DESCRIPTION OF STUDY:
Research design: LEAPS was a phase-III, single-blinded, multi-site (5 sites), randomized controlled rehabilitation trial that has prospectively followed 408 persons with stroke from 5-30 days to 1-year. Participants were stratified by moderate (0.4-<0.8m/s) or severe (<0.4m/s) walking impairment two months post-stroke and randomly assigned to one of three groups.
Primary outcome: The purpose of the LEAPS phase-III, single-blinded, randomized controlled trial is to compare two different individualized, therapeutic exercise programs provided by a physical therapist to improve walking after stroke: 1) a specialized locomotor training program (LTP) that included stepping on a treadmill with partial body weight support and overground training; and 2) progressive strength and balance exercises provided by a physical therapist in the patient's home (HEP).
Secondary outcomes: To determine if the timing of LTP delivery and severity of walking disability at stroke onset would affect walking speed at 1 year.

The trial was specifically designed to answer 3 clinical questions concerning physical therapy interventions for walking recovery after stroke:

1. At the end of 1 year post-stroke, is an intense, task-specific walking rehabilitation that includes a specialized locomotor training program more effective than progressive strength and balance exercises for improving walking speed and distance?
2. Does the timing (2 mos or 6 mos post-stroke) of the locomotor training program affect walking outcomes? How does severity (severe or moderate walking impairment) or timing post-stroke interact with the interventions to influence outcomes? For example, do individuals with severe stroke perform better if an intense walking rehabilitation program is provided later, at the 6 month time point, after stroke?
3. What is the optimal dose (12-, 24-, or 36-sessions) to achieve clinically meaningful changes in walking speed?
Multi-Site Phase III Randomized Trial of Physical Therapy Interventions To Improve Walking Recovery Post Stroke

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Centres for LEAPS Rehabilitation Center served as a recruitment site in collaboration with the LEAPS site at USC PT Associates, Los Angeles, CA

National Institute of Neurological Disorders and Stroke
National Center for Medical Rehabilitation Research
Defining the “black box” of rehabilitation

Define the content and process of rehabilitation interventions:

- Population
  - Stroke severity
  - Stroke acuity (time post-stroke)
  - Demographic and comorbid factors

- Intervention (independent variable)
  - Type of exercise intervention:
    - Resistive, power, endurance, task-specific
    - Dose

- Outcomes (dependent variables)
  - Primary; secondary

Horne et al., 2005
Duncan et al., 2002

LEAPS POPULATION:

**Inclusion Criteria**
- Age ≥ 18 years;
- Stroke within 45 days and living in the community at 2 months post stroke
- Residual paresis in the lower extremity;
- Ability to walk 10 feet with no more than 1-person assistance and self-selected 10 meter walking speed less than 0.8 m/s;
- Physician approval for participation
- Successfully pass an exercise tolerance test

**Exclusion Criteria**
- Dependent in ADLs prior to stroke
- Pre-existing neurological disorders
- Multiple co-morbidities that would be contraindications for exercise programs
- Inability travel to a treatment site
- Walking faster than .8m/sec

Horne et al., 2005
Duncan et al., 2002
LEAPS ACTUAL POPULATION:

Baseline demographics:
- 62±12.7 mean age
- 54.9% Male
- 22.1% Black or African American
- 83% Ischemic
- 99.5% Modified Rankin 2 – 4
- 63.8 days post-stroke at randomization

Baseline mobility:
- Mean Walking Speed – 0.38±0.22 m/sec
- 53.4% Severe impairment (< 0.4 m/sec)
- 46.6% Moderate impairment (0.4 - 0.8 m/sec)

LEAPS INTERVENTIONS:

Both interventions similar for:
1. duration (1-1/2 hr; 3xwk/12wks)
2. Structured (progressed, individualized, algorithm-guided)

Both interventions differed in intensity based on exercise type:

Locomotor training program (LTP)  Progressive exercise in home (HEP)
3 clinical questions concerning physical therapy interventions for walking recovery after stroke:

1. **TYPE:**
   - At the end of 1 year post-stroke, is an intense, task-specific walking rehabilitation that includes a specialized locomotor training program more effective than progressive strength and balance exercises for improving walking speed and distance?

2. **TIMING:**
   - Are walking outcomes at 1 year different if the walking training occurs early (2 mos) or later (6 mos) after stroke?

3. **SEVERITY:**
   - Do individuals with severe stroke perform better if an intense walking rehabilitation program is provided early or later, at the 6 month time point, after stroke?

