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Efficacy of microcurrent therapy for treatment of acute knee pain: A randomized double-blinded controlled clinical trial

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Abstract

Objective: We would like to determine whether electrotherapy, specifically microcurrent therapy, increases function and decreases pain in people who have acute knee pain.
Design: Randomized, double-blinded, placebo-controlled clinical trial.
Setting: University laboratory and patient home.
Subjects: A total of 52 subjects (35 females and 17 males) with acute knee pain.
Intervention: Treatment group ($n = 26$) wore the active microcurrent therapy device at home for 3 hours per day for 4 weeks and the control group ($n = 26$) wore the placebo for 3 hours per day for 4 weeks.
Main Measures: Numeric Pain Rating Scale (NPRS) and Short Form 12 (SF-12) health scale were used to measure the pain level and the functionality of the participants. Secondary assessments included musculoskeletal ultrasound imaging (MSK US) and Lower Extremity Functional Scale (LEFS).
Results: A total of 52 subjects completed the study; 26 in the treatment group and 26 in the control group. Microcurrent therapy significantly reduced pain over 4 weeks. Especially week three was significant ($P < 0.01$) after adjusting for the family-wise error rate. The analysis on SF-12 revealed those with microcurrent therapy showed an increasing trend in the improvement of physical function score until week three.
Conclusion: An active microcurrent therapy device decreased knee pain and increased function. Microcurrent therapy may be an alternative or used with a pharmacological approach for people with acute knee pain.

Keywords

Microcurrent, electrical stimulation, pain, knee

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Introduction

A common intervention for knee pain is medication. Pharmacological treatments including opioids are not especially successful and have significant harmful effects.[1–4] More research is now being done for the treatment of pain using non-pharmacological interventions. Microcurrent therapy is currently an FDA approved device, which involves the application of a very small electric current, less than 1 mA, to the body for therapeutic effect.

Microcurrent therapy remains a relatively obscure modality and is unfamiliar to many clinicians.[5] This may in part be due to the mixed evidence of its effectiveness, with studies using some forms of microcurrent therapy failing to find evidence of its use for pain relief.[5–9] Others observe studies having methodological shortcomings.[5,10] While others report a significant reduction in pain using microcurrent therapy.[5,11]

The mechanism of pain control using a microcurrent therapy device, also called microtens device, differs from traditional transcutaneous nerve stimulation using nerve excitation by sensory stimulation. One theory of the microtens device for pain control is it can create or change the constant DC flow of the neural tissues, which may have some way of biasing the transmission of the painful stimulus. Microtens devices may also make the nerve cell membrane more receptive to neurotransmitters that will block transmission. The mechanism for pain control using microtens device is still under investigation.

A recent pilot study conducted at Elon University demonstrated trends for decreasing pain and increasing function with acute knee pain over 4-weeks using microtens device. The purpose of this study was to improve the research design with a double-blind, randomized control design that included a control group (placebo microcurrent device). This study observed if microtens device increases function and decrease pain with people that have acute knee pain and if its effect is significant in any subgroup of the population.

Methods

Omron Health assisted with funding for this project, but Elon University was responsible for the integrity and conduct of the study. Shozo Takamatsu from Omron Health played a role in the study design but did not influence the data analysis, interpretation, writing of the paper, especially the discussion. This is a randomized, double-blinded, placebo-controlled clinical trial. The subjects enrolled from January 2018 until September 2019. All data were collected at Elon University, Elon, NC. The study was approved by the Ethics Committee of Elon University (ID: 17-186) and registered at Clinical Trials (NCT04084236). All subjects signed an informed consent form and received a $50.00 gift card upon the completion of the study.

The subjects were self-referred to the study via advertisements posted at Elon University and around the city of Burlington, NC, as well as via word of mouth (convenience sampling). The subjects were included in the study if they met the inclusion criteria of male or female between the ages of 21–70, injury/pain that began before 6-weeks before the beginning of the study, pain perceived as a minimum of 3/10 on a 0–10 pain scale, no phobia of electrical stimulation, no pain or anti-inflammatory medication taken during study and English speaking. Subjects were excluded if they were pregnant, diagnosed with Diabetes Mellitus I or II, Patella Femoral Joint Pain, Uncontrolled Hypertension, Rheumatoid Arthritis at the knee, cardiovascular disease, and ligament injury at the knee or allergic to tape/electrodes.

