



**RESEARCH 101**  
AN INTRODUCTION TO RESEARCH FOR  
PEOPLE WITH SPINAL CORD INJURY

**Elizabeth Regan, DPT, PhD**



## AGENDA

- ❖ Introductions
- ❖ Research Process
- ❖ Types of Research in Spinal Cord Injury
- ❖ Advances from Research for People living with Spinal Cord Injury
- ❖ How can you get involved in research?
- ❖ Questions

# ABOUT ME



University of South Carolina



Department  
of Exercise  
Science



WHAT ARE YOU HOPING TO LEARN?



# RESEARCH PROCESS

USING INTERNET  
TO FIND INFO

ASKING A FRIEND  
QUESTIONS

TESTING A  
THOUGHT OR  
IDEA



READING A BOOK  
OR ARTICLE

TRIAL &  
ERROR

OBSERVING  
OTHERS

RESEARCH IS...

*A SYSTEMATIC INVESTIGATION DESIGNED TO  
DEVELOP OR ADD NEW KNOWLEDGE TO THE  
WORLD*

RESEARCH IS...

A **SYSTEMATIC INVESTIGATION** DESIGNED TO  
DEVELOP OR ADD NEW KNOWLEDGE TO THE  
WORLD



RESEARCH IS...

*A SYSTEMATIC INVESTIGATION DESIGNED TO  
DEVELOP OR ADD NEW KNOWLEDGE TO THE  
WORLD*

GOOD RESEARCH  
IS **NOT...**



Manipulating data to only show the portion that you want



Testing out a wild idea without knowledge of what has already been done and good planning



Ends justifying means



Easy



Cheap

### Restoration of Grasp and Reach in Cervical Spinal Cord Injury

[4UH3NS103863-02](#) [PECKHAM, PAUL HUNTER](#) CASE WESTERN RESERVE UNIVERSITY 2019 NINDS NINDS \$2,175,400 [View >](#)

### Mechanisms of Rhythmicity in the Spinal cord

[1ZIAN003022-12](#) [O'DONOVAN, MICHAEL](#) NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE 2018 NINDS NINDS \$1,806,033 [View >](#)

### Inter-System Closed-Loop Control of Locomotor and Bladder Function in Individuals with Acute Spinal Cord Injury

[1UH3NS116238-01](#) [ANGELI, CLAUDIA](#) [BOAKYE, MAXWELL](#) UNIVERSITY OF LOUISVILLE 2020 NINDS NINDS \$1,645,830 [View >](#)

### High-Resolution, Spinal Cord Stimulation for Non-Opioid Treatment of Neuropathic Pain

[1U44NS115111-01](#) [MCLAUGHLIN, BRYAN L](#) MICRO-LEADS, INC. 2019 NINDS NINDS \$1,579,371 [View >](#)

### Feasibility of the First Known Adaptive Intervention Delivering Innovative Exercise Program Optimized for People with SCI

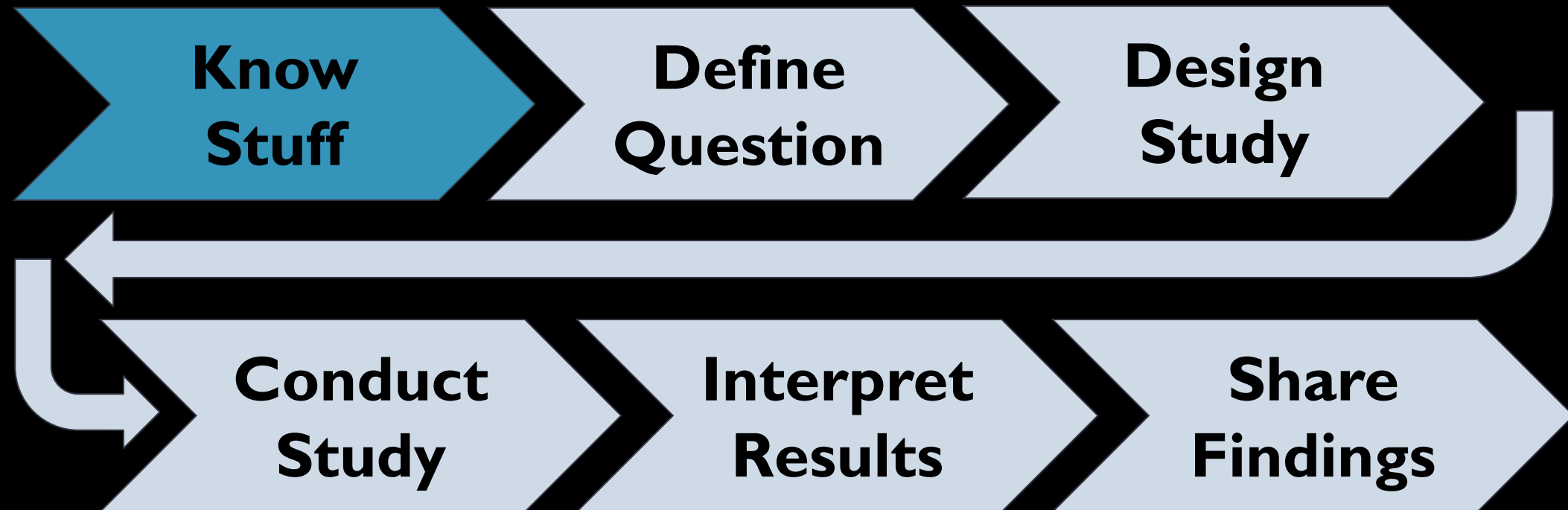
Craig H Neilsen Foundation

to Jereme Wilroy, James H Rimmer, Jereme Wilroy

Rationale: People with spinal cord injury (SCI) are more susceptible to adopting a sedentary lifestyle, which results in poor psychosocial and physical health outcomes. Current intervention strategies... [more](#)

