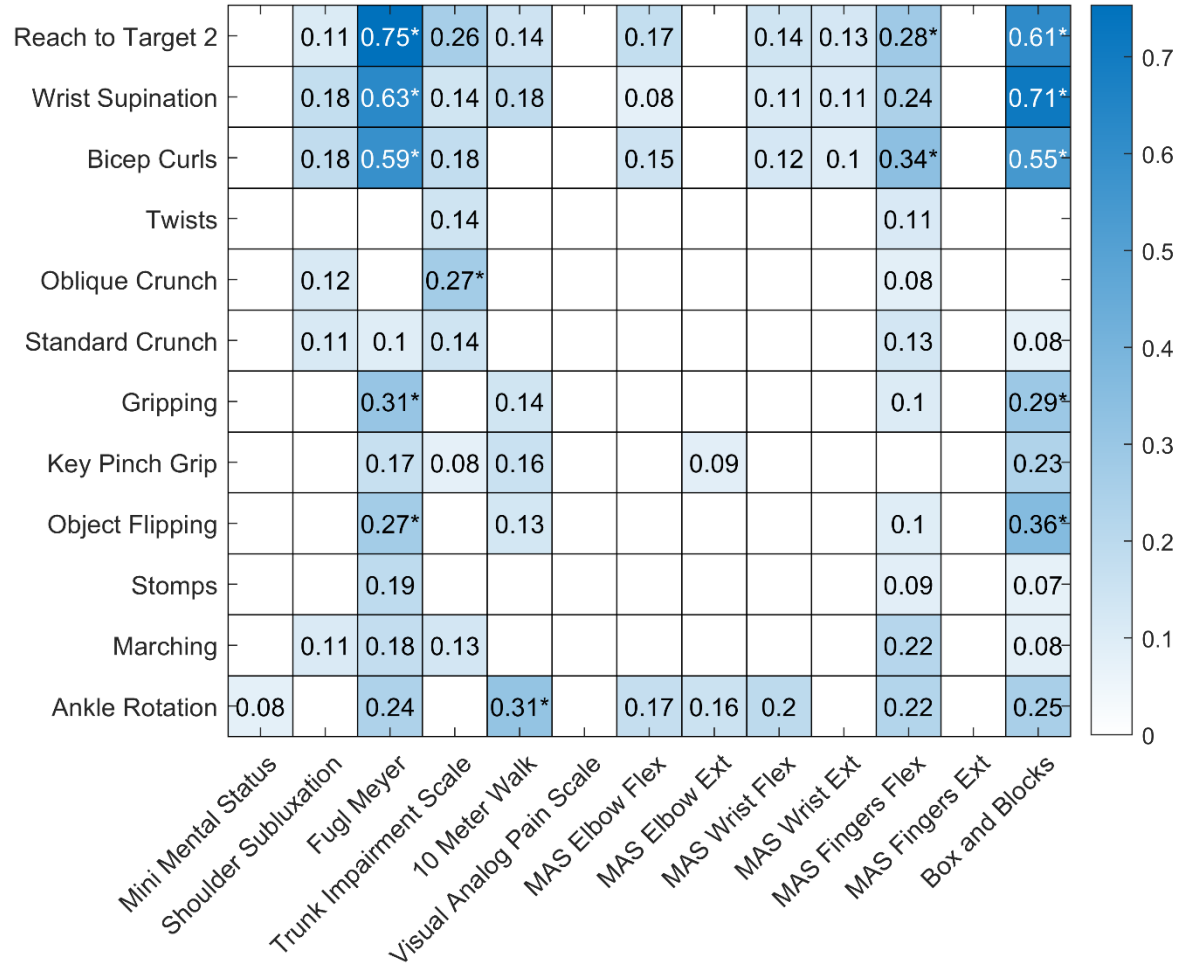

Figure 21: Heatmap showing the results of the regression analyses for each exercise and outcome pair. Regressions with an F-statistic p value > 0.05 are shown with a white box. r2 values for regressions with an F-statistic p value ≤ 0.05 are shown in blue, with darker colors indicating stronger relationships. Regressions with a p value below the Bonferroni adjusted alpha value (0.00032) are indicated with an asterisk.

Curve Fitting

The strongest correlation was present for the regression analysis between "A4: Reach to Target 2" and the Upper Extremity Fugl-Meyer (UEFM) assessment (adjusted $r^2 = 0.75$, p value < 0.001). To better model this relationship, we fit a second order polynomial, a power function, a logarithmic function, and an exponential function to the data (Figure 22).

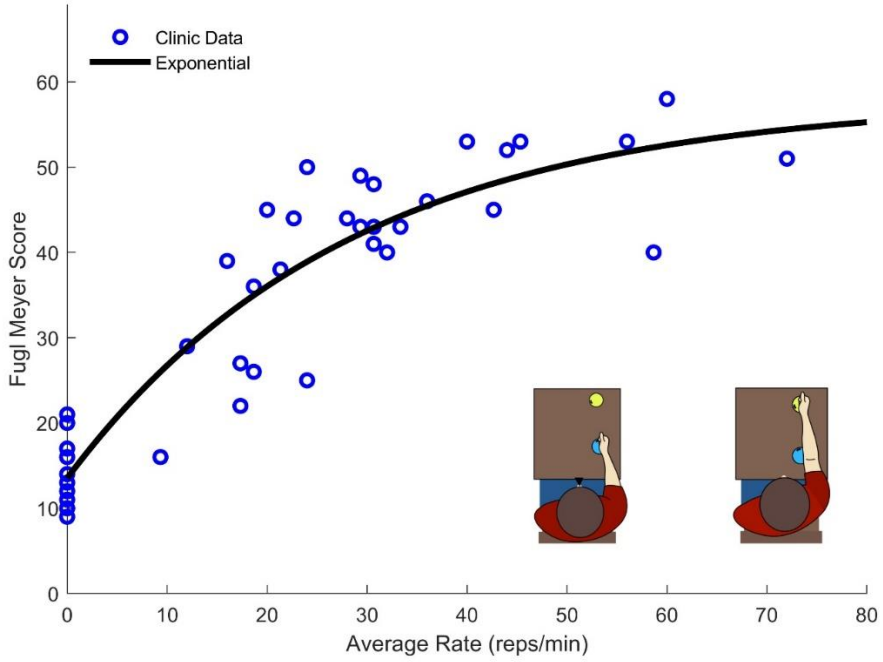

Figure 22: Exercise rate and UEFM data taken from 41 participants performing the "A4: Reach to Target #2". The exponential function provided the best fit while providing an asymptotic structure which well describes the maximum score of the UEFM.

Though the polynomial function produced better fit statistics (r^2 = 0.86, RMSE = 5.92), the exponential fit (r^2 = 0.85, RMSE = 6.00) was selected for its asymptotic structure, which is consistent with the fact that the UEFM score has a maximum. The final LOOCV resulted in an exponential model with r^2 = 0.83, RMSE = 6.22.

Home Data

To validate the model for use in the home setting, the exponential model shown in Figure 22 was used to estimate participant's UEFM scores using the exercise rate data from participants' first performance of the "A4: Reach to Target #2" exercise at home. Though participants' rates in their first home performance were correlated with their rates

performed in the clinic (r = 0.62), the resulting fit was lower quality than for the data collected in the clinic (Clinic Model with Clinic Data: r^2 = 0.85, RMSE = 6.00; Clinic Model with First Home Data: r^2 = 0.24, RMSE = 12.81). In their first at-home performance, more severely impaired participants tended to speed up and less severely impaired participants tended to slow down relative to their in-clinic performance (Figure 23a, d). This change in exercise rate was correlated with participants' initial UEFM scores (r2 = 0.38). While data from participants' last performance of the "A4: Reach to Target #2" at home exercise did not fit the clinic-based model well, they appeared to follow a more consistent pattern than the data from participants' first performance (Figure 23b). The final home performance and end-of-therapy UEFM data resulted in improved fit statistics compared to the first home performance paired with in-clinic UEFM scores, but results were still lower quality than for the data generated in the clinic (Clinic Model with Clinic Data: r^2 = 0.85, RMSE = 6.00; Clinic Model with Final Home Data: r^2 = 0.50, RMSE = 11.17). Fitting a model of the same structure to the final performance of "A4: Reach to Target #2" at home and the UEFM scores taken at end-of-therapy resulted in a model with scores closer to the clinic-generated model (Final Home Model with Final Home Data: r^2 = 0.80, RMSE = 8.09). Performing LOOCV on this final model produced a model with r^2 = 0.69, RSME = 8.70.

