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The Evolution of Personalized Behavioral Intervention Technology

Will It Change How We Measure or Deliver Rehabilitation?

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Telehealth access, mobile communication, instrumented devices, and wearable sensing technologies can be configured by internet connectivity to hover like an invisible personal drone, curating continuous data about physical activity, mental state, and physiology, even body and environmental chemistry, during everyday life.^{1,2} The figurative drone can gather ground truth via direct observation of disabled persons after a stroke during their daily activities or rehabilitation practice, then transmit measurements of interest to clinicians and researchers with high accuracy in real time. The technology can be configured to ask about and record in-the-moment self-reports about mood, pain, social interaction, activity, and other personal events. After stroke, it can enable patients to receive rehabilitation in their homes and communities when little or no therapy would otherwise be available.

Telerehabilitation includes tools for standard telemedicine in which personalized health care is delivered at a distance by, for example, videoconferencing. Mobile health (mHealth) supports these remote interactions between patients and clinicians with smartphone-based text messaging, video streaming, e-mail, health-related apps, and other wireless technologies, such as wearable motion and heart rate sensors. Instrumented exercise and practice devices with radio connectivity to the internet can also stream a record of training and progress.

The conceptual bases for such applications to outpatient rehabilitation and clinical trials are subsumed under the motor learning theory that dominates stroke rehabilitation practices. That is, an adequate dose of repetitive practice at relevant tasks that are increasingly challenging and optimized by behavioral reinforcement, along with exercise for strengthening and conditioning, will best support training-induced neuroplasticity and potentially improve outcomes.³ Usual outpatient rehabilitation tends not to offer feedback and relies on informal or ordinal measures of progress. Feedback from multidimensional mHealth monitoring technologies may better motivate and guide compliance, training intensity, and progression when therapists incorporate sensor-derived ground truth about the type, quantity, and quality of therapeutic practice.⁴ With the continuous, objective

measurements of change during real-world activity that are provided by devices, therapists gain potentially powerful behavioral intervention technologies that, for the first time, enable personalized, remotely managed rehabilitation during clinical trials and postinpatient care.⁵

Self-management training may improve motor learning outcomes.⁵ With remote technology-supported trials, the therapist has a tool to teach self-efficacy for training. Telerehabilitation interactions based on monitoring devices can reinforce the person's understanding of the health benefits of greater physical activity; identify possible personal and environmental barriers to activity and practice; teach problem solving; use behavioral intervention techniques, such as goal setting, feedback about performance drawn from sensor data, tailored instruction, and reassessment of goals no less than once a week; and provide ongoing personal social support.

A National Institutes of Health advisory group recently recommended studies of remote rehabilitation at 3 levels: full professional telemanagement, intermittent telecoaching, and self-management with sensors and mHealth apps. The group agreed that these approaches could also create new outcome measurements and better integrate rehabilitation into the lifespan of health care for disabled persons.⁶ Available and developing systems of tools, however, face barriers before the technology can fly for disabled persons after stroke.

Wearable Sensing Tools: Opportunities and Limitations

Stroke rehabilitation providers are especially interested in motor recovery, so being able to monitor practice and assess changes in the quantity and quality of limb and body motion, as well as increases or decreases of purposeful activity and exercise, has high potential value. Wearables offer what has been missing from most neurorehabilitation trials and daily care—high fidelity, objective measurement of clinically important naturalistic behaviors. Some of the most applicable technology to gather this data can be purchased off the shelf. All commercial and research sensing devices share common components, including a triaxial accelerometer and

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gyroscope. Most commercial sensors are designed to provide real-time feedback to healthy users. Data processing occurs on the device (eg, a wrist-worn sensor or smartphone app), limiting what can be captured and calculated. Counting steps and estimating distances walked or jogged are perhaps the most common tasks for these linear and rotational inertial sensors. Before incorporating them into stroke rehabilitation, it is important to understand a few basics about motion sensors, especially in regard to potential limitations.⁷

Walking

If users walk at speeds typical of the healthy adult population, relatively simple algorithms can be used to summarize physical activity, drawn from raw accelerometry data collected at the wrist, waist, or leg. Most devices use a peak detection algorithm for which any inertial or rotational signal greater than a set threshold equals an activity count or step. Some use a fast Fourier transform to make an estimate based on a frequency analysis of a short-time sample. These choices work rather well for appreciating step counts at usual walking speeds.