200,000  
2021 - 2023

# THE RESEARCH PROCESS



Know  
Stuff

# Google Scholar

shoulder pain sp|



shoulder pain spinal cord injury



shoulder pain sports

shoulder pain spasticity

shoulder pain spadi

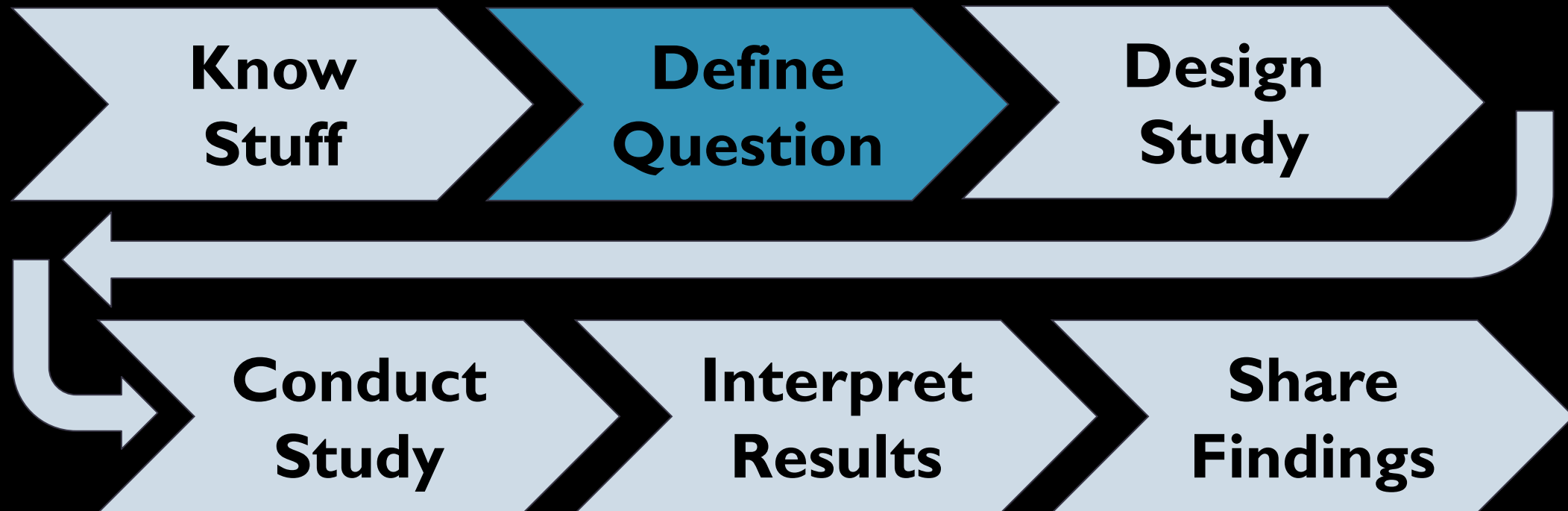
shoulder pain spinal manipulation

shoulder pain speed


shoulder pain spastic hemiplegia

shoulder pain spleen

# THE RESEARCH PROCESS



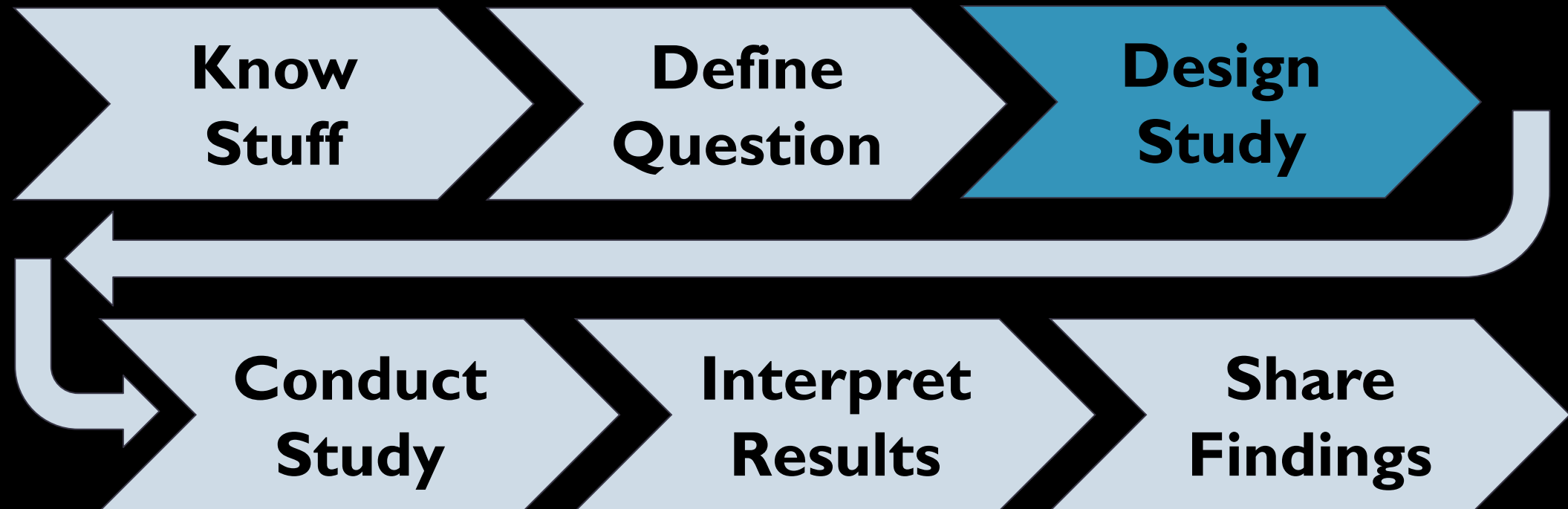
# THE RESEARCH PROCESS



## Define Question

- What is the relationship between grip strength and ability to transfer in people with SCI?
- Which wheelchair cushion is better at reducing pressure sores in people with SCI?
- How does regular exercise impact quality of life in people with SCI who are manual wheelchair users?

# THE RESEARCH PROCESS





# Design Study

QUANTITATIVE

DESCRIPTIVE

CORRELATIONAL

EXPERIMENTAL

QUALITATIVE

INTERVIEWS

DIRECT  
OBSERVATION

FOCUS GROUPS

# Design Study

QUANTITATIVE

DESCRIPTIVE

CORRELATIONAL

EXPERIMENTAL



DOES FES ROWING  
IMPROVE W/C  
PROPULSION SPEED?

# Design Study



WHAT IS THE EXPERIENCE OF PEOPLE WITH SCI WHO DO GROUP EXERCISE?