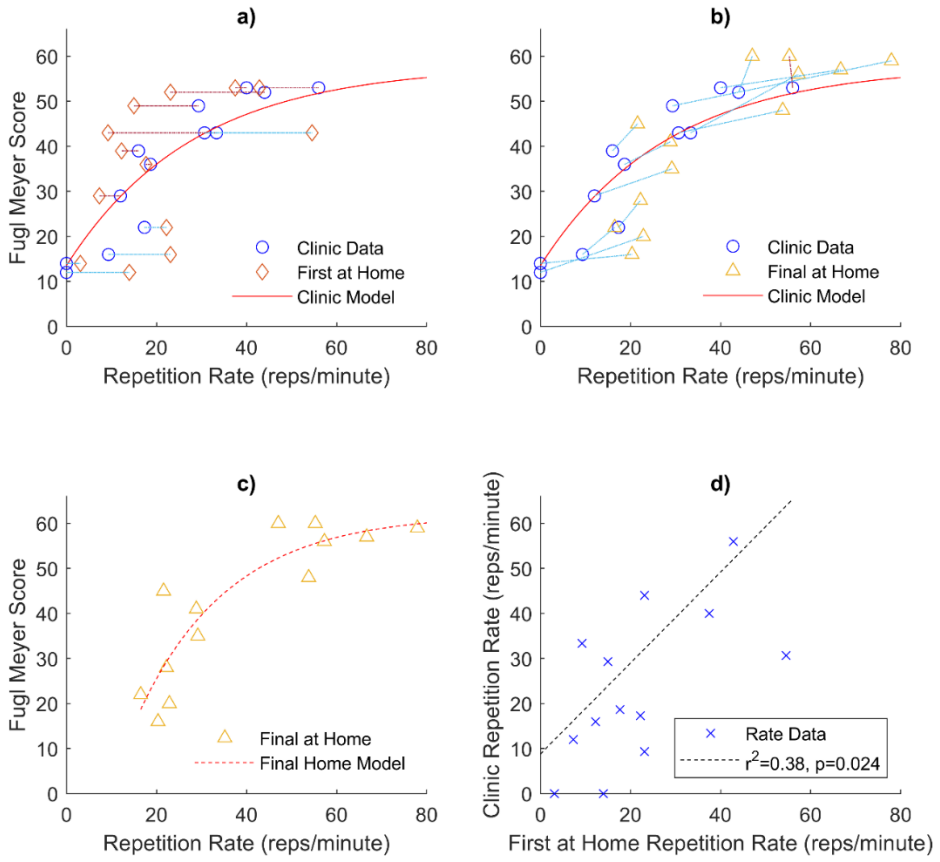

Figure 23: ***(A)*** *Data from participants' first performance at home of the "A4: Reach to Target #2" exercise plotted against their clinic exercise data and the model generated from the clinic data.* ***(B)*** *Data from participants' last performance at home of the "A4: Reach to Target #2" exercise and their UEFM score taken at the end-of-therapy assessment plotted against their clinic exercise data and the model generated from the clinic data. In both figures* ***(A)*** *and* ***(B)****, triangles are used to indicate exercises performed at home, circles are used to indicate exercises performed in the clinic, and dashed lines are used to connect each participant's clinic data and their respective home data. Red lines indicate that the participant's exercise rate slowed compared to their clinic performance, and blue lines indicate that the participant's exercise rate increased compared to their clinic performance.* ***(C)*** *A model with the same functional form as the model developed with the clinic data was fit using only the data from participants' last performance at home of the "A4: Reach to Target #2" exercise and their UEFM scores taken at the end-of-therapy assessment.* ***(D)*** *Comparison of participants' first performance at home of the "A4: Reach to Target #2" exercise plotted against their clinic exercise data evaluated using a linear regression.*

Decision Tree

From the iterative model generating process (Supplemental Figure 2), the decision tree with maximum allowable depth equal to 2 and minimum samples per leaf equal to 6 was chosen, Figure 24. This model presented improved training fit statistics (r^2 = 0.89, RMSE =

4.82) over the previous exponential model made with a single activity performed in the clinic (r^2 = 0.85, RMSE = 6.00). This data-driven process created a model using two of the 12 exercises: "A4: Reach to Target #2" and "H5: Key Pinch Grip". Patients below a certain performance threshold in the reaching task were sorted to the lower range of the scale, and then again sorted to a high impairment (14 points) or medium impairment (30 points) category by a lower threshold on the same task. Patients exceeding the initial performance threshold for the reaching task, were then evaluated by their ability in a gripping task using their hand, being further sorted to a mild (43 points) or very mild impairment (53 points) category.

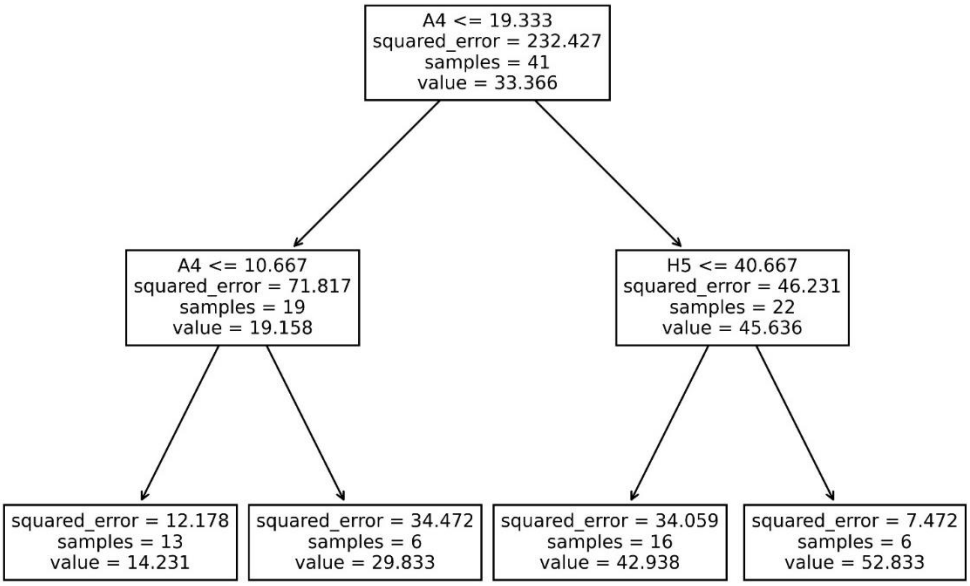

Figure 24: Decision tree generated using participants' rate of activities performed in the clinic as input features to estimate their Fugl-Meyer scores. For each splitting node, if a participant's rate for the specified task (A4: "Reach to Target #2 or H5: "Key Pinch Grip") was less than or equal to the threshold rate shown, participants were sorted to the left branch, otherwise, they were sorted to the right branch.

6.4 Discussion

In this work, rates of specific exercise activities, captured by a sensorized home stroke rehabilitation system, were used to estimate UEFM scores. The exercises that provided the most utility ("A4: Reach to Target #2" and "H5: Key Pinch Grip") could theoretically be measured with simple push buttons. Thus, this approach could be replicated with a simple low-cost system that would not require participants to precisely don and doff multiple sensors.

The data here were gathered using a commercially available system that has a demonstrated record of usage across thousands of users [203]. This history of usage data suggests that users are able to independently understand and operate the system, which could facilitate automated execution of assessment activities using these models.

The validated models presented here (i.e. the exponential model made with clinic data (r^2 = 0.83 RMSE = 6.22), the exponential model made with home data (Final Home Model with Final Home Data: r^2 = 0.69 RMSE = 8.70), and the decision tree made with clinic data (r^2 = 0.72, RMSE = 7.99)) provide comparable performance to more complicated approaches (Table 14). Additionally, this work presents a model using data from individuals practicing unsupervised in the home whereas most previous uses data taken in a clinical setting.

Insights from the Decision Tree Modeling Approach

Out of the 12 exercises performed in the clinic, the exercise with the more predictive power was "A4: Reach to Target #2". This feature appeared most strongly in the exploratory linear

regression heatmap and in the decision tree modeling process. The presented decision tree model uses this reaching task and "H5: Key Pinch Grip" to predict UEFM, which mirrors clinical knowledge that recovery typically starts with proximal ability, such as a gross arm movement, and proceeds to recovery of distal function, such as finer dexterity tasks for the hand [217]. As such, the decision tree model provides a data-driven approach that presents explanatory features that match clinical understanding of recovery patterns. Consistent with this idea, prior analyses of the UEFM have confirmed the individual items have a difficulty hierarchy, proceeding from proximal to distal [233], [234]. Further, the idea that measurements of a smaller number of movements can be used to predict total UEFM score is consistent with studies that have created shortened versions of the UEFM assessment [235].

