General Psychiatry

# Effect of transcranial direct current stimulation on postoperative sleep disturbance in older patients undergoing lower limb major arthroplasty: a prospective, double-blind, pilot, randomised controlled trial

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**To cite:** Yang J, Tao M, Liu R, *et al*. Effect of transcranial direct current stimulation on postoperative sleep disturbance in older patients undergoing lower limb major arthroplasty: a prospective, double-blind, pilot, randomised controlled trial. *General Psychiatry* 2024;**37**:e101173. doi:10.1136/gpsych-2023-101173

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/gpsych-2023-101173).

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Received 05 July 2023
Accepted 01 February 2024



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## ABSTRACT

**Background** Postoperative sleep disturbance (PSD) is a common and serious postoperative complication and is associated with poor postoperative outcomes.

**Aims** This study aimed to investigate the effect of transcranial direct current stimulation (tDCS) on PSD in older patients undergoing lower limb major arthroplasty.

**Methods** In this prospective, double-blind, pilot, randomised, sham-controlled trial, patients 65 years and over undergoing lower limb major arthroplasty were randomly assigned to receive active tDCS (a-tDCS) or sham tDCS (s-tDCS). The primary outcomes were the objective sleep measures on postoperative nights (N) 1 and N2.

**Results** 116 inpatients were assessed for eligibility, and a total of 92 patients were enrolled; 47 received a-tDCS and 45 received s-tDCS. tDCS improved PSD by altering the following sleep measures in the a-tDCS and s-tDCS groups; the respective comparisons were as follows: the promotion of rapid eye movement (REM) sleep time on N1 (64.5 (33.5–105.5) vs 19.0 (0.0, 45.0) min, F=20.10, p<0.001) and N2 (75.0 (36.0–120.8) vs 30.0 (1.3–59.3) min, F=12.55, p<0.001); the total sleep time on N1 (506.0 (408.0–561.0) vs 392.0 (243.0–483.5) min, F=14.13, p<0.001) and N2 (488.5 (455.5–548.5) vs 346.0 (286.5–517.5) min, F=7.36, p=0.007); the deep sleep time on N1 (130.0 (103.3–177.0) vs 42.5 (9.8–100.8) min, F=24.4, p<0.001) and N2 (103.5 (46.0–154.8) vs 57.5 (23.3–106.5) min, F=8.4, p=0.004); and the percentages of light sleep and REM sleep on N1 and N2 (p<0.05 for each). The postoperative depression and anxiety scores did not differ significantly between the two groups. No significant adverse events were reported.

**Conclusion** In older patients undergoing lower limb major arthroplasty, a single session of anodal tDCS over the left dorsolateral prefrontal cortex showed a potentially prophylactic effect in improving postoperative short-term objective sleep measures. However, this benefit was temporary and was not maintained over time.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patients often develop significant sleep disturbances immediately after surgery, especially major surgery, which can lead to hyperalgesia and cognitive problems. Many pathophysiological mechanisms for sleep disturbances have been suggested. However, whether postoperative sleep disturbance is associated with the treatment response to transcranial direct current stimulation (tDCS) is unclear for older adults undergoing lower limb major arthroplasty.

### WHAT THIS STUDY ADDS

⇒ In older patients undergoing lower limb major arthroplasty, a single session of anodal tDCS over the left dorsolateral prefrontal cortex showed a potentially prophylactic effect in improving postoperative short-term objective sleep measures.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This neuromodulatory approach can be part of the prophylactic alternatives for postoperative sleep disturbance. Clinicians should pay attention to postoperative sleep disturbance, for it is related to poor recovery and postoperative complications, such as fatigue.

## INTRODUCTION

Lower limb major arthroplasty, including total hip arthroplasty (THA) or total knee arthroplasty (TKA), is an effective approach for the end-stage treatment of degenerative hip or knee pathologies. The incidence of THA or TKA is anticipated to increase by approximately 71% or 85%, respectively, in the USA by 2030.[1] Although lower limb major arthroplasty can maintain or improve patients' joint function, it does entail

potential risks of significant postoperative complications, including postoperative sleep disturbance (PSD), postoperative delirium, pain, fatigue, pulmonary embolism and even death.[2]

PSD is a frequently overlooked complication after surgery, often presenting as postoperative sleep structure disorder, decline in sleep quality and shortened sleep duration.[3] The sleep architecture changes in the days following surgery, characterised by decreased total sleep duration, elimination of rapid eye movement (REM) sleep, a marked reduction in slow-wave sleep and increased non-REM sleep stage 2.[4 5] Research findings show a pronounced decrease (93%) in REM sleep time on the first postoperative night with severe disturbances in sleep architecture but a return to preoperative levels on the fourth night after fast-track THA or TKA.[6] PSD aggravates postoperative pain and neurocognitive disorders and is related to postoperative delirium, postoperative cognitive dysfunction, anxiety and depression.[7] Relevant studies have shown that PSD can last for 2 months after discharge. While PSD itself is well recognised, the perioperative management of PSD in patients remains an underexplored area of research. The current treatment of PSD primarily relies on pharmaceutical interventions, with limited emphasis on non-pharmacological preventive measures. Transcranial direct current stimulation (tDCS) is not only a kind of neuromodulation technique that non-invasively alters cortical excitability via weak polarising currents between two electrodes placed on the scalp but is also advantageous for its low cost-effectiveness, ease of administration, and non-invasive and painless treatment.[8] Accumulating evidence shows that tDCS is a promising method for improving neurocognitive and behavioural disorders, and it also has efficacy in the treatment of psychiatric symptomatology, including anxiety, depression and schizophrenia.[9] tDCS is safe and has the potential to improve the symptoms related to insomnia and sleep disturbances across different types of neurological and neuropsychiatric diseases.[10] However, the perioperative application of tDCS is relatively limited in the context of older patients undergoing lower limb major arthroplasty,[11] and there is a lack of published studies documenting the efficacy of tDCS on postoperative sleep outcomes as objectively measured through randomised controlled trials.