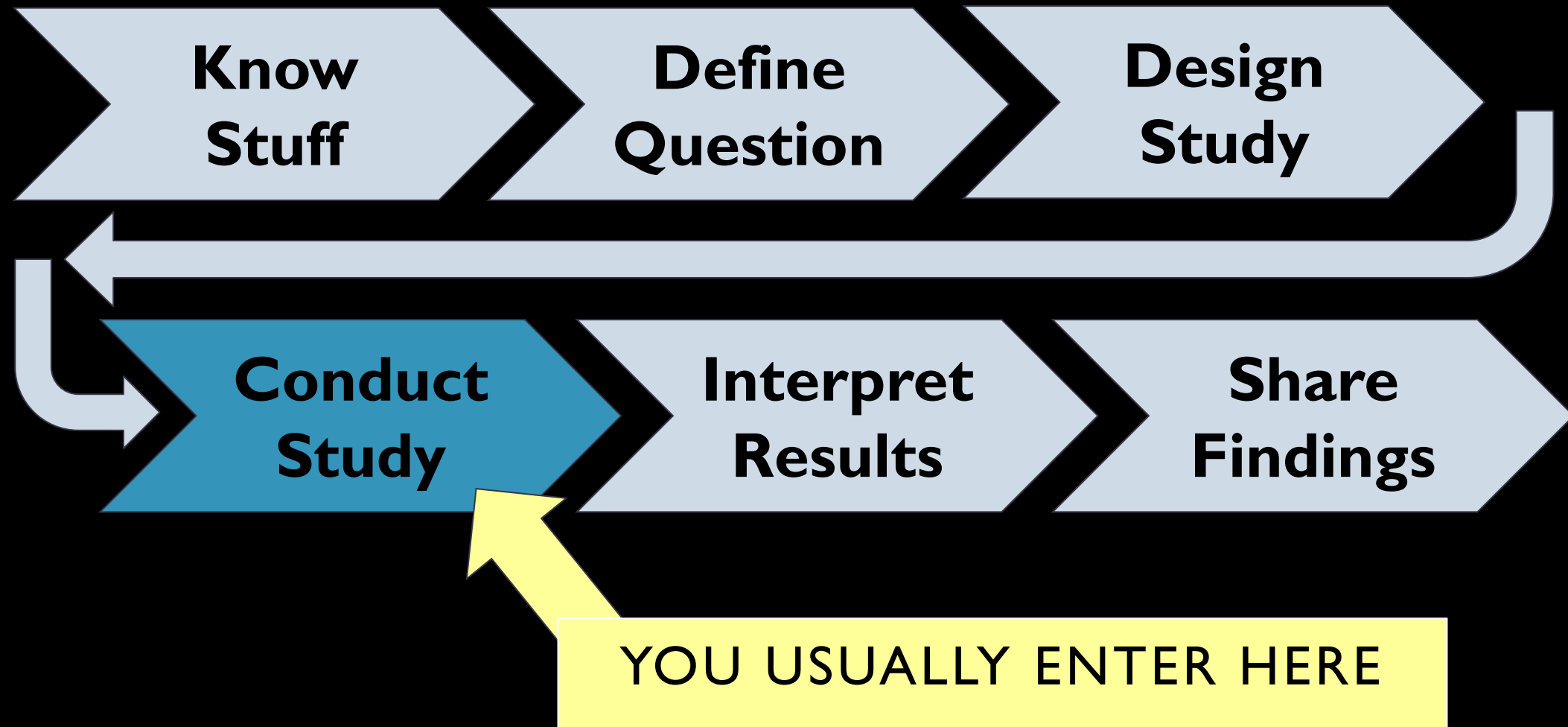
QUALITATIVE

INTERVIEWS

DIRECT  
OBSERVATION

FOCUS GROUPS

# THE RESEARCH PROCESS



## Conduct Study

# PROTECTING PARTICIPANTS

- **INSTITUTIONAL REVIEW BOARD (IRB)**
  - ❑ Protects rights and welfare of research participants
  - ❑ Approves, disapproves, monitors and asks for modifications to research plan



Source: [https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.paralympic.org%2Fnews%2Fusa-upset-australia-wheelchair-rugby-challenge&psig=AOvYaw2AGEBY79H2U1VWfc32K2rm&ust=1621697288086000&source=images&cd=vfe&ved=0CA0QjhxqFwoTCLCEp6yL2\\_ACFQAAAAAdAAAAABAj](https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.paralympic.org%2Fnews%2Fusa-upset-australia-wheelchair-rugby-challenge&psig=AOvYaw2AGEBY79H2U1VWfc32K2rm&ust=1621697288086000&source=images&cd=vfe&ved=0CA0QjhxqFwoTCLCEp6yL2_ACFQAAAAAdAAAAABAj)

## Conduct Study

# PROTECTING PARTICIPANTS

### Declaration of Helsinki

- ***The health of my patient will be my first consideration***

### Voluntary Informed Consent

- Know information about **the study requirements and risks**
- Knowing alternatives to study
- **Voluntarily** agreeing to participate
- Process for declining (before, during or after study)

### Vulnerable groups receive special protection

- Children
- Pregnant women
- Racial or ethnic minorities
- People in prison
- People with disabilities

# TUSKEGEE STUDY

## The New York Times

### Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER  
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