Difference between clinic and home performance

The models made with data taken in clinic had higher r^2 and lower RMSE than the model made with home data likely because there was less variance in the way participants performed their exercises in the clinic than in how they performed exercises at home. In the in-clinic phase of the study, a single therapist standardized the placement of the FitMi sensors, prevented patients from performing exercises with compensation, and set a uniform time limit for each exercise. At home, though the system provided instructions for each exercise, participants were unsupervised, so they may have performed the exercises with compensation and may have changed the placement of the pucks. The system is structured to increase the challenge of the activity as users complete target numbers of repetitions. So in contrast to the clinic scenario where patients perform as many

repetitions as they can in a set time limit, the home system sets increasingly difficult target numbers of repetitions over varying durations. This feature may increase user engagement, but it may also add elements of fatigue or may encourage users to employ strategies to pace themselves. Therefore, the rates of participants interacting with the system at home may not be directly comparable to the rates performed in the clinic. Even the presence of a supervising therapist may have been an additional motivator for patients to exert themselves, that would then be absent in the home environment. Some of this variation can be seen in Figure 23a. At home, participants with higher UEFM scores decreased their exercise rate relative to their in-clinic performance, and participants with lower UEFM score increased their exercise rate relative to their in-clinic performance.

Limitations

The sample size used in this study was relatively small (n=41 in-clinic, n=14 at home). Our ability to model data generated at home was further limited by the sparsity and diversity of exercises that participants performed at home. Participants were not given explicit instructions on what exercises to perform at home, which resulted in varying participation across available exercises among participants. Further, in the home setting, without supervision, participants may perform exercises differently than expected. This phenomenon likely contributed to the increased variance. Conversely, for the in-clinic phase of the study, the attending therapist stopped patients if they began performing the exercises with compensation and recorded only the repetitions performed correctly, which meant some participants recorded zero repetitions for some exercises. This led to a y-intercept for the in-clinic model at an UEFM score of 14, such that the model has a floor

effect for individuals with UEFM score < 14. During the recruitment, more male patients than female patients were admitted for stroke to the hospital where the trial took place, and through the inclusion screening process, only a few female participants were eligible to participate, able to be contacted, and agreed to participate in the study (n=4). Further, the randomization process was based on UEFM score alone, which resulted in all the female participants being allocated to the control group of the RCT. The participants who used the system at home were all in the subacute phase of stroke recovery. Individuals in the chronic phase of stroke recovery may not fit this model.

Future work

As assessment is an important part of the rehabilitation process, systems designed for home-rehabilitation should aim to incorporate periodic assessments. The present study suggests that incorporating a forward-reaching exercise and measuring rep rate is a simple way to estimate UEFM score. Given sufficient fidelity, such a measurement could potentially be used to inform a healthcare provider of a patient's progress, as justification for institutional reimbursements, or serve as a motivator for individuals pursuing their rehabilitation at home unsupervised. To allow this model to be used as a clinical assessment, further research needs to be conducted to verify the test-retest reliability and the model's sensitivity to changes in exercise rate and UEFM. This will require more data taken in the desired setting (home or clinic) paired with clinical outcome measures.

In the FitMi system studied here, such an assessment could be introduced after individuals complete a set number of activities. To match the scenario created for our clinic data, an

assessment should encourage participants to perform as many repetitions as they can in a set period of time and should reinforce the importance of performing the activity correctly without compensation. To limit compensation in an unsupervised home environment, IMUs could be placed on the chest and or arm [236], [237], or a motion capture system could monitor trunk motion [238]–[240].

Improving models such as the ones presented requires accruing larger sets of ground truth data of clinical measurements and sensorized activity. With enough resources, large trials can be conducted to recruit the participants needed, but commercial rehab system vendors and hospitals may represent an untapped dataset for natural experiments. Commercial vendors could offer video sessions with a therapist to collect clinical data, and hospitals using sensorized systems could work with researchers or developers to pair activity data with clinical measures from electronic health records.

An interesting finding was that the multivariate decision tree modeling approach did not improve model performance. This is likely due to the small sample size. Further, we did not attempt to fit a decision tree model to the home data due to the small sample size and the heterogeneity in the exercises performed. Though the decision tree algorithm could theoretically model a data set where not all participants perform the same exercises, again, a larger sample size would be required to produce reliable results. Other nonlinear modeling techniques could be applied, such as a boosted tree method, but their desirability may be limited because many such models would no longer be explanatory or interpretable.

Conclusion

In this work, we proposed using the rate of activities completed in a sensorized system to estimate the UEFM. The models presented use a reaching task and a gripping task, and the models captured approximately 70% of the variance in UEFM in our data. This approach could be replicated with simple push button systems that do not require participants to precisely don and doff multiple sensors and could be performed unsupervised in the home setting. The models developed here could also be used to estimate impairment, and changes in impairment, for the commercial users of the FitMi system.

Part II Summary

Given the importance of RT for use in the home as found in Part 1, Part 2 of the dissertation then focused on measuring the actual effects of RT uptake in the home setting. First, a systematic review was conducted to identify recommended design features for home RT. The SGES studied here incorporated most of the design features found, but it does not enable a therapist to monitor and communicate with the user. Next, the clinical efficacy of the SGES over conventional home therapy was demonstrated based on analysis of results from a single-blind, randomized controlled trial with 27 participants in the subacute phase of stroke. Adherence to the SGES in the context of the clinical trial was shown to be superior to adherence in an unsupervised context, suggesting that the missing design feature of therapist presence affected adherence. Finally, it was demonstrated that home RT has the potential to measure its own effect on the user, because it provides data that can be used to accurately estimate users' impairment level. This opens the door for self-assessing RTs for the home setting, but performance data from the home setting and clinical measures taken at a similar timepoint to the performance data will be needed to develop models for this aim.

Part III: Optimizing Rehabilitation Technologies for Uptake

The investigations of uptake described in this work have highlighted opportunities for redesigning aspects of the systems studied to improve their uptake. The following sections describe technology changes and subsequent measures of use to evaluate their effectiveness in improving their uptake. Thus, this work serves to illustrate the proposed "Design for Uptake" paradigm, in which the designs of rehabilitation technologies are refined through an understanding of actual usage patterns.

Chapter 7: Optimizing Sensor Enhanced Activity Management (SEAM) Uptake

Summary

During this dissertation work, there was an opportunity to attempt to change uptake in a clinical setting through a second pilot study of the sensor enhanced activity management (SEAM) system. The first pilot study provided feedback for potential system improvements. Following this first pilot study of the SEAM system described in Chapter **3**, the research team and the commercial development teams, Pt Pal and Flint Rehab, collaborated to design and implement changes based on feedback from the study. This chapter will describe the system changes made to SEAM and the results of the second pilot study that evaluated usage of the refined system.

7.1 Methods: SEAM Development and Phase II Study

The research team created and maintained a Trello board, a project management tool, to facilitate the product development process, and the commercial development teams implemented changes to their respective systems based on group discussions of desired features and fixes. After the major changes were implemented, a second pilot study was conducted at Shepherd Center, a rehabilitation hospital in Atlanta, Georgia. To assess the success of the system changes, the rates of exercises assigned that patients completed and the rates of exercises completed that had associated sensor data were compared to the corresponding metrics from the first pilot study conducted at UCI.

7.2 Results: SEAM Development and Phase II Study

7.2.1 Pilot Study Lessons and System Changes

Implementation themes that were frequently mentioned as barriers to use included time and complexity, adaptability and reliability, and the form factor of the sensor. To address these, the research and development teams made changes to the Bluetooth workflow, repetition counting algorithm, included more visual indicators in the interface, and changed the sensor, shown in Table 16.

Table 16: Changes made to the SEAM system showing the state of the features that were changed in Version I and Version II.

	Version I	**Version II**
Bluetooth Workflow	**Number of steps to establish the connection an perform the first exercise:**	
	9-10 user-initiated **1 app-automated**	**5-6 user-initiated** **3-4 app-automated**
Rep Counting Algorithm	**Acceleration threshold and algorithm to count movements:**	
	Movements that were too slow were not counted	**Reduced acceleration threshold to count movements**
	Counts all acceleration and force transients that cross the threshold	**Only counts one movement per repetition**
Visual Indicators	**Visual Indicators for connection status and movement activity:**	
		Exercises flagged for clip display "Disconnected" or "Connected"

	Incoming counts are displayed in the profile menu	**During exercise, a visual counter increments as reps are performed in real-time**
	After exercise, total movement count is displayed	**After exercise, total movement count is displayed**
Sensor Formfactor	**Puck:** • **88 cm diameter** • **31 cm thick** • **162 grams**	**Clip** • **31 cm width** • **42 cm height** • **0.1 cm thick** • **9 grams**

The changes streamlined the Bluetooth workflow to reduce the time and complexity related to setting up the system. The teams redesigned the repetition counting algorithm to make the system adaptable to the variety of exercises therapists wanted to prescribe and to increase the accuracy of counting motions that patients performed. The teams also incorporated more visual indicators in the interface to help users through the Bluetooth connection process and show users when motions were counted during an exercise. Finally, in response to comments that the sensor was too bulky, the sensor was replaced by a smaller sensor also produced by Flint Rehab. The barriers of time and complexity and adaptability and reliability and the design changes made in response to these are further detailed below.

