

# **Remotely-Supervised (RS) tDCS: Providing Standardized, “At-home” Treatment for Clinical Trials**

**Leigh Charvet PhD**

**NYU School of Medicine**

**NYU Langone MS Comprehensive Care Center**

# Large-scale studies are needed

- Faster recruitment of larger sample sizes
  - Adequate power
    - Individual differences in treatment response
- Extended treatment time
  - Cumulative effect of stimulation
  - Optimal number of sessions for lasting benefit
  - Pairing with rehabilitation

# Remote delivery to expand tDCS trial designs

- tDCS safe and transportable – ideal for access away from clinic
- Most patients cannot repeatedly travel to clinic for consecutive treatments
  - Work and family responsibilities
  - Caregiver burden
  - Limited accessible transportation
  - tDCS clinic may be far away
  - Costs for travel, lost wages
- Those with greatest obstacles may be the most important to study

# Maintaining trial standards through real-time supervision

- Consensus guidelines\*:
  - Training
    - Research staff, participants/caregivers
  - Initial and ongoing assessment of participant's capability
  - Supportive training procedures and materials
  - Simple and fail-safe electrode preparation and positioning
  - Strict dose control for each session
  - Ongoing monitoring
    - Compliance, adverse effects
- Self-directed use is not advisable
  - Safety concerns
  - Results are not consistent or reproducible
  - Need objective measurement of treatment effect

\*Charvet, Kasschau, Datta, Knotkova, Stevens, Alonzo, Loo, Krull, Bikson. [Remotely-supervised transcranial direct current stimulation \(tDCS\) for clinical trials: guidelines for technology and protocols.](#)  
Frontiers in Systems Neuroscience, March 2015



# Remotely-supervised (“RS”) protocol\* to pair with telerehabilitation

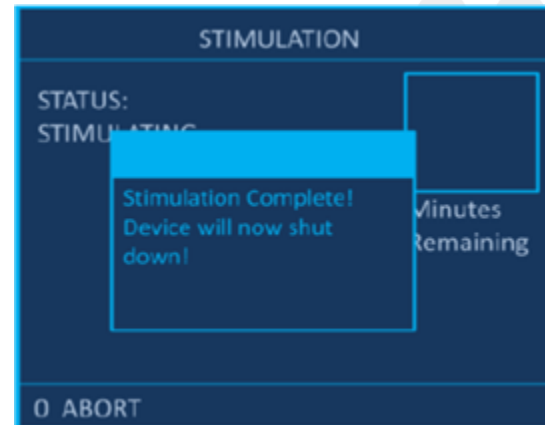
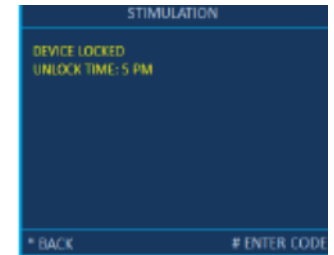
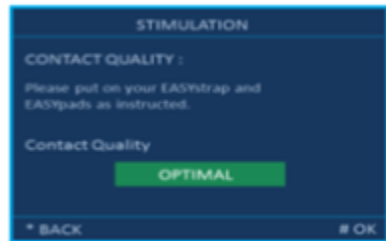
- Cognitive remediation in adults living with multiple sclerosis (MS)
  - Based on trial experience with at-home cognitive training (n=135)
  - Met strong demand, rapid recruitment, high compliance
  - tDCS may enhance or potentiate benefit
  - tDCS may also ameliorate other frequent MS symptoms (mood, fatigue, motor, pain)
- Developed in collaboration with Drs. Marom Bikson (CCNY) and Abhishek Datta (Soterix) and their teams

\*Kasschau, M., Sherman, K., Haider, L., Frontario, A., Shaw, M., Datta, A., Bikson, M., Charvet, L. [\*A Protocol for the Use of Remotely-Supervised Transcranial Direct Current Stimulation \(tDCS\) in Multiple Sclerosis \(MS\)\*](#). J. Vis. Exp.(106), e53542, doi:10.3791/53542 (2015).

