ISRCTN14767579 https://doi.org/10.1186/ISRCTN14767579

A three-month Electronic Nicotine Delivery System (ENDS)-based intervention in a homeless context: efficacy, challenges and opportunities

Submission date
19/10/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
16/10/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Smoking is highly prevalent amongst populations accessing homeless services and these populations may be disproportionately affected by tobacco-related harm. This study aims to investigate the efficacy, challenges and opportunities of conducting an Electronic Nicotine Delivery System (ENDS)-based intervention with a population accessing homeless services

Who can participate?
Smokers who intend to quit, who attend a Supported Temporary Accommodation (STA) homeless service in Dublin

What does the study involve?
Each study participant was supplied with an Endura T22e Electronic Nicotine Delivery System and two 10ml bottles of fluid which was available in following strengths (0, 6, 11, 18 and 20mg /ml) and flavours ('Purple Berry', 'Ice Menthol', 'Regular Blend' and 'American Tobacco'). Measurements related to tobacco use and dependence were taken every four weeks for three months.

What are the possible benefits and risks of participating?
The study aims to help participants quit or reduce tobacco smoking. This is the primary benefit of participating. Study participants will receive an Endura T22e™ device and weekly allotments of fluid during the study period. Participation in all components of the study will be compensated with 15 euro One4All™ vouchers at Weeks 1, 4, 8 and 12.
Short term harms may include sore throat, headaches, nausea or cracked lips. Long terms have not been clearly established. Participants are strongly encouraged to cease using the devices at the end of the study due to the unknown nature of long term harms.

Where is the study run from?
Dublin Simon Community, Ireland

When is the study starting and how long is it expected to run for?
February 2019 to June 2019

Who is funding the study?
Knowledge Action Change

Who is the main contact?
Florian Scheibein
fscheibein@gmail.com

Contact information

Type(s)
Scientific

Contact name
Mr Florian Scheibein

ORCID ID
https://orcid.org/0000-0001-9585-5068

Contact details
Waterford Institute of Technology
Cork Road
Waterford
Ireland
0
+353851122345
florian.scheibein@postgrad.wit.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ENDSHOMELESS

Study information

Scientific Title
A 3-month Electronic Nicotine Delivery System (ENDS)-based intervention in a homeless context: efficacy, challenges and opportunities

Acronym
ENDSHOMELESS

Study objectives
Smoking is highly prevalent amongst populations accessing homeless services and these populations may be disproportionately affected by tobacco-related harm. This study aims to investigate the efficacy, challenges and opportunities of conducting an Electronic Nicotine Delivery System (ENDS)-based intervention with a population accessing homeless services

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/11/2018, Waterford Institute of Technology Ethics Committee (Cork Road Campus, Waterford, Co.Waterford, Ireland; +353 51302609; skiely@wit.ie), ref: WIT2018REC0005

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Smoking of tobacco products.

Interventions
Study participants were recruited from a Supported Temporary Accomodation (STA) homeless service.

Baseline measures for self-reported number of cigarettes smoked, Fagerstrom score, Mood and Physical Symptom Scale and COppm were obtained. Participants were supplied with an Endura T22e Electronic Nicotine Delivery System and two 10ml bottles of fluid, participants could choose nicotine-containing fluid out of 4 flavours ('Ice Menthol', 'Purple Berry', 'Regular Blend' and 'American Tobacco') and five strengths (0, 6, 11, 18 and 20 mg/ml) which were dispensed in weekly allotments upon CO measurements. Fagerstrom Test, Mood and Physical Symptom Scale and daily cigarette consumption were recorded again at weeks 4, 8 and 12

Study participants were compensated with a 15 euro 'One4All' voucher at Week 1. The primary researcher attended the service on a weekly basis. Study participants could obtain additional fluid (maximum 2 bottles per week) and support. CO concentration was recorded at weeks 4, 8, and 12, any positive or negative experiences reported were recorded. Study participants were compensated with additional 15 euro vouchers for participating in these sessions. Participation in sessions at Week 1, 4, 8 and 12 were considered mandatory for the definition of study completion. An exit interview was completed at the end of the study

Intervention Type
Mixed

Primary outcome measure
At weeks 1, 4, 8 and 12:
1. Self-reported number of cigarettes smoked daily
2. Total COppm using a carbon monoxide breath analyzer
3. Nicotine Dependence measured by Fagerstrom score
4. Mood and Physical Symptom Scale

Secondary outcome measures
Qualitative reports obtained during interviews (any comments that study participants have regarding the efficacy of the device and issues and/or side effects they had)

Overall study start date
27/03/2018

Completion date
04/06/2019

Eligibility

Key inclusion criteria
1. >5 COppm
2. Active smoking status
3. Expressed intention to quit using ENDS-device

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
23

Key exclusion criteria
1. Active pregnancy status
2. Exhibition of acute florid mental health or substance use-related issues

Date of first enrolment
01/02/2019

Date of final enrolment
11/03/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin Simon Community
Assorted
Dublin
Ireland
000

Sponsor information

Organisation
Waterford Institute of Technology

Sponsor details
Health Science Building
Rossa Avenue
Waterford
Ireland
-
+353 (0)51302774
agalloway@wit.ie

Sponsor type
University/education

Website
https://www.wit.ie/schools/health_sciences/school-of-health-sciences

Funder(s)

Funder type
Research organisation

Funder Name
Knowledge Action Change

Results and Publications

Publication and dissemination plan
Intention to publish in Harm Reduction Journal. Intention to write follow up articles and to promote

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2020	16/10/2020	Yes	No