Time and Complexity

A reoccurring theme in our study of uptake in clinical settings is that therapists have limited time. The current US healthcare structure primarily reimburses patient encounters.

As such, therapists are scheduled to have many visits such that there is limited time outside of patient encounters for review or setup, and time spent on setup during an encounter is time taken away from treatment.

On the patient side, increasingly complex diagnoses frequently include cognitive impairments. Cognitive impairments can result in increased difficulty following directions, executing process steps, and navigating visual interfaces [241]–[243]. As such, if the setup was difficult for patients to complete independently, that resulted in therapist time spent on troubleshooting in the clinic during patient encounters and reduced patient uptake outside of the clinic setting.

A frequently mentioned problem was that patients and therapists had difficulty completing the Bluetooth connection between the Pt Pal app and the FitMi sensor device. To reduce the time required and the complexity of the setup process, the research and development teams aimed to streamline the Bluetooth workflow. In Version I, users initiated the Bluetooth connection from the app. After this, any sensor data sent to the app during an exercise would be associated with that exercise. This also required users to confirm if Bluetooth was enabled on the mobile device or tablet, which can require navigating through system menus. As participants could have Android or Apple devices, this meant that therapists had to be familiar with the process for both operating systems.

Version II aimed to automate as much of the process as possible such that the system would check if requirements were met and would prompt users to complete the necessary steps. In total, Version I required 9 or 10 user-initiated steps, depending on whether Bluetooth was enabled before beginning the process, and 1 app-initiated step. Version II

required 5 or 6 user-initiated steps and 3 or 4 app-initiated steps, reducing the number of user-initiated steps by half.

Adaptability and Reliability

The original intent of the SEAM system was to make the library of 40 gamified, sensorized exercises from the FitMi system (see section # for FitMi system description) available through the Pt Pal app. However, therapists prioritized being able to prescribe their own exercises over the ability to deliver gamified exercises. As such, the 40 FitMi exercises were removed from the system to focus on enabling therapists to incorporate the FitMi sensor into their own exercises. However, for the original 40 exercises in the FitMi system, Flint Rehab developed a unique repetition counting algorithm for each exercise. As the new goal was to allow therapists to prescribe any exercise, it was infeasible to create a unique algorithm for every exercise. Instead, the research and development teams created a single algorithm that could accommodate any exercise prescribed through the Pt Pal platform, Table 17.

Table 17: Steps of the revised algorithm used to quantify the number of repetitions performed by a user from the FitMi sensor data sent via Bluetooth.

Algorithm Steps
1. Wait for FitMi Bluetooth event
2. If event,
a. Increment rep count if and only if the user is in the active phase of a repetition, versus the rest phase
b. Increment the rep count only one time per active phase

This algorithm took advantage of a prescribing style available in the Pt Pal system, where the app provides visual and auditory cues to start and stop each repetition of an exercise. For each repetition, there is an active period and a rest period. During an exercise, a movement detected by the system is only counted if it occurs during an active period, and only one movement is counted per active period. This allowed us to quantify a movement as any sensor event exceeding a certain acceleration threshold.

Comments from the first pilot study regarding unreliability related to perceived inconsistency in performing the Bluetooth connection, but also to perceived differences in the number of movements performed and the number of movements counted by the system. In this setting, individuals perceived that they had performed more repetitions than the system reported. To capture more movements, the acceleration threshold to detect a movement was reduced. Lowering this threshold could create a risk that signal noise potentially generated by shaky or uneven movements might also be counted as repetitions, but the method of the algorithm to only count one movement per active period effectively filtered such noise.

To further improve the perceived reliability of the system, a visual counter was added to the exercise screen that incremented as the algorithm counted repetitions. Such that users could perceive what was and wasn't considered a repetition by the system. Visual indicators were also incorporated through the Bluetooth workflow in the form of a unique light sequence on the sensor device to indicate connect and disconnect events, and with a display in the app exercise interface showing the current connected or disconnected status of the sensor.

7.2.2 Shepherd Pilot Study Description

5 therapists (2 PT and 3 OT) were recruited for the second pilot study at Shepherd Center, and 11 patients (3 PT and 8 OT) with traumatic brain injuries (TBI) were recruited. All the therapists had prior experience using the Pt Pal patient management system but had not used the SEAM system before the start of the study. For each patient, their therapist prescribed 3 exercises through the Pt Pal system for the patient to complete with the sensor. Patients had a single introductory session with their therapist, took the system home to use for one week, and then returned for a follow-up session.

7.2.3 Comparison of Usage Rates

Table 18: Patients' usage rates from the first and second pilot studies.

Results	Pilot I	Pilot II
% of exercises with potential to use sensor that were completed, Mean (SD)	25.2 (24.7)%	30.4 (20.3)%
% of completed sensor exercises for which sensor data were successfully acquired, Mean (SD)	**22.1 (29.7)%**	**63.0 (39.1)%***

While patients in the second pilot study completed a larger percentage of their exercises and had a smaller standard deviation among their rates of completion than the patients in the first pilot study, there was no statistically significant difference between these adherence rates from the first and second studies. However, patients in the second study

had significantly higher rates of completed exercises with associated data (22.1 (29.7)% Phase I, 63.0 (39.1)% Phase II; $p < 0.5$ Wilcoxon Rank-sum) (Table 18).

7.3 Discussion: SEAM Development and Phase II Study

Though the system usability improvements did not significantly change exercise adherence rates between phase I and II, the improvements appear to have significantly increased sensor uptake by a factor of 2.9. The streamlined Bluetooth workflow may have enabled patients and therapists to connect the sensor to the app more easily, thus reducing a barrier to use, and the redesigned repetition counting algorithm paired with the real-time visual counter could have increased its perceived value.

However, the different contexts of the Phases could have also contributed to the difference in device usage rates. Phase I had no restriction on patient diagnosis, duration of treatment, or content of prescription. At least one patient in Phase I was prescribed exercises for improving balance and reported that the sensor did not seem relevant to their care. Phase II patients all had traumatic brain injuries, used the system for 1 week, and were prescribed 3 exercises, though they were also prescribed exercises by other treatment departments who were not involved in the study. Additionally, Phase II therapists were already familiar with Pt Pal while the therapists in Phase I were learning to use the Pt Pal system and the Flint sensor component simultaneously.

In both phases, the digital HEP and the sensor were given to patients at the same time, and the focus of the study was to examine factors of uptake and usability. A future study to be conducted at Shepherd Center will focus on the effectiveness of improving adherence. Patients will first be prescribed exercises through Pt Pal, and then the sensor component

will be added to their treatment to examine the effects of the sensor component on changing rates of adherence.

Chapter 8: Optimizing Sensorized Gamified Exercise System (SGES) Uptake

Summary

Chapter 4 described an investigation into usage of a sensorized gamified exercise system (SGES) called FitMi. This SGES is a commercial system marketed for stroke rehabilitation and typically sold direct to consumers. The usage data represented a large number of individuals' undirected pursuit of their own recovery, and the analysis probed relationships between user behaviors and experiences and metrics of usage perseverance. The analysis found evidence that the challenge level of the system and the user's willingness to regularly initiate exercise were key factors in determining perseverance. Specifically, significant relationships were observed between the levels of users' initial experience of success in the first week, their repetition rate in the first week, and the steadiness at which they initiated sessions, with respect to the perseverance metrics of the total number of repetitions their performed, the amount of time they spent exercising, and they number of days they interacted with the system over their first 8 weeks of system use. User's with higher rates of success in the first week, shown as completing a target number of repetitions within a time limit, had higher levels of perseverance. But, if a user achieved success in every exercise they completed during the first week, then they had the lowest levels of perseverance. Similarly, faster repetition rates, up to roughly 75% of the maximum rates observes, were associated with increasing perseverance. While rates above this level were then associated with decreasing levels of perseverance. Steadier initiation of sessions was associated with higher levels of perseverance while varying rates, initiating at

a rapid pace and then slowing or slowly initiation sessions and then increasing frequency, were associated with lower levels.