# RS-tDCS Approach: 1.) Device (Soterix Mini-CT)

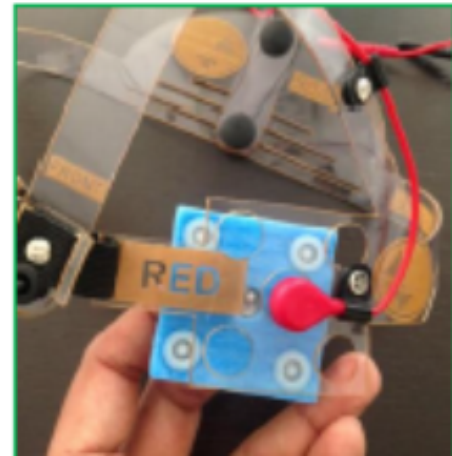
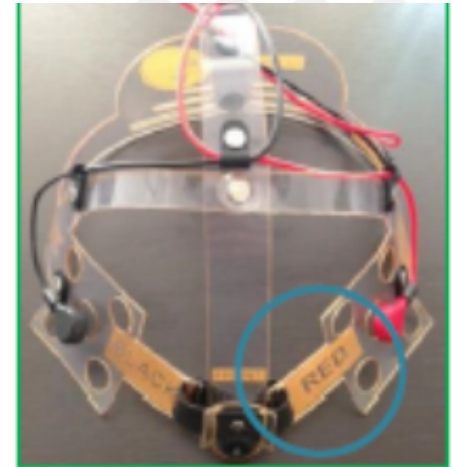
- Pre-programmed devices
  - Single-use “unlock code” for predetermined “dose”
  - Program session type (active or sham), stimulation time and dose
  - Generates a series of one-time use activation codes
- Design
  - Large number pad, simple interface
  - Now rechargeable- avoids sending home batteries
  - “Abort” and “pause” options for additional safety
  - Records session completion information
- Governance through videoconferencing
  - Visual confirmation and safety checklist completed by study technician before code is given to participant
  - Impedance must be no more than moderate in order for code to work
  - Correct headset/electrode placement

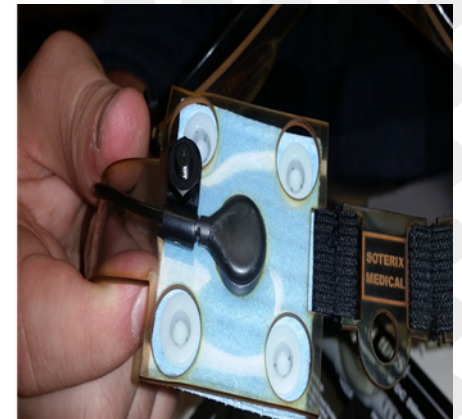
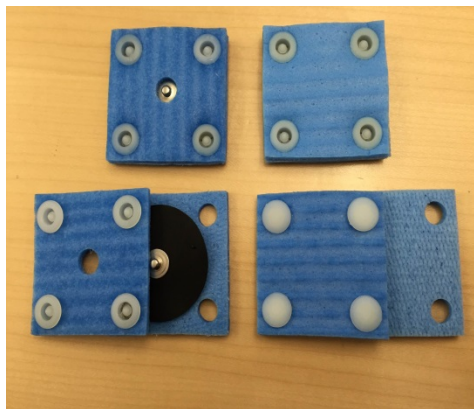
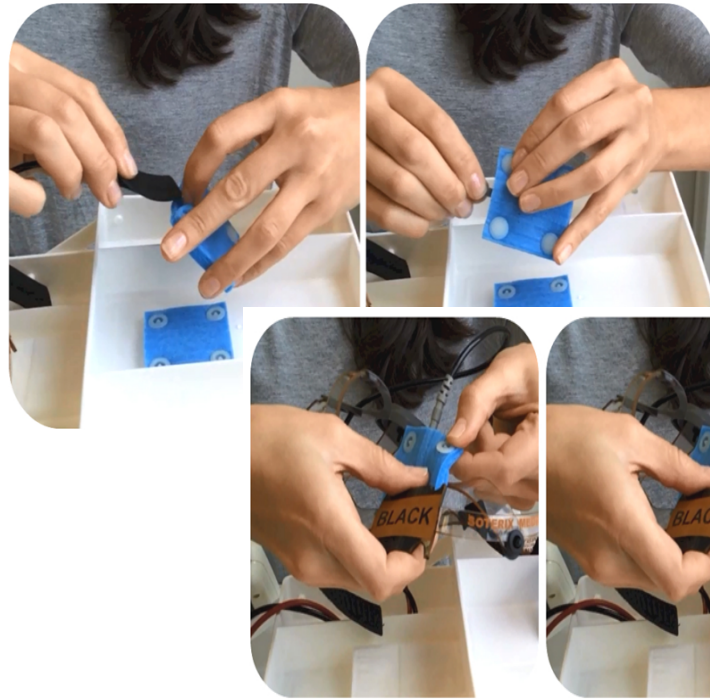
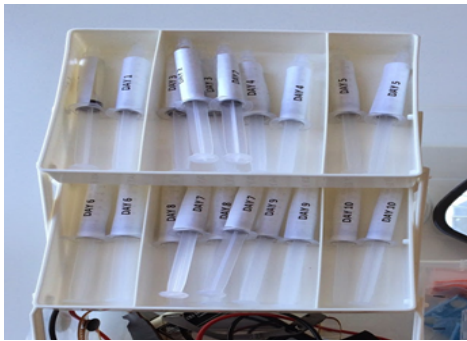




