Study Identification

Unique protocol identification number: STUDY00004627

Brief Title: Training LHD's to disseminate evidence-based interventions to small work sites

Official Title: Training Local Health Departments to Disseminate Evidence-Based Interventions to Small and Low-Wage Worksites

Secondary IDs: 2R01CA160217   [U.S. NIH Grant/Contract Award Number]
                    NCI-2021-02876   [Registry ID: CTRP (Clinical Trial Reporting Program)]
                    RG1121453   [Fred Hutch/University of Washington Cancer Consortium]

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This document includes the statistical analysis plan excerpted from our grant proposal. We completed this text on the above date.

Statistical analysis plan

       To test whether LHDs in the enhanced arm recruit more worksites than LHDs in the standard arm, we will use a generalized linear model with log link. Robust standard error will be performed to obtain valid test results, since we expect the number of worksites recruited to be overdispersed relative to the Poisson distribution. We will perform a secondary analysis to test whether the rate of recruitment increases over time and whether such an increase is modified by treatment status. To study the time effects, we will analyze the number of worksite recruitments in 6-month intervals. The estimation will be implemented using a generalized estimating equation with an autoregressive working correlation matrix of order 1. Robust standard error will be performed to obtain valid test results of correlated outcome data. We will use linear models to study the worksite implementation score. Since worksites are nested within LHDs, we will implement the estimation using generalized estimating equation with robust standard error.

       <u>Power analysis</u>. Our first primary outcome is the number of worksites recruited by each LHD during the study period (24 months). Based on power analysis using the Washington State pilot data, we propose a sample size of 40 LHDs (20 per arm) for this study. The mean number of worksites recruited over a 12-month period was 8.4 (sd=4.4). The proposed design will have at least 80% power to detect a mean difference of 2.6 worksites per year between the two arms. Our second primary outcome is the worksite implementation score, collected 12 months after the initial delivery of *Connect to Wellness*. Based on the preliminary results of the parent project, our design has at least 80% power to detect a 6% difference in implementation scores between the two intervention groups.

       <u>Implementation cost analyses</u>. We will assess the overall costs to implement the basic and enhanced training and TA strategies, including all training and TA activities conducted by the research team as well as *Connect to Wellness* activities performed by LHDs. We anticipate five categories of costs: 1) LHD staff time; 2) LHD-incurred costs for printing *Connect to Wellness* materials and traveling to worksites; 3) fixed costs of updating and maintaining the *Connect to Wellness* training materials and website; 4) research staff time to provide training and TA; and 5) ongoing evaluation and communication activities. LHD staff activities will be assessed by multiple approaches. Each LHD will be asked to identify a dedicated amount of time to the intervention for specific staff members, which will be updated quarterly through staff logs using zerosum methodology in which categories of activities must sum to 100% of total hours worked. To ensure generalizability, staff time will be costed from national wage information based on the LHD employees' job titles and years of experience. Research team activities will include staff and resources dedicated to start-up and ongoing training and TA costs. Only costs necessary for *Connect to Wellness* training and TA will be included; costs will not include research activities such as grant administration, human subjects documentation and reporting, and manuscript preparation. We will report all costs in 2020 U.S. dollars.