8.1 Methods

After this analysis was performed and published, the company that developed the SGES, Flint Rehabilitation Devices, made changes to the system to try to increase general user perseverance based on the relationships found. The overall goal of the changes was to increase the challenge of activities more quickly for less impaired users and provide more impaired users with the option to decrease the level of challenge manually. After the changes had been in place for several years, data were pulled for users who began using the system after the changes were in place. The main analyses performed to analyze the version 1 data were performed for the version 2 data, focusing on relationships between success rate in the first week, repetition rate in the first week, and steadiness of use with the three perseverance metrics, repetitions, exercise time, and days of use. The results for version 2 are overlayed with the results previously found for version 1 in the figures below. The distributions of behaviors and perseverance metrics were compared between the versions using Wilcoxon rank-sum tests.

8.2 Results

The system changes that Flint Rehabilitation made are shown in Table 19.

Table 19: Changes Made to the FitMi System by Flint Rehabilitation Systems.

Changes	Purpose
Added a "hold position" feature to several exercises. This requires users to maintain their starting position before moving to the ending position for a short duration and maintaining their ending position before returning to their start position for a short duration.	Increase the quality of movements and increase the challenge level of the exercise. This discourages rapidly tapping the sensors to generate repetitions quickly.
Added a "set reps" button that allows users to lower the target number of repetitions for an exercise. Users can only unlock new exercises by returning the target number to its original value and completing that target number of repetitions.	Allows more impaired users to lower the challenge level of the exercise so they can experience higher rates of successful exercise completion.
Lowered the target number of repetitions for certain exercises.	Allows users to complete levels more easily to increase the speed at which more difficult exercises unlock.
Reduced the number of time users need to complete exercises before unlocking a new exercise for certain exercises.	Allows users to access more difficult exercises sooner.
Added images of the exercises that have yet to be unlocked	Communicates to the user that there are more difficult exercises available.
Included icons indicating the number of times users need to complete exercises to unlock new exercises, and tracks their progress towards that goal	Communicates the user's progress towards more difficult exercises.

The first dataset was collected over a 3-year period between June 2016 and December 2019. The second dataset was collected over a 2.5-year period between September 2020

and March 2023. The data was filtered following the process described in Chapter 4 for test users, clinic users, users whose first exercise was less than eight weeks prior to the end the data collection period, and outliers by number of repetitions. After filtering, the first dataset contained 2,464 users, and the second dataset contained 1,251 users.

The distribution of performance for the version 1 and version 2 datasets for each of the three perseverance metrics, repetitions, time, and days, are shown in Figure 25. The overall levels for all three metrics are lower for the version 2 users compared to the version 1 users: number of repetitions performed (median 2,047 vs 1,277 repetitions), time spent exercising (median 52 vs 50 minutes), and number of days (median 6 vs 5 days) the system was used. However only the difference in the distribution of repetitions was statistically significant.

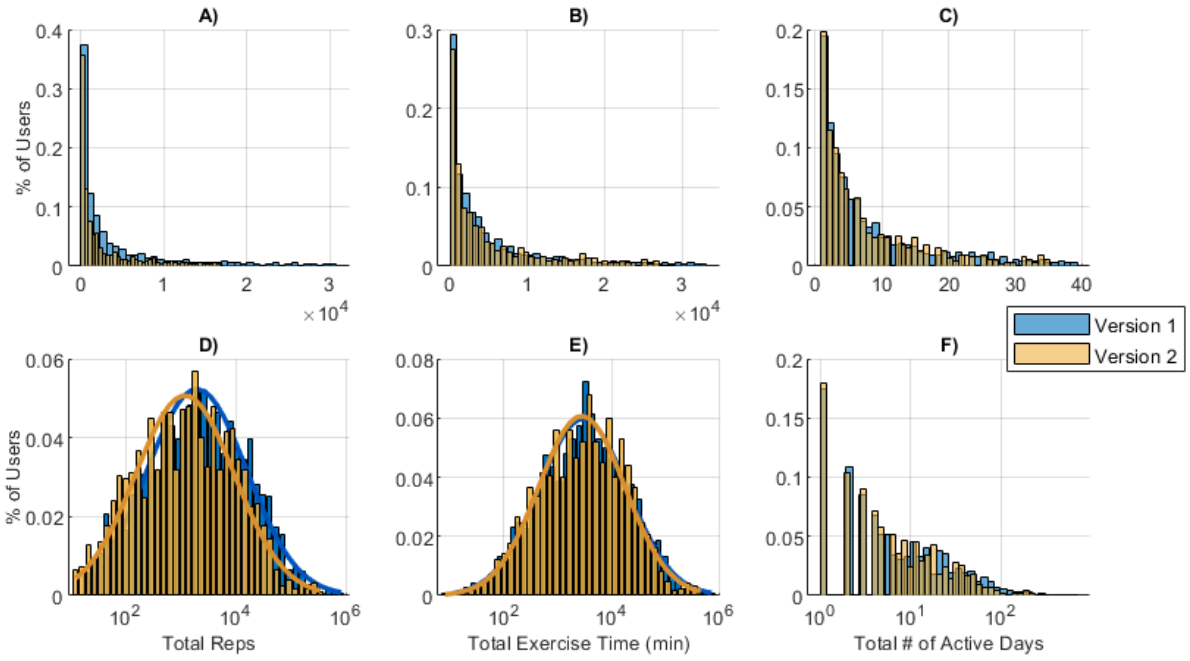

Figure 25: Comparison of perseverance statistics for version 1 and version 2. Histograms across 2,464 version 1 users and 1,251 version 2 users for (A) total repetitions (B) total exercise time and (C) total active days. For plots (A-C), users performance in the 90% percentile have been removed for clarity. Plots (D–F) show the logarithmic transform of the same data. The corresponding color lines are best-fit normal distributions.

The comparisons of relationships between behaviors and experiences and perseverance metrics are shown below, with success rate in the first week and perseverance in Figure 26, repetition rate in the first week and perseverance in Figure 27, and steadiness of use and perseverance in Figure 28**.** Comparing version 1 to version 2, the distributions of repetition rates (median 28.87 vs 24.24) and steadiness (median -0.82 vs -0.74) were significantly different (Wilcoxon rank-sum test, p value < 0.05). The steadiness distribution of version 2 also has a narrower spread with a kurtosis of 9.3 compared to a kurtosis of 8.3 for version 1. The distributions for success rates were not significantly different. The percentage of users who achieved a 100% success rate in their first week of use increased from version 1 to version 2 (15.8% version 1, 19.6% version 2). However, the change in proportions of users achieving 100% versus a lower rate did not significantly change between the versions as shown by a chi-square test.

