KU LEUVEN STUDY
Effectiveness of the Electronic Cigarette: An Eight-Week Flemish Study with Six-Month Follow-up on Smoking Reduction, Craving and Experienced Benefits and Complaints

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DESIGN KULEUVEN STUDY

INTAKE → SESSION 1 → SESSION 2 → SESSION 3 → FU 1 → FU 2

online diaries

T1 → T1 + W1 → T1 + W4 → T1 + W8 → T1 + 5M → T1 + 8M
DESIGN + MEASURES

INTAKE

- info
- I.C.
- CO
- smoke history
- FTND
- BDI

E-CIG 1 (n = 16)
E-CIG 2 (n = 16)
CONTROL (n = 16)
DESIGN + MEASURES

- E-CIG 1 (n = 16)
- E-CIG 2 (n = 16)
- CONTROL (n = 16)

SESSION 1
- 4h abstinence
- saliva
- CO + Q
- 5m vaping/smoking
- CO + Q
- CO + Q
- CO + Q
- CO + Q
- CO + Q

SESSION 2
- 4h abstinence
- saliva
- CO + Q
- 5m vaping/smoking
- CO + Q
- CO + Q
- CO + Q
- CO + Q
- CO + Q

SESSION 3
- 4h abstinence
- saliva
- CO + Q
- 5m vaping/smoking
- CO + Q
- CO + Q
- CO + Q
- CO + Q
- CO + Q
DESIGN + MEASURES

SESSION 3

- E-CIG 1 \((n = 16)\)
- E-CIG 2 \((n = 16)\)
- E-CIG \((n = 16)\)
DESIGN + MEASURES

FU 1

online Q
DESIGN + MEASURES

FU 2

saliva

CO

Q
Table 1. Participants’ characteristics.

<table>
<thead>
<tr>
<th>Group</th>
<th>Gender</th>
<th>Age</th>
<th>% Employed</th>
<th># Cigarettes</th>
<th>FTCD</th>
<th>BDI</th>
<th>eCO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecig1</td>
<td>7/9</td>
<td>44.75 (13.54)</td>
<td>78.75</td>
<td>20.13 (9.41)</td>
<td>5.81 (1.94)</td>
<td>6.81 (7.06)</td>
<td>19.13 (6.11)</td>
</tr>
<tr>
<td>Ecig2</td>
<td>10/6</td>
<td>46.06 (12.76)</td>
<td>71.25</td>
<td>20.63 (6.62)</td>
<td>6.31 (1.45)</td>
<td>6.14 (11.99)</td>
<td>17.38 (6.29)</td>
</tr>
<tr>
<td>Control</td>
<td>10/6</td>
<td>40.31 (13.21)</td>
<td>74.69</td>
<td>16.69 (5.49)</td>
<td>5.24 (1.62)</td>
<td>3.56 (4.34)</td>
<td>16.25 (8.92)</td>
</tr>
<tr>
<td>All groups</td>
<td>27/21</td>
<td>43.71 (13.13)</td>
<td>74.90</td>
<td>19.15 (7.41)</td>
<td>5.79 (1.70)</td>
<td>5.51 (8.35)</td>
<td>17.58 (7.17)</td>
</tr>
</tbody>
</table>

Note: all values means, except gender is a ratio female/male, SD between (); $n_{Ecig1} = 16$, $n_{Ecig2} = 16$, $n_{Control} = 16$. $n_{All \text{ groups}} = 48$. 
RESULTS: eCO

Note: all values mean (±/− 1 SEM) eCO levels; \( n_{\text{Ecig1—Intake}} = 16, n_{\text{Ecig1—Session 1/2/3}} = 15, n_{\text{Ecig1—FU2}} = 11; n_{\text{Ecig2—intake}} = 16, n_{\text{Ecig2—Session 1/2/3}} = 16, n_{\text{Ecig2—FU2}} = 12; n_{\text{Control—Intake}} = 16, n_{\text{Control—Session 1/2/3}} = 15, n_{\text{Control—FU2}} = 13. \)
RESULTS: CIGARETTE CRAVING
RESULTS: E-CIG CRAVING