## RS-tDCS Approach: 2) Headset

- “Cap”-like placement for simple positioning
  - Markers for guidance in placement
- Elasticized headband
- Uniform electrode placement
  - Fixed electrode positions with self-load
  - Clear electrode polarity labeling (fixed wiring)
- Easy electrode preparation
  - Individually-packaged pre-moistened sponges
    - Perforated for easy opening
  - Snap connectors (vs. button tabs)

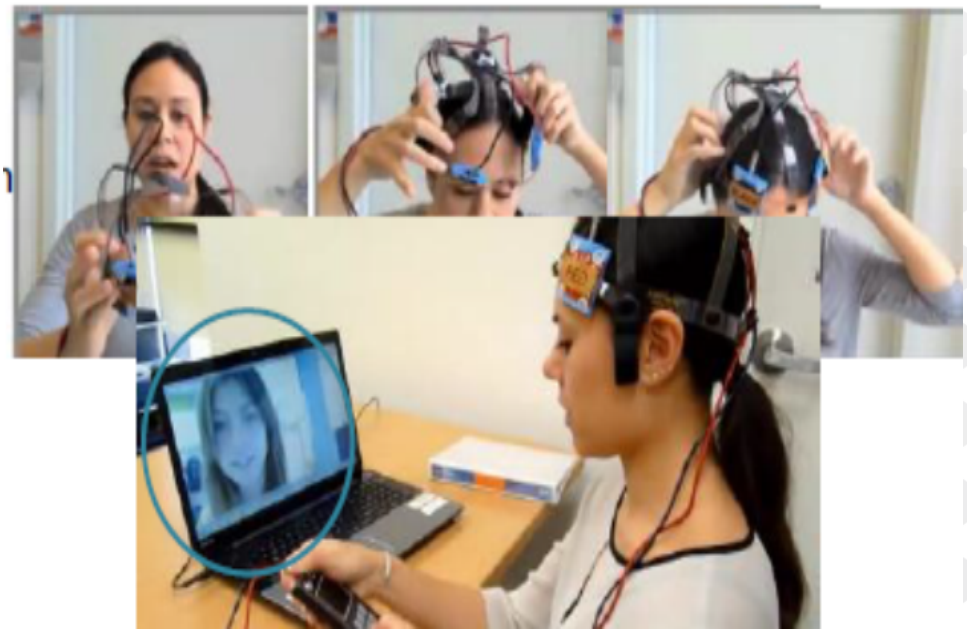
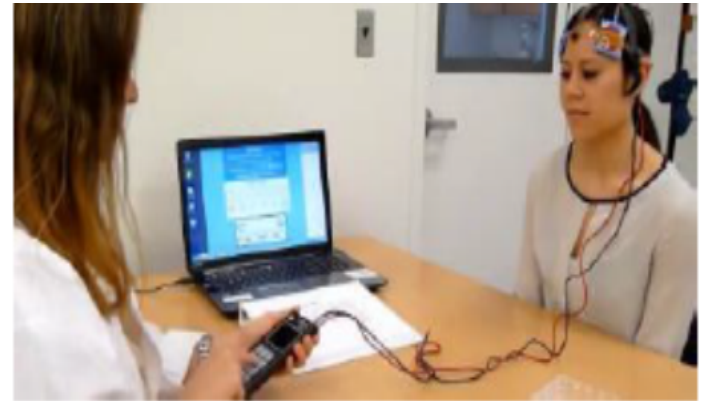