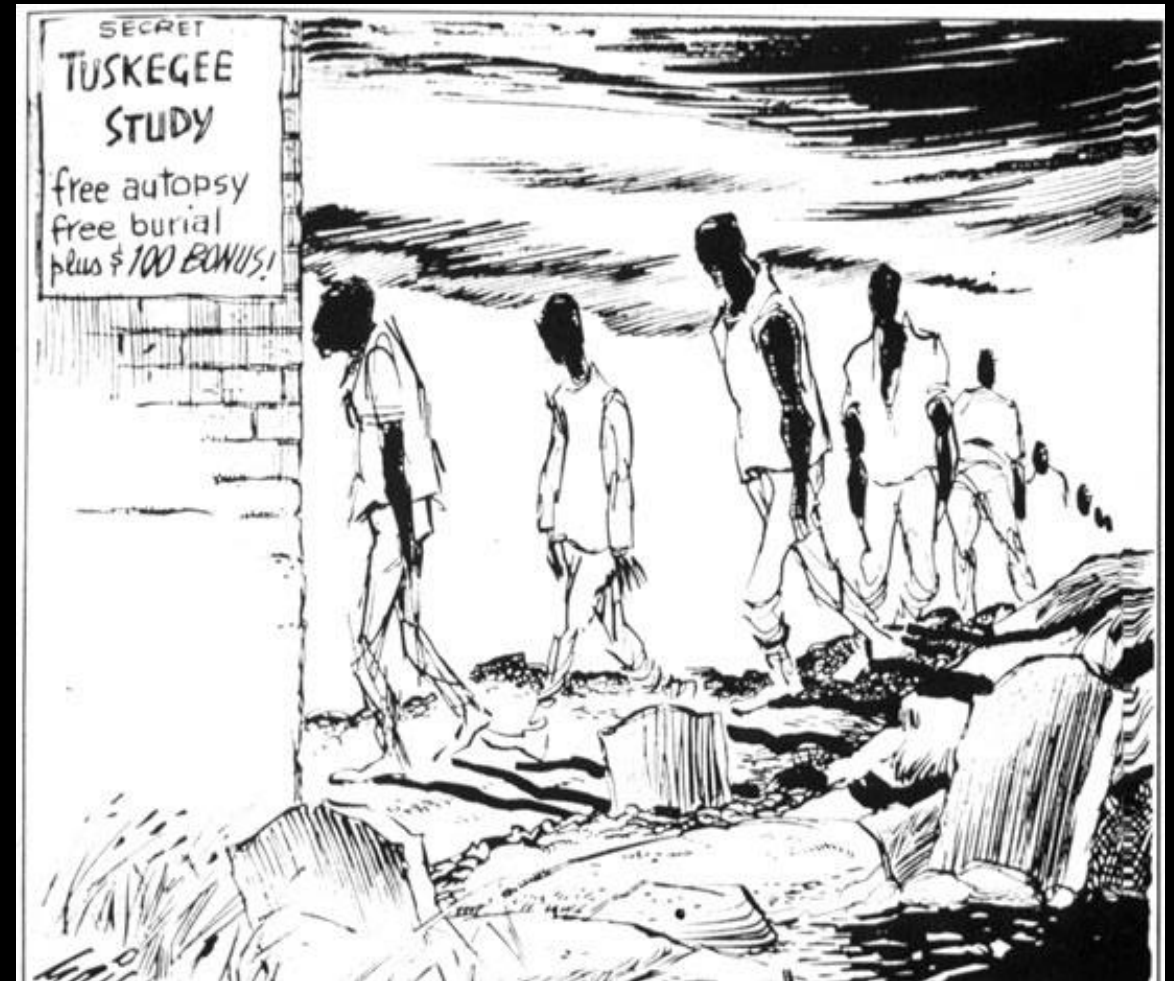
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,



# Conduct Study

# INFORMED CONSENT

UNIVERSITY OF SOUTH CAROLINA  
CONSENT TO BE A RESEARCH SUBJECT  
Cycling for Stroke

**KEY INFORMATION ABOUT THIS RESEARCH STUDY:**

You are invited to volunteer for a research study conducted by Reed Handlery. I am a doctoral candidate in the Department of Exercise Science, at the University of South Carolina. The University of South Carolina, Department of Exercise Science is sponsoring this research study. The purpose of this study is to examine the effects of a cycling program for people with stroke and care partners. You are being asked to participate in this study because you are an adult who has experienced a stroke or you are a care partner of someone with a stroke. This study is being done at a local YMCA in Irmo, SC, and will involve approximately 4 volunteers (two people with stroke and possibly two care partners)

This form explains what you will be asked to do, if you decide to participate in this study. Please read it carefully and feel free to ask questions before you make a decision about participating.

**Purpose of this Research Study**

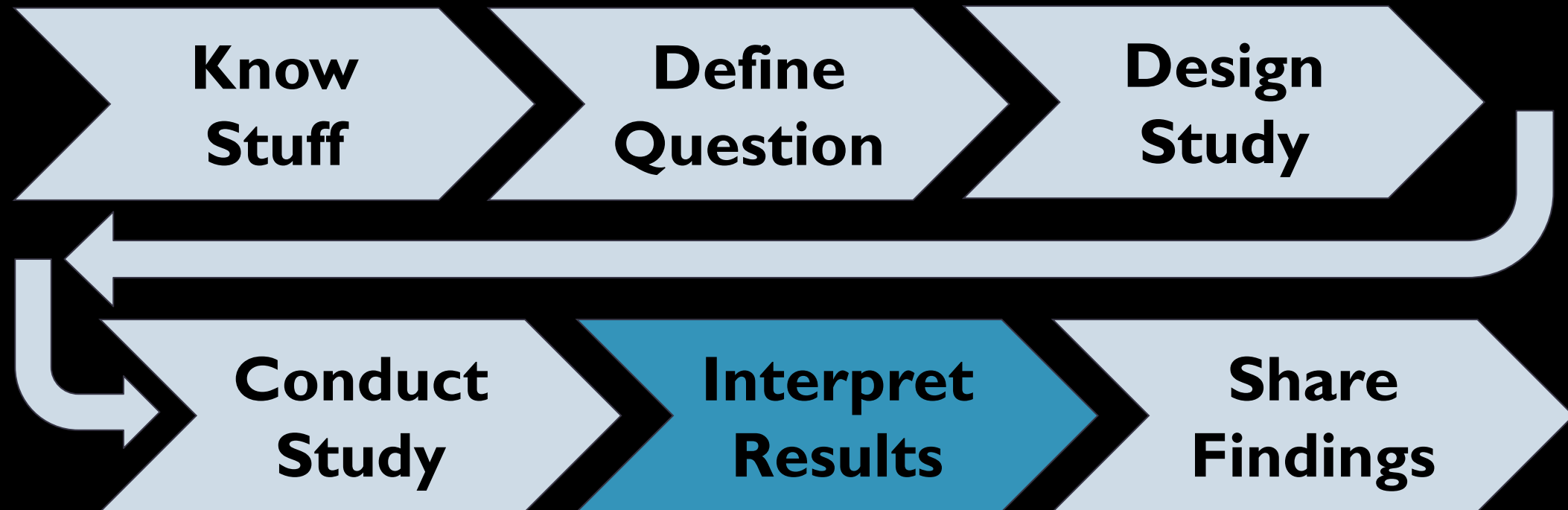
The purpose of this study is to examine the effects of a two week cycling program for people with stroke and their care partners. Results from this study may be used in a larger, longer study involving more volunteers. Prior to participating in the study you will be asked to perform several tasks including but not limited to walking, cycling and answering questions about your balance and physical activity level.

