An Avatar-led Intervention Promotes Smoking Cessation in Young Adults: A Pilot

Randomized Clinical Trial

Maria Karekla, PhD, Stella Nicoleta Savvides, PhD, University of Cyprus

& Andrew Gloster, PhD, University of Basel

Author addresses:

Maria Karekla, Ph.D., Department of Psychology, University of Cyprus, P.O.

Box 20537, Nicosia 1678, Cyprus; TEL: 357 22 892100; FAX: 357 22 892071;

mkarekla@ucy.ac.cymailto:mkarekla@ucy.ac.cy

Stella Nicoleta Savvides, PhD, Department of Psychology, University of

Cyprus, P.O. Box 20537, Nicosia 1678, Cyprus; TEL: 357 22 892100;

ssavvide@gmail.com

Andrew Gloster, PhD, University of Basel, Faculty of Clinical Psychology and

Intervention Science, Missionsstrasse 62, 4055 Basel, Switzerland; TEL: (+41) 061

20 70275; andrew.gloster@unibas.ch

Corresponding Author:

Maria Karekla, Ph.D., Department of Psychology, University of Cyprus, P.O. Box

20537, Nicosia 1678, Cyprus; TEL: 357 22 892100; FAX: 357 22 892071;

mkarekla@ucy.ac.cy

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Structured Abstract

Background: Smoking remains a global concern, especially for young adults. There is a

dearth of smoking cessation programs for this population, who seldom seek help or are

motivated to quit.

Purpose: This pilot study assessed the effectiveness of a digital avatar-led Acceptance and

Commitment Therapy (ACT) smoking cessation program (Flexiquit) for young adult smokers

at all levels of motivation to quit.

Methods: Smokers with no particular interest in quitting smoking (65.45% reported being in

pre-contemplation or contemplation stages of change) were recruited from 3 universities (105

smoking ≥ 1 cigarette per day during the past 30 days, 68 females). Those who completed

questionnaires on-line (N=84; M=22.44 years, SD=2.61, range 18-28 years old) were

randomized to either a 6-session avatar-led intervention (Flexiquit; N=49) or a waitlist-

control (N=35). Primary outcomes included cessation status (7-day point prevalence) and

number of cigarettes smoked per day; secondary outcomes were nicotine dependence,

intention-to-quit smoking and self-efficacy, assessed at pre- and post-intervention, and only

for Flexiquit at 6-month follow-up.

Results: In Intention-To-Treat analysis more participants (OR=3.10, 95% CI=0.92-10.41) in

the treatment group (28.57%) vs. the control group (11.43%) reported quitting smoking;

however, the difference was not statistically significant (p=.067). There were statistically

significant decreases in average number of cigarettes, nicotine dependence and increases in

self-efficacy, and intention-to-quit smoking compared to controls. Treatment gains in the

Flexiquit group were maintained through the 6-month follow-up.

Conclusions: An avatar-led digitized smoking cessation intervention based on ACT could

increase the odds of quitting smoking. Findings suggest that a digitized program designed to

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engage young adults in smoking cessation may result in quitting smoking and has a high

applicability potential especially among the hard-to-reach population of young adults.

Trial Registration: Clinicaltrial.gov (number masked for review purposes),

https://clinicaltrials.gov/

The full trial protocol is available from the first author.

Implications

Question: Can an avatar-led digitized Acceptance and Commitment therapy (ACT) smoking

cessation intervention result in quitting smoking and increasing intention to quit among

young smokers at various levels of motivation to quit, compared to a wait-list control group?

Findings: In this pilot randomized clinical trial that included 84 smokers, 28.57% in the

treatment condition vs. 11.43% in the wait-list control group were abstinent at post (ITT

analysis). An avatar-led digitized ACT smoking cessation intervention results in high quitting

smoking rates and has a high applicability potential especially among the hard-to-reach

population of young adult smokers.

Declaration of Interests

All authors declare no conflict of interest.

Keywords: Smoking cessation; Young adults; Digital interventions; Avatar-led intervention;
Acceptance and Commitment Therapy

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Young adults aged 18-25years have among the highest prevalence of tobacco use of

any age group, with dangerously high 10.4% smoking prevalence rates in the US [1], 28.70%

on average in Europe with southern Mediterranean countries presenting the highest smoking

rates, and over 1.1 billion individuals 15 years or older who smoke [2]. Given the rapid rise

in electronic means of nicotine delivery, there is considerable concern about increases in

progression to daily smoking and reductions in cessation [3]. It is imperative to target

smoking habits in young adults, as this age constitutes a critical period in which health-

compromising behaviors are established [4]. Indeed, smoking cessation and prevention of

future smoking relapse is more likely achieved if cessation occurs before the age of 30 [5].

Despite having identified this promising window of opportunity, few intervention evaluation

studies specifically target young adults [6], and those that have, reported difficulty in

achieving efficacious cessation for these young smokers. In addition to the low cessation

levels among this population (varying from 0%-11%; mean 3% [6]), interventions for young

adults are stymied by age-specific factors: relative to older adults, they utilize cessation

programs less and, crucially, show lower levels of interest in quitting [7].

Many cessation programs assume that participants are motivated to change, which

cannot be assumed – especially when it comes to young adult smokers [8]. However, even

when motivated young adults are enrolled, cessation programs have been largely

unsuccessful [9]. Multiple difficulties contribute to the low participation rates in smoking

cessation programs for young adults, including reaching, engaging and retaining them [10].