During the first visit, the consent form was reviewed along with the inclusion and exclusion criteria. Upon completion of signing the consent form, the subjects self-reported their demographic data such as their age (years), height (inches), and weight (lbs.) and completed the following primary outcome questionnaire measures: Numeric Pain Rating Scale (NPRS) in terms of current pain, least pain, worst pain, and average pain,[12,13] Lower Extremity Functional Scale (LEFS),[14] and the Short Form 12 (SF-12).[15] Graduate students at Elon University collected the measurements under the supervision of the principal investigator. Secondary outcome measurements included lower extremity manual muscle testing (MMT),[16] range of motion (ROM),[16] and, musculoskeletal ultrasound imaging

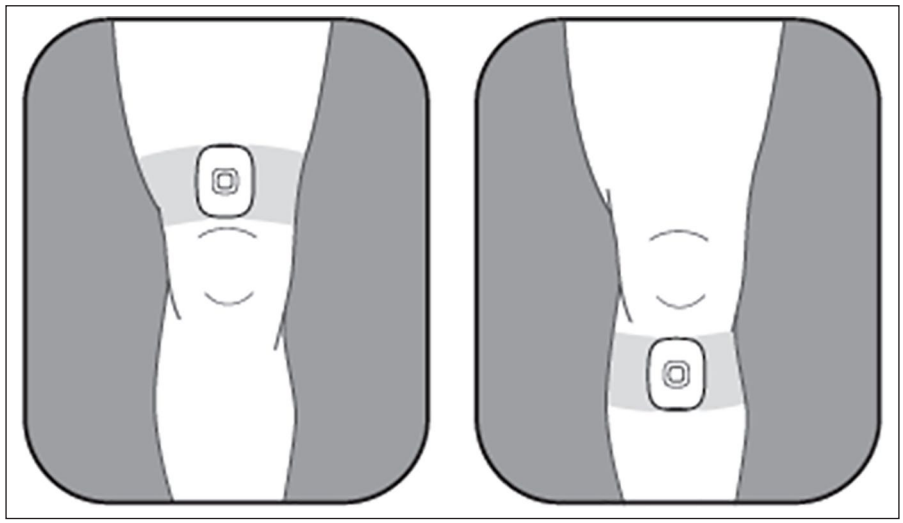

Figure 1. There are two electrodes on one pad, placement was to cover the painful location at the knee.

(MSK US). The musculoskeletal ultrasound imaging protocol was performed according to the European Society of Musculoskeletal Radiology (ESSR) guidelines at the involved knee.[17] The images were obtained at the involved knee by placing the probe longitudinal at the supra-patellar bursa and quadriceps tendon, patellar tendon, lateral and medial collateral ligaments, and meniscus along with the biceps femoris tendon. Measurements were taken at baseline and weeks one to four. These imaging data were collected by the principal investigator, who had 5 years of experience in musculoskeletal ultrasound imaging.

The random assignment of active or placebo microtens device was blinded to the subject and the investigator to avoid any subject or investigator bias. A total of 26 subjects were given microtens devices and 26 subjects were given placebo devices.

Electrode placement at the knee was placed in the area of pain.[18] To maintain the reliability of the electrode placement, the electrodes were placed at a specific distance from the center of the pain. For example, the large electrodes ($220 \times 83.5 \times 9.3$ mm) were placed 57 mm to the edge of each electrode with the pain being the measuring point. The small electrodes ($180 \times 79.5 \times 9.3$ mm) were placed 38 mm to the edge of the electrode from the focal area of pain (Figure 1). The unit was attached to the electrodes, and the placebo or active microtens device was worn for 3 hours per day at home. Time duration per day was estimated from other microcurrent therapy studies.[19,20] The parameters were fixed for the device at 50 μA, frequency of 0.2 Hz, bipolar pulse square waveform, and constant current control.

