# A Post-Discharge Smoking-Cessation Intervention for Hospital Patients

## Helping Hand 2 Randomized Clinical Trial

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**Introduction:** Hospitalization provides an opportunity for smokers to quit, but tobacco-cessation interventions started in hospital must continue after discharge to be effective. This study aimed to improve the scalability of a proven effective post-discharge intervention by incorporating referral to a telephone quitline, a nationally available cessation resource.

**Study design:** A three-site RCT compared Sustained Care, a post-discharge tobacco-cessation intervention, with Standard Care among hospitalized adult smokers who wanted to quit smoking and received in-hospital tobacco-cessation counseling.

**Setting/participants:** A total of 1,357 daily smokers admitted to three hospitals were enrolled from December 2012 to July 2014.

**Intervention:** Sustained Care started at discharge and included automated interactive voice response telephone calls and the patient's choice of cessation medication for 3 months. Each automated call advised cessation, supported medication adherence, and triaged smokers seeking additional counseling or medication support directly to a telephone quitline. Standard Care provided only medication and counseling recommendations at discharge.

**Main outcome measures:** Biochemically confirmed past 7–day tobacco abstinence 6 months after discharge (primary outcome) and self-reported tobacco abstinence and tobacco-cessation treatment use at 1, 3, and 6 months and overall (0–6 months). Analyses were done in 2015–2016.

**Results:** Smokers offered Sustained Care ($n$=680), versus those offered Standard Care ($n$=677), did not have greater biochemically confirmed abstinence at 6 months (17% vs 16%, $p$=0.58). However, the Sustained Care group reported more tobacco-cessation counseling and medication use at each follow-up and higher rates of self-reported past 7–day tobacco abstinence at 1 month (43% vs 32%, $p<0.0001$) and 3 months (37% vs 30%, $p$=0.008). At 6 months, the difference narrowed (31% vs 27%, $p$=0.09). Overall, the intervention increased self-reported 7-day abstinence over the 6-month follow-up (relative risk, 1.25; 95% CI=1.10, 1.40; $p$=0.0006).

**Conclusions:** A 3-month post-discharge smoking-cessation intervention for hospitalized smokers who wanted to quit did not increase confirmed tobacco abstinence at 6 months but did increase self-reported abstinence during the treatment period (3 months). Real-time linkage of interactive voice response calls to a quitline, done in this trial to increase scalability of a previously proven cessation intervention, demonstrated short-term promise but did not sustain long-term intervention effectiveness.

**Trial Registration:** This study is registered at www.clinicaltrials.gov NCT01714323.

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## Introduction

Cigarette smoking is the leading preventable cause of death in the U.S.[1] Clinical guidelines recommend that clinicians offer tobacco-cessation counseling and pharmacotherapy to all adult smokers.[2,3] Hospital admission offers smokers a unique opportunity to quit because U.S. hospitals are smoke free, requiring smokers to temporarily abstain from tobacco use while in an environment free of their usual smoking cues. At the same time, the illness requiring hospitalization, especially if tobacco related, may enhance a smoker's motivation to quit by making the health risks of tobacco more salient.[4] Offering tobacco-cessation treatment to hospitalized smokers increases by 40% the proportion of smokers who quit after discharge, but only if treatment started in hospital continues after discharge.[4] A hospital quality measure adopted in 2012 by the Joint Commission and endorsed by the National Quality Forum requires hospitals to offer tobacco-cessation counseling and pharmacotherapy to all hospitalized smokers and provide or refer smokers to treatment resources after discharge.[4,5]

For hospitals, major challenges to providing evidence-based care and satisfying the tobacco quality measure are providing in-hospital cessation services and sustaining tobacco treatment after discharge.[6] To address the latter problem, the authors' previous study developed a system-level intervention to facilitate delivery of tobacco-cessation counseling and medication after hospital discharge. Smokers received a refillable 1-month supply of tobacco-cessation medication at discharge and a series of automated telephone calls using interactive voice response (IVR) technology for 3 months. At each call, a smoker could request a return call from a live tobacco counselor. The previous single-site RCT, Helping HAND (Hospital-initiated Assistance for Nicotine Dependence, HH1), demonstrated the effectiveness of this intervention over standard care for increasing smoking-cessation rates after discharge.[7]

This model was adapted to improve its scalability for dissemination. In HH1, smokers who requested cessation support at an automated call received a subsequent return call from a hospital-based counselor funded by the research project. In the new model, smokers were transferred directly in a two-step process from the automated call to a telephone quitline provider. Quitlines are an evidence-based resource offering free cessation counseling to U.S. smokers who call a toll-free phone number.[8,9] Quitlines' universal accessibility makes them ideal resources for sustaining tobacco treatment after hospitalization. The new model's ability to transfer a smoker in real time from an automated call to a quitline service was expected to facilitate treatment use, thereby enhancing tobacco abstinence after discharge.

The new Sustained Care intervention was compared with Standard Care in a multi-site RCT. The hypothesis was that Sustained Care would increase the proportion of individuals who used evidence-based tobacco-cessation treatment and were tobacco abstinent 6 months after hospital discharge. This report also compares these results with those of the previous trial in a post hoc analysis.

## Methods

The Helping HAND 2 Trial (HH2), a three-site RCT, was approved by the IRBs of Partners HealthCare and the University of Pittsburgh and registered with the NIH Clinical Trials Registry (#NCT01714323). A detailed study protocol has been published.[10]

### Setting and Subjects

The study was conducted at three hospitals: Massachusetts General Hospital (MGH), a 900-bed teaching hospital in Boston, MA; University of Pittsburgh Medical Center, a 799-bed teaching hospital in Pittsburgh, PA; and North Shore Medical Center, a 411-bed community hospital in Salem, MA. Patients admitted to these hospitals were eligible if they were adults (aged $\geq$18 years); current smokers (smoked one or more cigarette daily when smoking normally in the month before admission); had $>$5 minutes of smoking-cessation counseling in the hospital; stated that they planned to try to quit smoking after discharge; and agreed to accept a smoking-cessation medication. Patients were excluded if they had no telephone, were non-English speaking, could not give informed consent or participate in counseling owing to psychiatric or cognitive impairment or communication barrier, were admitted to obstetric or psychiatric units, were admitted for intravenous drug overdose, had medical instability, or had $<$1 year of estimated life expectancy.

Each hospital documented new patients' smoking status electronically at admission, generating a daily roster of hospitalized smokers. A tobacco-cessation counselor visited each smoker in the hospital to help manage nicotine withdrawal symptoms and offer cessation assistance. For smokers who planned to quit or to try to quit after discharge, counselors provided specific post-discharge medication and counseling recommendations, screened them for study eligibility, and referred them to research staff who confirmed eligibility, obtained informed consent, conducted the baseline assessment, randomly assigned them to study condition, and notified the primary care provider with a note in the electronic health record or sent by fax.

### Assignment to Condition

Participants were randomly assigned (1:1) to Sustained Care or Standard Care in permuted blocks of eight, stratified by daily cigarette consumption (ten or fewer versus ten or more) and admitting service (cardiac versus other). Treatment assignment was concealed in sequentially numbered sealed envelopes within each stratum. Research staff opened the next envelope corresponding to the participant's randomization stratum. The study was not blinded.