PRIOR TO STARTING A RESEARCH STUDY,  
PARTICIPANTS SHOULD HAVE ALL  
QUESTIONS ANSWERED AND PROVIDE  
INFORMED CONSENT  
(USUALLY IN WRITTEN FORM)

KNOW WHAT YOU'RE  
SIGNING  
AND ASK QUESTIONS



# THE RESEARCH PROCESS



# THE RESEARCH PROCESS



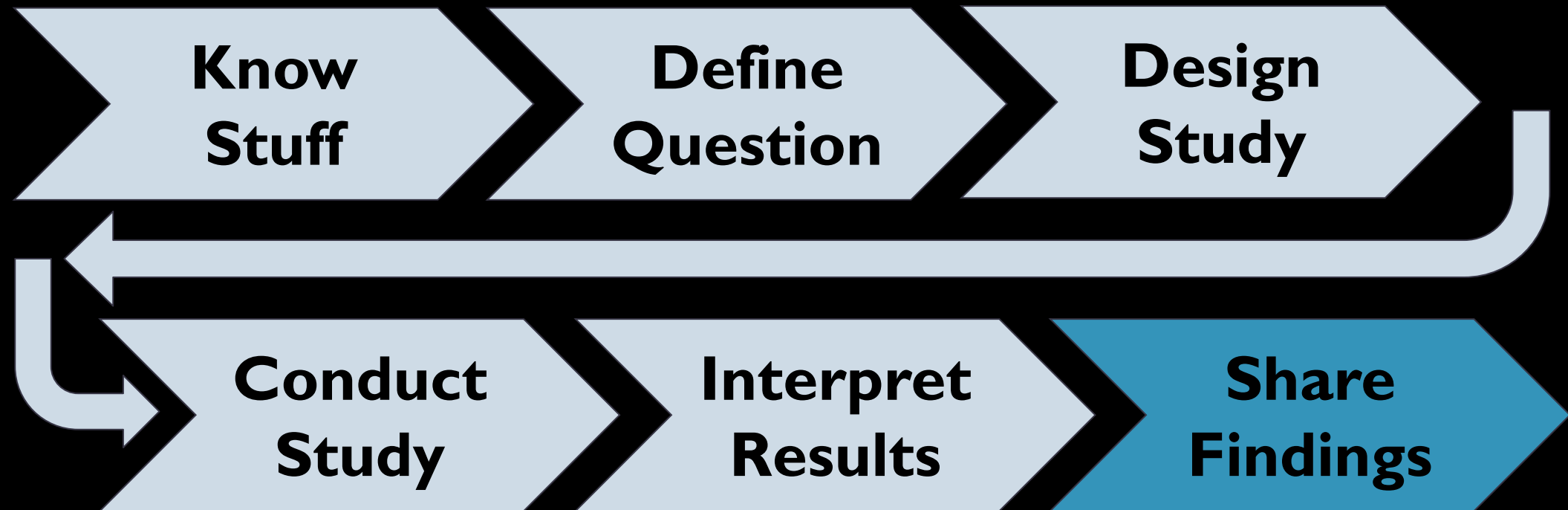
**Interpret  
Results**



Photo by [Clay Banks](#) on [Unsplash](#)

Photo by [Ruthson Zimmerman](#) on [Unsplash](#)

# THE RESEARCH PROCESS



# THE RESEARCH PROCESS

## Original Article

### Long-term exercise training in persons with spinal cord injury: effects on strength, arm ergometry performance and psychological well-being

AL Hicks\*<sup>1</sup>, KA Martin<sup>1</sup>, DS Ditor<sup>1</sup>, AE Latimer<sup>1</sup>, C Craven<sup>2</sup>, J Bugaresti<sup>2</sup> and N McCartney<sup>1</sup>

<sup>1</sup>Department of Kinesiology, McMaster University, Hamilton, Ontario, Canada; <sup>2</sup>Department of Medicine, McMaster University, Hamilton, Ontario, Canada

**Study design:** Randomized controlled trial of exercise training in persons with spinal cord injury.

**Objective:** The purpose of this study was to examine the effects of 9 months of twice-weekly exercise training on strength, arm ergometry performance, and indices of psychological well-being and quality of life.

**Setting:** Centre for Health Promotion and Rehabilitation, McMaster University, Hamilton, Ontario, Canada.

**Methods:** Thirty-four men and women (aged 19–65 years) with traumatic spinal cord injury (C4–L1; ASIA A–D) of 1–24 years duration volunteered to participate, and were randomized into exercise (EX;  $n=21$ ) and control (CON;  $n=13$ ) groups. Twenty-three subjects (11 EX; 12 CON) successfully completed the 9-month study. Subjects were assessed for one repetition maximum (1RM) strength, arm ergometry performance, and several indices of quality of life and psychological well-being at baseline, 3, 6, and 9 months.

**Results:** At baseline, there were no significant differences between groups in age, submaximal arm ergometry performance, muscle strength, or psychological well-being. Following training, the EX group had significant increases in submaximal arm ergometry power output (81%;  $P<0.05$ ), and significant increases in upper body muscle strength (19–34%;  $P<0.05$ ); no significant changes occurred in CON. Participants in EX reported significantly less pain, stress and depression after training, and scored higher than CON in indices of satisfaction with physical function, level of perceived health and overall quality of life ( $P<0.05$ ). Exercise adherence (per cent of prescribed sessions attended) in those subjects who completed the 9 months of training was 82.5%.

**Conclusions:** These results demonstrate that long-term twice-weekly exercise training in this population is feasible, and results in significant gains in both physical and psychological well-being.

*Spinal Cord* (2003) 41, 34–43. doi:10.1038/sj.sc.3101389

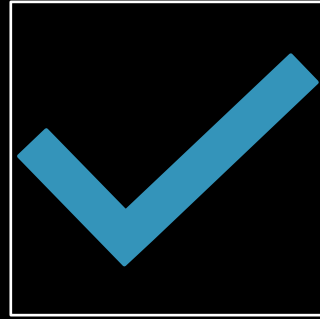


Share  
Findings

# RESEARCH PROCESS TAKEAWAYS



Good research is hard to  
do



Participation in research  
can be tough but rewarding



Ask questions at every  
stage

**WE WILL NEVER LEARN ANYTHING  
OF VALUE WITHOUT YOU**

A woman with a prosthetic left leg is seated in a wheelchair in a laboratory. A man in a lab coat is adjusting the prosthetic. The woman is wearing a dark blue long-sleeved shirt and a black headset. The man is wearing a yellow lab coat. The background shows laboratory equipment, including a blue device on a stand and a window with blinds. A black rectangular box with a white border is overlaid on the center of the image, containing the text "RESEARCH IN SPINAL CORD INJURY".