Subjects were asked to wear the electrodes with the active or placebo microcurrent treatment for three consecutive hours per day and reminded to abstain from any pain or anti-inflammatory medication throughout the study. Daily text reminders were sent to the subjects as a friendly reminder to use the device. This method demonstrated high compliance with another study.[21] The subjects would respond with an affirmative response. If no response, another text would be sent until confirmation of compliance has been achieved. This method provided good compliance with the daily use of the microcurrent. The demonstration of the appropriate place for the electrodes was demonstrated on the first visit by the principal investigator. Subjects were followed once per week for 4 weeks and given feedback through verification by demonstrating how they were placing the electrodes on the knee.[22] The weekly feedback enabled excellent verification of the appropriate placement

of the electrodes. Compliance may also have been enhanced with a $50.00 gift card that was awarded at the end of the study. New electrodes were provided weekly to optimize conductivity. The unit could be worn while doing functional activities at home. After 3 hours, the unit would automatically shut off.

After the subject's initial visit, they would return between 7 and 8 days for 4-weeks to fill out the outcome surveys and be imaged using musculoskeletal ultrasound at the knee.

The sample size was determined by power analysis with an effect size greater than 0.8, a significance level of 5%, a power level of 80%, and an allocation ratio of one. The resulting sample size was 52 with 26 in each group.

Treatment allocation has been done using a permuted block randomization method with a block size of two. A random number between zero and one is generated for each block using excel function, and if the number is lower than 0.5, then the block is assigned as active-placebo, and if the number is greater than or equal to 0.5, then the block is assigned as placebo-active. The randomization is done and stored by Shozo Takamatsu who is not involved in data collection so that both the subjects and the investigators are blinded to the allocation until the end of the trial (double-blinded trial). Figure 2 shows the study flow diagram.

For data analysis, the statistical software R version 3.6.2[23] was used. The analysis was carried out using parametric tests after checking the assumptions. For the comparison of baseline demographics (age and BMI), baseline pain scores (current, least, worst, and average), baseline LEFS scores, and baseline SF-12 scores (overall, mental, and health), a two-sample t-test was used. To evaluate the performance of microtens device, we had the following three aims. Our main measure for analysis was the worst numeric pain rating. A significance level of 0.05 was used for all analyses.

Aim 1 (Worst pain reduction): Our first aim was to see whether microtens device reduces the worst knee pain. We performed two-sample t-tests to see whether the worst knee pain of two groups are different at each week and whether the worst knee pain reduction of the two groups are different from the baseline. In both analyses, we had a set of hypotheses that we wanted to test simultaneously. Therefore, we used the Bonferroni correction to avoid multiple testing problems and control the family-wise error rate.

Aim 2 (Physical function improvement): Our second aim was to see whether the microtens device improves the physical function. To see whether the physical function score improved from the baseline, we calculated the score differences from baseline to each week and presented in a descriptive method.

Aim 3 (Subgroup analysis): Our third aim was to see if the worst pain reduction is more significant in any subgroup of the population. To do so, we ran repeated measures ANOVA on the data. We ran a mixed-effects model with fixed effects of main and interaction terms with treatment (microtens/placebo), gender (female/male), age group (young/middle-aged/older), and BMI and with random effects of subjects. Age group refers to "young" with ages up to 35, "middle-aged" with ages between 36 and 55, and "older" with ages greater than 55.[24] The response variable is the worst pain change, meaning how much of the pain reduced from baseline to each week. If it is a positive number, that means the worst pain has reduced from the baseline, and if it is a negative number, then the worst pain has increased from the baseline.

*Omron Healthcare Co., Ltd., model:PM601 prototype.

Results

A total of 52 subjects enrolled in the study. The placebo group had 26 subjects and the treatment group had 26 subjects. Table 1 illustrates the demographics. The two groups with active and placebo microtens devices were not different at baseline except for the overall Short Form 12 (SF-12) and for the mental component of the Short Form 12 (SF-12) where active group scored higher. We used two-sample t-tests for comparison of demographics to see if the mean measure of the active group was different from the mean measure of the placebo group.

