Large rehabilitation study looks at getting stroke patients back on their feet

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In the largest stroke rehabilitation study ever conducted in the United States, stroke patients who had physical therapy at home improved their ability to walk just as well as those who were treated in a training program that requires the use of a body-weight supported treadmill device followed by walking practice.

The study, funded by the National Institutes of Health, also found that patients continued to improve up to one year after stroke, defying conventional wisdom that recovery occurs early and tops out at six months. In fact, even patients who started rehabilitation as late as six months after stroke were able to improve their walking.

The results of the study will be published in the May 26, 2011 edition of the New England Journal of Medicine. NIH's National Institute of Neurological Disorders and Stroke (NINDS) provided primary funding for the study.

"More than 4 million stroke survivors experience difficulty walking. Rigorously comparing available physical therapy treatments is essential to determine which is best," said Walter Koroshetz, M.D., NINDS deputy director. "The results of this study show that the more expensive, high tech therapy was not superior to intensive home strength and balance training, but both were better than lower intensity physical therapy."

The walking program involves having a patient walk on a treadmill in a

harness that provides partial body weight support. This form of rehabilitation, which is known as locomotor training, has become increasingly popular. After the patients complete their training on the treadmill, they practice walking.

Previous studies suggested that these devices, also called commercial lifts or robot-assisted treadmill steppers, are an effective intervention in helping stroke patients walk. But this walking program had not been tested on a large scale or examined in terms of the most appropriate timing for therapy.

The investigators of the Locomotor Experience Applied Post-Stroke (LEAPS) trial set out to compare the effectiveness of the body-weight supported treadmill training with walking practice started at two different stages--two months post-stroke (early locomotor training) and six months post-stroke (late locomotor training). The locomotor training was also compared against an equivalent schedule of home exercise managed by a physical therapist, aimed at enhancing patients' flexibility, range of motion, strength and balance as a way to improve their walking. The primary measure was each group's improvement in walking at one year after the stroke.

The investigators had hypothesized that the body-weight supported treadmill and walking program, especially early locomotor training, would be superior to a home exercise program. However, they found that all groups did equally well, achieving similar gains in walking speed, motor recovery, balance, social participation and quality of life.

At the end of one year, 52 percent of all the study participants had made significant improvements in their ability to walk. The timing of the locomotor training program did not seem to matter. At one year, no differences were found in the proportion of patients who improved walking with the early or late treadmill training program, nor did the

severity of their stroke affect their ability to make progress by the end of the year.

The patients' measure of improvement was based on how well they were able to walk independently by the end of the study period. For example, severely impaired stroke patients were considered improved when they were able to walk around inside the house, whereas the patients who were already mobile at home were considered improved when they could progress to walking independently in the community.

All groups achieved similar gains in the speed and distance of their walking, their physical mobility, motor recovery and social participation, resulting in an improved quality of life.

Simultaneous with intensive therapies, all study participants received usual care, physical therapy consistent with current practice standards, which involved a variable number of sessions of about an hour each. The study found that both the locomotor training and the home physical therapy were superior to usual care. After six months, the patients who were assigned to usual therapy recovered only about half as much as the participants who received one of the two study therapy programs for three months. This finding suggests that either the treadmill training program or the at-home balance and strength training sessions are effective forms of physical therapy, and both are superior to usual care.

Despite reports that most improvement after stroke is complete by six months, the patients assigned to usual care for six months made significant improvements in walking speed after they entered the body-weight supported treadmill and walking program. The researchers said this suggests that recovery beyond six months can be enhanced by further therapy.

Individuals in the locomotor training groups were more likely to feel

faint and dizzy during the exercise, and those severely affected patients who received early locomotor training experienced more multiple falls. Fifty-seven percent of participants in the study experienced one fall, 34 percent had multiple falls and 6 percent had a fall resulting in injury. Falls are a common problem among stroke survivors, and the investigators say this study builds on evidence that additional research is needed to prevent falls.

The at-home strength and balance therapy group was the most likely to stick with the program; only 3 percent dropped out of this arm of the study, compared to 13 percent of the locomotor training groups. The authors noted that the home training programs were progressive, intensive, and repetitive, and were highly effective in improving functional status and levels of walking ability, and quality of life at one year post-stroke.

"We were pleased to see that stroke patients who had a home physical therapy exercise program improved just as well as those who did the locomotor training," said Pamela W. Duncan, Ph.D., principal investigator of LEAPS, and professor at Duke University School of Medicine in Durham, N.C. "The home physical therapy program is more convenient and pragmatic. Usual care should incorporate more intensive exercise programs that are easily accessible to patients to improve walking, function and quality of life."

The home exercise programs require less expensive equipment, less training for the therapists and fewer clinical staff members. The LEAPS authors suggest that this intervention may help keep stroke survivors active in their own homes and community environments.

More than 400 patients were randomly assigned into the three study groups and participated in 36 90-minute sessions over 12 to 16 weeks. They had either severe or moderate walking impairments. The average

age of the patients was 62 years. Fifty-four percent were men and 22 percent were African American. The trial took place at six inpatient rehabilitation centers in Florida and California.

More information: Duncan PW, Sullivan KJ, Behrman AL, Azen SP, Wu, SS, Nadeau SE, Dobkin BH, Rose DK, Tilson, JK, Cen S, Hayden SK "Body-Weight-Supported Treadmill Rehabilitation Program After Stroke." *New England Journal of Medicine*, May 26, 2011, Vol. 364;21, pp. 32-42.

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