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mHIMSS 2013 Abstract

WelTel LTBI: A Randomized Controlled Trial Protocol of a Text-Messaging Intervention to Improve Patient Adherence to Treatment for Latent Tuberculosis Infection

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Journal MTM 2:4S:4, 2013 DOI: 10.7309/jmtm.2.4S.3 www.journalmtm.com

Abstract

Successful treatment of latent tuberculosis infection (LTBI) is critical to reduce the impact of TB; however, in North America, fewer than half of individuals starting LTBI treatment complete therapy. While existing TB treatment adherence interventions have not yet proven consistently successful, evidence has shown that weekly text messages can improve treatment adherence in HIV. One of these evidence-based interventions is WelTel, a service involving weekly text-message "check-ins" with patients. The aim of this study is to determine the effectiveness of the WelTel intervention on adherence to LTBI treatment.

The objectives of this study are to: 1) determine the effect of the WelTel intervention on completion of LTBI treatment; 2) determine the effect of the WelTel intervention on daily adherence to LTBI treatment; 3) measure patient satisfaction with the WelTel intervention; 4) evaluate the cost-effectiveness of the WelTel intervention.

A multi-site randomized controlled trial will be conducted at three TB control clinics in British Columbia, Canada. Over two years, we expect to enroll 486 individuals diagnosed with LTBI and initiating isoniazid (INH) (300mg daily for nine months). Participants will be randomly allocated to an intervention or control arm (standard care) at a 1:1 ratio. Intervention arm participants will receive a weekly SMS 'check-in', "Are you OK?", to which they will be instructed to respond within 48 hours either "yes" or "no". A TB clinician will follow-up and triage any problems that are identified. Participants will be followed for one year, with a primary endpoint of treatment completion, defined as having taken at least 80% of prescribed doses within 12 months. Follow-up questionnaires will be used to assess participant satisfaction with the intervention. Cost-effectiveness will be analyzed through decision-analytic modeling. Data will be analyzed according to intention to treat principles. Chi-squared tests will be used for categorical outcomes; and t-tests or Mann-Whitney U tests for continuous outcomes

Ethical approval has been received from the University of British Columbia Clinical Research Ethics Board (H13-01450). The trial is registered with ClinicalTrials.gov (NCT01549457). Recruitment began in July 2012, and the study is currently enrolling participants.

The WelTel LTBI trial will contribute important information on the effectiveness of the WelTel text-messaging intervention to improve treatment adherence among patients with LTBI. Trial results and a cost-effectiveness evaluation will inform how WelTel might contribute to the long-term success of TB control and elimination efforts.