The dorsolateral prefrontal cortex (DLPFC) includes the dorsal frontal cortex region of the brain and the primary and secondary motor cortex. It has been implicated in various psychological and physiological functions and connects extensive neural networks.[12] Research shows that sleep disturbances such as sleep-disordered breathing are more likely to happen due to executive function impairment, including mental flexibility, problem-solving and working memory, which are under DLPFC control.[13] Research on the association between the DLPFC region and sleep disorders found that repetitive transcranial magnetic stimulation (rTMS) effectively reduced cortical hyperexcitability and improved sleep quality in patients with chronic primary insomnia.[14] Therefore, this trial aimed to assess the effect of tDCS over the left dorsolateral prefrontal cortex on postoperative sleep in older patients undergoing lower limb major arthroplasty.

## METHODS

### Study design and participants

This prospective, randomised, double-blind, controlled pilot trial was conducted in the Department of Orthopedics and the Department of Anesthesiology Surgery at the Affiliated Hospital of Xuzhou Medical University from 1 March to 31 August 2022.

One-hundred and sixteen inpatients (mean (standard deviation, SD) age, 74.2 (12.3) years) who participated in the trial were initially assessed for eligibility. They received detailed information about the study protocol from a team member who was responsible for data collection and unaware of the group assignments. Patients 65 years or older with American Society of Anesthesiologists Classification (ASA) scores of 3 or less who were scheduled for lower limb major arthroplasty—either THA or TKA—under elective general anaesthesia were eligible for the trial inclusion. Exclusion criteria were a history of epileptic disorders and seizures; brain tumours or trauma; sleep disturbances (defined as a Pittsburgh Sleep Quality Index (PSQI) score >7); severe psychosis and mental diseases; substance abuse or dependence; dementia; severe cardiac conditions requiring a pacemaker or defibrillators; pregnancy; severe central nervous system disorders; communication difficulties; intake of excitatory beverages, such as coffee or tea, within half a month before surgery; and previous or current involvement in other tDCS or rTMS trials. We also removed any patients from the study who reported significant adverse effects, did not tolerate the intervention session or did not intend to continue the study. If adverse effects occurred, they were managed in accordance with their severity; patients with severe adverse effects were discontinued and withdrawn from the trial, and harm caused by adverse effects was actively monitored and treated.

### Randomisation and blinding

The study protocol was explained to all enrolled patients before randomisation. After obtaining written informed consent, patients were centrally randomised using the R language software (R ×64 V.4.0.3) and assigned to receive either active tDCS (a-tDCS) or sham tDCS (s-tDCS). The s-tDCS procedure was conducted to simulate the sensory experience elicited by a-tDCS, ensuring effective blinding of the patients. To blind research personnel to both patient treatment and assessment, the randomisation results were securely enclosed in sequentially numbered envelopes until patients reached the post-anaesthetic care unit (PACU). A randomisation sequence was created by a nurse who did not participate in the implementation or statistical analysis of the trial. The assessor and statistician

were blinded to treatment allocation throughout data collection and analysis.

## Procedures and interventions

### Anaesthesia procedures

After the patient entered the operating room, peripheral intravenous cannulation and radial artery cannula were performed. We recorded patients' electrocardiogram, heart rate and saturation of peripheral oxygen while monitoring end-tidal carbon dioxide, body temperature, fluid intake and output, as well as urine volume. The anaesthetic technique was standardised. The following induction medications were used: sufentanil (0.5 µg/kg), etomidate (0.3 mg/kg) and rocuronium (1 mg/kg) were administered, and a tracheal tube was inserted after about 3 min. After anaesthesia was induced, a 15 mL solution was used for the femoral nerve block (lidocaine 2.5 mg/mL+ropivacaine 2.5 mg/mL) and a 5 mL solution for the lateral femoral cutaneous nerve block (lidocaine 2.5 mg/mL+ropivacaine 2.5 mg/mL). A continuous infusion of remifentanil at a rate of 0.1–0.3 µg/kg/hour was administered for intraoperative analgesia. Anaesthesia was maintained with continuous infusion of propofol (4–6 mg/kg/hour) and 1% sevoflurane. The infusion speed and inhaled sevoflurane concentration were adjusted to keep the depth of the anaesthesia index (ConView Anesthesia depth Tester, Zhejiang Puke Medical Technology Co) between 40 and 60 during surgery and stabilise the haemodynamics. Vasoactive drugs were given as necessary to maintain heart rate and blood pressure fluctuations within 20% of baseline. The end-expiratory carbon dioxide partial pressure was maintained within 35–45 mm Hg range. In addition, rocuronium (0.15 mg/kg) was intermittently injected intravenously to maintain an appropriate level of muscle relaxation (the train-of-four ratio value was around 0.2). The surgeon gave the patient a 'cocktail' injection of analgesia (ropivacaine 50 mg, tranexamic acid 0.7 g and flurbiprofen axetil 50 mg) into the joint before suturing the surgical wound. The inhalation of sevoflurane was stopped 30 min before the end of the operation, the intravenous maintenance dose was moderately deepened, and the propofol and remifentanil infusions were stopped at the end of the operation. Postoperative analgesia was managed with a patient-controlled analgesia pump that consisted of 1.5 µg/kg of sufentanil, 6 mg of tropisetron and saline in a total volume of 100 mL; the background infusion rate was set at 2 mL/hour and the self-administered dose was adjusted to 0.5 mL with a lockout interval of 15 min. The initial pain assessment was conducted during the preoperative visit, and the first postoperative pain assessment took place in the PACU after extubation when the patient regained consciousness. If the participant's postoperative Numerical Rating Scale (NRS) score exceeded 3, additional analgesic medication was given after the pain assessment. After surgery, all patients were transferred to the PACU for postoperative monitoring and were given atropine 0.5 mg and neostigmine 1 mg.