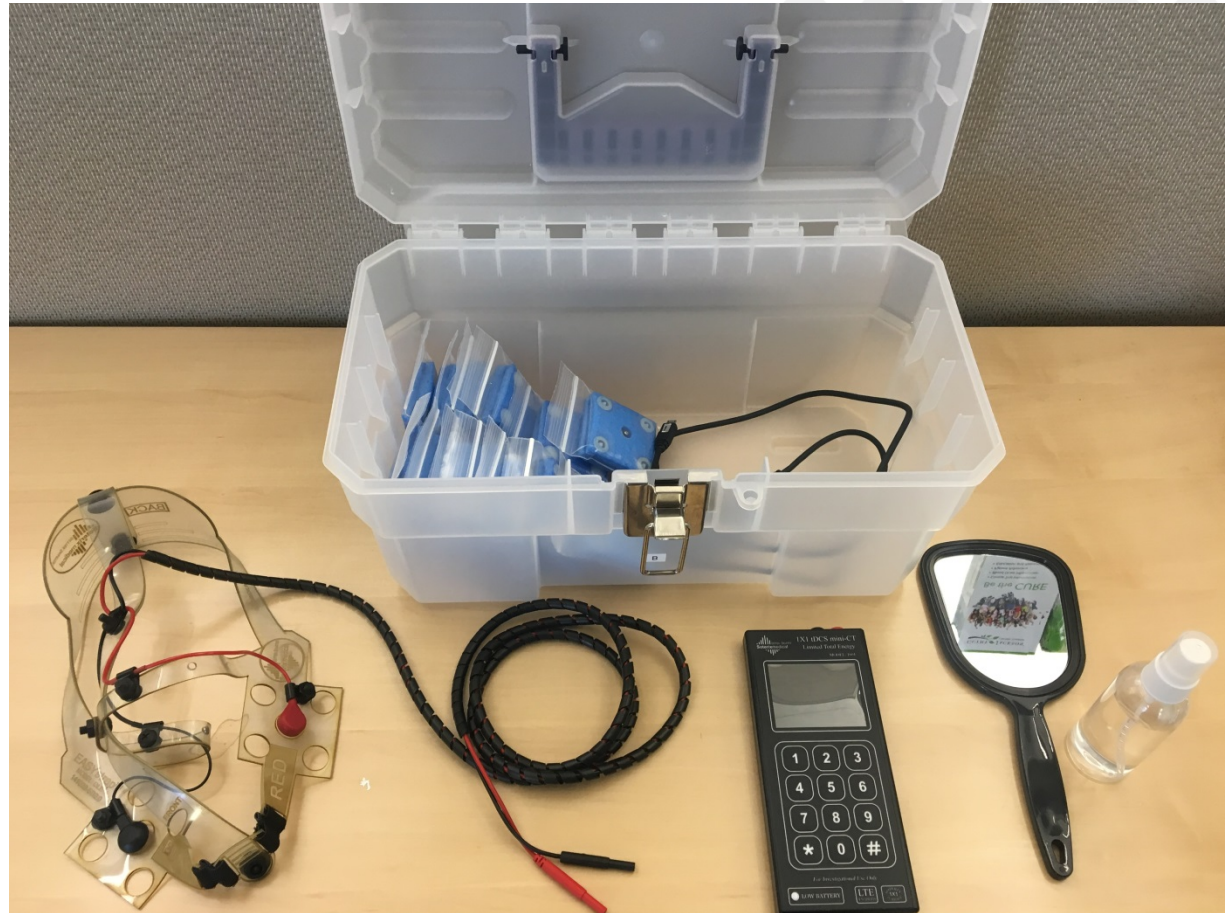
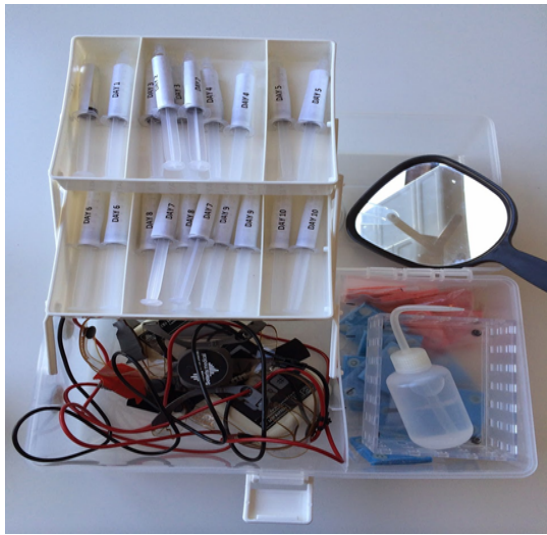


## RS-tDCS Approach: 3) Computer

- Low-cost laptop computers
  - Large screens
  - Adaptive mouse (if needed)
  - Background rating scales
- Connected in real-time
  - VSee
    - HIPAA-compliant
    - Low-bandwidth
    - Cell-phone backup
- Remote control of computer
  - TeamViewer
- Minimum technical requirements
  - Connect to Wi-Fi
  - Open computer
- Cognitive training and assessment