In contrast, the motion of disabled persons may require more detailed analyses of inertial waveform features and machine learning algorithms. The most flexible algorithms are unbiased in that they make no prior assumptions on the movements being monitored. They recognize every step taken based on analysis of multiple features in the inertial signals, such as key accelerations and decelerations during the phases of the gait cycle of both lower extremities. We prefer this approach and add a template-based method of gait classification and analysis that fuses data from sensors worn on each ankle or shoe-top. Participants are asked to walk at their usual, slowest, and fastest speeds for 10 to 15 m, which provides sufficient information to develop individualized statistical models of the gait cycle, not just whether or not a maximal acceleration occurred during the swing phase of gait.⁸ We obtain a personalized motion signature for that individual which includes stance and swing times, heel-off, toe-off, peak swing, and heel stroke. Walking speed and distance can then be calculated without the need for global positioning satellite monitoring. This strategy and others could be adopted by commercial systems so that their data are more reliable for slow, irregularly walking persons.

Data collected from the SIRRACCT clinical trial⁹ (Stroke Inpatient Rehabilitation Reinforcement of Activity) provide an illustrative example of the importance of having an analytic strategy that is robust enough to account for the potential variations in the speed, smoothness, and regularity of hemiparetic leg or arm movements. Patients admitted for inpatient stroke rehabilitation at 16 international sites wore inertial sensors on each ankle. As one component of the trial, the participants performed a stopwatch-timed 10-m walk on study entry and then once each subsequent week of their hospital stay. A strong log–log relationship ($r=0.827$; $P<0.001$) was present between gait speed and stride variability across the 576 walks collected from the 135 trial participants (Figure). This relationship explains why most commercial sensor reports are increasingly inaccurate at walking speeds <0.6 m/s.¹⁰ The algorithms on commercial devices assume a constant relationship between

stepping pattern and gait speed but do not account for the non-linearity at slower speeds. Many patients with hemiparesis, however, especially those selected for clinical trials, typically walk with a varying stride length and duration at speeds <0.6 m/s. The calculation of spatiotemporal metrics of gait requires additional levels of data processing to accurately capture the irregular movements of disabled persons. Until commercial systems that can perform better analytics on raw inertial data obtained from the ankles or dorsum of the feet become available, clinicians and investigators may be obtaining unreliable step counts and distance metrics.

Similar problems plague the classification of other behaviors of interest to rehabilitation. The accelerometer and barometer in a smartphone may be able to detect standing up and sitting down, but sensors on the sternum and thigh provide a more accurate classification of supine, sitting, and standing positions. Sensors may be deployed to detect falls, but hemiparetic persons often fall too slowly or in such variable ways that algorithms derived from even several sensors may be unreliable. Wearable inertial tracking sensors in experimental studies have been positioned to identify a wide range of other movements with reliability and accuracy that vary considerably across different tasks.¹¹ Lower extremity kinematics can be derived from multiple accelerometers, gyroscopes, and goniometers, but doing so in daily real-world settings for remote monitoring is not yet feasible.¹²

Reaching and Grasping

The upper extremity has 9 degrees of freedom with many potential joint and directional movements, unlike the legs when walking. Upper extremity activity counts from bilateral wrist accelerometers have successfully compared the amount of use of the paretic to the nonparetic arm during daily activities.¹³ To do so required developing an ideal algorithm for the inertial data, one that discounted the arm movements associated with walking. The ability to ascertain whether a reaching movement is purposeful during a task or to calculate the speed, precision, or smoothness of movement in real-world

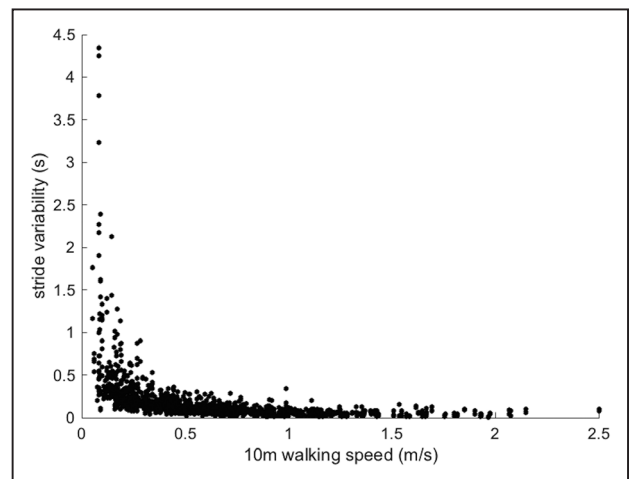


Figure. A log-log relationship is present between gait speed and stride variability. Algorithms that do not account for the variations at speeds <0.6 m/s may miss step counts. Data collected from inertial sensors worn on both ankles during 10-m walks.

settings would be valuable but at present, requires a controlled laboratory setting.

