

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

<b>Submission date</b> 19/10/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/10/2020	<b>Condition category</b> Other	<input type="checkbox"/> 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  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Smoking of tobacco products.

## **Interventions**

Study participants were recruited from a Supported Temporary Accommodation (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(s)**

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

## **Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

## Funder(s)

### Funder type

Research organisation

### Funder Name

Knowledge Action Change

## Results and Publications

### 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?
<a href="#">Results article</a>	results	12/10/2020	16/10/2020	Yes	No