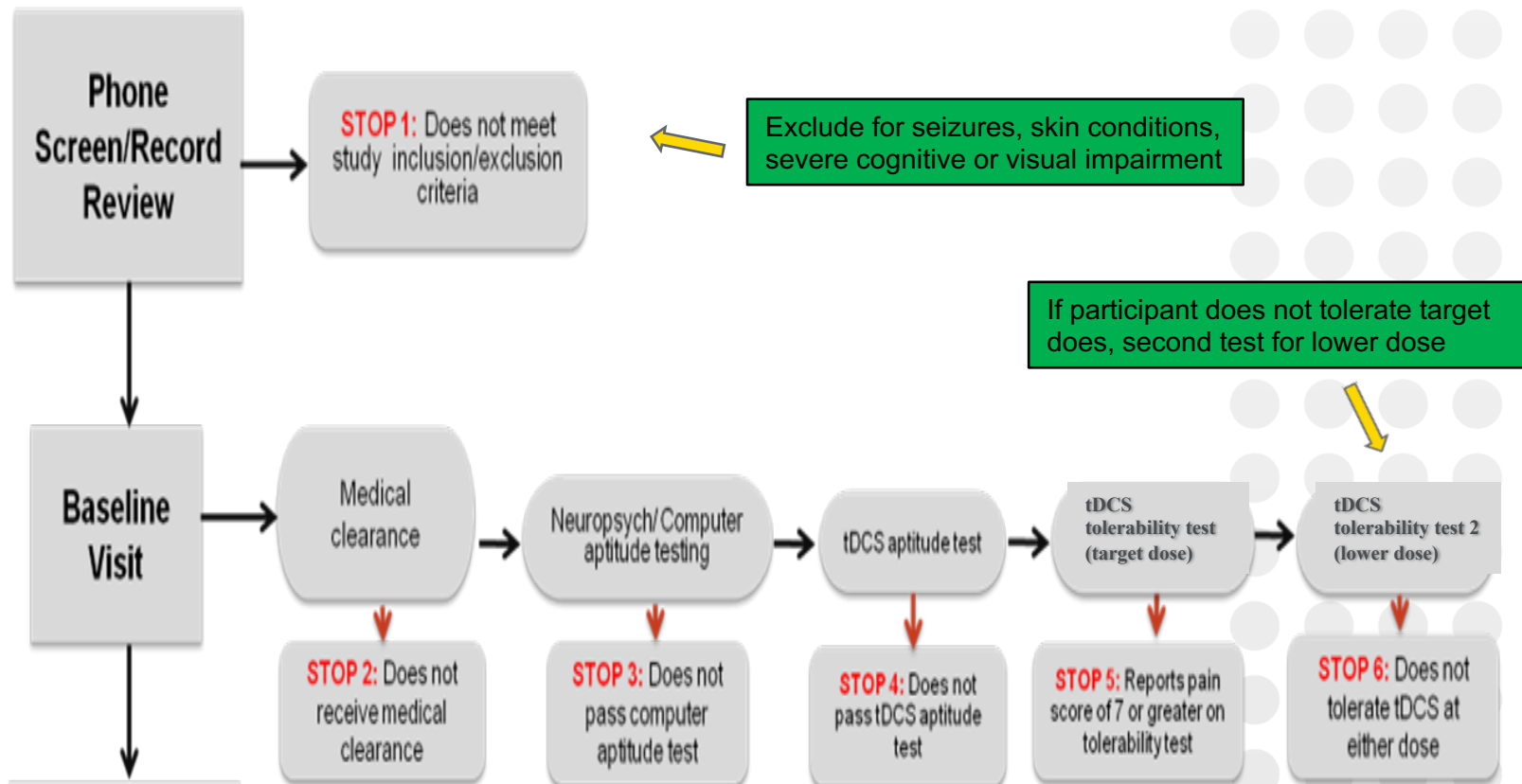






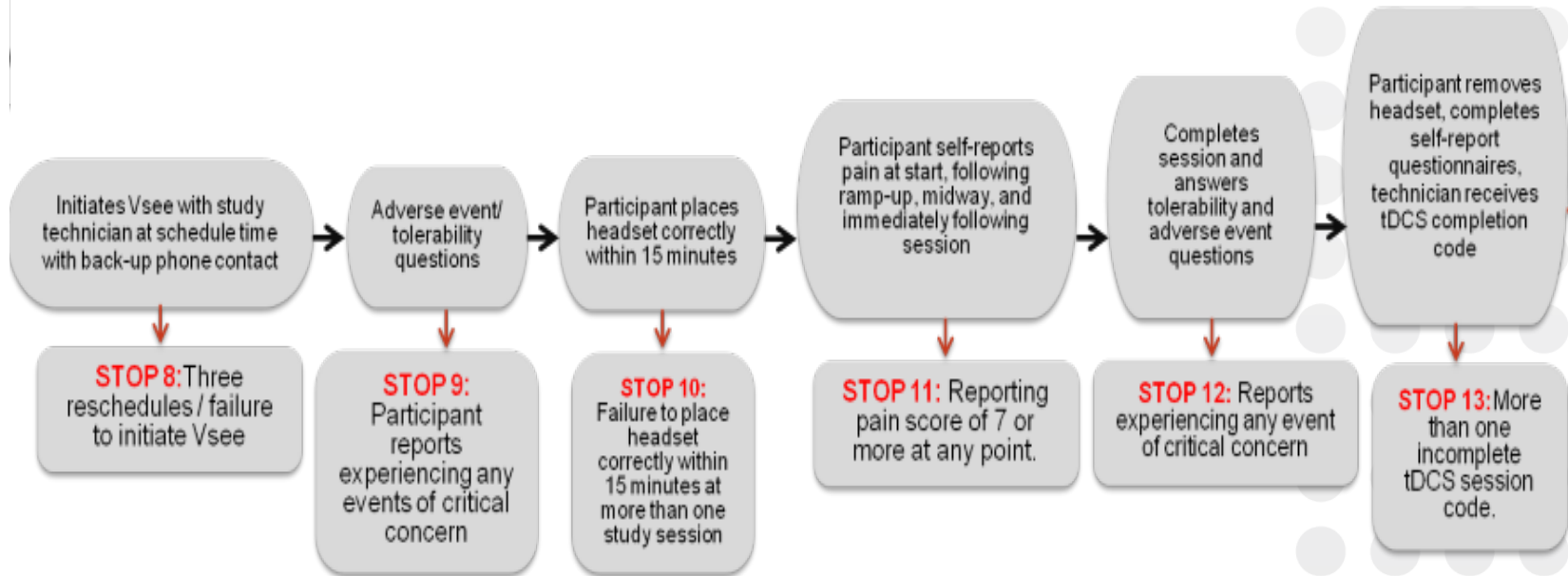
# Procedures- Screening and Baseline

- Aptitude (computer and tDCS)
- tDCS tolerability test (60 second ramp up/down)