A calculation of the number of purposeful upper extremity movements can be ascertained during planned practice sessions at home but not yet during free ranging daily activities. Hand–arm motor control and truncal movements can be monitored during planned tasks at home with a Kinect (Microsoft) depth-sensing camera that detects joint movements in 3 dimensions within the limited field of view of the camera.¹⁴ Specific movements, such as those involved in the Fugl-Meyer Motor Assessment, were successfully tested remotely.¹⁵ Alternate camera technologies, such as the LEAP Motion Controller (LEAP Motion), can be used to remotely monitor practice within peri-personal space on a countertop for reach, grasp, pinch, or bringing an object from hand to mouth.³ Future development of smaller microelectromechanical sensors that are embedded in clothing fabric may enable patients to readily tolerate body-worn sensor networks in real-world settings, rather than just 1 or 2 sensors carefully placed. The classification and measurement of many more movements may then proceed, but processing will require robust algorithms and patient-support systems.

Trials of Technology Tools for Stroke Rehabilitation

The experimental evidence for the efficacy of adding telerehabilitation and sensing tools to rehabilitation trials is wanting, but the designs of these trials have been less than optimal to date. Most important, trials usually have not included a cogent behavioral intervention drawn from the data provided by wearable sensors and instrumented practice devices.

Wearable Sensors

A review of trials that deployed lower extremity wearable sensors for persons with stroke found some evidence for improvement in activity and participation, but the designs and aims of the 11 studies with 550 participants were too varied to perform a meta-analysis.¹⁶

mHealth Apps

Apps on smartphones have had some success in reducing the risk factors for stroke, such as diabetes mellitus and cigarette smoking.¹⁷ Apps that aim to increase physical activity in the absence of a behavioral intervention with frequent contact to motivate and resolve barriers have had modest, if any, success in disabled persons with stroke, as they often do in healthy persons.

Telerehabilitation

Home-based stroke rehabilitation has been shown to be equal to and in some respects better than hospital-based therapy in small trials of modestly impaired persons.¹⁸ A lesson from in-home trials is that supervision and development of problem-solving skills is essential; otherwise, only about one third of patients follow a regimen and possibly benefit.¹⁹ Telesupervising rehabilitation trials suggest that home-based and conventional face-to-face management usually produce equivalent motor and self-care outcomes, but telerehabilitation with phone or videoconferencing may lead to greater self-efficacy.²⁰ That is, the patients are more likely to carry over what they learned about practice and problem solving

after the trial has ended. Thus, home-based, remotely offered stroke rehabilitation may be as good as one-on-one care for many patients but could potentially exceed clinic-based care if patients practiced more often in the context of the home and received feedback based on behavioral intervention technologies.

Instrumented Devices

To date, equivalent outcomes have also been the result when instrumented devices in the home were compared with conventional treatment carried out at home or in a clinic. These results are encouraging in that therapists may be able to improve outcomes using remote rehabilitation techniques rather than require disabled patients to travel to a clinic. For example, a randomized clinical trial (RCT) of 99 participants compared home-based exercise to a combination of home-based exercise plus training with a robotic-assisted hand device for 3 hours per day for 8 weeks.²¹ The instrumented device transmitted the amount of use and performance measures. Therapists contacted each participant by phone or e-mail weekly to adjust the therapy and encourage participation, spending on average 13 minutes per week per subject. Compliance was good, especially when personal motivation was high. Outcomes were improved but equal. Another RCT of 16 subjects compared self-guided, home-based rehabilitation of conventional arm exercises versus use of a mechanical lever that guides the affected arm through a coordinated movement for shoulder and elbow flexion–extension in a pattern similar to reach-and-retrieve tasks.²² A smartphone on the lever recorded repetitions, which averaged 383 daily for 3 weeks. Telephone supervision included monitoring for adverse events, but no feedback was offered.

Many other small trials have also tried to improve arm and hand motor control, using finger sensors for self-guided pinch movements and visual feedback,²³ joystick movements, pressure sensors attached to items, and virtual reality movements²⁴ in game environments that could be deployed at home. Modest postintervention gains were shown, usually equivalent to more conventional clinic-based therapies. Home-based functional electric stimulation to elicit functional movements and for strengthening and, recently, brain–computer interfaces for practice of upper extremity motor control can also be monitored remotely.

Several large international RCTs are in progress.^{25,26} A multicenter upper extremity telerehabilitation trial that uses instrumented game boards at home versus outpatient therapy is being conducted by the National Institutes of Neurological Diseases and Stroke's StrokeNet collaboration. The designs and outcomes of these and other trials should increase our understanding about the components that can better serve technology-based behavioral interventions.

