



## Phone Enabled Implementation of Cessation Support

15/02/2025 19:11:06

### 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 منظمة الصحة العالمية توصي بالتدخلات 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.

(2) تعديل برنامج الإقلاع عن التدخين الحالي لتقديم الاستشارة عبر الهاتف للمدخنين في لبنان. 1 سيتم السعي لتحقيق الأهداف المحددة التالية: (تحديد العوامل - متعددة3اختبار فعالية وتكلفة برنامج قائم على الإحالة يقدم خدمات الإقلاع عن التدخين لمركز الرعاية الأولية؛ 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  $\geq 18$  years
- patient at a participating primary health care center with a visit in the past 6 months
- daily smoker ( $\geq 5$  cigarettes or  $\geq 1$  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**