- Device training for at-home use

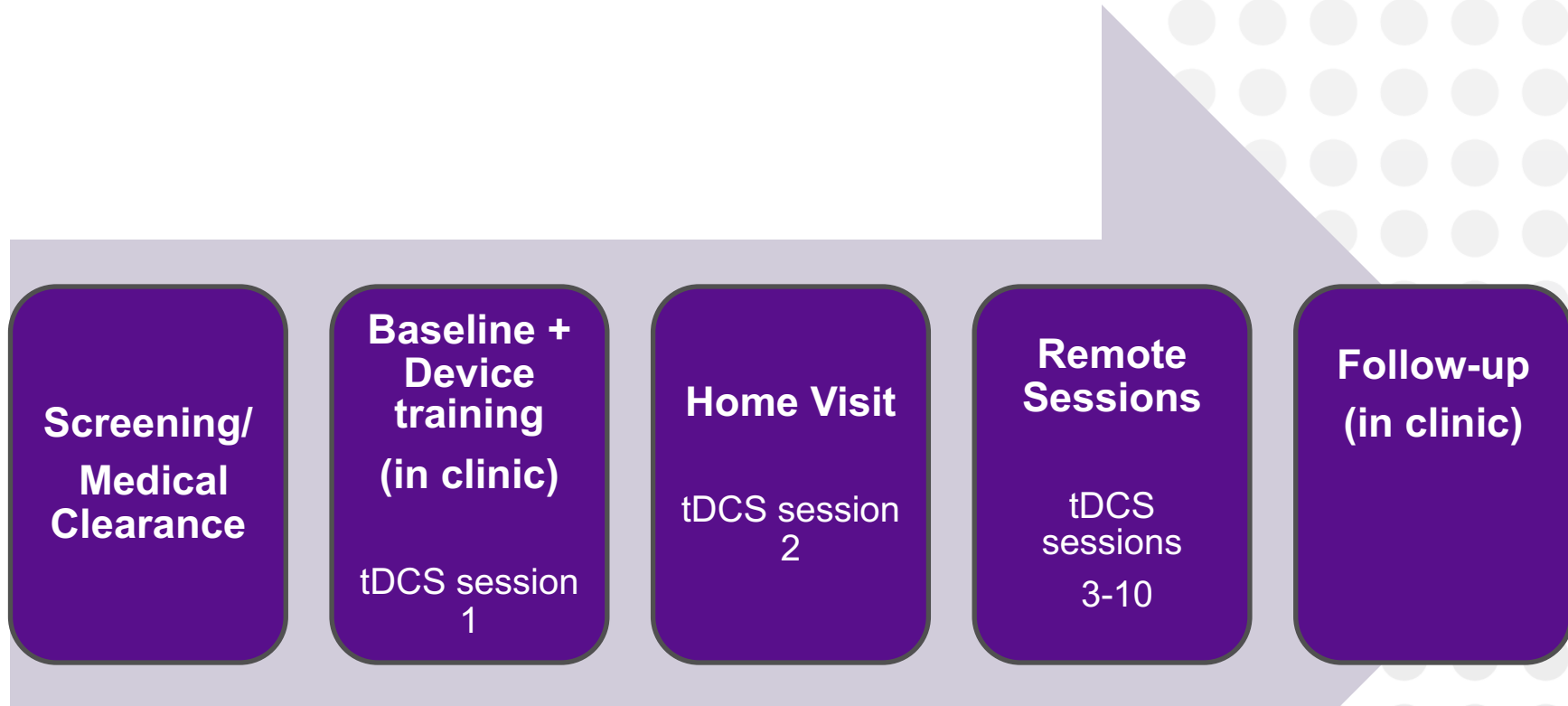


# Procedures- Remote Sessions

- **Go/No Go for each step**
- **Visual confirmation by study technician**
- **Safety and tolerability**
- **Compliance**