# RESEARCH IN SPINAL CORD INJURY

# TYPES OF SPINAL CORD INJURY RESEARCH

Neuroprotection

Neurorepair and Restoration

Neurorecovery and Rehabilitation

Health, Wellness and Quality of Life

Epidemiology



# TYPES OF RESEARCH: SPINAL CORD INJURY

## NEUROPROTECTION

- Prevent further cell damage immediately following SCI



## NEUROREPAIR & RESTORATION

- Bridging
- Cellular Replacement
- Cellular Regeneration





# TYPES OF RESEARCH: SPINAL CORD INJURY

## NEURORECOVERY & REHABILITATION



Epidural Stimulation

Supported Treadmill Training

Robotic Leg Braces

Functional Electrical Stimulation

Intensive Therapies

Myoelectric Limb Orthosis



# TYPES OF RESEARCH: SPINAL CORD INJURY

## HEALTH: SECONDARY COMPLICATIONS

Shoulder Injuries

Pressure Ulcers

Bowel/Bladder

Blood Clots

Pain

Mental Health



## WELLNESS, QUALITY OF LIFE

General Health

Nutrition Programs

Virtual/Telehealth

Performance Programs

Exercise Interventions

Physical Activity

# TYPES OF RESEARCH: SPINAL CORD INJURY

## DATABASES & EPIDEMIOLOGY

Patterns, Correlations, Trends  
Risk Factors  
Data Tracking  
Bioinformatics

### Age at Injury

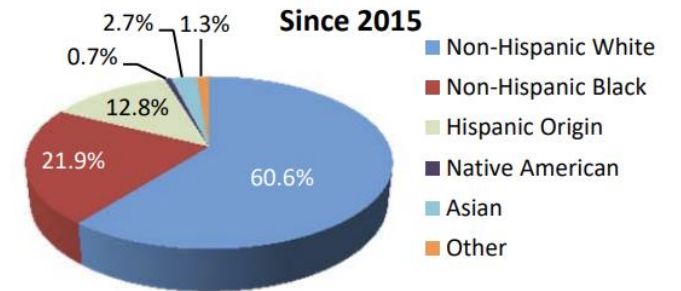
The average age at injury has increased from 29 years during the 1970s to 43 years currently.

### Gender

About 78% of new SCI cases are male.

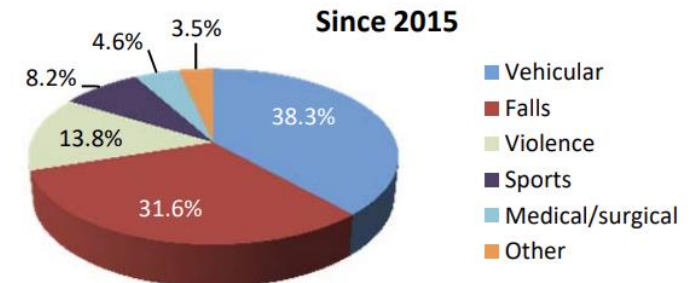
### Race/Ethnicity

About 22% of injuries have occurred among non-Hispanic blacks since 2015, which is higher than the proportion of non-Hispanic blacks in the general population (12%).



### Cause

Vehicle crashes are currently the leading cause of injury, closely followed by falls. Acts of violence (primarily gunshot wounds) and sports/recreation activities are also relatively common causes.



<https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%20-%202018.pdf>



# HOW HAS RESEARCH HELPED PEOPLE LIVING WITH SPINAL CORD INJURY

# PRESSURE ULCERS

## PREVENTION:

1. Comparison of regular mattress, speciality mattress
2. Common areas → Find Source
3. Pressure relief mechanisms
4. Nutrition

## TREATMENT:

1. Importance of nutrition (kCals & protein)
2. Wound Care
3. Surgical Interventions

## Comprehensive management of pressure ulcers in spinal cord injury: concepts and

Erwin A. Kruger

**Table 4**

Pressure ulcer common flap options by location

| Pressure Ulcer   | Common Flap                                                | Blood Supply                         |
|------------------|------------------------------------------------------------|--------------------------------------|
| Sacral Coccygeal | Gluteus maximus (rotation, sliding, muscle splitting flap) | Superior and inferior gluteal artery |
|                  | Superior gluteal artery perforator                         |                                      |
| Ischial          | Gluteus maximus (rotation)                                 | Superior and inferior gluteal artery |
|                  | Gracillis (tunneled or not)                                | Medial femoral circumflex artery     |
|                  | V-Y Hamstring advancement                                  | Profunda femoris perforators         |

**Table 1**

NPUAP-EPUAP Guidelines for Nutrition\*

Trochanteric

- Screen and assess nutritional status on admission and with change in condition/lack of progress toward ulcer closure
- Refer all individuals with a pressure ulcer to dietitian
- Provide sufficient calories (30–35 Kcal/kg)
- Provide adequate protein for positive nitrogen balance (1.25–1.5 grams protein/kg)
- Provide and encourage adequate daily fluid intake for hydration
- Provide adequate vitamins and minerals
- Offer vitamin and mineral supplements when dietary intake is poor or deficiencies are confirmed or suspected

\*NPUAP, National Pressure Ulcer Advisory Panel; EPUAP, European Pressure Ulcer Advisory Panel.

Source: Dorner *et al.* 2009.

# SECONDARY COMPLICATIONS

## Autonomic Dysreflexia

## Bladder Management

### *Scientific Review*

#### **Autonomic dysreflexia**

AK Karlsson<sup>\*1</sup>

<sup>1</sup>*Spinal Injuries Unit, Institution of Clinical Neuroscience, University of Göteborg, Sweden*

Autonomic dysreflexia (AD) may complicate spinal cord injured (SCI) subjects with a lesion level above the sixth thoracic level. There are several ways to remove triggering factors and, furthermore, new trigger mechanisms may be added by the introduction of new treatments. New data about the pathogenic mechanisms have been suggested in recent years as well as signs of metabolic effects associated with the reaction. This review of the syndrome includes clinical aspects of the AD reaction; the known pathogenic mechanisms, the incidence and prevalence and triggering factors. AD is associated with some cases of severe morbidity, including cerebral haemorrhage, seizures and pulmonary oedema. Symptomatic as well as specific treatments are discussed. Finally, some further questions are raised by the necessity of a proper definition of the syndrome, the revealing of the underlying pathophysiology, and new investigations concerning incidence and prevalence.

