Digital health: Smartphone-based monitoring of multiple sclerosis using Floodlight

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In order to improve care for people with multiple sclerosis (MS), we need to understand more about their disease. The way we measure the impact of MS on daily life has remained relatively unchanged for decades and is heavily reliant on clinic visits that may only occur once or twice each year. Unfortunately, this paradigm fails to capture the subtle mental and physical changes, possibly reflecting MS disease worsening, that can occur between visits. With the emergence of digital health there is the potential for daily monitoring of disease activity and progression in MS using tools such as Floodlight, a smartphone-based digital assessment developed by Roche and Genentech. Floodlight could help people with MS and healthcare professionals to have a greater understanding of the disease, ultimately leading to improved patient care. Approaches such as Floodlight may kick-start the use of novel measures to help detect whether symptoms of a disease are worsening. Floodlight and other digital tools aim to support Roche's ability to develop medicines with smaller, more efficient, and more patient-centric trials.
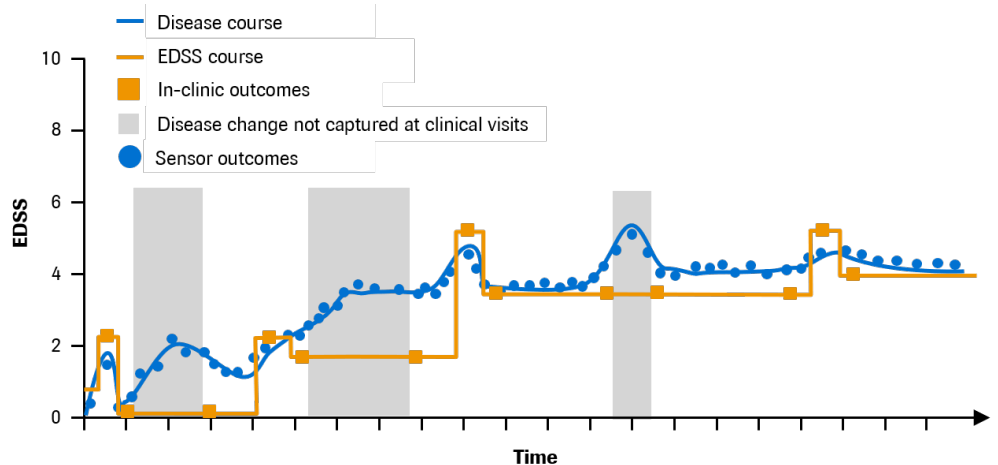

Figure 1. The disease course of multiple sclerosis (MS) is insidious and unpredictable. In-clinic assessments can detect some of the changes in MS, such as the Expanded Disability Status Scale (EDSS) score, which quantifies a person's disability level. However, some of these measures do not capture subtle changes in the MS disease course, and the infrequency of clinic visits means that many changes are missed. Digital sensor outcomes, such as smartphone-based applications, allow continuous real-time monitoring of MS to capture all of these changes, allowing the disease course to be monitored more accurately.

THE UNPREDICTABILITY OF LIVING WITH MS

MS is an incurable chronic disease in which the body's own immune system destroys tissue in the brain and spinal cord[1]. It affects 2.3 million people worldwide and is the leading cause of non-traumatic disability in young adults[2]. Symptoms may include visual disturbances, fatigue, pain, mobility problems and mental decline, although the specific disease course of MS is unpredictable and highly variable across individuals[3] (**Fig. 1**). Many people with MS experience permanent disability.

The negative consequences of MS can be life-changing. Notably, MS is primarily diagnosed in active young adults in their twenties and thirties[3], two-thirds of whom are women[4]. Put another way, MS has a substantial impact on people who have their whole lives ahead of them, who may be early on in their careers and making decisions about starting and raising families[1].