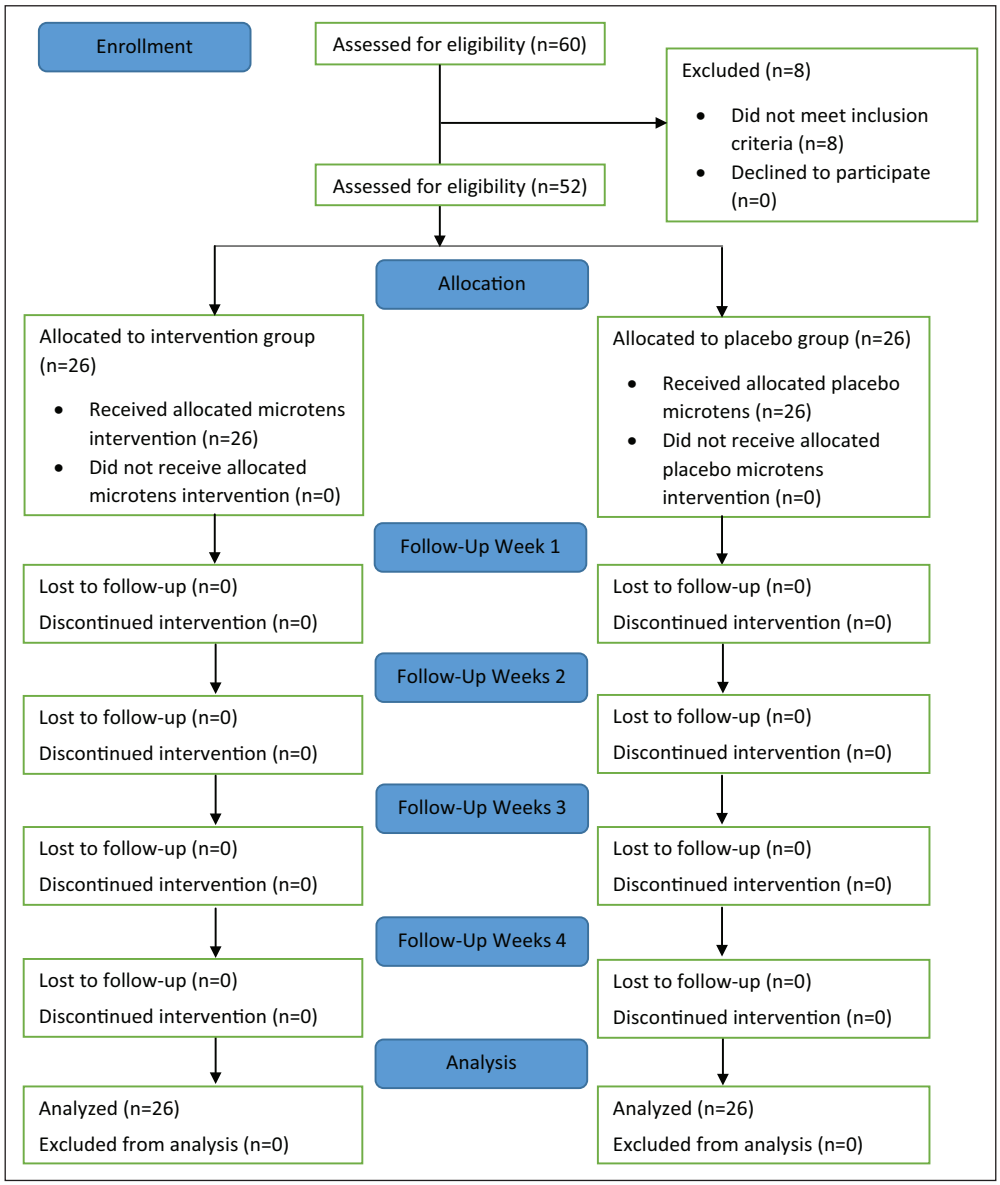

Figure 2. CONSORT flow diagram.

Table 2 shows how the worst pain changed over weeks for both active microtens group and the placebo group. Although there was no statistically significant difference in worst pain each week when we compared the active group to the placebo group, the mean worst pain decreased more for the subjects in the active group than the subjects in the placebo group until week three. Table 3 shows the worst pain reduction from baseline to each week *i* that is calculated by (baseline score - week *i* score). Here, we found the active group's reduction in worst pain was significantly higher than the placebo group's. After we adjusted for the family-wise error rate, the reduction was especially

Table 1. Baseline numbers are the mean scores and the standard deviations from week zero or first visit.

