Arthritis Australia Grant-in-Aid (2024) Summary

Project Title:

Home-based neuromodulation: Boosting the analgesic effects of exercise in knee osteoarthritis

Investigators:

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1. Project Overview

This study evaluated the feasibility, safety, and clinical potential of home-based transcranial direct current stimulation (tDCS) as an adjunct to exercise for people living with knee osteoarthritis (OA). tDCS is a portable, non-invasive form of brain stimulation with growing evidence for modulating central pain mechanisms. Prior work has shown tDCS can enhance exercise-induced analgesia in laboratory settings, but no research had yet evaluated its use in the home environment alongside standard OA care.

This project employed a mixed-methods approach combining a pilot randomised controlled trial and a qualitative interview. The aim was to assess whether home-based tDCS is acceptable, safe, and effective when paired with strengthening exercises, and to explore user perceptions that could guide future clinical translation. The study generated new insights into patient experience, treatment adherence, and device usability, laying the groundwork for scalable, patient-centred neuromodulation interventions.

2. Objectives

The project had three primary objectives:

- 1. To determine the feasibility, safety, and adherence associated with home-based tDCS when delivered alongside a lower limb strengthening program.
- 2. To evaluate the preliminary efficacy of this combined intervention in reducing pain and improving physical function in individuals with knee OA.
- 3. To explore participant perceptions, facilitators, and barriers regarding the use of home-based tDCS through qualitative interviews and thematic analysis.

3. Methods

Quantitative component

A double-blind, parallel-group pilot randomised controlled trial was conducted in accordance with Osteoarthritis Research Society International (OARSI) guidelines. Twenty-four adults with knee OA and moderate pain (\geq 4/10 average weekly pain) were enrolled. All participants received an 8-week home-based quadriceps strengthening program, delivered with remote supervision twice weekly.

Participants were randomised to receive either active or sham home-based tDCS using pre-programmed, wearable devices. The active group underwent 10 sessions of anodal stimulation over the primary motor cortex (20 minutes per session, 2 mA, Monday–Friday for two weeks). The sham group received devices programmed to mimic stimulation without delivering current. Researchers and participants were blinded to group allocation.

Primary outcomes included feasibility (adherence, adverse events), pain (visual analogue scale), and function (WOMAC). Secondary outcomes included pressure pain thresholds and tolerability. Assessments occurred at baseline, week 4, and post-intervention (week 8). Additional details regarding the methodology can be found in the publications listed in the 'Outputs and Dissemination' section of this report.

Qualitative Study

All participants from the trial were interviewed prior to receiving tDCS. Interviews were semi-structured and analysed using Braun and Clarke's reflexive thematic analysis approach. Thematic coding explored expectations, perceived value, and concerns related to home-based tDCS. This component captured user perspectives and informed implementation strategies.

tDCS Protocol

All participants received an 8-week home-based strengthening program targeting the quadriceps. The exercise protocol was familiarised in person and delivered remotely twice per week (Tuesdays and Fridays), incorporating resistance exercises using TheraBands and body weight. Initial resistance was prescribed using a 10-repetition maximum test, and exercises were completed in 3 sets of 10 repetitions. A mid-point review (Week 4) allowed for load progression based on performance and tolerance.

Participants were randomised to receive either:

- Active home-based tDCS + exercise
- Sham home-based tDCS + exercise

The tDCS intervention was delivered for 20 minutes per day, Monday to Friday, during the first two weeks of the 8-week program (total of 10 sessions). The protocol aimed to 'prime' the motor cortex prior to exercise to enhance neuroplasticity. On exercise days, stimulation was applied immediately before completing the strengthening exercises.

Stimulation was applied using a Soterix Mini-CT stimulator with 5×7 cm saline-soaked sponge electrodes secured in a custom headpiece targeting the primary motor cortex. Active tDCS delivered 2 mA of direct current for 20 minutes. The sham protocol followed identical procedures, but the device was pre-programmed to ramp down after 30 seconds, providing no ongoing current. Both participants and researchers were blinded to allocation.

Participants were provided with a video guide, printed instructions, and remote supervision via secure videoconferencing during the first week of treatment. The tDCS device and headgear were designed for fail-safe use, with pre-set parameters and single-button activation.

Statistical Analysis

Quantitative data were analysed using mixed-model ANOVA with factors "Group" (active vs sham) and "Time" (Week 0, Week 4, Week 8). Post-hoc comparisons were Sidak-corrected. A biostatistician oversaw the analysis to ensure rigour and compliance with reporting standards. Descriptive statistics were used to summarise adherence, safety, and demographic data.

4. Key Findings

The intervention was both feasible and well tolerated. Adherence rates exceeded 85% across both groups, and no serious adverse events were recorded. Minor side effects in the active tDCS group—such as scalp tingling—were transient and expected, requiring no medical intervention. These findings confirm that home-based tDCS can be delivered safely alongside exercise in individuals with knee OA.

Preliminary efficacy outcomes indicated promising clinical effects in favour of the active tDCS group. Participants receiving active stimulation showed greater improvements in weekly pain intensity (measured via visual analogue scale) and functional outcomes (assessed by the WOMAC index) compared to the sham group. Pressure pain threshold testing revealed a trend toward increased pain tolerance among those in the active group, suggesting that tDCS may reduce central sensitisation and enhance exercise-induced hypoalgesia. These findings align with the proposed neuromodulatory mechanisms by which tDCS may "prime" the brain for better response to exercise.