### tDCS intervention

The tDCS was supplied by a battery-powered microprocessor-controlled constant current stimulator (machine manufacturer: MBM-1 equipment, Jiangxi Hua Heng Jing Xing Technology Company, patent application number: 201810566020.3). The electrostimulation was delivered through two electrodes placed in saline-soaked sponges, fixed on the scalp with a non-conductive hat. The anode was placed in the left DLPFC, and the cathode was placed in the right supraorbital frontal lobe and then simultaneously connected to a transcutaneous electroacupuncture apparatus (see online supplemental figure 1A). After the patients entered the PACU and their tracheal tubes were removed, the tDCS was applied. The parameters and electrode placement of the tDCS used in this study were based on previous research regarding the parameters of tDCS therapy and the guidelines for electrode positions.[15 16] The tDCS device was configured to deliver an oscillating current with a dispersed-dense waveform at a frequency of 2/10 Hz, exhibiting a gradual rise and fall before and after the stimulation period that lasted for 30 s. Before the procedure, the scalp skin of both groups was disinfected to make the skin more conductive. The same treatment protocol was used for the a-tDCS and s-tDCS groups. However, the s-tDCS group experienced an automatic cessation of current and stimulation through the use of a simulated device after a 30-second ramp-up and 30-second ramp-down with tDCS. The patients in the a-tDCS group received 2 mA tDCS for 20 min, after which we removed the device, observed the patient, recorded any adverse reactions and promptly addressed any serious ones. Upon completing the experimental intervention, we removed the patient's electrodes. We returned the patients to the ward when they met the discharge criteria of the PACU (see online supplemental figure 1B).

## Outcomes

The primary outcome was the objective sleep measures, assessed one night before the operation and two consecutive nights after. To measure postoperative sleep data, the Withings Sleep Analyzer (WSA) was used (see online supplemental figure 1C).

We used the WSA to record sleep data from 20:00 to 08:00 on the night before the operation (N0), the night of the operation (N1) and the second night following the operation (N2). The patients' monitoring screens on the ward were silenced to minimise sleep environment interference. Moreover, the patients were placed in a tranquil room on the ward, distant from noisy hallways, where unnecessary night-time medical interventions were avoided, and lights were turned off early.

Secondary outcomes measured changes in subjective sleep quality, including anxiety, delirium, recognition, fatigue and restoration quality evaluations. The quality of sleep was evaluated by the Leeds Sleep Evaluation Questionnaire (LSEQ), which is composed of four domains: ease of initiating sleep, quality of sleep, ease of waking

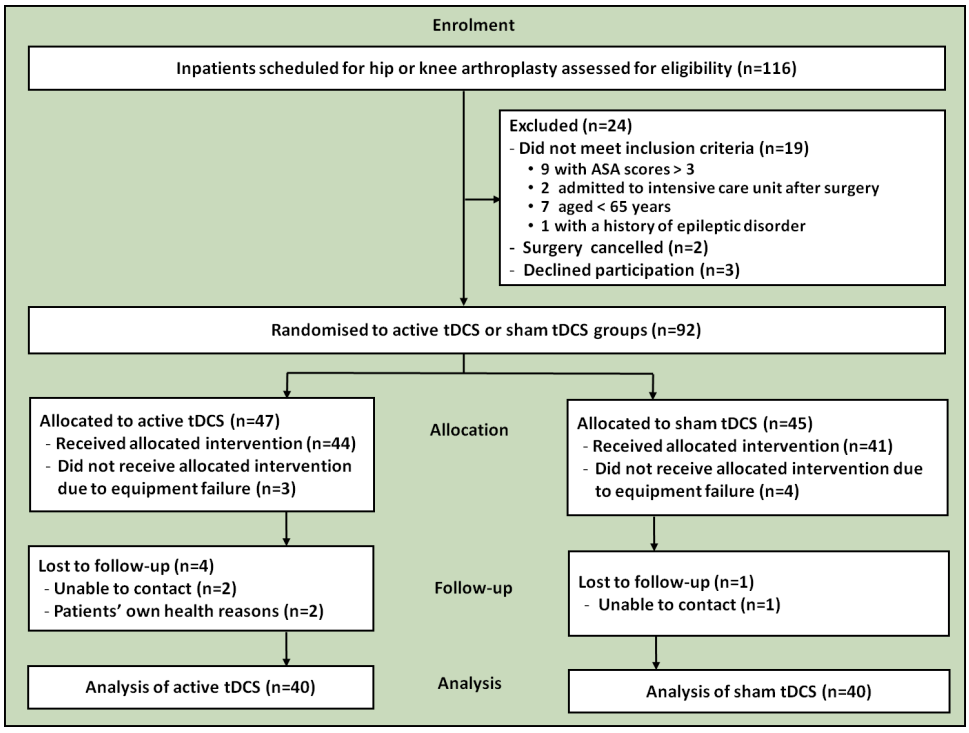


**Figure 1** Flowchart of the study. ASA, American Society of Anesthesiologists Classification; tDCS, transcranial direct current stimulation.

and behaviour following wakefulness.[17] The LSEQ was administered by study personnel to each patient every morning at 08:00, starting the day before the surgery and continuing until the second day post-surgery. We also used the PSQI on the day before surgery and again after discharge for follow-up postoperative sleep quality measures at weeks 1, 2 and 4.[18] Anxiety was evaluated (preoperation and postoperation) using the Self-Rating Anxiety Scale (SAS)[19]; delirium was assessed using the Self-Rating Delirium Scale (SDS)[20]; and early postoperative quality of recovery and fatigue[21] was evaluated with a 15-item Quality of Recovery Scale (QoR-15)[22] and Fatigue Scale-14 (FS-14), respectively. The Mini-Mental State Examination (MMSE) was used to assess postoperative cognitive function.[23] The assessments of anxiety, fatigue, cognitive function, delirium and other conditions were conducted at 08:00 on the day before the surgery and again at 08:00 on the first day post-surgery. The management of postoperative pain is crucial to minimising sleep disturbances. Thus, our goal was to maintain the patient's NRS score below 3. Should the score exceed 3, our plan was to administer rescue analgesics such as non-steroidal drugs. However, as a result of the patient-controlled intravenous analgesia and nerve block, we did not observe any patients with pain scores equal to or greater than 4 points during the 2 days postoperation. Any discomfort experienced was primarily due to lower limb immobilisation. Adverse events throughout the trial were documented by group outcome assessors and followed up until resolution.