**Keywords:** autonomic dysreflexia; spinal cord injury; paraplegia; sympathetic nervous system

## **EFFECTS OF BLADDER DISTENSION ON AUTONOMIC MECHANISMS AFTER SPINAL CORD INJURIES**

L. GUTTMANN, D. WHITTERIDGE

*Brain*, Volume 70, Issue 4, December 1947, Pages 361–404,

<https://doi.org/10.1093/brain/70.4.361>

**Published:** 01 December 1947

# LOCOMOTOR (WALKING) TRAINING

Clinical Trial

> Spinal Cord. 2005 Nov;43(11):649-57. doi: 10.1038/sj.sc.3101774.

## Body weight supported treadmill training in acute spinal cord injury: impact on muscle and bone

> J Spi

**Loco  
inco**

L M Giangregorio <sup>1</sup>, A L Hicks, C E Webber, S M Phillips, B C Craven, J M Bugaresti, N McCartney

Review

Affiliations + expand

PMID: 15968302 DOI: 10.1038/sj.sc.3101774

Arun Ja

Mark Bishop, Glenn Walter, Andrea Behrman, Krista Vandendorne

Affiliations + expand

PMID: 18581666 PMCID: PMC2578797 DOI: 10.1080/10790268.2008.11760710

**Free PMC article**

Susan J Harkema <sup>1</sup>, Jessica Miller, Mary Schmitt-Read, Elizabeth Arguino, Sue Ann Gisto, Andrea L Behrman

Affiliations + expand

PMID: 22920456 DOI: 10.1016/j.apmr.2012.04.032

Case Re

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Kathleen J

Affiliations

PMID: 208

**Free article**

D S Ditor <sup>1</sup>, M J Macdonald, M V Kamath, J Bugaresti, M Adams, N McCartney, A L Hicks

Affiliations + expand

PMID: 15968298 DOI: 10.1038/sj.sc.3101785

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doi: 10.1

**Loco  
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PMID: 16398945 DOI: 10.1097/01.npt.0000282245.31158.09

The image features three stylized silhouettes of people with different types of disabilities. On the left, a person is shown in a wheelchair. In the center, a person is standing and using a yellow cane. On the right, a person is walking with the aid of a blue walker. A dark blue horizontal bar with a white border is positioned across the middle of the image, containing the text 'GETTING INVOLVED IN RESEARCH' in white, uppercase letters.

# GETTING INVOLVED IN RESEARCH



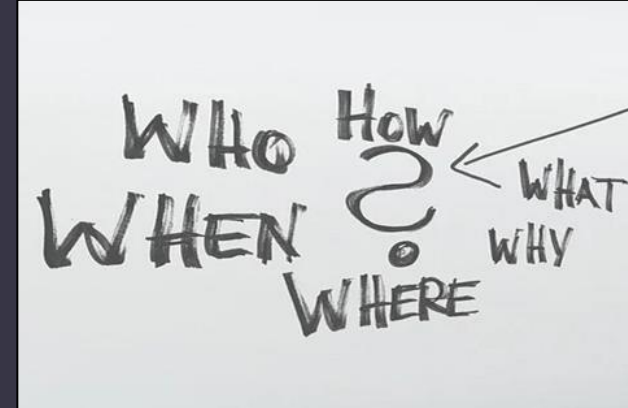
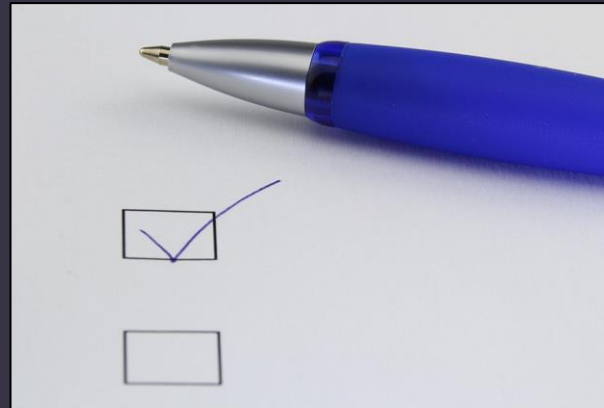
# WHAT IS THE PROCESS FOR YOU?

Reach out to  
Investigators

Screening for  
Qualification

Approved

Ask Questions!