The qualitative component of the study provided valuable insights into participant experiences and implementation considerations. Three overarching themes were identified through reflexive thematic analysis, outlined below:

tDCS as an appealing alternative to medications and surgery

Participants were optimistic about tDCS as a non-pharmacological pain treatment. Many hoped it would reduce their reliance on medications or delay the need for joint replacement:

"If it meant I didn't have to keep going and popping pills... I'll pay a couple of thousand, no worries. Even cheaper than a knee replacement."

"A good result would be less medication, or no medication, and anything to avoid a knee replacement."

Convenience and accessibility of home-based delivery

The ability to use the device at home was seen as a major strength, particularly among participants who would otherwise struggle to access regular clinic-based treatments:

"Having it at home, that would be perfect. If I had to keep coming back here every day, that would be difficult."

"It's exciting to think I might have less pain... that I might be able to get off even the Panadol."

Perceived complexity of the device as a potential barrier

While most participants expressed enthusiasm, some reported initial concerns about whether they would be able to operate the device correctly:

"Well, I don't know if I can manage to use the device. I'm not very technical, so that is a concern for me."

Importantly, these concerns were largely overcome with clear instructions and remote support. Participants emphasised that device usability was more important than cost, and many indicated they would recommend the intervention to others if effective.

Together, these qualitative insights reinforce the acceptability of home-based tDCS and highlight key considerations for broader implementation—particularly the importance of simple training resources and patient support.

5. Outputs and Dissemination

Published protocol (attached)

McNally, K. R., Summers, S., Stanton, T. R., McAuley, J., Chang, W. J., Chowdhury, N., & Cavaleri, R. (2024). Exploring whether home-based neuromodulation can boost the analgesic effects of exercise in people with knee osteoarthritis: protocol for a double-blinded, pilot randomised controlled trial. BMJ open, 14(11), e090523.

Conference presentation: APS 2025 (poster [attached] and associated presentation)

Mcnally, K., Summers S.J., & Cavaleri R. (2025). Home-based tDCS for the treatment of pain in knee osteoarthritis. Australia Pain Society Conference, Melbourne, Australia, 13-16 April.

Publication of quantitative findings (under review)

McNally, K. R., Summers, S., Stanton, T. R., McAuley, J., Chang, W. J., Chowdhury, N., & Cavaleri, R. (2024). Exploring whether home-based neuromodulation can boost the analgesic effects of exercise in people with knee osteoarthritis: a double-blinded, pilot randomised controlled trial (under review with BMJ Open)

Publication of qualitative findings (under review)

McNally, K. R., Summers, S., Stanton, T. R., McAuley, J., Chang, W. J., Chowdhury, N., & Cavaleri, R. (2024). Perceptions of home-based brain stimulation amongst people living with knee pain associated with osteoarthritis (under review with J Pain)

6. Impact and Future Directions

This study represents one of the first investigations to explore the feasibility, safety, and patient perspectives of home-based transcranial direct current stimulation (tDCS) for knee osteoarthritis. The findings provide a strong proof-of-concept that home-delivered neuromodulation can be safely integrated with exercise therapy, with high levels of acceptability among participants. Importantly, participants perceived the intervention as a desirable alternative to pharmacological treatments and invasive procedures, highlighting its relevance to people seeking low-risk, self-managed approaches to pain relief.

The success of this pilot trial paves the way for a larger, multi-site randomised controlled trial to evaluate the clinical efficacy of this combined intervention at scale. Such a trial would enable the detection of statistically robust treatment effects and allow exploration of subgroup responses (e.g. by age, severity, or pain phenotype). In parallel, further work is warranted to optimise device usability and onboarding processes, particularly for older adults or those with low technical confidence.

Beyond clinical research, this study contributes to broader health system priorities. It aligns with Arthritis Australia's strategic goals by promoting evidence-based, non-pharmacological self-management options, and supports the principles of accessible care delivery. The home-based format is especially suitable for individuals in rural and remote communities, who often face barriers to in-person therapy. If shown to be effective at scale, this approach could reduce healthcare burden, improve quality of life, and support long-term pain management in people with musculoskeletal conditions.

7. Acknowledgements

We thank Arthritis Australia for their support, as well as all study participants and consumer advisors.

8. Plain Language Summary

Knee osteoarthritis (OA) is a painful joint condition that affects millions of people in Australia and around the world. For many people living with knee OA, ongoing pain can make it difficult to walk, exercise, work, or enjoy time with family. Although medications and surgeries are available, these are not always effective or accessible for everyone—and often come with side effects.

This project set out to test a new way of helping people manage knee pain from the comfort of their own home. We combined a safe, relatively low-cost brain stimulation technique called transcranial direct current stimulation (or tDCS for short) with a simple home exercise program. People wore a small device on their head that delivered a gentle electrical current for 20 minutes per day for two weeks. This was done at home, with support from our research team. Everyone in the study also did strengthening exercises for their knee muscles over 8 weeks.

We wanted to know three things: Could people use the brain stimulation device safely at home? Would they stick with the program? And would it help reduce their knee pain? We also asked people what they thought about the treatment.

We found that people were able to use the device safely and consistently, and most had a positive experience. Many participants said they would prefer this kind of treatment to medications or surgery. Some even said it gave them hope. There were no serious side effects. Early results suggest that the combination of brain stimulation and exercise helped reduce pain and improve function more than exercise alone. This research is important because it shows that a new, drug-free, home-based option may be possible for people with knee osteoarthritis. With further testing, this could lead to wider access to effective, non-invasive pain relief.