Combining App-based Behavioral Support with Electronic Nicotine Delivery System Devices for Smoking Cessation: A Randomized Controlled Trial

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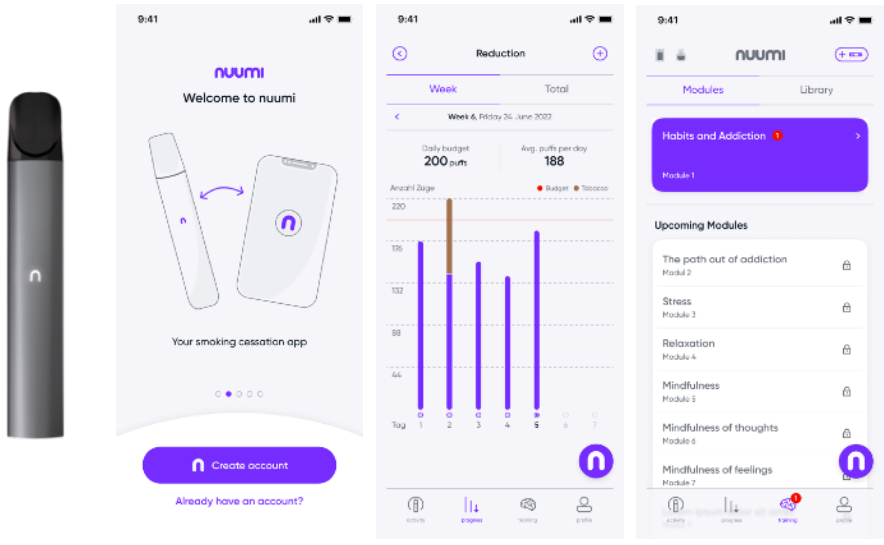
Main Message

- Novel smoking cessation approaches are needed to decrease detrimental health outcomes among tobacco cigarette smokers.
- This will be the first trial to evaluate a combined app-supported behavioral intervention and electronic nicotine delivery system (ENDS) based nicotine reduction therapy in a real-life setting.
- Findings will inform future digitally-supported cessation efforts and will provide information on the effectiveness of ENDS for smoking cessation.

Background

- Smoking remains the greatest preventable health risk in Germany, with 36% of adults currently smoking [1].
- Treatments for smoking cessation outlined in medical guidelines are rarely used, and the effectiveness of and adherence to these interventions is low [2, 3].
- Novel approaches are needed to help smokers quit permanently.
- Sanos Group developed a smoking cessation intervention ('nuumi') integrating app-based behavioral support and an ENDS.
- ENDS have been shown to increase quit rates compared to conventional nicotine replacement therapy (NRT) [4].
- ENDS provide the possibility to progressively reduce nicotine content, which has previously been shown to decrease dependence and improve cessation in conventional cigarettes [5].
- Mindfulness training has been shown to support smoking cessation [6].



Aim: To evaluate whether an app-based behavioral intervention combined with an ENDS device will support smoking cessation more effectively compared to a treatment-as-usual control group.

Method

Sample

- In 2023, a two-arm parallel RCT will be conducted among 200 adult tobacco cigarette smokers (>9 cigarettes/day for >12 months; Fagerström Test for Cigarette Dependence (FTCD, [7]) >3) motivated to quit.
- Exclusion criteria are pregnancy/breastfeeding, allergy to vegetable glycerin, propylene glycol or nicotine patches, current use of ENDS or NRT, participation in another smoking cessation program and serious mental or physical illness.
- Recruitment channels will include online study advertisements, social media, handbills and flyers, online community boards and health insurance magazines.

Measures

Primary Outcome

Self-reported one-week point prevalence abstinence from smoking cigarettes at 6-months follow-up.

Secondary Outcomes

- Biochemically verified (saliva cotinine & carbon monoxide) smoking abstinence
- Treatment adherence
- Cigarette cravings (VRS v4-1 [9])
- Dyspnoea (mMRC dyspnoea scale)
- Nicotine withdrawal symptoms (WSWS2-B [9])
- Health-related quality of life (SF-12 [10])
- Mindfulness (CAMS-R [11])
- Perceived stress (PSS-10 [12])

Procedure

Participants will be randomized to either an intervention or a control group.

Intervention

- After randomization, participants will be provided with access to an app and will be sent an ENDS device.
- Nicotine reduction is achieved by reducing the nicotine concentration in the liquid solution of the pods from 18mg/ml to 0mg/ml over a period of 12 weeks.
- The device can be used exclusively with the liquid solution supplied as part of the RCT to reduce risk of abuse.
- It is connected with the app via bluetooth, allowing tracking of patterns of use.
- Simultaneously, participants will be given access to app-based behavioral training incorporating components of a mindfulness-informed stress management course [13] expanded by smoking and relapse prevention specific content.
- To ensure retention, the app incorporates gamification and nudging features [14].
- After completing the behavioral training and the nicotine reduction components of the intervention, participants are encouraged to cease use of the ENDS device

Control

- After randomization, participants will be provided self-help materials for smoking cessation by the German Federal Center for Health Education and will be sent an initial supply of nicotine patches.
- Additional supplies of nicotine patches will be provided for up to 12 weeks; patches with lower nicotine concentration will be provided upon request.

Online survey-based data collection will take place at baseline, and 2 weeks, 4 weeks, and 8 weeks, 12 weeks and 24 weeks post-baseline.

Planned Analyses

Per-protocol and intention-to-treat analyses will be conducted and mixed linear models will be performed to assess the main effects of time and condition on all outcomes.

Expected Results

- We expect to find a significant ($p<0.05$) main effect of group, with the app+ENDS condition outperforming the control condition on all outcomes.
- We expect to observe a main effect of time; relative to baseline, significant improvements of all outcomes will be found at all time points.
- We expect to find a significant interaction effect, with the app+ENDS condition showing significantly greater improvement across all outcomes over time.

We are looking forward to your feedback!

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Declaration of conflict of interest:
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Helen Schiek is a doctoral student at University of Witten/Herdecke and is employed full-time by Sanos Group. Tobias Meister is the founder and CEO of Sanos Group. Prof. Tobias Esch is co-developer of nuumi and shareholder of Sanos Group. Cosima Hoetger, PhD has no conflict of interest to declare.

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