

Whole-Body Hyperthermia for the Treatment of Major Depressive Disorder: A Randomized Clinical Trial.

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ABSTRACT

Importance

Limitations of current antidepressants highlight the need to identify novel treatments for major depressive disorder. A prior open trial found that a single session of whole-body hyperthermia (WBH) reduced depressive symptoms; however, the lack of a placebo control raises the possibility that the observed antidepressant effects resulted not from hyperthermia per se, but from nonspecific aspects of the intervention.

Objective

To test whether WBH has specific antidepressant effects when compared with a sham condition and to evaluate the persistence of the antidepressant effects of a single treatment.

Design, Setting, and Participants

A 6-week, randomized, double-blind study conducted between February 2013 and May 2015 at a university-based medical center comparing WBH with a sham condition. All research staff conducting screening and outcome procedures were blinded to randomization status. Of 338 individuals screened, 34 were randomized, 30 received a study intervention, and 29 provided at least 1 postintervention assessment and were included in a modified intent-to-treat efficacy analysis. Participants were medically healthy, aged 18 to 65 years, met criteria for major depressive disorder, were free of psychotropic medication use, and had a baseline 17-item Hamilton Depression Rating Scale score of 16 or greater.

Interventions

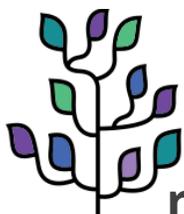
A single session of active WBH vs a sham condition matched for length of WBH that mimicked all aspects of WBH except intense heat.

Main Outcomes and Measures

Between-group differences in postintervention Hamilton Depression Rating Scale scores.

Results

The mean (SD) age was 36.7 (15.2) years in the WBH group and 41.47 (12.54) years in the sham group. Immediately following the intervention, 10 participants (71.4%) randomized to sham treatment believed they had received WBH compared with 15 (93.8%) randomized to



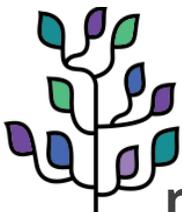
WBH. When compared with the sham group, the active WBH group showed significantly reduced Hamilton Depression Rating Scale scores across the 6-week postintervention study period (WBH vs sham; week 1: -6.53 , 95% CI, -9.90 to -3.16 , $P < .001$; week 2: -6.35 , 95% CI, -9.95 to -2.74 , $P = .001$; week 4: -4.50 , 95% CI, -8.17 to -0.84 , $P = .02$; and week 6: -4.27 , 95% CI, -7.94 to -0.61 , $P = .02$). These outcomes remained significant after evaluating potential moderating effects of between-group differences in baseline expectancy scores. Adverse events in both groups were generally mild.

Conclusions and Relevance

Whole-body hyperthermia holds promise as a safe, rapid-acting, antidepressant modality with a prolonged therapeutic benefit.

Tags:

depression, hyperthermia, thermotherapy, major depressive disorder, antidepressants



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