SOMETIMES MY BODY AND ENERGY LEVELS FEEL LIKE AN OLD CELL PHONE BATTERY. I CAN CHARGE IT ALL NIGHT BUT RUN OUT OF ENERGY AND SHUT DOWN COMPLETELY AND UNEXPECTEDLY.
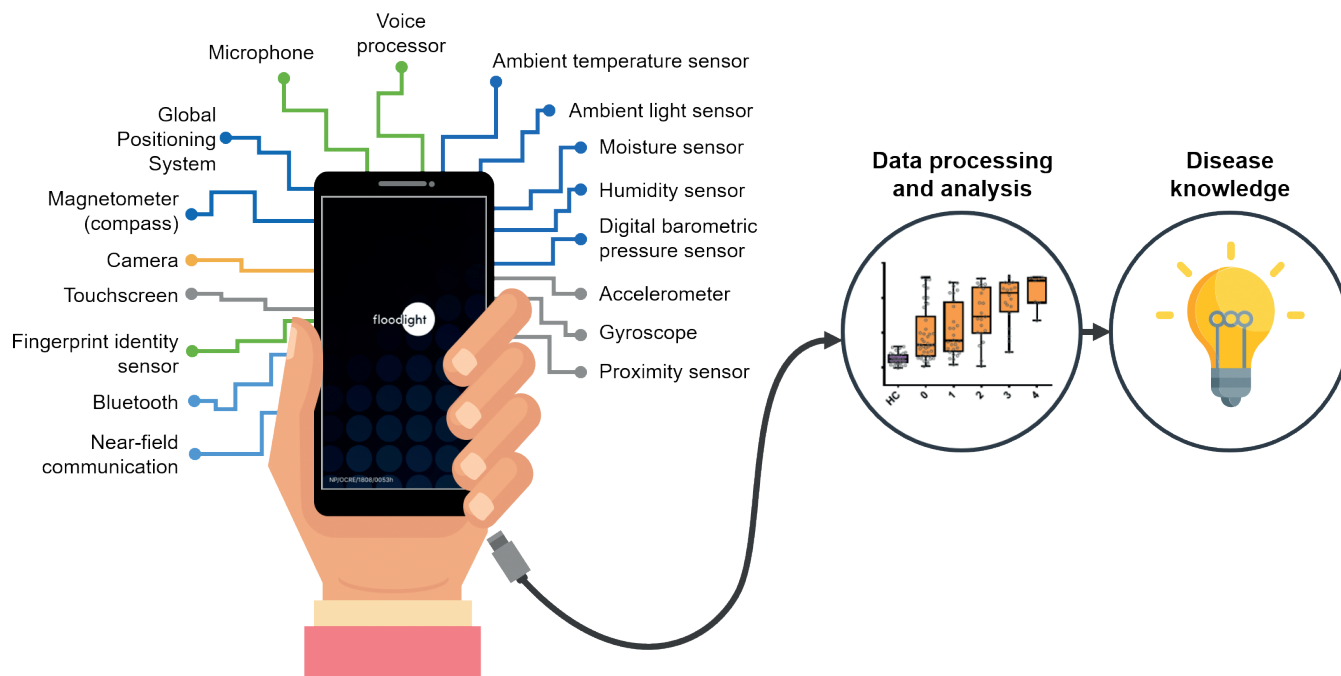FIRST-PERSON ACCOUNT OF A PERSON LIVING WITH MS

Figure 2. The potential of digital health is expanding because there have been many advances in smartphone technology combined with the ubiquity of personal devices. There is hope that one day a person's disease progression may be continuously monitored remotely[7].

THE DIFFERENCE BETWEEN AN AMAZING VISIT AND A WASTED CO-PAY CAN BE AS SIMPLE AS MY PROVIDER CLARIFYING WHAT I JUST SAID: 'SO, LET'S GET THIS STRAIGHT, YOU'RE HAVING AN ISSUE WITH...' FIRST-PERSON ACCOUNT OF A PERSON LIVING WITH MS

CHALLENGES FACING THE CURRENT STANDARDS OF CARE IN MS

The main goal of a healthcare provider involved in treating a person with MS is to manage disease activity and reduce the risk of disability worsening in a way that is meaningful to that individual. A critical factor for achieving this goal is the ability to monitor MS symptoms and disability progression, which is difficult with the current standards of care: clinic visits may be infrequent, appointment times tend to be short, and examinations can vary between clinicians. Consequently, the more subtle changes in disease progression that may occur between visits are missed (**Fig. 1**). Moreover, the tools typically used to assess symptoms are often irrelevant to an individual's everyday life or impractical for routine assessment. For example, the Expanded Disability Status Scale (EDSS), which is a globally recognized assessment of disability in people with MS both in trials and clinical practice, is heavily focused on ambulation[5] and may not adequately capture many other important symptoms for patients, such as upper limb function and cognition. Another commonly used measure, the nine-hole peg test, assesses hand function by measuring how quickly a person can place into and then remove nine pegs from nine holes, one at a time[6]. Measures such as these do not directly assess tasks that might be considered important to people with MS, such as writing or ability to work, making it difficult to translate findings into meaningful care.

The consequence of these challenges is delayed recognition of disease activity by the healthcare professional; a delay can subsequently impact timely treatment decisions and, ultimately, lead to irreversible disability. Real-time digital monitoring of MS outside of the clinic has the potential to overcome such challenges. Efforts are already ongoing to develop tools for enhanced monitoring of MS, and with the evolution of both mobile technology[7] and wearable biosensors[8], digital health tools promise change.

THE RISE OF NEW TECHNOLOGY

The rise of smartphones has given us the ability to connect with our family, friends and doctors, and to continuously monitor our health no matter where we are, every day.

Smartphones combine multiple, high-quality sensors into one indispensable device

Figure 3. Floodlight is a smartphone-based digital assessment that allows passive and active monitoring of multiple sclerosis disease activity. The app prompts the user to perform various assessments, referred to as 'active tests'.

(**Fig. 2**). These sensors allow us to take basic measurements such as acceleration, and calculate parameters that describe how a person walks or the number of steps that they take during a day. Most smartphones can also sense geographic position, ambient light, voice and touchscreen pressure, and some even monitor atmospheric pressure. Utilizing sensors can turn a smartphone into a useful tool for monitoring heart rates or detecting falls[7].

