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# Vascular Discovery: From Genes to Medicine

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## **Effect Of Home-Based Leg Heat Therapy On Walking Performance In Symptomatic Peripheral Artery Disease: A Pilot Randomized Clinical Trial**

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### **Abstract:**

**Introduction:** Few non-invasive therapies currently exist to improve functional performance and restore quality of life in people with lower extremity peripheral artery disease (PAD). We previously demonstrated that supervised leg heat therapy using tube-lined trousers perfused with warm water elicited a clinically meaningful improvement in perceived physical functioning in patients with PAD. **Hypothesis:** We tested the hypothesis that unsupervised, home-based leg HT is safe and well-tolerated and improves walking performance in patients with symptomatic PAD. **Methods:** Thirty-four participants with an ankle-brachial index (ABI) values < 0.90 and a history of claudication were randomized into one of two groups: those receiving leg HT (n=18) or those receiving a sham treatment (n=16). Patients in both groups were provided with identical water-circulating trousers and a portable heating pump and were asked to apply the therapy daily (7 days/week, 90 min per session) for 8 consecutive weeks. The pump given to participants in the HT group circulated water at 43°C through the trousers, while in the sham group the pump circulated water at 33°C. The primary study outcome was the change in 6-min walk distance from baseline to 8 weeks. **Results:** Among the thirty-four patients enrolled in the study, 3 were excluded for failing to comply with study procedures and 1 voluntarily withdrew. One patient in the sham-treated group could not complete the 8-week assessment due to the COVID-19 pandemic. Overall, participants completed 96±4% of the required treatment sessions (Control: 97±4%, HT:96±3%). Further, no serious adverse reactions to treatment were observed. Changes in 6-minute walk

distance between baseline and the 8-week follow-up were compared between groups using the Wilcoxon rank sum test, since the data distribution was non-normal. The change in 6-minute walk distance was significantly higher ( $p=0.029$ ) in the group exposed to HT ( $n=15$ ; median: 21.3; 25%,75% percentiles: 10.0,42.3) as compared to the control group ( $n=14$ ; median: -0.91; 25%,75% percentiles: -5.7,14.3). **Conclusions:** These preliminary results suggest that home-based leg HT for 8 weeks promotes clinically meaningful changes in 6-minute walk distance in patients with symptomatic PAD.

**PresentationPreference (Complete):** Oral Preferred

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**\*Has this work received funding from the AHA Strategically Focused Research Network (SFRN) on Vascular Disease?:** No

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