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Modifications to the HEALing Communities Study in Response to COVID-19 Related Disruptions

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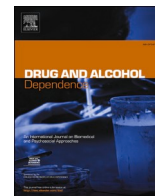
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Letter to the Editor

**Modifications to the HEALing Communities Study in response to COVID-19 related disruptions**

The COVID-19 pandemic has coincided with a rise in opioid-related overdose deaths and placed significant burdens on medical, substance use and mental health treatment systems that might otherwise implement evidence-based practices (EBPs) to reduce these deaths (Centers for Disease Control and Prevention, 2020). These COVID-19 related disruptions significantly impacted the implementation of the Communities That HEAL (CTH) Intervention. As a consequence, the study leadership and federal sponsors agreed to modify the design of the HEALing Communities Study (HCS; *The HEALing Communities Study Consortium, 2020*) in January 2021. While the study design, hypotheses, measurement, and primary and secondary outcomes remain unchanged, the study end date will be extended by 12 months (ending 3/31/24) as follows:

- The implementation period for Wave 1 communities will be extended by 6 months (ending 6/30/22), and the implementation period for Wave 2 communities will be delayed by 6 months (7/1/22–6/30/23).
- The comparison period for testing the main and secondary hypotheses between Wave 1 and Wave 2 communities will be 7/1/21–6/30/22.
- The community engagement intervention (Sprague Martinez et al., 2020) remains unchanged except that the implementation phases (Phases 5 and 6) will be extended by 6 months in Wave 1 communities. Many of the advisory and coalition meetings have been converted to video format (e.g., Zoom).
- The menu of EBPs outlined in the ORCCA (Winhusen et al., 2020) remains unchanged except that the strategies will be delivered for an additional 6 months in Wave 1 communities. Coalitions have emphasized strategies that can be delivered using telehealth.
- The communication campaigns (Lefebvre et al., 2020) in Wave 1 communities will be reduced to 4 unique campaigns (i.e., stigma, naloxone, MOUD initiation, MOUD retention) with the option to re-run any of the previous four for a 5th campaign. We anticipate Wave 2 communities will select and tailor 2 campaigns.
- The implementation science (Knudsen et al., 2020) and health economics (Aldridge et al., 2020) components will remain largely unchanged.
- With the exception of aligning follow-up measures to correspond with new time periods, the approach to data collection and analysis for the main and secondary hypotheses (Slavova et al., 2020) remains unchanged.

These modifications will allow additional time and resources to mitigate the impact of the COVID-19 pandemic on the implementation of the CTH intervention. The extension also allows us to preserve the full 12-month intervention for Wave 2 communities, as per the original

commitment. HCS remains committed to reducing opioid overdose deaths by 40 % and creating a model for addressing the national opioid crisis.

Contributors

STW drafted the manuscript. All authors provided input and have approved the final letter.

Trial registration

Clinical Trials.gov <http://www.clinicaltrials.gov>; Identifier: NCT04111939.

Role of the funding source

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Declaration of competing interest

The authors report no declarations of interest.

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