Measure	Active	Placebo	*P*-value
Age	44.27 (15.27)	40.38 (15.99)	0.3828
BMI	30.74 (10.36)	26.34 (7.27)	0.0907
Pain (current)	2.94 (1.54)	2.65 (1.85)	0.5442
Pain (least)	1.33 (1.07)	1.19 (1.36)	0.6926
Pain (worst)	6.35 (2.06)	5.46 (2.14)	0.1350
Pain (average)	3.54 (1.35)	3.10 (1.46)	0.2690
LEFS	53.27 (12.70)	57.92 (9.61)	0.1426
SF-12 (overall)	32.58 (2.42)	31.15 (2.22)	0.0318
SF-12 (physical)	12.31 (1.62)	12.35 (1.13)	0.9213
SF-12 (mental)	20.27 (1.93)	18.81 (1.96)	0.0009

BMI: body mass index; LEFS: lower extremity functional scale; SF-12: short form 12.

Table 2. Numbers in the table are mean worst pain scores in each week for the active group and the placebo group and the standard deviations are reported inside the parenthesis.

Week	Mean worst pain score	
	Active group	Placebo group
0	6.35 (2.06)	5.46 (2.14)
1	4.54 (2.70)	4.38 (2.47)
2	4.00 (2.40)	4.19 (2.37)
3	3.15 (1.74)	3.96 (2.42)
4	3.42 (2.50)	3.77 (2.42)

significant when we compared the third week to the baseline ($P < 0.01$). Here our p-value has been compared with $1 - (0.95)^{1/4} = 0.0127$ to accommodate the Bonferroni correction.

Table 4 shows the improvement in Short Form 12 (SF-12) mean physical score when we compared each week to the baseline. Since higher SF-12 score means a higher level of health, we calculated the mean improved score for each week *i* by (week *i* score – baseline score). We found an increasing trend in improvement until week three for the subjects with active microtens device. Although the improvement decreased in week four, the mean score was still higher than the baseline. On the other hand, we found a decreasing trend in improvement for the subjects in the placebo group.

From the repeated measures ANOVA results, we have found that the interaction term among treatment, age group, and BMI shows significance with a p-value of 0.047. When we took a closer look at the three-way interaction effect as in Table 5, it was found that the effect of microtens device was greater for the "older" group with higher BMI. The "older" age group with active microtens device shows 0.735 further decrement in worst pain with one unit increase of BMI than the "middle-aged" group with active microtens device. This decrement showed significance with a p-value of 0.025. The "young" group with active microtens device seems to show 0.148 less worst pain reduction with an increment of BMI than the "middle-aged" group with active microtens device, meaning that "middle-aged" group shows a higher reduction in worst pain for same BMI with microtens device, but this difference was not significant.

Discussion

The primary aim of this investigation was the effect of microtens on pain and function. We found that active microtens device reduced the subject's worst pain significantly more than placebo. We also found that with the active microtens device there was an increasing trend in function measured by Short Form 12 (SF-12) physical component (PCS). This increased function correlated well with decreased worst pain. Over the 4-weeks of microtens intervention, some natural tissue healing occurred.[25,26] The subgroup analysis revealed that the active microtens had further decreased

Table 3. Numbers in the table are mean worst pain reduction from the baseline for the active group and the placebo group and standard deviations are reported inside the parenthesis.

Week	Mean worst pain reduction from baseline		*P*-value
	Active group	Placebo group	
1	1.81 (1.79)	1.08 (2.19)	0.097
2	2.35 (2.26)	1.27 (2.05)	0.040
3	3.19 (1.74)	1.50 (2.35)	0.002*
4	2.92 (2.15)	1.69 (2.09)	0.021

P-value is based on t-test for active group worst pain reduction greater than that of the placebo group.
*Significant after Bonferroni correction.

Table 4. Number in the table are mean SF-12 physical score improvement from the baseline for the active group and the placebo group and standard deviations are reported in the parenthesis.

Week	Mean SF-12 physical score change from baseline	
	Active group	Placebo group
1	0.00 (1.33)	0.23 (1.21)
2	0.23 (1.34)	0.12 (1.34)
3	0.50 (1.30)	0.08 (1.09)
4	0.19 (1.47)	0.08 (1.13)

SF-12: short form 12.

Table 5. Detailed summary of three-way interaction among treatment (microtens/placebo), age group (young/middle-aged/older), and BMI. Compared to the middle-aged group, older age group have significantly higher reduction in worst pain.