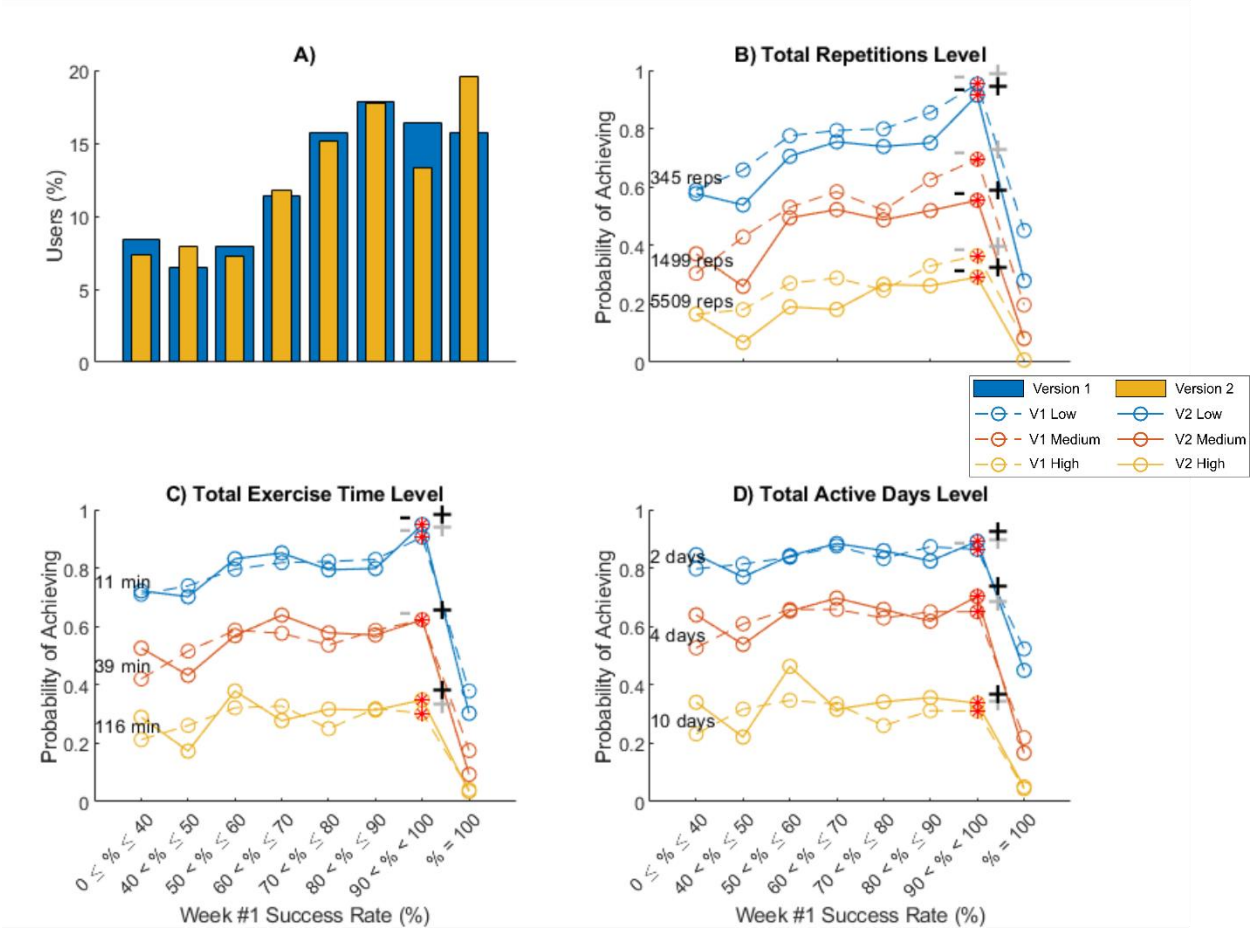

Figure 26: Comparison of relationship of initial success and perseverance for version 1 and 2. (A) Distribution of users with various rates of success during Week #1 (B–D) Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across 8 weeks of use for version 1. The – and + symbols indicated significant declines to left and right, respectively, from the peak value using the "sweet spot" test described in the methods of Chapter 4 ($p < 0.05$).

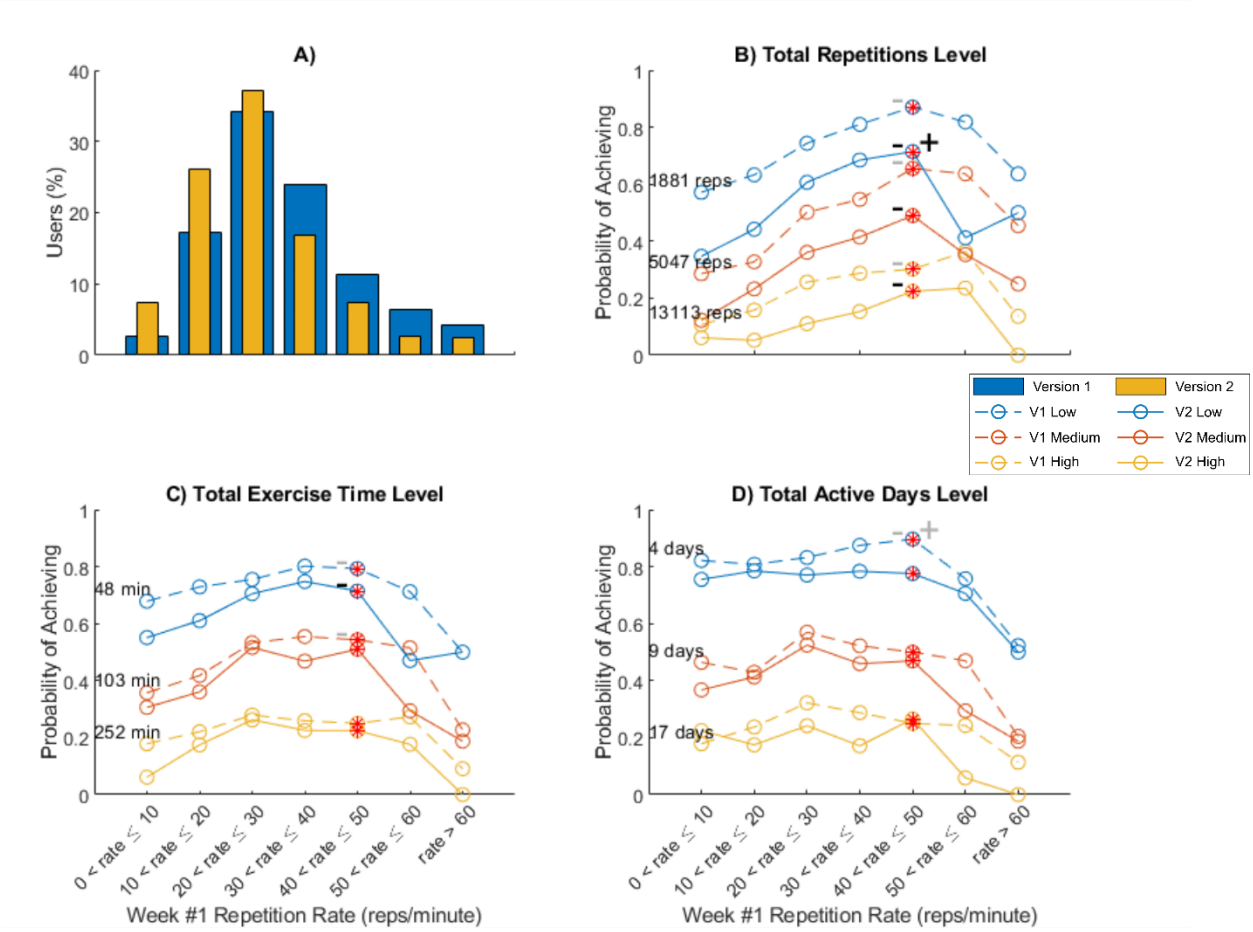

Figure 27: Comparison of repetition rate of the Reach to Target # 2 exercise in Week 1 and perseverance for version 1 and 2. (A) Distribution of users with various repetition rates (B–D) Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across 8 weeks of use for version 1. The – symbol indicates a significant decline from the peak value moving to the left, and + sign indicates a significant decline from the peak value moving to the right, using the "sweet spot" test described in the methods of Chapter 4 ($p < 0.05$).

