Phone Enabled Implementation of Cessation Support

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Main Information

Primary registry identifying number
LBCTR2023015204

Protocol number
NCT05628389

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
15/11/2023

Primary sponsor
University of Florida

Primary sponsor: Country of origin
United States

Date of registration in primary registry
20/03/2023

Date of registration in national regulatory agency
15/11/2023

Public title
Phone Enabled Implementation of Cessation Support

Acronym
PHOENICS

Scientific title
Phone Enabled Implementation of Cessation Support

Acronym
PHOENICS

Brief summary of the study: English

The tobacco use burden in Lebanon is exceptionally high. Although the World Health Organization endorses evidence-based interventions for population-level tobacco dependence treatment, recommended treatments are not integrated as a routine part of primary care in Lebanon, as is the case in other low-resource settings. The objective of this proposal is to evaluate the comparative effectiveness of promising multi-component interventions for implementing evidence-based cessation treatment in Lebanon's national system of primary health care centers.

The following specific aims will be pursued: 1) adapt and tailor an existing smoking cessation program to deliver phone-based counseling to smokers in Lebanon; 2) test the effectiveness and cost-effectiveness of a referral-based program that delivers smoking cessation services to primary care patients; and 3) identify the multilevel determinants of implementation and sustainability using mixed methods.

Brief summary of the study: Arabic

إنّ عبء استخدام التبغ في لبنان مرتفع بشكل استثنائي. على الرغم أنّ منظّمة الصحة العالمية توصي بالتدخّلات القائمة على الأدلة بهدف علاج الاعتماد على التبغ على المستوى السكاني، لم يتم دمج هذه العلاجات كجزء روتيني من الرعاية الأولية في لبنان، كما هو الحال في بلدان أخرى ذات موارد محدودة. تهدف هذه الدراسة الى تقييم فعالية تدخلات قائمة على الأدلة لتنفيذ علاج الإقلاع عن التدخين في مراكز الرعاية الصحية الأولية في لبنان.
سيتم السعي لتحقيق الأهداف المحددة التالية: 1. تعديل برنامج الإقلاع عن التدخين الحالي لتقديم الاستشارة عبر الهاتف للمدخنين في لبنان. (2) اختبار فعالية وتكلفة برنامج قائم على الإحالة يقدم خدمات الإقلاع عن التدخين لمرضى مراكز الرعاية الأولية ؛ 3) تحديد العوامل - متعددة المستويات - التي تؤثر على التنفيذ والاستدامة.

Health conditions/problem studied: Specify

Smoking. We will include exclusive cigarette, exclusive waterpipe and dual cigarette/waterpipe smokers.

Interventions: Specify

The research team will conduct a group-randomized trial comparing three arms: 1) Ask about tobacco use, advise to quit, assist with brief counseling (AAA) as standard care; 2) Ask, advise, connect to phone-based counseling (AAC); and 3) AAC+ nicotine replacement therapy (NRT). Our central hypothesis is that connecting patients to phone-based counseling with NRT is the most effective alternative.

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion criteria:
- age ≥18 years
- patient at a participating primary health care center with a visit in the past 6 months
- daily smoker (≥ 5 cigarettes or ≥1 waterpipe session per day)
- reachable by phone
- interested in quitting
- lives in Greater Beirut
- able to provide informed consent

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

- pregnant or nursing patients
- patients for whom NRT is medically contraindicated
- patients enrolled in other tobacco treatment programs

Type of study

Interventional

Type of intervention

Behavioral treatment

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

N/A

Therapeutic indication

N/A

Therapeutic benefit

NRT will promote successful smoking abstinence by addressing nicotine withdrawal symptoms.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

1500

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/10/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

30/06/2026

Recruitment status

Pending

Recruitment status: Specify

Date of completion

01/09/2027

IPD sharing statement plan

Yes

IPD sharing statement description

We consider sharing of data and resources generated by this project to be an essential component of our proposed activities. We will make our results available to the community of scientists interested in interventions for tobacco dependence treatment in low-resource settings. This has the purpose both of sharing science and
avoiding unintentional duplication of research. As we establish a large dataset of clinical trial and implementation measures and outcomes, we anticipate that the data will become a resource to researchers with an interest in tobacco control, global health, primary care, and implementation science. Although we intend to allow investigators who are associated with the study to have priority for analyzing questions of interest to them, we will make the data available in compliance with relevant guidelines and compliance with consent forms, IRB approvals, as well as University of Florida (UF) and American University of Beirut (AUB) regulations. Before making data available to others outside this project, we will ensure that the data to be shared are de-identified or provided in a Limited Dataset and comply with both IRB regulations and the Privacy Rule under HIPAA regulations. No protected health information, including personally identifiable information (PHI) such as name, address, telephone, or other identifying information will be shared outside of UF and AUB except when needed for study purposes, and only after IRB approval. We will invite other investigators not associated with the study to propose ancillary studies that will of necessity require sharing of data that we have collected or that come from UF and AUB, because we view this study as an important resource for building evidence for the implementation of evidence-based tobacco treatment interventions in low-resource settings. Any such requests from non-study investigators will be reviewed by the principal investigators and co-investigators to ensure they do not conflict with planned analyses, conserve resources, are respectful of study participants, and comply with relevant IRB and HIPAA regulations. We will make study data available to other investigators under data use agreements between the data collection site and data recipient site(s). These agreements will ensure that the data will be used only for specified research purposes, that any individual participant's data will not be disseminated beyond the data recipient, that the data will not be used to identify an individual participant, that data will be protected under appropriate data security measures including encryption and password protection, and that the data will be destroyed or returned to us upon completion of relevant analyses. Furthermore, we will also determine whether at least one member of our investigator team should be involved scientifically in any projects that result from data sharing requests. We also plan to present findings at scientific conferences and through publications. We will share results and products (e.g., patient education materials) with community members, NGOs, and governmental organizations
in Lebanon through a variety of forums tailored to each target population, including through the Knowledge to Policy Center at AUB.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
National Institutes of Health - Department of Health and Human Services

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Ruba Abla	AUB	Lebanon	01-350000	ra328@aub.edu.lb	AUB
Scientific	Maya Romani	AUB	Lebanon	01-350000	mr39@aub.edu.lb	AUB - MC

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
AUB-MC	Maya Romani	Practicing family physician, clinical educator, researcher and Director of the AUB Smoking Cessation Program	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	26/01/2023	Lina El-Onsi Daouk	le08@aub.edu.lb	T +961 1 35 00 00 – Ext 5445
Other University of Florida	26/08/2022	Peter Iafrate,	irb@ufl.edu	(352) 273-9600

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

No Problems Studied

Interventions

Intervention	Description	Keyword
Ask-Advice-Assist	All patients will be screened for tobacco use, and offer brief cessation advice and counseling	AAA
Ask-Advise-Connect	Patients will be connected to phone counseling and will receive six sessions of telephone counseling	AAC
Ask-Advise-Connect + Nicotine Replacement Therapy	In addition to AAC, patients will be offered NRT.	AAC+NRT

Primary Outcomes

Name	Time Points	Measure
Smoking abstinence	6-month	Carbon monoxide confirmed-abstinence from smoking in the last 7 days prior to assessment

Key Secondary Outcomes

Name	Time Points	Measure
Continuous abstinence	1, 3, and 6 months	Self-reported measure
24-hour quit attempts	1, 3, and 6 months	Self-reported measure
Reduction in smoking	1, 3, and 6 months	Self-reported measure

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files