### Sample size and statistical analyses

The G*Power software (G*Power V.3.1.9.7) was used to determine the required sample size for this study. Since it was a pilot study to assess the effect of tDCS on postoperative sleep outcome, we based our sample size calculation so that the preset equivalent stress in existence was d=0.25, the test power was 0.80 and the allowable error was 0.05.[24 25] The size of each group was calculated to be 35, and after factoring in a 10% drop-out rate, we concluded that 39 patients were required for each group.

Statistical analyses were performed with R language software version (R ×64 V.4.0.3) and SPSS V.25.0 software (IBM SPSS). Data were analysed according to our protocol. The study statistician was blinded to group assignment until all analyses were completed. Continuous variables were reported as mean (SD) or median and interquartile range (IQR), and categorical variables were reported as frequencies and proportions. Group comparisons of baseline demographics and clinical characteristics were assessed with independent-sample t-tests for normally distributed data and non-parametric tests (Mann-Whitney U test) for non-normally distributed data. Although our data satisfied normality, it did not satisfy the test of sphericity, so a statistical analysis was carried out on the repeated measurement data of the main outcome indicators, with the participants' objective sleep measures as the main variable, three repeated measurements as the internal variable. The baseline differences between the two groups were balanced by incorporating the unbalanced variables into the statistics through covariance analysis for adjustment purposes. Generalised estimating equations were developed for subsequent statistical analysis. The treatment-by-time interaction term was tested first. If it was significant, the between-group differences at each time point were tested, and the analyses were

**Table 1** Demographics and baseline characteristics of study participants

| | Control group (n=40) | Intervention group (n=40) | F/Z | P value |
|---|---|---|---|---|
| Age, years, mean (SD) | 70.3 (3.8) | 73.1 (5.5) | 5.57 | 0.011 |
| Gender, n (%) | | | 3.71 | 0.329 |
| Male | 14 (35.0) | 10 (25.0) | | |
| Female | 26 (65.0) | 30 (75.0) | | |
| ASA, n (%) | | | 0.72 | 0.576 |
| I–II | 33 (82.5) | 31 (77.5) | | |
| III | 7 (17.5) | 9 (22.5) | | |
| Physical factors | | | | |
| Weight (IQR), kg | 65.0 (60.0–74.3) | 61.5 (60.0–70.0) | 1.41 | 0.357 |
| Body mass index, mean (SD), kg/m$^2$ | 25.1 (3.8) | 25.4 (2.9) | 1.92 | 0.763 |
| Level of education, n (%) | | | 0.91 | 0.769 |
| Illiterate | 21 (52.5) | 23 (57.5) | | |
| Primary school | 11 (27.5) | 12 (30.0) | | |
| Junior high school | 6 (15.0) | 3 (7.5) | | |
| Senior high school | 2 (5.0) | 2 (5.0) | | |
| Hospitalisation factors | | | | |
| Hospital stays, days (IQR) | 8.0 (7.0–9.8) | 8.5 (7.0–10.0) | 9.08 | 0.165 |
| Hospitalisation costs (CN¥), mean (SD) | 54 766.4 (3266.8) | 55 647.0 (3426.1) | 2.21 | 0.303 |
| Personal habits | | | | |
| Smoking, n (%) | 6 (15.0) | 8 (20.0) | 0.43 | 0.556 |
| Alcohol use, n (%) | 5 (12.5) | 7 (17.5) | 0.72 | 0.531 |
| Assessment results | | | | |
| PSQI (IQR) | 3.0 (2.0–3.0) | 3.0 (2.0–4.0) | 0.02 | 0.988 |
| LESQ-1 (IQR) | 16.9 (15.0–18.0) | 17.8 (15.3–19.8) | 1.77 | 0.077 |
| LESQ-2 (IQR) | 11.3 (10.0–13.0) | 12.8 (10.3–15.0) | 2.14 | 0.320 |
| LESQ-3 (IQR) | 11.6 (10.0–13.8) | 11.9 (10.0–13.8) | 0.90 | 0.368 |
| LESQ-4 (IQR) | 17.7 (15.0–21.0) | 18.2 (14.0–20.0) | 0.84 | 0.349 |
| NRS (IQR) | 2.0 (1.0–3.0) | 1.5 (1.0–3.0) | 0.35 | 0.730 |
| MMSE score (IQR) | 24.0 (21.3–25.0) | 22.5 (19.0–26.0) | 0.85 | 0.851 |
| SDS score, mean (IQR) | 42.9 (7.8) | 40.6 (5.3) | 0.19 | 0.191 |
| QoR-15 score, mean (SD) | 121.6 (12.1) | 121.4 (10.6) | 0.39 | 0.870 |
| SAS score, mean (SD) | 41.3 (5.6) | 42.6 (4.8) | 0.88 | 0.377 |
| FS-14 (IQR) | 2.0 (1.0–4.0) | 2.0 (1.0–3.8) | 0.69 | 0.874 |
| ACCI (IQR) | 2.0 (2.0–2.0) | 2.5 (2.0–2.5) | 1.49 | 0.135 |
| Perioperative variables | | | | |
| Anaesthesia time (min), mean (SD) | 125.0 (17.2) | 129.0 (23.6) | 3.57 | 0.541 |
| Operation time (min), mean (SD) | 90.9 (14.2) | 99.7 (23.6) | 9.08 | 0.143 |
| Propofol (IQR), mg | 245.0 (200.0–310.0) | 245.0 (202.5–317.5) | 0.04 | 0.636 |
| Sufentanil (IQR), mg | 35.0 (30.0–35.0) | 30.0 (30.0–33.8) | 0.11 | 0.790 |
| Remifentanil (IQR), mg | 1.7 (50.0–60.0) | 1.7 (50.0–60.0) | 0.06 | 0.398 |
| Etomidate (IQR), mg | 18.0 (18.0–20.0) | 17.0 (16.0–20.0) | 0.32 | 0.232 |
| Rocuronium (IQR), mg | 60.0 (10.0–13.8) | 65.0 (10.0–13.8) | 3.22 | 0.908 |
| Blood loss (IQR), mL | 155.0 (60.0–250.0) | 120.0 (60.0–255.0) | 0.99 | 0.710 |
| Urine volume (IQR), mL | 200.0 (0.0–350.0) | 0.0 (0.0–290.0) | 2.07 | 0.133 |
| Crystalloid fluid (IQR), mL | 900.0 (750.0–1100.0) | 1000.0 (805.0–1137.5) | 0.03 | 0.482 |
| Colloidal liquid (IQR), mL | 0.0 (0.0–0.0) | 0.0 (0.0–0.0) | 0.02 | 0.850 |