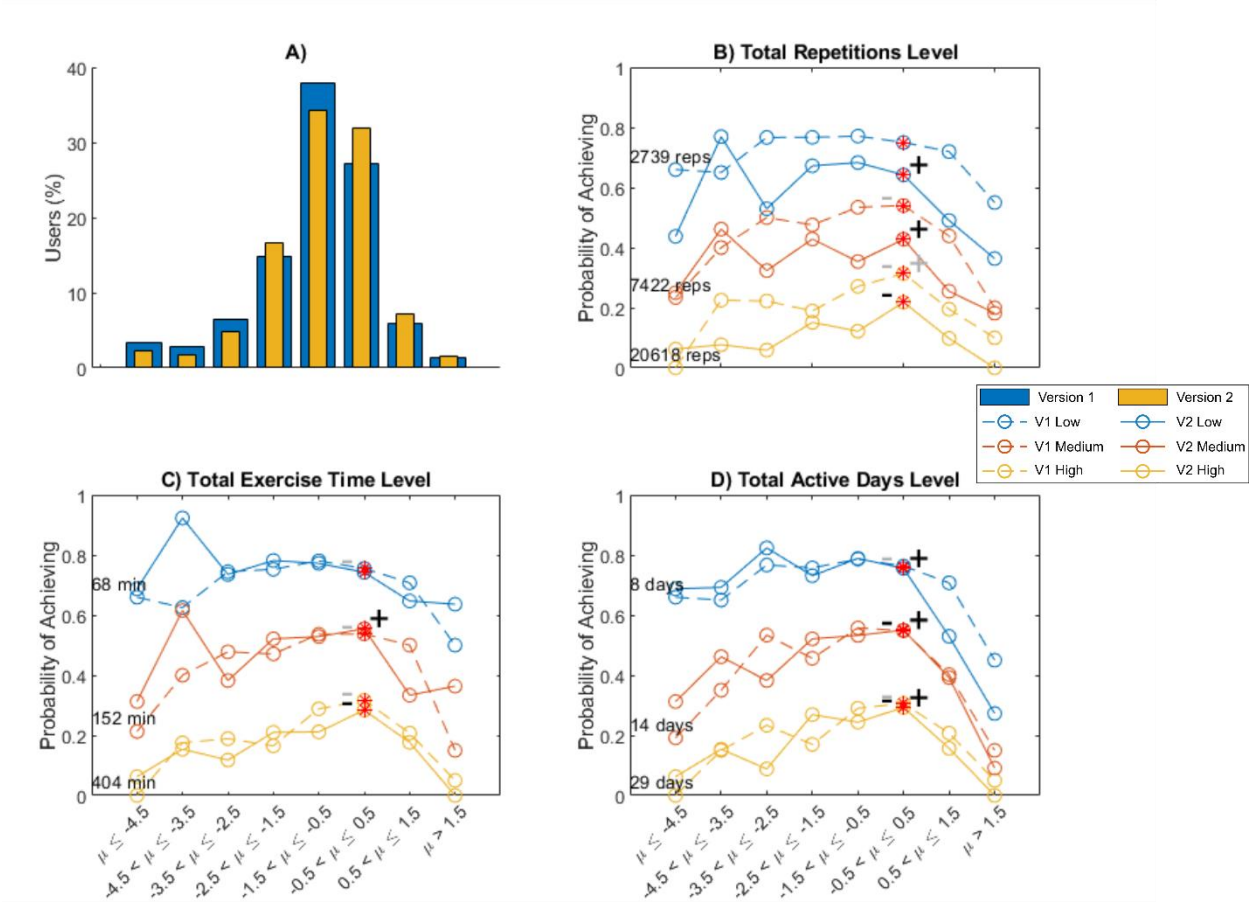

Figure 28: Comparison of relationship of steadiness curvature and perseverance for version 1 and 2. (A) Distribution of users with various steadiness curvatures. Probability of achieving low, medium, and high levels of perseverance, defined to be the 25th, 50th, and 75th percentiles of three measures of usage – total repetitions (B), total exercise time (C), and total active days (D) – measured across 8 weeks of use for version 1. The – and + symbols indicated significant declines from the peak value to the left and right, respectively, using the "sweet spot" test described in the methods of Chapter 4 ($p < 0.05$).

8.3 Discussion

Several changes were made to the SGES between the version 1 and 2 datasets in response to the findings regarding challenge and initiation in Chapter 4. After the changes had been in place for 2.5 years, usage metrics were analyzed from a new group of 1,251 users. The version 2 data showed a reduction across all three perseverance metrics, though

only the change in number of repetitions performed was significant. The relationships between success rate in the first week, repetition rate, and steadiness of use and the perseverance metrics held similarly for both version 1 and 2. That is, there was a similar optimal range for each of the behavioral and use metrics that was related to the highest levels of the perseverance metrics. However, there were fewer significant relationships found by the "sweet spot" analysis between levels of perseverance and ranges of repetition rates for exercise time and active days.

Between version 1 and 2, the distributions of success rate in the first week, repetition rate, and steadiness of use varied, which may explain the changes in overall perseverance. From version 1 to version 2, the steadiness distribution narrowed and moved towards the optimal range, the repetition rate distribution shifted to slower, away from the version 1 optimal range, and more users experienced 100% success in the first week.

Why did more users slow down and experience 100% success in their first week of use with version 2 of the system? The changes to repetition rates may stem from the new hold feature, which imposed a reduction of rates across users. Repetition rates may now have a different association with the users' impairment levels than they did in the version 1 dataset, and this hypothesis is supported by the decrease in significant relationships found by the "sweet spot" analysis. And though the overall number of repetitions performed decreased between version 1 and version 2, it is difficult to determine whether users received less benefit from the system, as the quality of each repetition may have been higher due to the hold feature. The software changes which reduce the target number of

repetitions for certain exercises may have increased the percentage of users who achieved 100% success in the first week. This was done to counterbalance the increase in difficulty caused by the introduction of the hold feature and to help users access more challenging exercises more quickly. However, the reduction in the required numbers of repetitions may have tuned the difficulty of the initial experience too low. Though steadiness improved in version 2, the potentially negative changes to the success rate and repetition rate distributions may have combined to decrease overall perseverance.

With varying changes in the three features associated with perseverance (success rate, repetition rate, and steadiness) and several system changes, it is difficult to make exact claims on what combination of system changes directly lead to the observed overall change and through what mechanism. To improve uptake using experiments like this, it would be desirable to test isolated system changes and test multiple levels of the system changes at once following a microrandomization design [244]. For example, given that the hold feature was implemented, several versions of the SGES could be released with different levels of altered target number of repetitions. One version where the target numbers remain the same, one version where the numbers are reduced, and one version where the target numbers are increased. This would allow for finer levels of testing of the effects of individual changes. Implementing this kind of experimental protocol would require infrastructure enabling easy deployment of software updates, a relatively large user base to support multiple test groups and avoid user fatigue from over testing any one group, and a system of tracking and collecting not only the user data but also the user experimental group assignment.

Part III Summary

In Part 3 of the dissertation, refinements to the design of the SEAM and SGES RTs for home exercise were implemented and evaluated. Changes to the SEAM system focused on automating the connections to the sensor via Bluetooth and improving the repetition counting algorithm. In a subsequent trial of the system, 63% (39% SD) of the exercises that patients completed in the system had sensor data compared to 22.1% (29.7% SD) of the completed exercises from the first trial, a three-fold increase in the uptake of the sensor component. Changes to the SGES studied here aimed to ramp up the difficulty more quickly for less impaired users and give an option to manually lower the difficulty for more impaired users. However, examining a second set of user data (N = 1,251) 2.5 years after these changes were implemented showed a decrease in overall levels of perseverance relative to the previous versions of the system in the number of repetitions performed (median 2,047 vs 1,277 repetitions), time spent exercising (median 52 vs 50 minutes), and number of days (median 6 vs 5 days) the system was used. Though the goal was to have users experience more challenging exercises more quickly, changes resulted in more users achieving 100% success during their first week of use, an experience which corresponds to the lowest rates of perseverance in the system. These refinements and usage comparisons show that changing aspects of RT has the power to influence user behavior. Further, they show the value of RT that can track usage metrics to evaluate the efficacy of changes, particularly for home environments, where measures of use and adherence have been historically difficult to obtain.

Chapter 9: Conclusions

This dissertation aimed to understand uptake of rehabilitation technologies (RT) in the context that they are used and then apply those findings to refine RTs to influence uptake. Where it was available, the experiences and perceptions of therapists and patients were key to understanding the primary factors driving uptake, but the success of uptake was measured with device usage data. For the SGES studied, this usage data was the only source of data available for users of the system at home. In this way, the design philosophy followed practices of user-centered design but shifted the final optimization target to uptake as shown by the usage data, modifying a User-Centered Design approach to a Design-for-Uptake approach. We first summarize the specific findings of this dissertation and then highlight major themes and conclusions that can be drawn from these findings.

9.1 Summary of Findings

Part I focused on investigating facilitators and barriers to uptake of RT in the three main settings of rehabilitation. Chapter 1 used vignettes written by three occupational therapists (OTs) and two physical therapists (PTs) describing their RT use decisions during treatment sessions with nine patients to understand use factors in an inpatient facility. Therapists characterized candidate RT as having a relative disadvantage compared to conventional treatment due to lack of relevance to functional training and poor adaptability to unique patient needs. Clinicians' comfort with RT was increased by their previous training but was decreased by the perceived complexity of RT. Time in clinical practice is difficult to allocate, both for training to use devices and for setting up devices with patients.

And this limitation on time to gather, setup, and use RT, exacerbates problems created by limited numbers of training sessions and perceived complexity. In the vignettes, RT was mainly used if it enabled an activity that conventional treatment could not.

Chapter 3 moved to the outpatient setting and asked three, two PTs and one OT, were asked to use a specific sensor enhanced activity management (SEAM) system. Exercise data from the SEAM system were used to understand HEP adherence. Patients were active for a mean of 40% (26% SD) of prescribed days and completed a mean of 25% (25% SD) of prescribed exercises. In therapist interviews, there was a strong emphasis that the SEAM system used provided a key advantage through monitoring and motivating patient activity in the home setting, meeting the requirement for use of high relative advantage over current treatment practices.

As in Chapter 2, Chapter 3 focused on a particular system. Chapter 3 studied the unsupervised use of a sensorized gamified exercise system (SGES) in the home setting with a large number of users (N = 2,581). Individuals showed the greatest perseverance with the system over a two-month period if they had 1) a moderate level of motor impairment and 2) high but not perfect success during the first week at completing the exercise game. Further, a steady usage pattern (versus accelerating or decelerating use) was associated with more overall exercise, and declines in exercise amount over time were associated with exponentially declining session initiation probability rather than decreasing amounts of exercise once a session was initiated. These findings show that an optimized challenge level and regular initiation of exercise sessions predict achievement of a greater amount of overall rehabilitation exercise in a group of users of commercial home rehabilitation

technology and suggest how home rehabilitation programs and exercise technologies can be optimized to promote perseverance.