SMARTPHONE-BASED SELF-MONITORING OF MULTIPLE SCLEROSIS USING FLOODLIGHT

Floodlight is an app developed by Roche that contains a range of active and passive remote monitoring tests that measure a person's ability to perform simple tasks on their smartphone (**Fig. 3**). The aim of Floodlight is to gain an understanding of the effects of MS on the brain, hands and body, and allow the symptoms of MS to be continuously monitored every day.

REDISCOVERING MS WITH FLOODLIGHT

The Floodlight app consists of several tasks that measure cognition, hand motor function and mobility in order to collect precise, real-time data and that one day may track subtle changes in symptoms between doctor visits. Simple tasks were designed by physicians to help people with MS understand their personal journey. The tests are intended to enhance the findings from several gold standard in-clinic tests, accurately tracking disease activity and progression while at the same time providing a clearer and more continuous picture of the reality experienced by people living with MS (**Fig. 4**).

Consider hand motor function, which, as previously described, is typically measured by the nine-hole peg test. In the Floodlight app, one of the tests used to assess hand motor function is a test called draw a shape, in which users hold the smartphone in one hand and draw six different shapes of increasing difficulty on the

touchscreen with the finger of the opposite hand[9]. The complete interaction with the touchscreen is recorded, performance features such as accuracy and speed are measured, and changes are tracked over time. The hope is that the draw a shape test is faster and more accurate, can be carried out every day, and reflects a person's ability to write, a task that is particularly meaningful to people with MS.

EMPOWERING PEOPLE LIVING WITH MS

Giving people living with MS the opportunity to actively engage in understanding and managing their disease can be empowering. This is becoming increasingly important because therapeutic decisions are mostly made in partnership between the doctor and the patient, and there is evidence to suggest that involvement of people with MS in shared decision-making is central to improving their treatment satisfaction and adherence[10,11]. The hope is that one day, tools such as the Floodlight app will

allow people with MS to do this by tracking their own disease journey on their smartphone, enabling them to accurately identify changes in their symptoms and to engage in informed patient-led discussions. Digital monitoring is not about replacing a healthcare professional. Rather, it has the potential to bring people together, make healthcare more personalized and improve the patient–clinician relationship[12]. In a recent exploratory study, we found that people living with MS who completed the Floodlight tests regularly over a six-month period were highly engaged and satisfied with the app, supporting the feasibility of using smartphone-based monitoring of MS in a person's daily life.

MAKING DIGITAL HEALTHCARE A REALITY

Roche's commitment to neuroscience extends beyond the development of new medicines. In the age of the digital healthcare revolution, tools like Floodlight represent a promising avenue to enable minimally intrusive, precise and continuous

Brain: To assess a person's mood and cognitive functioning

Daily Mood Question
Quick daily questions about how the person feels to help understand well-being and mood

Matching Symbols
Matching symbols to digits measures how quickly information is processed

Hand: Hand motor function tasks designed to measure manual dexterity, strength and precision over time

Squeeze a Tomato
Designed to measure changes in hand–eye coordination and fine motor skills

Draw a Shape
Measures the speed and accuracy of hand and finger movements

Mobility: Walking and posture tasks measure changes in a person's mobility, stability, speed and balance

Two-Minute Walk
Walking quickly for two minutes measures stamina and mobility

Balance
Standing still for 30 seconds measures posture and stability

U-Turn
Task measures how the person walks and their ability to change direction

Passive Monitoring:

Passive Monitoring
Measures incremental changes in the way people move throughout the day
Gathering information through the smartphone sensor on step counts/duration and asymmetry

Figure 4. The Floodlight app contains a range of tests that measure brain function, hand function and mobility. In addition, passive monitoring is carried out throughout the day[9].

THE FINE MOTOR COORDINATION IN MY LEFT HAND WAS AFFECTED, AT TIMES MY SPEECH WAS SLURRED, AND THE STIFFNESS IN MY LEGS MADE WALKING EXTREMELY TIRING AND DIFFICULT...I HAD GONE FROM A VERY HEALTHY AND PHYSICALLY ACTIVE PERSON TO A VERY HANDICAPPED ONE. MY WHOLE LIFE HAD CHANGED[1].
FIRST-PERSON ACCOUNT OF A PERSON LIVING WITH MS

assessment of MS disease activity integrated into people's daily routines. Implementing digital monitoring could identify disease progression earlier, leading to more rapid and appropriate treatment decisions, and therefore has the potential to improve long-term health in people with MS. With the advent of the digital healthcare revolution and the rapid advances in technology, it may be possible that one day, a patient's disease can be passively monitored 365 days a year, using the technology that exists around us. To make the idea of digital healthcare a reality and ensure that we measure what matters to patients, collaborations are required between digital experts, healthcare providers, people with MS and the wider community of MS researchers. The digital assessments and tests need to be designed alongside people with MS, and the results need to be reported in a way that facilitates smooth integration into research and healthcare workflows. A cross-industry and ultimately even cross-healthcare system approach is required to define the standards of digital monitoring, with the ultimate goal of improving the lives of people living with MS.

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