**Informed  
Consent**

# WHAT IS THE PROCESS FOR YOU?

Begin the Study



Participate/Complete  
the Study



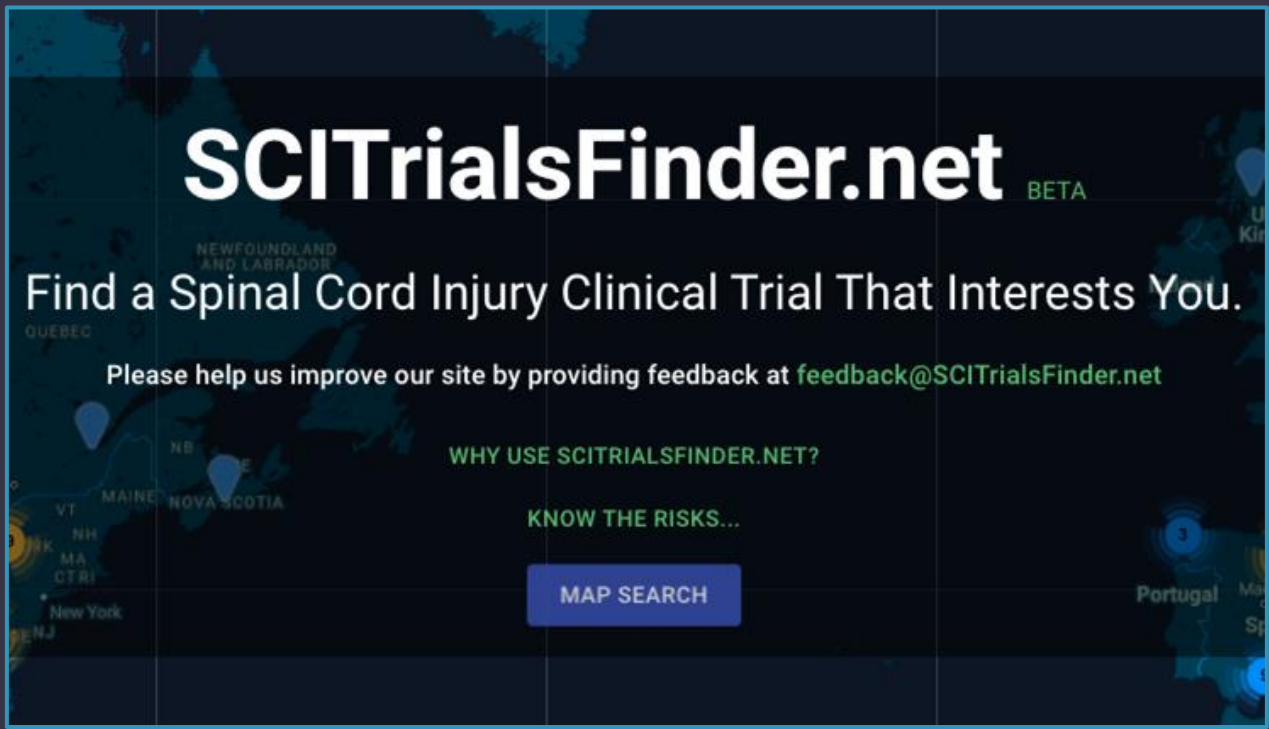
Receive Results



Contact List



GETTING INVOLVED



The screenshot shows the SCITrialsFinder.net website. At the top, it says "SCITrialsFinder.net BETA". Below that, the main heading is "Find a Spinal Cord Injury Clinical Trial That Interests You." There is a sub-heading: "Please help us improve our site by providing feedback at [feedback@SCITrialsFinder.net](mailto:feedback@SCITrialsFinder.net)". Below this, there are three links: "WHY USE SCITRIALSFINDER.NET?", "KNOW THE RISKS...", and a blue button labeled "MAP SEARCH". The background features a world map with various regions highlighted.

<https://scitrialsfinder.net/home>



The screenshot shows the researchmatch.org website. At the top, there is a navigation menu with links: "JOIN NOW", "ABOUT", "RESEARCHERS", "NETWORK", "TRIALS", "RESULTS", "CONTACT US", and "LOGIN". On the right, there is a link for "En Español". The main header features the "researchmatch.org" logo and a statistics section: "As of right now there are:" followed by five orange boxes containing the numbers: "volunteers 153,079", "researchers 9,886", "studies 967", "institutions 183", and "publications 509". There is also a link for "more metrics". Below the statistics is a banner image of a female doctor in blue scrubs talking to a male patient. To the right of the image is a blue box with white text: "A Researcher's most important discovery might be you!". Below the banner, there is a paragraph of text: "Medical discoveries are not possible without volunteers like **you**. Researchers need your help! Health research changes people's lives every day, but many studies end early because there are not enough volunteers. We help by matching you with research studies. Researchers need both healthy people and people with all types of conditions. Everyone can be the perfect research match!". At the bottom right of the banner area is an orange button labeled "Join Now". At the bottom of the page is the "researchmatch.org" logo.

<https://www.researchmatch.org/>

GETTING INVOLVED

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 376,981 research studies in all 50 states and in 220 countries.

See [listed clinical studies related to the coronavirus disease \(COVID-19\)](#)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

### Find a study (all fields optional)

#### Status ⓘ

- Recruiting and not yet recruiting studies  
 All studies

#### Condition or disease ⓘ (For example: breast cancer)

Spinal Cord Injuries X

#### Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

#### Country ⓘ

United States X

#### State ⓘ

X

#### City ⓘ

X

#### Distance ⓘ

X

Search

[Advanced Search](#)



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Referring a Patient

How to Search

Contact Us

### COVID-19 Research Studies

[View all current COVID-19 Studies at the NIH Clinical Center](#)

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[Participate in a study](#) ⓘ  
[Referring a Patient](#) ⓘ

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[Emailed Inquires/Requests](#)



#### Find NIH Clinical Center Trials

The National Institutes of Health (NIH) Clinical Center Search the Studies site is a registry of publicly supported clinical studies conducted mostly in Bethesda, MD.

Search Tip: Skip any items that are unknown or not applicable

Keyword:

Enter Diagnosis or Keyword ⓘ

Status:

Select One

Age Group:

- Child (birth -17)  
 Adult (18-65)  
 Senior (66+)

Sex:

Select One

Institute/Center:

All Institutes

Accepts Healthy Volunteers ⓘ

Search

Clear



[Browse by institute of the principal investigator](#)

<https://clinicaltrials.gov/>

<https://clinicalstudies.info.nih.gov/>

# WHAT CAN I DO TODAY?

[HTTPS://WWW.SHEPHERD.ORG/RESOURCES-HEALTHCARE-PROFESSIONALS/RESEARCH/SPINAL-CORD-INJURY/CURRENT](https://www.shepherd.org/resources/healthcare-professionals/research/spinal-cord-injury/current)



Shepherd Center

## - Project WOWii (Project Workout on Wheels Internet Intervention)

### About this Study

We are currently recruiting participants for a study called Project Workout on Wheels Internet Intervention (WOWii). Project WOWii examines how useful and effective an online format is for helping people with SCI get more exercise over four months. Eligible participants will meet over Zoom weekly for 16 weeks and work through weekly online modules to start and stick with an accessible and individualized exercise program. Participants will get to keep the provided exercise starter pack, and Garmin watch after study participation.

### Participation Eligibility

# SUMMARY

The research process is a standardized inquiry with various methods governed by institutional review boards to protect participants

IRB oversight and informed consent keep research safe and ethical

Research in spinal cord injury topics includes protection, repair, rehabilitation, health, wellness and trends over time

There are multiple ways to find research studies to get involved in. Closest major centers in Charleston, Jacksonville, FL, Atlanta, GA

[eregan@mailbox.sc.edu](mailto:eregan@mailbox.sc.edu)



**Questions?**