Part I showed that a key value of RT is that it motivated use in the unsupervised home context. Part II then focused on measuring the efficacy of home RT and estimating clinical outcomes from RT usage data. Chapter 5 described the results of a randomized controlled trial (RCT) of the SGES studied in Chapter 4 that compared the effectiveness of the SGES with a paper-based approach. In the single-blind, RCT, 27 participants in the subacute phase of stroke were instructed to perform self-guided movement training at home for at least three hours/week for three consecutive weeks. During this time, the intervention group used the SGES, and the conventional therapy group used sheets of paper with exercises printed on them. Participants who used FitMi improved by an average of 8.0 ± 4.6 points on the Upper Extremity Fugl-Meyer (UEFM) scale compared to 3.0 ± 6.1 points for the conventional participants, a significant difference (t-test, $p = 0.029$). The median use of the RCT participants was significantly higher than the medians from the unsupervised users in Chapter 4 (Reps: Unsupervised = 1,036, RCT = 8,093; Time: Unsupervised = 28, RCT = 187 minutes; Days: Unsupervised = 3, RCT = 7). This increase in use may be related to interactions with a healthcare professional, which is a recommended feature for home RT, but is absent in the SGES itself and the Chapter 4 data.

Chapter 6 tested whether the rate of repetitions performed in the SGES could be used to estimate Upper Extremity Fugl-Meyer (UEFM) score. A linear regression model using clinical assessment data and repetition rates for exercises from the SGES showed that UEFM score was well estimated using the repetition rate of one forward-reaching exercise

from the set of 12 exercises (r2 = 0.75). UEFM score was even better estimated by this exercise when using an exponential model (Leave One Out Cross Validation (LOOCV), r2 = 0.83). A similar model again well estimated the UEFM scores for the home data for the RCT participants from Chapter 5 (LOOCV, r2 = 0.69), but only after the coefficients were re-estimated using the home data. These results show that activity performed in an SGES can be used to infer an arm impairment score, but they suggest that generating models for a particular setting requires training data from that setting, as users of the SGES exhibited different performance patterns when they moved from the supervised clinic environment to the unsupervised home environment.

Part III described design changes made to the systems studied during this work and the resulting changes in uptake as measured by usage data captured by the systems. Chapter 7 described changes to the SEAM system which aimed to automate a large portion of the user workflow and improve the accuracy and transparency of the exercise data captured and reported to users. In a subsequent trial of the system following these changes, 63% (39% SD) of the exercises that patients completed in the system generated sensor data compared to 22.1% (29.7% SD) of the completed exercises from the first trial, a three-fold increase in the uptake of the sensor component. The increased automation of the workflow may have enabled patients and therapists to connect the sensor to the app more easily, thus reducing a barrier to use, and the improved repetition counting algorithm paired with the real-time visual counter could have increased its perceived value.

Chapter 8 described the design changes made to the SGES studied here which aimed to ramp up the difficulty more quickly for less impaired users and give an option to manually lower the difficulty for more impaired users. However, examining a second set of

user data (N = 1,251) 2.5 years after these changes were implemented showed a decrease in overall levels of perseverance relative to the previous versions of the system in the number of repetitions performed (median 2,047 vs 1,219 repetitions), time spent exercising (median 52 vs 48 minutes), and the number of days (median 6 vs 5 days) the system was used. Though the intent of the changes was to have users experience more challenging exercises more quickly, the actual result was that more users achieved 100% success during their first week of use, an experience which corresponds to low rates of perseverance in the system. This study illustrated at large scale how RT software design changes modulate user behavior in complex ways and the importance of usage data to evaluate these effects.

9.2 Factors Affecting Uptake

Rehabilitation happens in three main stages, inpatient, outpatient, and home, and in these three stages, the choice to use technology shifts from a choice by the attending therapist, to a choice by the therapist which then needs to be adhered to by the patient at home, to a choice by the patient at home. Thus, the influence on uptake shifts from primarily therapist driven to primarily patient driven.

This dissertation observed that the factors that affect therapist uptake are different but overlap with the factors that influence patients and users. For therapists, time in clinical practice is difficult to allocate, both for training to use devices and for setting up devices with patients. The study in Chapter 2 showed that conventional treatments were preferred to RT for the reduced time it took to implement them and their apparent greater relevance to functional outcomes. RT was only used if it enabled a valuable activity that conventional

treatment could not. The study in Chapter 3 showed that, for patients in the outpatient setting using the SEAM system, technological difficulties and perceived relevance to treatment goals similarly dissuaded use. For the in-the-wild study in Chapter 4, which examined users of the SGES in the unsupervised home setting, a similar phenomenon of abandonment due to perceived lack of relevance was observed in the relationship between 100% success rates for users in their first week of use and low rates of overall perseverance. However, there was also an observed increase in overall perseverance associated with increasing success rates in the first week up to 99% success, showing that motivation in the unsupervised context can be influenced by modulating the challenge level. Uptake also appears to be influenced by healthcare provider presence, even if rehabilitation is performed at home without the provider, as shown by the greater levels of engagement with the SGES performed by participants of an RCT compared to unsupervised home users as found in Chapter 6.

9.3 The Role of Device Measurements in RT Design

Stakeholder perceptions and commentary are important to consider when developing solutions and systems. They bring a rich and nuanced understanding of user needs and context. But, as with all self-reported measurements, they can be biased by factors such as an individual's ability to recall previous events, or stakeholders themselves may not anticipate needs that only become apparent once the system is in place in its intended use context. Device usage data can therefore add a direct and objective measurement of uptake to provide additional accurate measurements, details, and a method of quickly comparing usage behaviors across a large sample of users [245]. In this

work, usage metrics were used to both understand patterns and levels of use (in Chapters 3-5) and to then evaluate system changes that were made based on those findings (in Chapters 7 and 8). Further, this work showed that usage metrics could also be used to remotely estimate levels of impairment given the appropriate dataset to generate the necessary models (Chapter 6). This has the potential to enable remote assessments and remotely estimate the efficacy of a system for improving users' scores on those assessments over time.

9.4 From User-Centered Design to Design-for-Uptake

The dominant design paradigm in RT design theory is currently User-Centered Design (UCD) [246]–[250]. UCD advocates for "the active involvement of users for a clear understanding of users and task requirements, iterative design and evaluation, and a multi-disciplinary approach" [251]. Early descriptions of UCD specify that empirical measurements should be taken of learnability and useability during interactions between users and prototypes [252]. Designs are intended to be iterated to incorporate user feedback or measurements taken during observations. Frequently, this user-information is gathered through an interview or a survey, including standard surveys such as the system usability scale (SUS) or the technology acceptance model (TAM) [253]. User perspectives are valuable for understanding goals and specific features that need to be changed, but self-reported data about use has been shown to both over and under estimate device use as quantified by sensor measurements [245]. This dissertation leveraged principles of User-Centered Design by using surveys, interviews, and engaging with users during trials of systems in development (Chapter 3), but extended this approach to a Design-for-Uptake

paradigm. In this paradigm, the ultimate proof of a valid design is not the subjective opinion, but rather amount of use the device receives, as measured objectively with sensors. Usability is particularly important for technologies where users can freely choose to interact with the system or ignore the system and when they have multiple alternative systems to choose from. The UCD paradigm aims to develop systems with high usability that closely meet the functional needs of users, but focusing on usability does not guarantee maximized use. There are categories of systems where benefit from the system is only obtained through persistent or high-volume use such as rehabilitation technologies, learning technologies, and assistive technologies. For these, the amount of use is a key target for system optimization. Design for Uptake is an extension of UCD that leverages amount of use as an important metric during the validation of systems between design iterations. This will become increasingly accurate and available given the proliferation of low-cost remote sensing technologies and connected devices.

9.5 Directions for Future Research

This work showed the potential value of and use cases for usage data collected by RTs. Similar studies could be conducted with devices other than the SEAM system and the SGES studied here. Indeed, there are a large number of sensor-based RTs that have been developed [51], [254], and the methodology and insights developed here could be tested with them as well.

Chapter 8 showed that, while simultaneously implementing multiple RT design changes may be attractive from a software release standpoint, such an approach may result in unpredictable, unintended results. Given a sufficiently large user population, individual or

smaller sets of system changes could be made and comparatively evaluated. For example, the changes to the SGES to adjust the challenge level included adjusting the target number of repetitions for several exercises and introducing the hold feature. A subsequent round of changes could include leaving the current hold feature but returning the target number of repetitions to their previous values for some users and increasing the target number of repetitions for other users. This would allow the effect on overall perseverance of levels of these tuning parameters to be investigated. The appropriate level of challenge strongly influenced participation in the SGES. Therefore, initial assessments to determine the level of challenge needed for individual users could help designers create tailored experiences at varying levels of challenge. Finally, declining session initiation appeared to be the primary mechanism of disuse, so motivating external agents such as providing a connection with a healthcare professional or an automated chatbot to promote session initiation may improve perseverance.

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