SIX MONTH OUTCOMES FROM CLICKOTINE®: A DIGITAL THERAPEUTIC™ PROGRAM FOR SMOKING CESSATION

Brian M. Schwebel, Joshua R. Sternerman, David B. Hahn, Victor Gue, Carla K. Kaiser, Nicholas J. Schum

BACKGROUND
- In 2013 there were 400 smoking cessation mobile apps with over 3.2 million downloads in the US alone.
- Only a small number follow the US Clinical Practice Guidelines (USCPG).1
- Most apps do not include empirically supported behavior change techniques.
- Most apps are not customized to users’ needs or personal characteristics.
- Clickotine is designed to deliver and personalize all components of the USCPG that are amenable to delivery via MI.
- The efficacy of Clickotine for smoking cessation was assessed in a preliminary, 8-week, single-arm clinical trial in which 169 participants were enrolled.
- The 6-week efficacy results have been previously reported. 36.2% of Clickotine users self-reported 30-day abstinence.
- Here we report the efficacy results at six months post-enrollment.

METHODS
An 8-week, single-arm, clinical trial of Clickotine was conducted. All study procedures were IRB approved. The trial was registered with ClinicalTrials.gov (NCT02060547).

APP DESCRIPTION
- Clickotine adheres to the MI for smoking cessation: delivery through goal setting, with personal goal and mission evaluations; avoid what’s not planned and connect with intervention; in a daily breaking, advising participants on how to remain on track and dispel any obstacles.
- For example, the Clickotine app, the user profile is created, the home screen displays a message to the user, and the user’s goals are set.
- The user receives a message via text 7 days after enrollment.
- Clickotine consists of five core components: targeted messaging, personalization, evidence-based behavior change techniques, motivation/encouragement, and social support.
- The components of the Clickotine program are: motivational interviewing, digital messaging, logging progress, messaging personalized messages, expecting to receive messages, participating with “just for fun,” competing interviews, logging messages, regular messages, learning about smoking, and receiving feedback.
- The user is notified about new tasks, and the app is updated with new tasks.

RESULTS
- After 63 days of social media advertising and recruitment, 2,050 contacts were received and 617 telephone pre-screens were conducted.
- Table 1 provides the baseline demographic and smoking characteristics of the ITT sample.
- Figure 2 depicts the study flow.
- At 24-weeks post-enrollment, 295 of 416 in the ITT sample completed the outcome survey with 147 (66.3%) of the ITT sample reporting 30-day point prevalence abstinence (PPA).

DATA COLLECTION
- Data were collected in an online survey administered via the study portal at baseline and at 8 and 24 weeks after enrollment.
- In return for completing the survey, participants received a $25 Amazon gift card.

FIGURE 1. REPRESENTATIVE CLICKOTINE SCREENS
These simple and fundamental interactions with Clickotine are illustrated.

FIGURE 2. STUDY FLOW DIAGRAM
This is a visual representation of the Clickotine interactions.

TABLE 1. DEMOGRAPHIC AND SMOKING CHARACTERISTICS OF STUDY SAMPLE

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Smoking Characteristics</th>
</tr>
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<tbody>
<tr>
<td>AGE (YRS)</td>
<td>39 (10.6)</td>
</tr>
<tr>
<td>RACE/ETHNICITY</td>
<td></td>
</tr>
<tr>
<td>NATIVE AMERICAN</td>
<td>165 (39.9%)</td>
</tr>
<tr>
<td>AFRICAN AMERICAN</td>
<td>119 (28.6%)</td>
</tr>
<tr>
<td>HISPANIC</td>
<td>26 (6.3%)</td>
</tr>
<tr>
<td>FEMALE</td>
<td>315 (75.7%)</td>
</tr>
<tr>
<td>MALE</td>
<td>90 (24.3%)</td>
</tr>
<tr>
<td>NUMBER OF QUIT ATTEMPT</td>
<td></td>
</tr>
<tr>
<td>ONE QUIT ATTEMPT</td>
<td>147 (37.7%)</td>
</tr>
<tr>
<td>MORE THAN ONE QUIT ATTEMPT</td>
<td>166 (40.6%)</td>
</tr>
<tr>
<td>NO QUIT ATTEMPTS</td>
<td>88 (21.2%)</td>
</tr>
<tr>
<td>FAGERSTROM TEST FOR NICOTINE DEPENDENCE</td>
<td>13.1 (8.2)</td>
</tr>
<tr>
<td>NO. SMOKES PER DAY</td>
<td>18.4 (15.8)</td>
</tr>
<tr>
<td>NO. CIGARETTE PER DAY</td>
<td>10.7 (7.4)</td>
</tr>
</tbody>
</table>

CONCLUSION
In this single-arm trial, over one-third of Clickotine users reported 30-day abstinence at 6 months post-enrollment. Clickotine appears to continue to exert an effect over time, evidenced by the increase in 30-day abstinence observed between the 8-week and 24-week time points.

REFERENCES

DISCLOSURES
No author has any financial disclosures.

TABLE 2. ITT ANALYSIS RESULTS

<table>
<thead>
<tr>
<th>Time Point</th>
<th>ITT Analysis Results</th>
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<tbody>
<tr>
<td>AT 8-WEEKS</td>
<td>109 (26.2%)</td>
</tr>
<tr>
<td>AT 6-MONTHS</td>
<td>147 (35.3%)</td>
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</table>

Note: values provided indicate mean (SD) or n (%).