ACCI, age-adjusted Charlson Comorbidity Index; ASA, American Society of Anesthesiologists physical status classification; FS-14, Fatigue Scale-14; IQR, interquartile range; LESQ-1(2,3,4), Leeds Sleep Evaluation Questionnaire part 1(2,3,4); MMSE, Mini-Mental State Examination; NRS, Numerical Rating Scale; PSQI, Pittsburgh Sleep Quality Index; QoR-15, Quality of Recovery Scale-15; SAS, Self-Rating Anxiety Scale; SD, standard deviation; SDS, Self-Rating Delirium Scale.

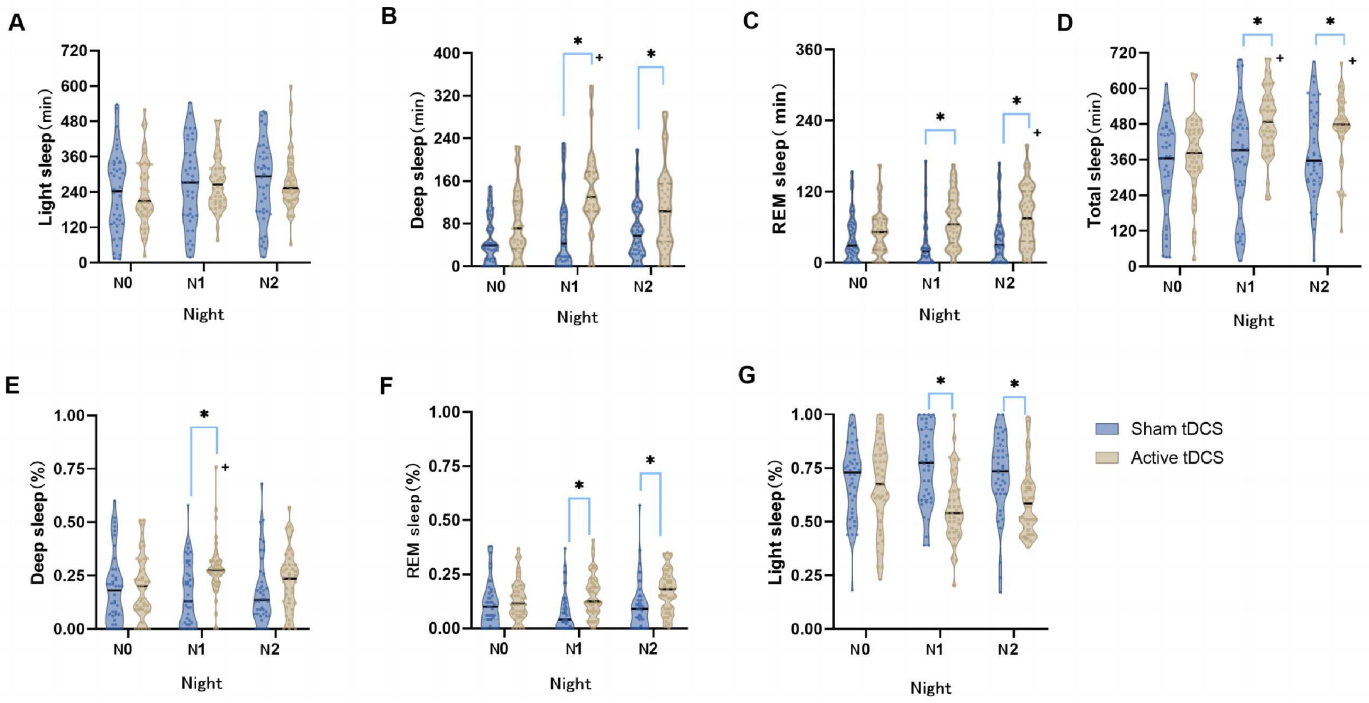


**Figure 2** Comparison of objective sleep time and sleep phase. (A) Light sleep time, (B) deep sleep time, (C) REM sleep time and (D) total sleep time. (E) The proportion of deep sleep, (F) the proportion of REM sleep and (G) the proportion of light sleep. N0, the night before the operation; N1, the first night after the operation; N2, the second night after the operation. *Significant differences in within-group comparisons. +Significant differences between the groups, p<0.05. REM, rapid eye movement; tDCS, transcranial direct current stimulation.

adjusted for multiple comparisons using the Bonferroni test. Otherwise, the main effect of treatment was tested next, and no Bonferroni correction was made to assess the treatment effect at each time point. The Bonferroni-adjusted level of 0.0166 accounted for the testing of our primary outcomes. Statistical significance was defined as p<0.05.