Note: top figure: all values mean (+/- 1 SEM) craving levels with minimum 0 and maximum 10; \(n_{\text{Ecig1—Session 1/2/3}} = 14\), \(n_{\text{Ecig2—Session 1/2/3}} = 14\), \(n_{\text{Control—Session 1/2/3}} = 15\); bottom figure: all values mean (+/- 1 SEM) e-cig craving levels with minimum 0 and maximum 10; \(n_{\text{Ecig1—Session 1/2/3}} = 14\), \(n_{\text{Ecig2—Session 1/2/3}} = 14\). No measurement of e-cig craving at the start (T1) of Session 1, because participants had not yet used the e-cig.
RESULTS: #cigarettes

Note: all values mean (+/- 1 SEM) number of cigarettes; $n_{\text{Ecig1—Intake}} = 15$, $n_{\text{Ecig1—W1-W7_8}} = 12$, $n_{\text{Ecig1—FU1}} = 13$, $n_{\text{Ecig1—FU2}} = 13$; $n_{\text{Ecig2—Intake}} = 15$, $n_{\text{Ecig2—W1-W7_8}} = 13$, $n_{\text{Ecig2—FU1}} = 12$, $n_{\text{Ecig2—FU2}} = 12$; $n_{\text{Control—Intake}} = 16$, $n_{\text{Control—W1-W7_8}} = 15$, $n_{\text{Control—FU1}} = 12$, $n_{\text{Control—FU2}} = 12$. 
RESULTS: COTININE

Note: all values mean (+/- 1 SEM) saliva cotinine levels; \( n_{E cig1-Session\ 1/2/3} = 15, \)
\( n_{E cig1-FU2} = 11, \)
\( n_{E cig2-Session\ 1/2/3} = 16, \)
\( n_{E cig2-FU2} = 12, \)
\( n_{Control-Session\ 1/2/3} = 15, \)
\( n_{Control-FU2} = 12. \)
Note: all values reduction rates (%); \( n_{\text{E-cig groups}} - W7_8/FU1/FU2 = 32, \ n_{\text{Control}} - W7_8/FU1/FU2 = 16. \) The category “Failures” included 3%, 6%, and 28% of participants with missing data at W7_8, Follow-up 1, and Follow-up 2 in the E-cig groups, versus 0%, 6%, and 19% in the Control group. For quitters, the difference between e-cig groups and control group was statistically significant at W7_8 (\( p < 0.01 \)).
RESULTS: COMPLAINTS

<table>
<thead>
<tr>
<th>Complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad taste</td>
</tr>
<tr>
<td>Dry mouth / throat</td>
</tr>
<tr>
<td>Irritated mouth / throat</td>
</tr>
<tr>
<td>Dizziness</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Increased heart rate/palpitations</td>
</tr>
<tr>
<td>Increased weight</td>
</tr>
<tr>
<td>Concerns about health risks</td>
</tr>
</tbody>
</table>

![Graph showing complaints over weeks and follow-up periods](image)
RESULTS: BENEFITS

Benefits
- Pleasant sensation when inhaling
- Improved breathing
- Pleasant taste when inhaling
- Less coughing or sore throat
- Improved health and fitness
- Helps to reduce or stop smoking
- Improved taste and smell
- Less unpleasant smells
- Improved sleep

Graph showing benefits over weeks for Ecig1, Ecig2, and Control groups.
SUMMARY

• Also confirmed in Italian study:

Results

Sustained 50% and 80% reduction in cigs/day at week-24 was reported in 15/50 (30%) and 7/50 (14%) participants with a reduction from 25cigs/day to 6cigs/day ($p < 0.001$) and 3cigs/day ($p < 0.001$), respectively. Smoking abstinence (self-reported abstinence from cigarette smoking verified by an eCO ≤10 ppm) at week-24 was observed in 18/50 (36%) participants, with 15/18 (83.3%) still using their PVs at the end of the study. Combined 50% reduction and smoking abstinence was shown in 33/50 (66%) participants. Throat/mouth irritation (35.6%), dry throat/mouth (28.9%), headache (26.7%) and dry cough (22.2%) were frequently reported early in the study, but waned substantially by week-24. Participants’ perception and acceptance of the products was very good.