4. **DOSE:**
   - What is the optimal dose (12-, 24-, or 36-sessions) to achieve clinically meaningful changes in walking speed?

Which **TYPE** of PT intervention is most effective?

**INTERVENTION TYPE:**

- Both **HEP & LTP provided between 2-6 mos post-stroke** were **equally effective at 1-year**.
- **HEP and LTP were both more effective than usual & customary care.**

**WHY?**

- **HEP therapeutic exercise addresses sensorimotor impairment** after hemiparetic stroke
- **LTP task-specific training and overground training** to addresses **walking-activity restriction**

NOTE: data will be presented at session
Does **TIMING** of PT intervention matter?

TIMING EFFECT -

*Timing matters.*
- HEP or LTP early
  - achieved walking gains sooner and sustained them at 1-yr
- LTP provided later was also effective
- **SIGNIFICANCE:** Recovery potential extends throughout 1-yr regardless of severity.

HOWEVER -

- **Usual & customary care not as effective as structured LTP & HEP programs**

**WHY?**
- High variability in # of PT visits
- High variability in treatments provided
- 30% received NO PT visits

**NOTE:** data will be presented at session

Does **SEVERITY** of stroke affect intervention outcomes?

**Severity matters.**
- People with more severe strokes make less improvement and have higher number of injurious falls.

**Severity and early LTP interact:**
- People with more severe strokes who received LTP early had greater falls.
- However, LTP later at 6-mos did not result in greater falls

**Significance:**
- People with high severity should receive a program that builds strength and balance capacity prior to starting a high intensity locomotor training program.

**NOTE:** data will be presented at session
Does **DOSE (number of treatments received matter)?**

**Dose matters.**
- People with more severe stroke need greater treatment sessions to achieve clinically meaningful gains.

**Dose, severity, and treatment type interact:**
- People with moderate stroke who receive LTP early made clinically meaningful gains by 24 sessions and sustained these gains at 1-yr

**Significance:**
- Interventions should be selected based on impairment severity; high intensity LTP provided early to moderately impaired is safe, effective, and results in functional improvement.

NOTE: data will be presented at session

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**HOPE AFTER STROKE**

**POTENTIAL FOR RECOVERY AFTER STROKE:**

- Challenge to conventional wisdom; intense task-specific programs and therapeutic exercise are both effective for different reasons
- Recovery extends through the 1st year after stroke
- LEAPS secondary analyses guide clinical practice.

32 yr old mother; after ischemic RCV

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HOPE AFTER STROKE

MESSAGE TO PHYSICAL THERAPISTS

• Value of structured and progressive exercise and task-specific programs after stroke
• Do not need expensive equipment
• Do need to apply principles of exercise (specificity & intensity)
• Manage health risks both the benefits of exercise (cardiovascular) and risks of mobility (falls)

How do we translate clinical research to practice?
KNOWLEDGE-TO-ACTION FRAMEWORK
Clinical assumptions drive our clinical decisions:

Clinical question:
Do our PT interventions contribute to improvements in participation?

Effective treatments:
IMPAIRMENT-focused?

ACTIVITY-focused?

Clinical assumptions drive our clinical decisions:

Clinical assumptions: AGREE or DISAGREE?

Should clinical measurements be selected to represent the ICF categories?

Should clinical measurements be selected based on psychometric properties?
  – Reliable, valid, sensitive to change, clinically meaningful
Clinical assumptions drive our clinical decisions:

Clinical Assumptions

- Neuromuscular impairments

  - Hyperreflexia
  - Weakness
  - Sensory loss

- Walking activity limitations

  - Walking endurance
  - Walking ability
  - Walking speed

Categories of ICF

- Participation
  - SIS ADL/ADL

Participant-Centered Outcomes

Principles ABLEMENT & DISABLEMENT:

MCA Stroke – damage to primary motor areas of the cortex that affect force production

MCA Stroke – primary motor neurons project to convergent and divergent motor neuron pools in the spinal cord

Sullivan & Cen, PTJ Dec 2011
What do the LEAPS findings tell us as clinicians?

**Build capacity** in the impairments that affect a functional skill through therapeutic exercise.

**Build capability** in performance of skills through task-specific training.

Principles of rehabilitation can be as "simple" or "difficult" as riding a bike.

It takes a village to complete a multi-site RCT
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Trevor Paris, MD

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Bettina Brutsch, PT
SITE MD: Mitchell Freed, MD

Thank-you!

….and to our participants with STROKE!