## RESULTS

### Patient characteristics

From 1 March 2022 to 30 August 2022, 116 inpatients scheduled for THA or TKA were assessed for eligibility for study participation. Among them, 24 individuals were excluded: 19 did not meet the inclusion criteria (9 had ASA scores higher than 3, 2 were admitted to the intensive care unit after surgery, 7 were less than 65 years old and 1 had a history of epileptic disorder), 2 had their surgery cancelled and 3 declined participation. Thus, 92 patients were enrolled and randomised into the sham group or the active group. After randomisation, seven patients (three in the a-tDCS group and four in the s-tDCS group) could not receive the allocated intervention due to equipment failure for monitoring or simulation. Eventually, 80 patients completed the trial, and the retention rates were 87.0% (80 of 92) at the 4-week follow-up. However, five patients could not be reached by telephone for follow-up (see figure 1). The baseline characteristics of the included participants were described as medians with IQRs for continuous variables and frequency and percent (%) for categorical variables. The age difference between the

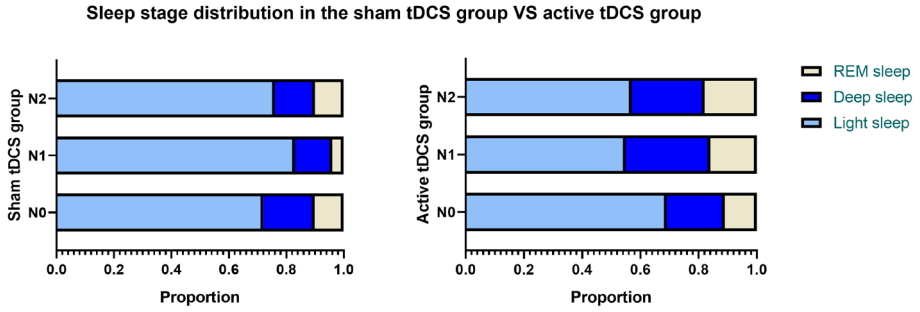


**Figure 3** Sleep stage distribution in two groups. REM, rapid eye movement; tDCS, transcranial direct current stimulation.

Table 2 Secondary outcome scores of study participants

| Instruments | Sham tDCS group (n=40) | Active tDCS group (n=40) | Z | P value |
|---|---|---|---|---|
| MMSE | 24 (21–25) | 22.5 (19–26) | −0.68 | 0.498 |
| SDS | 41 (35–45) | 40 (37–43) | −0.60 | 0.547 |
| SAS | 42 (40–45) | 42 (39–46) | −0.33 | 0.743 |
| QoR-15 | 121 (109–127) | 128 (121–133) | 3.38 | 0.001 |
| FS-14 | 4 (3–5) | 2 (1–3) | −4.23 | <0.001 |

Data are presented as median (IQR).
FS-14, Fatigue Scale-14; MMSE, Mini-Mental State Examination; QoR-15, 15-item Quality of Recovery Scale; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Delirium Scale; tDCS, transcranial direct current stimulation.

a-tDCS group and the s-tDCS group was statistically significant(Z=5.57, p=0.011). Other than age, there were no statistically significant differences among demographic and baseline characteristics. (table 1).

## Primary outcome

After sleep monitoring for two consecutive nights post-operation, there was no significant difference in light sleep time between the two groups (p>0.05) (figure 2A and online supplemental table 1). The a-tDCS group had a statistically significant increase in deep sleep time compared with the s-tDCS group (130.0 min/N1, IQR (103.3–177.0), p<0.001 and 103.5 min/N2, IQR (46.0–154.8), p=0.004) (figure 2B). Similarly, statistically significant patterns of change were found for REM sleep time (64.5 min/N1, IQR (33.5–105.5), p<0.001 and 75.0 min/N2, IQR (36.0–120.8), p<0.001) (figure 2C), total sleep time (506.0 min/N1, IQR (408.0–561.0), p<0.001 and 488.5 min/N2, IQR (455.5–548.5), p=0.007) (figure 2D), the percentage of deep sleep (27.8%/N1, IQR (21.2%–31.8%), p<0.001) (figure 2E) and the percentage of REM sleep (12.0%/N1, IQR (7.9%–21.8%), p<0.001 and 17.9%/N2, IQR (8.3%–23.7%), p=0.009) (figure 2F). However, the active tDCS group had a statistically significant decrease in the percentage of light sleep compared with the s-tDCS group (54.4%/N1, IQR (46.0%–64.6%), p<0.001 and 56.7%/N2, IQR (45.7%–68.3%), p=0.006) (figure 2G). It can be seen from figure 2 that not only the differences between the a-tDCS group and the s-tDCS group at the same time point as mentioned above, but also the N1 of deep sleep time, the N2 of REM sleep time, the N1 and N2 of total sleep time and the N1 of the percentage of deep sleep of the a-tDCS group were improved compared with baseline sleep measures before treatment. The distribution of sleep stages is shown in figure 3.

## Secondary outcome

No significant differences in subjective scores of everyday sleep quality were found between the two groups for 3 consecutive days after surgery. The postoperative pain assessment results showed no significant time×group interaction (F=0.52, p=0.916), and no main effect of tDCS (F=0.01, p=0.905) was observed. A significant effect of time showed that pain scores changed significantly over time (F=101.0, p<0.001; see online supplemental table 1).

Patients' QoR-15, SDS, SAS and FS-14 scores on the first day after surgery are shown in table 2. The Mann-Whitney U test is used and the standardized statistic Z is used to represent the statistic. The QoR-15 score of postoperative recovery quality of the a-tDCS group was higher than the s-tDCS group (Z=3.38, p=0.001). The FS-14 score in the a-tDCS group was lower than the s-tDCS group (Z=−4.23, p<0.001). The MMSE, SAS and SDS scores after surgery were not statistically different between the two groups (Z=−0.68, p=0.498; Z=−0.33, p=0.743; Z=−0.60, p=0.547). The PSQI scores measuring sleep quality during three follow-up visits post-discharge showed no difference between the two groups (F=0.008, p=0.974; see online supplemental table 2).