# Feasibility Study in Multiple Sclerosis (MS) – 10 sessions x 1.5 mA (open-label)



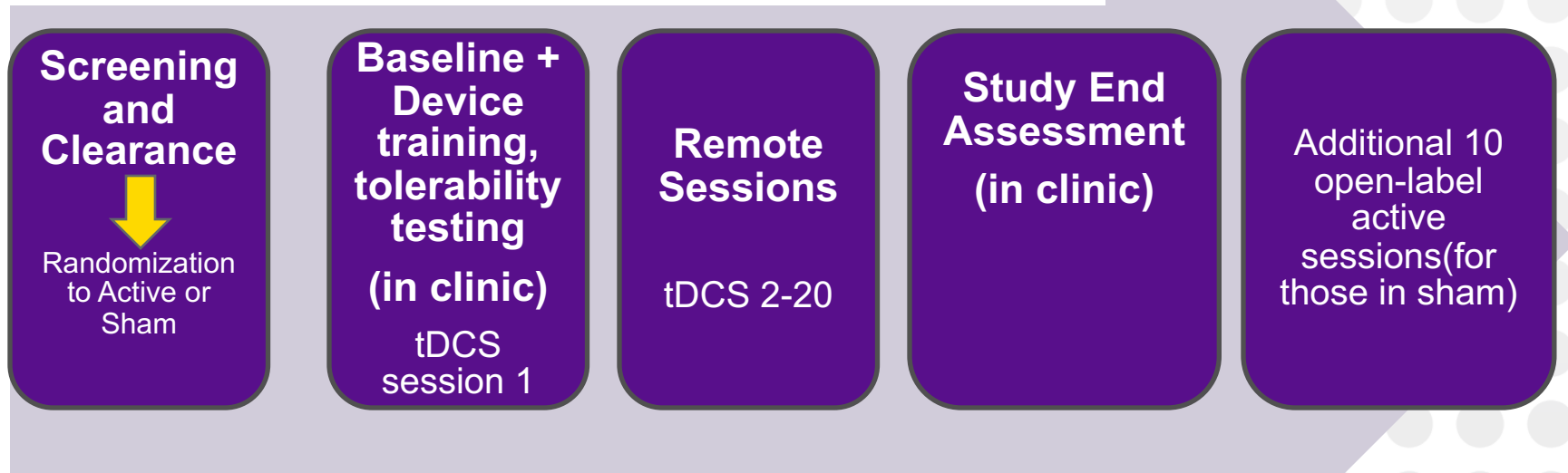
# RS-tDCS in MS is feasible\*

- EDSS 1.0-8.0 (n=26, n=8 with proxy)
  - Included those with severe neurologic impairment
- 247/260 sessions completed (96%), no session discontinued once started
- 22/26 patients completed all 10 sessions (85%)
  - Reasons for discontinuation not related to treatment

\*Kasschau, Reisner, Sherman, Bikson, Datta, Charvet.

