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

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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

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 Abhishekh Datta (Soterix) and their teams

*Kasschau, M., Sherman, K., Haider, L., Frontario, A., Shaw, M., Datta, A., Bikson, M., Charvet, L.  
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
CODE VERIFICATION

You will need DOSE CODE from the ADMINISTRATOR to proceed.

DOSE CODE: 22123

STIMULATION

CONTACT QUALITY:
Please put on your EASystrap and EASypads as instructed.
Contact Quality
OPTIMAL
* BACK # OK

STIMULATION PAUSED

CONTACT QUALITY:
Please adjust the EASystrap and EASypads to proceed.
Contact Quality
MODERATE
O ABORT # RESUME

STIMULATION PAUSED

CONTACT QUALITY:
Please adjust the EASystrap and EASypads to proceed.
Contact Quality
CRITICAL
O ABORT # RESUME

STIMULATION

DEVICE LOCKED
UNLOCK TIME: 5 PM

* BACK # ENTER CODE

STIMULATION

STATUS:
STIMULATING

Stimulation Complete!
Device will now shut down!

0 ABORT
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

Exclude for seizures, skin conditions, severe cognitive or visual impairment

If participant does not tolerate target does, second test for lower dose
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

RS-tDCS with Sham-Control: 20 Sessions

- **Screening and Clearance**: Randomization to Active or Sham
- **Baseline + Device training, tolerability testing (in clinic)**: tDCS session 1
- **Remote Sessions**: tDCS 2-20
- **Study End Assessment (in clinic)**
- **Additional 10 open-label active sessions (for those in sham)**
Frequency of side effects reported with RS-tDCS

% Sessions with reported symptom(s)

- Skin tingling
- Skin itching
- Skin burning
- Nausea
- Headache
- Facial muscle twitching
- Blurred vision
- Localized head pain
- Forgetfulness
- Difficulty concentrating
- Dizziness
- Difficulty breathing

- Active, 2.0 mA
- Active, 1.5 mA
- Sham
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