Specific Needs of Trials Met by Technology

The National Institutes of Health StrokeNet Recovery and Rehabilitation Working Group recently described many of the unique challenges that rehabilitation trials face.²⁷ We think that telerehabilitation, along with combinations of mHealth apps, wearable sensors, and instrumented therapy devices, can address many of these challenges. The review included

the following problems: (1) payer rather than clinical needs often drive the amount of rehabilitation care, making delivery of physical and occupational therapy highly variable during a trial. Lack of therapy could have a confounding effect, for example, on a neural transplantation trial that did not specify and fund a lengthy course of rehabilitation; (2) rehabilitation trials have a time window for entry of days to months, which requires new recruitment strategies to find and retain subjects. Social, personal, and disability factors impact retention; (3) behavioral states change rapidly in the weeks after a stroke, which complicates trial designs; (4) rehabilitation research must better characterize the most important intersubject differences with respect to treatment responsiveness, and clinical trials need to incorporate such measures; (5) finally, better studies examining the psychometric characteristics of biomarkers of recovery are needed.

How might behavioral intervention technologies address these chronic problems? The delivery of physical and occupational therapy during the testing of a new pharmacological, biological, or any other intervention could be offered to the control and experimental groups using standardized training targeted to best motor learning principles but performed with wearable sensors and instrumented devices at home with a remotely managed phone or Web-based review of behavioral achievements once a week.^{3,28} One therapist could inexpensively manage 30 to 50 patients weekly in short but rich sessions that build on what has been accomplished since the last visit. Because they are at home, participants could practice several times a day, which is not feasible using clinic-based therapy, but may be more optimal to elicit training-induced neuroplasticity for motor learning. No less important, this strategy reduces the burden of travel and difficulties in arranging transportation to a clinic. That reduction in burden could also enable recruitment of persons who live far from a rehabilitation site and would not otherwise participate, as well as promote retention of participants through remote, but regular and frequent personal Web-based interactions. Social networking apps may also reinforce participation and encourage participation during a trial.

Some of the changes in behavioral states early after onset of stroke and during the course of a rehabilitation trial could be more accurately monitored remotely to identify unexpected variations. For example, participants might perform a weekly 10-m walk as fast as feasible in their home wearing bilateral ankle accelerometers for data transmission. This data may reveal different trajectories of recovery in walking speed or spatiotemporal features of gait. Other behavioral information might be gathered via smartphone-based self-assessment tools, like the so-called ecological momentary intervention apps that have been used for mental health and addiction studies to solicit and provide tailored information in real time.²⁹

The StrokeNet Group was also concerned about the management of intersubject differences. With the real-world data collected by wearable sensors and instrumented devices, trial designs and therapeutic strategies can be adjusted depending on rates of change; end points are collected frequently, so best outcomes are detected as they occur; and the continuous data points allow better statistical methods to impute or predict

measurements of recovery. In addition, drone-like observational ground truth about the type and amount of physically active conventional rehabilitation, as well as how much practice and exercise occurs in between formal therapies, could inform a pharmacological, cellular, robotic, noninvasive brain stimulation, or virtual reality intervention about differences among potential participants that affect treatment responsiveness. The continuous inertial and physiological responses to skills practice and exercise obtained by remote sensing could serve as unbiased, multidimensional metrics of recovery that contribute to the identification of biomarkers.

Thus, in-home technologies may markedly enrich the opportunities for new trial designs and solve festering confounders identified by the StrokeNet Working Group.

Barriers to Telerehabilitation With Sensing

The scientific evaluation of mHealth apps and devices poses several dilemmas. The field is highly innovative, quickly develops and often changes hardware and software, and has to adjust designs so that data can become integrated into health-record systems that are also in flux. Information about the reliability and efficacy of any app, device or telerehabilitation protocol, ease of use across ethnicities and socioeconomic status, acceptance for continued use, especially in less motivated persons than those selected for trials, and comparability between apps and devices is generally not available. Studies in those who have disabilities from a stroke are also complicated by cognitive (language, attention, hemineglect, hemianopsia, impaired recall, denial of impairment, depression, etc) and sensorimotor impairments. Such cognitive impairments usually make a patient ineligible for RCTs. They may also interfere with an individual's ability to use apps and sensors and incorporate feedback. Telerehabilitation trials, however, ought to try to include these disabled persons.