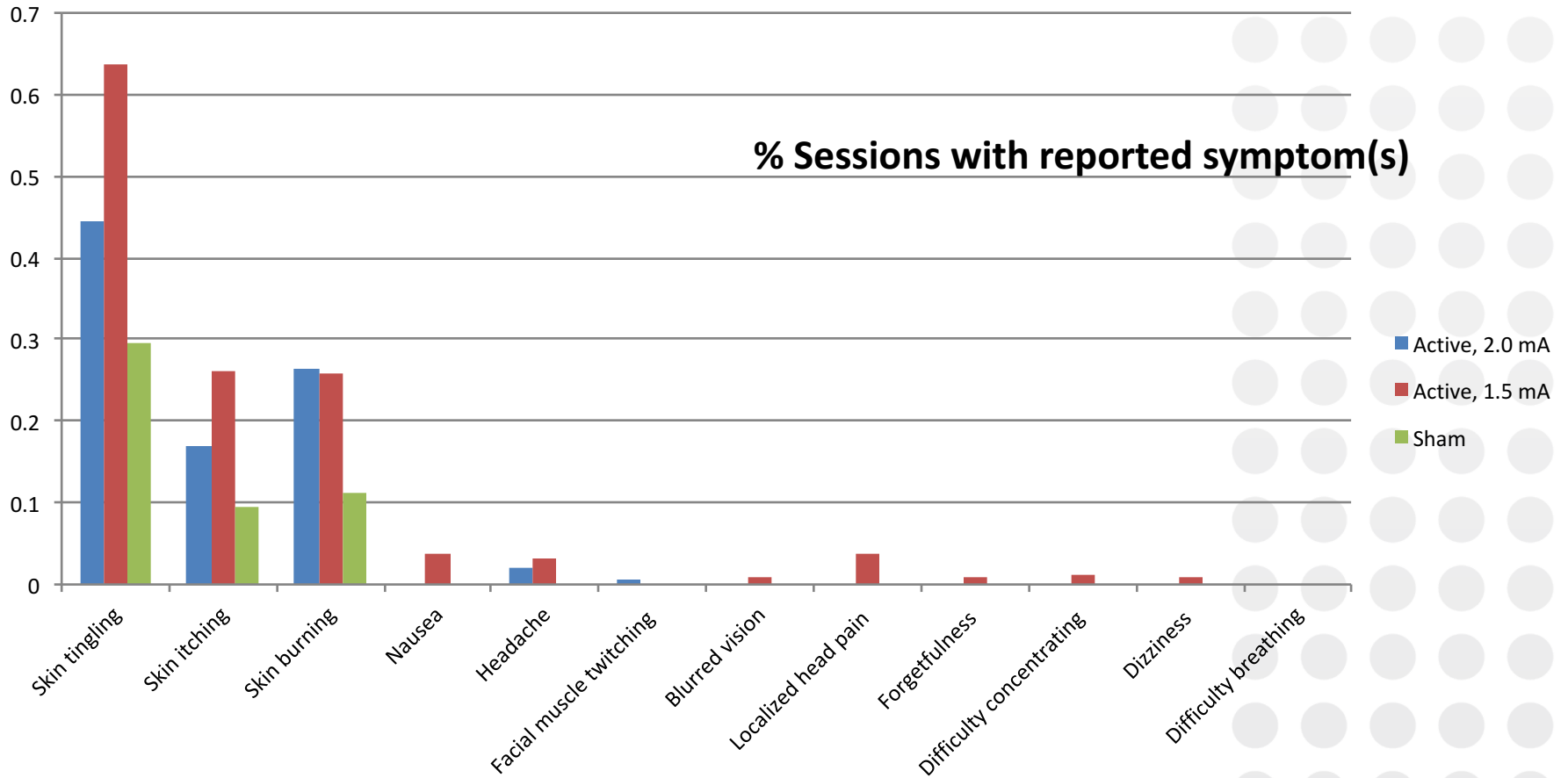
Transcranial direct current stimulation is feasible for remotely supervised home delivery in multiple sclerosis. Neuromodulation, 2015.

# RS-tDCS with Sham-Control: 20 Sessions





# Frequency of side effects reported with RS-tDCS



# RS-tDCS provides access

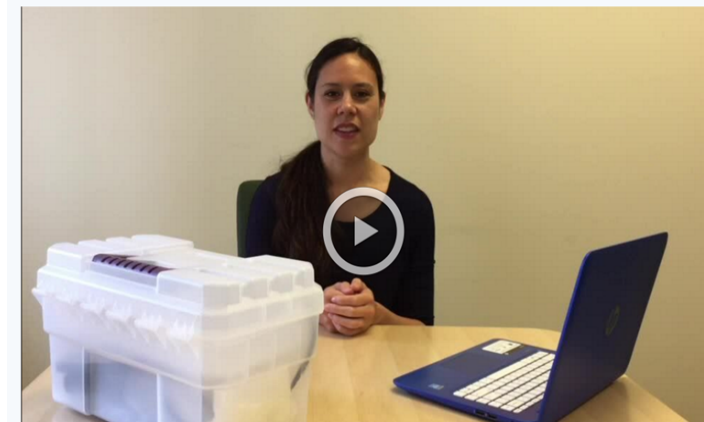
- Overcoming barriers to treatment access
  - Reaching participants who are target treatment recipients
    - Greater disability
    - Other limitations in treatment access
- In less than one year of active recruiting, >610 sessions
  - MS studies published to date (n=8) = 671 sessions
  - 20 treatment sessions

# Next steps for RS-tDCS: Ongoing studies

- Extending to randomize to active or sham condition for clinical trials
  - 20 sessions x 1 month
  - 10 open-label sessions for those in sham condition
- Extending to other conditions
  - Ongoing feasibility trial in Parkinson's disease
- Extending to other telerehabilitation/telepsychology
- Extending to new montages
  - M1-SO to pair with motor training

# The Potential of RS-tDCS: Scalability

- Protocol designed to be “fail-safe”
  - Low burden on participant to use equipment
  - Operator control
- Generalizable
  - A range of symptoms across varying conditions
  - Paired with telerehabilitation/telepsychology
- Allows for large scale studies
  - Rapid recruitment
  - Extended treatment
  - Limited only by devices and study technicians



# A team effort!

- Mike Shaw
- Kai Sherman
- Bryan Dobbs
- William Pau
- Natalie Pawlak
- Margaret Kasschau
- Dr. Lauren Krupp



Kai Sherman, MSED



Mike Shaw



Bryan Dobbs



Natalie Pawlak



William Pau