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Dissemination of a smoking Quitline to the underserved

Submission date
19/08/2013

Recruitment status
No longer recruiting

Registration date
17/09/2013

Overall study status
Completed

Last Edited
18/07/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Since smoking has a deep impact on socioeconomic inequality in illness and death, it is important that vulnerable populations of smokers be targeted with treatment. The US Public Health Service recommends that all patients be asked about their smoking at every visit, and that smokers be given brief advice to quit and referred to treatment. Initiatives to facilitate these practices include the five As (i.e., Ask, Advise, Assess, Assist, Arrange) and Ask Advise Refer (AAR). Unfortunately, primary care referrals are low, and most smokers referred fail to enroll. This study evaluated the effectiveness of the Ask Advise Connect (AAC) approach to linking smokers with treatment in a large, safety-net public healthcare system.

Who can participate?
Participants were patients who presented for care at any of the 10 clinics participating in the trial, reported any level of current smoking, and were age 18 or older.

What does the study involve?
AAC was evaluated in 10 community health clinics that are part of the Harris Health System, a large multi-specialty safety-net medical organization with three hospitals, two specialty clinics, 13 community health clinics, and eight school-based clinics. The Harris Health System community health clinics serve nearly 200,000 unique patients over the age of 18 per year, and the majority of patients (90%) are members of racial/ethnic minority groups. Nearly half have annual household incomes below the poverty level and more than 80% qualify for Harris Health System s charity care program or other insurance programs for the poor (e.g., Medicaid). Their secure electronic health record (EHR) system was in place before the start of this study.
Five community health clinics were randomly allocated to AAC (intervention) and five were randomized to a control condition (AAR). In both AAC and AAR, Licensed Vocational Nurses (LVNs) were trained to assess and record the smoking status of all patients at all visits in the EHR when vital signs were collected. They were also trained to provide all patients reporting current smoking with brief advice to quit consistent with the Guideline. An initial 30-minute training session on how to assess smoking status, deliver brief advice to quit, and connect (in AAC) or refer (in AAR) patients to the Quitline was held at the beginning of the study. The intervention delivered by the Quitline comprised five proactive telephone calls that were delivered over a period of up to 3 months and the total study duration was 19 months.

What were the possible benefits and risks of participating?
Participants were provided with referrals to smoking cessation programs other than the Quitline when desired or appropriate. There were minimal risks associated with this study. It was unlikely that connections and referrals to the Quitline, or counseling provided by the Quitline, would lead to any potential legal, social or psychological problems.

Where is the study run?
This study was a collaboration between the University of Texas MD Anderson Cancer Center, the Harris Health System and the Texas Quitline. Data were collected at the Harris Health System and sent to MD Anderson. Data regarding Quitline treatment enrollment were collected by the Texas Quitline and provided to MD Anderson.

When is the study starting and how long is it expected to run for?
The intervention period for AAC and AAR within each clinic was 18 months. All data were collected between June 2010 and March 2012.

Who is funding the study?
Centers for Disease Control and Prevention (CDC) (USA).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2008-0608

Study information

Scientific Title
Dissemination of a smoking Quitline to the underserved: a group-randomized trial

Study objectives
It was hypothesized that Ask Advise Connect (AAC) would have greater reach than Ask Advise Refer (AAR) because many of the barriers to successful treatment enrollment were eliminated in AAC relative to AAR. It was also hypothesized that the efficacy of AAR would exceed that of AAC because smokers who contacted the Quitline would be more motivated to enroll in cessation treatment. Finally, it was hypothesized that the impact of AAC would greatly exceed the impact of AAR because of its much broader reach.

Further reading: Conceptual paper describing the Ask Advise Connect (AAC) approach: Vidrine JI, Rabius V, Alford MH, Li Y, Wetter DW. Enhancing dissemination of smoking cessation quitlines through T2 translational research: A unique partnership to address disparities in the delivery of effective cessation treatment. J Public Health Manag Pract 16(4):304-308, Jul-Aug, 7/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was originally approved by the MD Anderson IRB on November 7, 2008. It was approved by the Texas Department of State Health Services IRB on March 17, 2009. The protocol was approved by the Harris Health System IRB on November 12, 2009.

Study design
Pair-matched-two-treatment arm group-randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Tobacco cessation treatment delivery in primary care

Interventions
Clinics were randomized to AAC (n=5; intervention) or AAR (n=5; control).

Licensed Vocational Nurses (LVNs) were trained to assess and record the smoking status of all patients at all visits in the electronic health record (EHR). Smokers were given brief advice to quit. In AAC, the names and phone numbers of smokers who agreed to be connected were sent electronically to the Texas Quitline daily, and patients were proactively called within 48 hours. In AAR, smokers were offered a Quitline referral card and encouraged to call on their own.

The intervention delivered by the Quitline comprised five proactive telephone calls that were delivered over a period of up to 3 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Impact was defined as the proportion of identified smokers that enrolled in treatment.

1. Whether or not smokers agreed to be connected (AAC) with or referred (AAR) to the Quitline at the time of the clinic visit
2. Whether or not those individuals enrolled in the treatment program offered by the Quitline. Quitline counsellors attempted to reach participants within 48 hours of receiving their contact information, and they made five attempts to reach each participant before declaring them unreachable. The time period over which the call attempts were made spanned a period of approximately 2 weeks.

Secondary outcome measures
1. Reach was defined as the number of smokers visiting the clinics that talked with the Quitline / total number of smokers that visited the clinics.
2. Efficacy was defined as the total number of smokers visiting the clinics that enrolled in treatment with the Quitline / total number of smokers visiting the clinics that talked with the Quitline.

Overall study start date
15/06/2010

Completion date
30/03/2012

Eligibility

Key inclusion criteria
1. Participants were patients who presented for care at any of the 10 participating clinics
2. Reported any level of current smoking
3. Aged 18 or older

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
6,700

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/06/2010

Date of final enrolment
30/03/2012

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Health Disparities Research
Houston
United States of America
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Sponsor information

Organisation
Centers for Disease Control and Prevention (CDC) (USA)

Sponsor details
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Government

Website
http://www.cdc.gov/

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https://ror.org/042twtr12

Funder(s)

Funder type
Government

Funder Name
Centers for Disease Control and Prevention (CDC) (USA) Grant Number R18DP001570

Alternative Name(s)
United States Centers for Disease Control and Prevention, Centros para el Control y la Prevención de Enfermedades, Centers for Disease Control, U.S. Centers for Disease Control and Prevention, CDC, U.S. CDC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No