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Research

Combining App-based Behavioral Support with Electronic Nicotine Delivery System Devices for Smoking Cessation

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Worldwide, tobacco use causes over 7 million deaths annually [1]. As of 2022, over 35% of Germans report current use of cigarettes. Approximately 38% of current smokers report wanting to quit smoking [2]. However, about 80% of individuals who attempt to quit smoking without support relapse within a month; only 3% remain abstinent six month later [3]. Treatment methods outlined in medical guidelines are rarely used, and both the effectiveness of and adherence to these interventions remain low [4,5], necessitating the development of novel and effective smoking cessation methods.

Electronic nicotine delivery systems (ENDS) have been found to be more effective in helping smokers quit than recommended cessation methods [6]. Their effectiveness can be further increased if coupled with a behavioral support component [7]. These findings highlight the need for smoking intervention efforts that target the physical as well as the psychological mechanisms of nicotine dependence. Recognizing the importance of holistic approaches to smoking cessation, the Berlin-based startup company Sanos Group developed an integrated smoking cessation intervention ('nuumi'). The smoking cessation program is accessible via a smartphone app, thus allowing users to personalize their intervention experience by having control over the place and time they wish to interact with the app [8]. Additionally, digitalized interventions allow for further personalization of health-related information by tailoring content to users' needs, e.g. via personalized text messages [9].

Nuumi offers an app-based behavioral support consisting of video and audio recordings and interactive exercises, coupled with a bluetooth-supported ENDS device. The behavioral support consists of the digitalized content of a health promotion course developed by Tobias Esch; the course framework is described elsewhere [10]. The digitalized course features content derived from four areas, including Behavior, Exercise, Relaxation, and Nutrition (BERN). In order to meet the specific needs of smokers motivated to quit, the course content has been tailored to help individuals overcome barriers frequently encountered during smoking cessation attempts. For example, smokers report greater stress levels relative to nonsmokers, and one of the most frequently reported reasons for continued smoking is the management of stress and negative emotions [11,12]. Stress and negative emotions can even increase during withdrawal [13], creating a barrier to successful smoking cessation [14]. App content and exercises draw from Mind-Body Medicine-based techniques designed to foster social, psychological, behavioral, and spiritual wellbeing [15] and decrease negative emotions including depressive symptoms, anxiety, and stress [16,17]. Nuumi users learn to effectively manage stress and negative emotions and learn to apply coping strategies when experiencing withdrawal symptoms. Instead of taking a one-size-fits-all approach, nuumi provides the opportunity of using the exercises to reflect on one's own smoking history, identify individuals and situations that serve as triggers for cigarette cravings, and to recognize which individuals in one's environment serve as an effective source of social support during one's smoking cessation process.

Simultaneously, users are asked to substitute an ENDS device equipped with a nicotine-containing liquid solution for their tobacco cigarettes. Over a period of several weeks, participants are provided with pods containing gradually decreasing concentrations of nicotine. Reducing nicotine

content in tobacco products has been suggested to lead to a reduction of reinforcing effects, and a subsequent decrease in positive sensations typically associated with nicotine self-administration, both of which are key factors of nicotine dependence [18].

The scientific evaluation will be conducted by principal investigator Tobias Esch and his team of research associates including Cosima Hoetger and Helen Schiek at the Institute for Integrative Health Care and Health Promotion at Witten/Herdecke University. In early 2023, a two-arm parallel randomized controlled trial will be conducted among a sample of current tobacco cigarette smokers (n=250) who self-report having smoked more than 9 cigarettes per day for a period of at least 12 months, who are deemed to be dependent on nicotine as indexed by a score of >3 on the Fagerström test for Cigarette Dependence, and who are motivated to quit. Participants will be randomized to either an intervention group or a control group. While the intervention group will be given access to nuumi (i.e., app plus ENDS device), the control group will receive self-help cessation support consisting of a pamphlet provided by the German Federal Center for Health Education and a supply of nicotine patches. Biochemically verified abstinence, as indexed by saliva cotinine and carbon monoxide testing results will serve as the primary outcome. Secondary outcomes will include, but not be limited to, self-reported one-week point prevalence abstinence at six-month follow-up, treatment adherence, cravings, health-related quality of life, mindfulness, and perceived stress. If found to be effective, nuumi could constitute a cost-effective and convenient smoking cessation method for smokers motivated to quit. Long-term, nuumi could contribute to decreasing the risk of smoking-related morbidity and mortality.

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