Because personalized therapy is a goal, how can the many types of individualized activities be monitored? A reasonably practical strategy is to obtain a template of the inertial signals from wearable sensors or instrumented devices during a clinic visit for the primary activities of interest that are meant to be practiced at home. In the home, participants would perform a set of those practice tasks in a specified order and number of repetitions. In usual outpatient therapy, a similar set of instructions or diagrams is often provided for home-based practice; with technology, the personal drone captures what is actually performed. At present, however, this strategy requires a home-grown solution by an engineer with signal processing expertise.

A related barrier is the dominance of sensor systems that work well for healthy persons but perhaps not for those who move slowly and awkwardly. Tool kits for healthcare applications are available from Google, Apple, Microsoft, and others, and sensors are becoming inexpensive, but one is hard pressed to find a ready-to-go system and platform that aims to capture hemiparetic gait during daily activities. Development and scaling up the access to tools and supportive services for research and patient care seems more complicated than commercial organizations usually undertake. Users will need, at a minimum, (1) consultation about what technology to apply

and what specific data to collect at particular frequencies and durations to answer research questions; (2) systems to monitor how effectively investigators and participants make use of sensors; (3) ongoing support of equipment, data analysis, and database management on a platform that can handle additional devices; (4) new algorithms and sensors for new applications; (5) updates for hardware and software; and (6) routinized methods to facilitate feedback using the behavioral intervention technologies.

The National Institutes of Health, the National Science Foundation, and collaborations within academic centers have been supporting these technological developments, but the strategy of individual grants for development, testing, and application of telerehabilitation with smartphone apps, wearable sensors, and in-home instrumented devices may fail if left to commercial entities to design and scale. The National Institutes of Health funds workshops (MHEALTH-TRAINING@LIST.NIH.GOV) and clinical trials that include sensors and internet connectivity, and offer guidance to point a home-grown system toward commercialization. The National Science Foundation funds engineering and computer science grants that tie signal processing data into other types of big data, and support the flow of available information (eg, SMARTHEALTH_COMMUNITY@LISTSERV.NSF.GOV). However, a deeper and broader level of national organization and support, more like what was performed to create and disseminate NeuroQOL (Quality of Life in Neurological Disorders) and PROMIS (Patient-Reported Outcome Measure Information System) measurement tools,³⁰ will be needed to develop, test, scale-up and maintain, grow, and continuously adapt tools for disabled persons.

The regulation of medical apps and sensors was recently addressed. The US Food and Drug Administration will focus on the risks associated with the interpretation of data collected and guidance offered, rather than opine about noninvasive technology per se. Their concern will be for any automatic decision making provided by software programs or errors in the data that may mislead patients and clinicians. Guidelines for institutional review boards,³¹ especially in relation to safety and privacy, as well as for reporting trials of mHealth apps and sensor technology are evolving.³²

Telehealth applications face other generic barriers for care that include reimbursement, possible degradation of the patient–clinician relationship, licensing across states, medical–legal liability, and difficult access by patients to telecommunications technologies because of socioeconomic and geographic factors.³³ An American Heart Association policy statement concluded that telehealth technologies should aim to increase access to care and meet criteria of safety, timeliness, effectiveness, efficiency, and be patient-centered and equitable.³⁴

Another barrier is the entrenched notion that every technology should be tested for discrete applications in a RCT for efficacy. Technologies are continuously being developed and optimized to be more facile, robust, interoperable, inexpensive, and user friendly. So perhaps, rather than testing strategic components one at a time, technologies that support theory-based training for specific goals could be combined in interchangeable ways as a rehabilitation internet-of-things.³ Technologies are tools to be exploited—friendly drones that

provide insight and directions to improve outcomes. So clinicians and researchers need to consider alternatives to individual tests of efficacy. (1) Is it the device or the way the behavioral intervention is delivered that matters? (2) Should we be asking how the technologies fit into existing systems of care or how existing systems of care and clinical trial designs can be altered to optimally take advantage of these technologies?¹ The latter alternative for each question seems to offer the best direction for the future of technology-assisted stroke rehabilitation.

Conclusions

Behavioral intervention technologies can become practical tools for stroke rehabilitation, but their development and application require more systematic, academic, and commercial support. If therapeutic interventions monitored by a figurative personal technology drone are theory-based for motor learning, then a variety of devices that supply reliable ground truth may offer similar benefits. Especially for the study of novel therapies for walking and the upper extremity, telerehabilitation and remote activity–sensing tools may add valuable monitoring, feedback, and outcome measurements; increase compliance and retention of participants; and augment skills practice and exercise to best modulate outcomes wherever disabled persons live.

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