## Post-hoc analysis

The statistical analyses were conducted separately for hip and knee replacement surgeries; the results are presented below. The results of the two interoperative trials exhibited a marginal disparity. Objective sleep structure analysis of patients after knee arthroplasty revealed no statistically significant distinction in the duration of light sleep between the two groups (p=0.877). The a-tDCS group had a statistically significant increase in deep sleep compared with the s-tDCS group (132 min/the N1, IQR (101–186), p<0.001 and 101 min/N2, IQR (67–153), p=0.033). Similarly, statistically significant patterns of change were found for REM sleep time (64 min/N1, IQR (19–104), p<0.001 and 86 min/N2, IQR (18–121), p<0.001), total sleep time (484 min/N1, IQR (408–561), p=0.002 and 484 min/N2, IQR (455–553), p=0.015), the percentage of deep sleep (27%/N1,IQR(22%–34%), p=0.003) and the percentage of REM sleep (12%/N1, IQR (8%–21%), p=0.001 and 18%/N2, IQR(10%–24%), p=0.011). However, the a-tDCS group had a statistically significant decrease in the percentage of light sleep compared with the s-tDCS group (p=0.027).

Data analysis of patients after hip replacement showed that there was no significant difference in light sleep time (p=0.457) between the two groups. The a-tDCS group had a statistically significant increase in deep sleep compared with the s-tDCS group (128 min/N1, IQR (110–173), p<0.001 and 110 min/N2, IQR (67–153), p=0.011). Similarly, statistically significant patterns of change were found for REM sleep time (91min/N1, IQR(31–112), p<0.001 and 58min/N2, IQR (24–123), p<0.001), total sleep time (524 min/N1, IQR (415–588), p=0.002 and 468min/N2, IQR (358–560), p=0.015), the percentage of deep sleep (28%/N1, IQR (22%–31%), p=0.003), and the percentage of REM sleep (16%/N1, IQR (6%–25%), p<0.001 and 14%/N2, IQR (6%–24%), p=0.043). However, the a-tDCS group had a statistically significant decrease in the percentage of light sleep compared with the s-tDCS group (54%/N1, IQR (48%–70%), p<0.001 and 65%/N2, IQR (44%–69%), p=0.038). (see online supplemental table 3).

## DISCUSSION

### Main findings

We conducted a study involving 102 inpatients aged 65 years or older who were randomly assigned to receive a-tDCS with anode placement on the DLPFC and cathode placement on the right supraorbital region for 20 min (n=47), or s-tDCS (n=45) following lower limb major arthroplasty and extubation to investigate whether PSDs could be improved.

The findings of our study indicate that a single session of tDCS administered during the perioperative period may lead to temporary improvements in objective sleep measures, as evidenced by an increase in various sleep stages. tDCS increased the duration of deep sleep, REM sleep and total sleep in the short-term postoperative period. Additionally, it improved the proportion of deep sleep and REM sleep while reducing the proportion of light sleep. The findings also indicate that tDCS has the potential to enhance the quality of recovery and mitigate fatigue. In the current study, our data further demonstrated that postoperative sleep disturbances occurred in the s-tDCS groups of patients during the first night after surgery. These disturbances were characterised by a reduction in total sleep duration, an increase in the proportion of light sleep, a decrease in the proportion of deep sleep, and a decrease or absence of the REM sleep stage. During the second night after surgery, the above data gradually recovered to the preoperative state. These results were consistent with the polysomnographic data reported in the postoperative medical and surgical patients.[7] As far as we know, this is the first sham-controlled study evaluating the effect of PSD using a-tDCS over the left DLPFC in older patients undergoing THA or TKA. Our study used a rigorous and replicable methodology to study patients undergoing lower limb major arthroplasty and found that the protocol of tDCS we applied has a therapeutic effect on the structure of sleep.

The improvement in objective sleep structure in response to tDCS treatment might have occurred for specific reasons. One possible explanation is the several therapeutic mechanisms of tDCS that are involved: the modification of cortical excitability, neural plasticity and long-term potential depression processes. It is widely recognised that cathodal stimulation decreases neuronal excitability in the targeted area, whereas anodal stimulation increases it.[26]

Another explanation is the relevance of our target regions (ie, DLPFC) for sleep. The DLPFC is a functionally and structurally heterogeneous region and a key node of several brain networks implicated in cognitive, affective and sensory processing.[27] Related studies have shown that rTMS of the DLPFC can treat primary insomnia. Several explanations are currently available. Stimulation can directly hyperpolarise neural cells of the DLPFC by a pulsed magnetic field and inhibit the overexcited state (hyperarousal) of the cerebral cortex. It can also increase pineal melatonin secretion and concentrations of brain serotonin and norepinephrine, which play an essential role in maintaining the normal sleep–wake cycle.[28] Furthermore, tDCS and rTMS are both non-invasive neuroregulatory techniques, and tDCS can affect the DLPFC by interfering with functional connectivity, synchronisation and oscillatory activities in various cortical and subcortical networks. The effects of tDCS on the motor cortex, the prefrontal cortex or during slow-wave sleep have been demonstrated.[29]

Nonetheless, the improvement of objective sleep data does not lead to an improvement in subjective sleep quality. There could be several reasons for this. One is that the effect of tDCS is not solely determined by the target regions and stimulation timing but is also influenced by the duration and frequency of stimulation. A meta-analysis of single-session tDCS applied to healthy participants showed no significant effects of tDCS on either reaction times or accuracy, with the overall effects being close to 0. Although this effect was not significant with reaction times, it approached significance with accuracy scores. We hypothesised that perhaps because our stimulation was a single session and lasted only for 20 min, the effect of our stimulation on sleep was weak relative to that of repeated stimulation, and it may only improve objective sleep architecture; patients cannot perceive the improvement in subjective sleep quality caused by such changes. The effect of a single session of tDCS is consistent with some previous studies.[30]

After major surgery, most patients are prone to a lighter sleep with the amounts of deep and REM sleep obviously reduced; PSD affects the total sleep time, sleep structure and sleep efficiency of patients to varying degrees.[31] PSD has many potential side effects, including cognitive impairment (such as delirium),[32] changes in pain perception, emotional disorders, metabolic disorders and proinflammatory changes.[7] Considering the complications, our study shows that tDCS can improve the quality of postoperative recovery and fatigue.

