The UW Latin American TBI Project
NIH NS080648-01

Managing Severe TBI Without ICP Monitoring:
Guidelines Development And Testing

Prospective sequential parallel cohort study to investigate the influence of protocol initiation in general, and optimization of sTBI management protocols (in the absence of ICP monitoring) in particular, on outcome from severe traumatic brain injury
Uncle Llama wants YOU

IRB Protocol

Delphi-based consensus process

Input from site investigators

No Protocol

Input from “matched” outside clinicians

No Protocol

Data from Part 1

Data from BEST TRIP

Ad Hoc RCT Protocol
Influence of protocols in general

780 patients
¿BEST TRIP Kids?

BEST TRIP Trial

Benchmark Evidence from South American Trials:
Improving the diagnosis and treatment of mTBI in children and youth: the power of common data

Team members:
Michelle Keightley  Nick Reed  Kathryn Schneider
Debbie Friedman  Judith Marcoux  Charles Tator
Miriam Beauchamp  Jocelyn Gravel  Karen Barlow
Elise Mok  David Junker  Lucie Pelland
Lisa Grilli  Roger Zemek  Patrick Stroman
Katia Sirois  Martin Mrazik  Bonnie Swaine
Ryan Hung  Chand Taneja  Brad McFadyen
Karl Zabjek  Brian Christie  Phil Fait
Carol DeMatteo  Gerry Gioia  Alain Ptito
Sheila Singh  Tina Duhaime  Brian Brooks
What are **key accomplishments** in the past year?

- Choice of elements and measures
  - Combining our **2 sources** for data elements
  - Survey of our **investigators + clinicians**
  - Interviews with **children and youth**
  - **Systematic review** on measures used in published literature with this population
  - Consensus meeting Nov 20-21 2013 Montreal
    - Using ICF Core Set development methodology
    - Discussion and voting on domains, outcome measures and timing of assessment
Canadian peds CDE distribution according to the ICF model

Body Functions
- Consciousness
- Orientation
- Current post-concussion symptoms
- Energy Level-fatigue
- Motivation
- Impulse control
- Sleep Problems
- Thought Processing
- Attention
- Memory
- Working Memory
- Emotion
- Executive Function
- Seeing function (acuity, diplopia, blurred vision)
- Oculomotor function
- Light sensitivity
- Neck proprioception
- Vestibular function
- Dizziness
- Headache
- Neck Pain
- Exercise Tolerance
- Neck mobility
- Muscle strength-grip
- Muscle strength-global
- Coordination
- Advanced Motor Function
- Gait pattern
- Reaction Time
- Autonomic function
- Nausea
- General Intelligence

Body Structure
- brain structure and pathophysiology
  - Skull Structure
  - Neck Structure

Activities and Participation
- Health Condition
  - mTBI/Concussion
- Injury Information
  - Date of Injury
  - Time of Injury
  - Loss of consciousness
  - Post traumatic amnesia (anterograde, retrograde)
  - Seizure
  - Initial symptoms at time of injury
  - Cause of injury
  - Location of injury on body (all body parts)
  - Initial services received
  - Protective devices used

Activities
- Multiple tasks
- Handling stress
- Static Balance
- Driving human powered transportation
- Driving motorized vehicles
- Interpersonal relationships
- Social cognition
- Academic performance
- Work performance
- Recreation and Leisure
- Sport participation and performance
- Quality of life

Personal Factors
- Sex
- DOB (age at injury)
- Previous concussion and recovery history
- History of headaches/migraine
- History of learning disabilities
- History of ADHD
- History of Developmental Disorders
- History of anxiety/depression
- History of Sleep problems
- History of sports participation
- History of academic functioning
- Other comorbidities
- Primary language-current language
- Socio-economic status
- Dominance-foot
- Dominance-hand
- Height
- Weight
- BMI
- BP
- Resting Heart Rate
- Compliance to treatment

Environmenta l factors
- Medication
- Light environment
- Drugs and alcohol
- Sound Environment
- Family Situation
- Friends
- Health professionals
- Health Services/providers
- Education Services/providers
- Work services/providers
- Sport-leisure services/providers
What are the major challenges or issues, if any?

- Agreement on outcome measures
  - Looking for sensitive measures for our population

- Choosing a Platform
  - Choice of REDCap for feasibility study
    - Ease of use, secure
    - Live data collection with checks in place
    - Ability to federate with other International Initiative for TBI Research (IntBIR) projects to pool and share data

- Align with existing data dictionaries
  - Other Canadian funded studies
  - International initiatives

- Organizing feasibility study
  - Clinical/research setup
What percentage of your data is comprised of the International TBI Common Data Elements and what percentage are unique data elements?

- Core: All aligned except race/ethnicity

- Basic: All aligned except imaging details (we collect imaging information passively); family ethnicity;

- Supplemental: not clear yet since we are yet to finalize a few of the outcome measures