Rehabilitación (Madr). 2011;45(3):192—193

REHABILITACIÓN

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EDITORIAL

Clinical research in neurologic rehabilitation for clinicians

Investigación clínica en rehabilitación neurológica para clínicos

It is easy to get caught up in the daily challenges of being a doctor. The time and potential demands of adding a clinical research project to daily tasks would seem like an additional burden. Clinical research, however, under the right circumstances, can refresh the thinking of clinicians and improve patient care.

What if a rehabilitation specialist in the community could participate in a multi-site clinical trial within the daily requirements of usual care? What if the goal was to compare two therapeutic interventions that were rather simple to provide, but could reveal whether one rehabilitation strategy was markedly superior to the other? What if the physician's obligation was limited to screening for subjects that came into the clinic for care, taking patients through informed consent, and entering information into a Web-based checklist in less than 20 minutes? Would you be tempted? Would your patients have additional respect for you, knowing that you were actively looking for better ways to help them? Can you see how participation in a randomized clinical trial might enrich your day by adding intellectual stimulation related to the trial, bring you back to the days of your academic environment, and give you a small but significant responsibility to your team of clinical researchers? How might academic rehabilitation specialists encourage involvement amongst clinicians who do not have extensive clinical trials experience and time to devote to studies?

Recruiting adequate numbers of participants to randomized clinical trials is one of the complex challenges for clinical research. Multi-center randomized clinical trials (RCTs) that are as inclusive as possible and draw upon sites that might not ordinarily have an opportunity to become involved in clinical research could improve recruitment to study both common and less frequent problems of impairment and disability. To try to solve this problem and engage colleagues around the world, we developed and completed the Stroke Inpatient Rehabilitation Reinforcement of Walking Speed (SIRROWS) RCT.[1] Simplicity of the research design for SIRROWS was imperative, because we conducted the study without funding and sophisticated protocols. Still, we were able to test the hypothesis that daily feedback to patients about walking speed, compared to no feedback, would lead to faster walking at discharge from inpatient stroke rehabilitation and possibly shorten the length of stay.

Establishing an international clinical trials network

An open invitation to join the international clinical trials network was emailed to all members of the World Federation for NeuroRehabilitation (WFNR) and the American Society of NeuroRehabilitation (ASNR) and advertised at national meetings and in the journal, Neurorehabilitation and Neural Repair. The coordinating center at the University of California Los Angeles (UCLA) received inquiries from 33 inpatient stroke rehabilitation programs in 23 countries outside of the U.S. and 14 in the U.S., suggesting pent up desire to participate in clinical research. The UCLA team engaged the site investigators by email to manage instructions and questions, as well as through a convenient study Web site and a quarterly electronic newsletter. The study results were remarkable. Eighteen sites obtained Institutional Review Board ethical approval and randomized 185 subjects from their units through the Internet in 15 months. The type and intensity of rehabilitation at the sites was left to each one. The hemiplegic patients who received simple feedback about their walking speed during a daily 10-m walk increased their walking speed by 23% at discharge and even more at follow up. The dropout rate was <10%. Nearly 75% of subjects were followed up at 1-3 months after discharge. The outcomes were better than almost any other type of therapy for walking in this period of rehabilitation, including Bobath and related programs, body weight-supported treadmill training, robotic-assisted walking, functional electrical stimulation, and strengthening and conditioning exercise interventions.

The results of SIRROWS can be put immediately into practice. Formal feedback about performance can improve outcomes.

We aimed to make the instructions, data acquisition, and management so easy that SIRROWS could be completed with integrity with only an electronic internet-based data entry

0048-7120/$ – see front matter
doi:10.1016/j.rh.2011.04.006

strategy and within the usual daily therapy plans of centers. In this first attempt at an RCT for colleagues, we did not anticipate being able to increase the complexity of feedback, define the type or amount of daily physical therapy or collect neuroimaging studies, quality of life scales, and other data that could be confounded by language, cultural differences, and demands on the time of the investigators. We also could not count on all sites to obtain outpatient measurements beyond the day of discharge, given likely differences in convenience of accessibility. But SIRROWS was successful enough to challenge the network to complete a more complex trial, the Stroke Inpatient Rehabilitation Reinforcement of ACTivity (SIRRACT) RCT, again within their usual practices. This time, small accelerometers worn on the ankles and mathematical algorithms will be able to determine the types, quantity, and aspects of the quality of walking and other exercises during inpatient care and early outpatient therapy. We will learn whether this expanded feedback can improve motivation and challenge patients to practice more and walk safer and faster.

Technology will ease participation

Web-based, neurorehabilitation multi-site RCTs with spare protocols can include sites from any place in the world, enabling a large number of investigators to contribute to the development of everyday, evidence-based practices, despite living in different health care cultures. This opportunity can increase the number of subjects available to trials, enrich the daily practices of participating clinicians, and increase the ability to generalize the results of studies across populations. If collaborative networks like SIRROWS and SIRRACT can enter large numbers of subjects over relatively short periods, they can also continuously test promising therapies for common and uncommon impairments and disabilities, develop dose-response curves prior to a phase 3 RCT, and gradually employ more complex interventions and outcome measurements. As the trials grow in sophistication, some funds will be needed for coordinators, therapists or medications, but the goal is not to reproduce the types of trials funded by federal grants.

Any regional or national group of clinicians can create a similar research collaboration. A few willing leaders can enable many willing colleagues to join, enjoy, and contribute.

Reference

1. Dobkin BH, Plummer-D'Amato P, Elashoff R, Lee J, SIRROWS Group. International randomized clinical trial, stroke inpatient rehabilitation with reinforcement of walking speed (SIRROWS), improves outcomes. Neurorehabil Neural Repair. 2010;24:235—42.

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