We used WSA to measure sleep data. The WSA is a medical device with a hardware piece, the Withings Sleep, and software that estimates the apnoea–hypopnoea index (AHI).[33] The device is positioned under the mattress, beneath the patient's mattress. In brief, the device uses a sensor that measures pressure in the air bladder relative to the atmospheric pressure. The pressure signal is filtered and amplified to isolate three separate mechanical sources: body movements, displacement of the chest (breathing) and vibrations due to cardiac ejection. They are transmitted by the mattress to the air bladder and are recorded. The pressure and sound signals are analysed by WSA-embedded software. Filtered in different frequency bands, the pressure signal provides data on the sleep structure. Relevant research shows that WSA closely agrees with polysomnography (PSG) for estimating the AHI. Compared with PSG and polygraphy, the WSA has several advantages: it is non-intrusive and requires no technician for sensor placement and analysis. Furthermore, the WSA has the advantage over polygraphy to measure total sleep time and sleep efficiency accurately.[34]

## Limitations

This study is limited by a lack of PSG, which is the standard equipment for measuring sleep metrics, neurophysiology and neuroimaging methods (eg, electroencephalogram, TMS-electroencephalogram). We also did not use tDCS side effect questionnaires and high-definition stimulation that can precisely locate individual DLPFC. There is an association between chronotypes—the natural preferences of the body for wakefulness and sleep—and sleep cycles. Recently, it has been found that the chronotype also affects tDCS-induced plasticity. Although we measured all patients at a fixed time and reduced the effect of the time of day, especially in different chronotypes, in future studies, the use of chronotypes is recommended. Moreover, being a prospective trial investigating the impact of tDCS on PSD, the present study employed a per-protocol analysis approach, potentially enhancing the treatment effect. However, it is important to note that our trial required the collection of patients' sleep data for three consecutive nights. The significance of each sleep data point is paramount, and although our data remain intact, we employed a composite analysis to mitigate potential biases in the trial design and prevent any loss of information. The missing data could be processed using statistical methods, such as random interpolation, if necessary.

## Implications

Despite these limitations, this study represents the starting point for studying the effectiveness of a single-session tDCS in targeting the DLPFC to enhance postoperative sleep quality. Future studies are required to explore more cortical targets, and the use of repetitive stimulation for patients is recommended.

In conclusion, our findings under the current experimental conditions suggest a potential prophylactic effect of a single session of anodal tDCS over the left DLPFC in improving postoperative short-term objective sleep measures characterised by an extended duration of slow-wave sleep, increased REM sleep and overall sleep time, as well as higher proportions of REM sleep and deep sleep. The long-term efficacy of tDCS as a sleep intervention has not yet been sufficiently demonstrated. We suggest that this neuromodulatory approach may be part of the prophylactic alternatives available for PSD. The validation of our findings in future studies necessitates the implementation of multisite randomised controlled trials.

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**Acknowledgements** We are grateful for the support of the orthopaedic surgeons and nursing teams of the Affiliated Hospital of Xuzhou Medical University. We also appreciate all the research staff and all the patients who participated in the study.

**Contributors** JY: conceptualisation, methodology, formal analysis, writing (original draft). MT: conceptualisation, methodology, formal analysis, writing (original draft). RL: conceptualisation, methodology, formal analysis. JF: conceptualisation, methodology, software, investigation. CL: intervention implementation. DC: intervention implementation. QW: intervention implementation. XX: software, investigation, data analysis. WZ: software, investigation, data analysis. WT: software, investigation, data analysis. YH: resources, supervision, funding acquisition. HZ: resources, supervision, funding acquisition. HL: conceptualisation, funding acquisition, resources, supervision, writing (review and editing). SZ: conceptualisation, funding acquisition, resources, supervision, writing (review and editing). JC: conceptualisation, funding acquisition, resources, supervision, writing (review and editing). All authors approved the manuscript for publication. The work described was original research that has not been published previously and is not under consideration for publication elsewhere, in whole or in part. The first author, JY, and the corresponding author, JC, are responsible for the overall content as guarantors.

**Funding** This study was supported in part by grants from the National Key R&D Program of China (2021ZD0203100 to JC); National Natural Science Foundation of China (NSFC81720108013, NSFC31771161 and NSFC81230025 to JC; NSFC81300957 and NSFC82171227 to HL; NSFC81771453 and NSFC31970937 to HZ); Jiangsu Provincial Special Program of Medical Science (BL2014029 to JC); Basic and Clinical Research Center in Anesthesiology of Jiangsu Provincial 'Science and Education for Health' Project (JC); Zhejiang Provincial Natural Science Foundation (LY22H090019 to HL); Jiangsu Provincial Natural Science Foundation (BK20190047 to HZ); the Priority Academic Program Development of Jiangsu Higher Education Institutions (19KJA610005 to HZ); Distinguished Professor Program of Jiangsu (HZ); Jiangsu Province Innovative and Entrepreneurial Talent Program and Jiangsu Province Innovative and Entrepreneurial Team Program (HZ); Xuzhou Medical University start-up grant for excellent scientist (D2018010 and D2019025D to HZ); the Natural Science Foundation of Shanghai (21ZR1411300 to YH); and Shenkang Clinical Study Foundation of Shanghai (SHDC2020CR4061 to YH).

**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by the Ethics Committee of the affiliated hospital of Xuzhou Medical University (ethics identifier: XYFY2022-KL004-01; date: 20 January 2022; chairperson: Professor Tie Xu). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. De-identified individual clinical data will be made available upon request to the corresponding authors only for non-commercial research to individuals affiliated with academic or public health institutions.

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