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Title: Targeting pain after cancer: Results from a feasibility randomized controlled trial of wearable respiratory intervention for chronic pain in childhood cancer survivors

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Abstract

Context: Approximately 40% of adult survivors of childhood cancer experience chronic pain, with 33% of these survivors also experiencing clinically significant anxiety. As respiration, anxiety, and pain are inter-related, regular practice of deep diaphragmatic breathing and continuous tracking of respiration may help survivors manage both pain and anxiety. The present study aimed to examine the feasibility, acceptability, and preliminary efficacy of wearable respiratory intervention among survivors of childhood cancer with chronic pain.

Methods: Survivors reporting ≥3 months with chronic pain (n=76) were recruited from the Childhood Cancer Survivor Study, a cohort of ≥5-year survivors of childhood cancer who were treated at institutions across North America. Sixty-five survivors (85.5%; median age=44.0 [range=25–62] years) consented and were randomized to the intervention (*Stone device, Spire Health*; n=32) or control (n=33). Participants in the intervention and control groups completed a set of valid and reliable self-report measures of pain-related disability, average pain, anxiety, sleep, and negative affect at pre- and post-treatment. Qualitative feedback was obtained regarding barriers and facilitators of device use and analyzed using thematic content analysis.

Intervention: The intervention group was instructed to wear the device for 30 days and complete daily breathing exercises via an app. The control group did not receive a device and did not complete breathing exercises. Reminder phone calls, texts, and emails were sent by the study team to enhance intervention engagement.

Results: Ninety-seven percent of survivors completed the study. Among the intervention group, 29 (93.5%) participants wore the stone device ≥50% of the required days and 74.2% were satisfied/very satisfied with the device. Total cost associated with device delivery/use/return was $528 USD, with 93.8% of devices returned. Post-treatment improvement was significantly greater in the intervention group compared to control group for negative affect (Cohen's d=0.59, p=0.02). Effect sizes indicated some improvement on measures of pain-related disability (Cohen's d=0.36), and average pain (Cohen's d=0.29), but they were nonsignificant. Facilitators to device use included ease of use, increased awareness, and learning new pain management skills. Barriers included forgetting to charge and wear the device as well as disruptions due to device notifications.

Conclusions: Study findings support the feasibility, acceptability, and potential efficacy of wearable respiratory intervention. Larger scale trials are needed to assess efficacy and maintenance of this intervention for chronic pain among survivors of childhood cancer.

Implications: If found to be effective in a larger trial, wearable respiratory intervention represents a scalable (i.e., accessible by many survivors, simultaneously and repeatedly) and low-cost intervention that could complement already available care.