Term	Value	Std.Error	*P*-value
Treatment + Older + BMI	0.735	0.310	0.025
Treatment + Young + BMI	−0.148	0.247	0.553

BMI: body mass index.

worst pain from the baseline for older individuals with higher BMI. This finding is encouraging, especially for a large target group that fits this description with acute knee pain. As the analysis is based on a small sample size ($n = 52$), the clinical significances found here could be due to a random chance, but we have promising results to conduct a larger study.

This was the first double-blinded randomized clinical trial using microtens device with people that have acute knee pain. Since microtens delivers a subthreshold stimulation to the skin, the device also serves as a very good placebo. The placebo device has identical appearance, identical display operation specifications, and identical perception of stimulation as the active device.

A pilot study using microtens at home for chronic tennis elbow pain also saw similar decreases in pain as our study.[20] This study looked at two current intensities and found the groups who had the most significant decrease in pain was observed with a peak current intensity of 50 μA vs. 500 μA. Our study also used 50 μA for knee pain.[20]

Our study found a trend in increased function that correlated well with a decrease in pain, especially at week three. Microtens was also found to increase function with increased cervical range of motion in infants with congenital muscular torticollis using a home program.[27] This study compared therapeutic exercise with ultrasound alone with another group that had the addition of home microtens.[27] After 3 months of post-treatment, the cervical range of motion was significantly increased and the cross-sectional area of the affected sternocleidomastoid muscle was significantly smaller in the group that used microtens.[27]

One of the questionnaires we used for the function was the Lower Extremity Functional Scale (LEFS). It was interesting that this questionnaire was not as sensitive to change in function with this specific group as the physical component (PCS) Short Form 12 (SF-12). The difference between the

groups and within groups was not significant using the Lower Extremity Functional Scale (LEFS). This may be that the instrument used was not sensitive enough in this population to capture changes in function. Other studies using the Lower Extremity Functional Scale (LEFS) and knee pain demonstrated only a moderate response.[28]

As for other secondary outcome measures, both lower extremity manual muscle testing and range of motion were within normal limits with all subjects.

One limitation is a lack of long-term follow-up. Natural healing expectations of muscle and tendon injury usually occurs in 2–6 weeks and ligaments up to 12 weeks.[25] Outcomes up to 12 weeks would have been helpful with both groups.

The clinical implications of this study suggest that people who received active microtens perceived reduced pain with acute knee pain. The investigation also used musculoskeletal ultrasound imaging to observe any swelling or effusion. A trend was observed of decreased effusion in this area in the active microtens group over the first 2 weeks versus the placebo group at the suprapatellar region. Although the decrease in effusion is encouraging, we had a smaller sample size with an active microtens group ($n = 7$) compared to the placebo group ($n = 17$). The uneven sample size creates caution with the interpretation of these results. Future studies may want to use musculoskeletal ultrasound elastography to observe tissue changes[29] over 4-weeks in addition to swelling or effusion. This information may give a better insight into tissue healing and the use of microtens. Future studies may also want to look at different dosages of microtens per day to see any changes in the perception of specific acute knee pain and function along with the role it plays with edema and tissue healing using musculoskeletal ultrasound imaging and elastography. Observation of any "carry over" or post-treatment effect of microtens with pain, function, muscle, or edema should be included in future studies. Other studies may look at the use of microtens and chronic knee pain especially in the area of knee Osteoarthritis.

Clinical messages

- Microcurrent therapy, when worn at home for 3 hours per day, demonstrated a weekly decrease in pain with it being significant at 3 weeks.
- Microcurrent therapy, when worn at home for 3 hours a day also demonstrated increase function, especially at 3 weeks.

Author contributions

D.J.L contributed to the conception of the study, supervised the clinical trial, and performed manuscript writing and edition. H.K. and K.L. performed data analyses and manuscript writing and edition. S.T. contributed to the conception and design of the study. N.Y. and T.L. performed data collection. All authors have agreed with the submitted version of the manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics Approval

All study participants signed informed consent. The study was approved by the Ethics Committee of Elon University (ID: 17-186).

Trial Registration

ClinicalTrials.gov (NCT03482518).

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