Most efforts focus on modifying existing interventions developed for adult smokers for use

with younger populations [11]. However, these modified programs are often flawed in design

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because they lack a theoretical framework about cessation, they are based on programs

tailored for adult chronic smokers, and they do not address the social roles of smoking or the

self-image of young adults [6,12,13]. Young adults are also socialized in a technology-

intense manner that makes their expectations idiosyncratic compared to other age groups. It is

thus important to reach younger age groups with innovative methods that appeal to them

while simultaneously reaching as many individuals as possible regardless of current quit

intentions (i.e., not only including those already highly motivated to quit).

Despite these limitations, some evaluated interventions lead to significant quit rates

when compared to passive control conditions (no treatment or waitlist) or self-help cessation

rates [13]. Based on findings from a systematic review, the mean cessation rate achieved by

young adult programs is 14% at post-intervention and 12% at post-intervention follow-up,

whereas for control groups (i.e., no active treatment) the average cessation rate is 7% [6]. A

systematic review of smoking cessation interventions in young adults (18-24 years old)

identified 14 studies [10]. Of these, only 4 showed substantial abstinence rates post-treatment

[14] and only 2 had marked smoking cessation results at 4-6 months follow up [14,15]. These

more successful studies used innovative and mostly digitized methods (e.g., addition of

telephone counseling, tailored emails and personalized online college magazine) in

combination with existing theoretically based programs to attract youth and improve smoking

cessation rates.

Digital interventions are more cost-effective than face-to-face treatments, cater to

individuals who are unable or unwilling to attend weekly treatment sessions with a therapist,

including those in remote locations, show promise in improving success rates with various

health behaviors [16], and have a much lower or no treatment bias [17]. Treatment bias refers

to the bias presented by the therapist, which is hypothesized to be lower or non-existant in

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digital interventions where the intervention received is exactly the same for all participants [17]. They use technology that has the potential to attract youth (e.g., interactive games, animation, video clips etc.) and thus may engage a wider range of young adults than traditional face-to-face interventions, while at the same time competently address their developmental, psychosocial and behavioral needs [18,19].

Despite the promise of digital interventions, their full potential has not yet materialized. The few trials with young adults have been rated as being at high risk for bias (especially selection and attrition bias) with low to moderate quality of evidence, rendering the evidence on the effectiveness of digital interventions for young adults as insufficient, and not particularly successful in achieving smoke-free status [17,41]. Additionally, existent digital programs mainly envision digital means as mere vehicles of delivering intervention content (i.e., text in a static, one size fits all presentation), failing to recognize the dynamic nature of technology and utilize its full potential [19]. Gamification and persuasive-technology are theory-driven frameworks for designing digital interventions with the potential to be persuasive and engaging, especially for youth, and it is recommended that they are used when developing digital interventions [19]. It is paramount that future programs should be grounded in both sound behavior change and digital intervention theories, optimal study designs, with multiple modes of delivery and assessment, that aim to achieve smoking cessation and increase success even among young smokers and those with a low motivation to quit.

A novel behavior change approach, which utilizes a persons' values and what provides meaning to life may be well suited to address the unique barriers to quitting faced by young adults including the low likelihood of initiating a quit attempt and disinterest in using standard treatments and may facilitate behavior change. Acceptance and Commitment

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Therapy (ACT [20]) is such an approach. ACT is similar to traditional treatments that

promote awareness of the physical, cognitive, and emotional cues that trigger smoking

behavior, however it differs in that it promotes acceptance of triggers (e.g., through

mindfulness) rather than teaching methods of avoiding or altering those triggers. ACT is a

functional contextualistic cognitive-behavioral approach and the intervention follows the

Psychological Flexibility (PF) model. PF refers to a set of six underlying functional classes of

behavior [42]. These are: (1) experiential acceptance (as opposed to avoidance or

suppression); (2) cognitive defusion or distancing from ones thoughts (vs. cognitive fusion

and entanglement with ones thinking patterns); (3) flexible attention to the here and now and

mindfulness (in contrast to losing contact with the present moment or being in an "autopilot"

mode of functioning); (4) having a stable and transcendental sense of self (vs. attachment to a

conceptualized self); (5) clarification of and living based on deeply meaningful chosen values

(as opposed to being confused about what is important and/or living life in incongruence to

what really matters for the person); (6) committed purposeful action (vs. inaction,

impulsivity, non-functional or persistent avoidant behaving). ACT differs from other

approaches that attempt to improve participants' motivation to quit, such as Motivational

Interviewing (MI [21]), in that it focuses more on acceptance and mindfulness that do not

constitute targets in MI. Empirical support for ACT as a smoking cessation intervention

comes from six trials with motivated-to-quit adult smokers, which collectively support its

feasibility and efficacy in comparison with pharmacotherapy-only treatments and traditional

behavioral treatments[22,23]. Overall, ACT for tobacco cessation has demonstrated

acceptability and efficacy for adult smokers who are ready to quit.

The present study evaluates the first digital ACT-based program to utilize engagement

strategies such as gamification, persuasive technology, and virtual human coaches, with the

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aim to motivate user interaction and achieve smoking cessation among young adults at all stages of readiness to change (even among those not yet motivated to quit or present for treatment). Using a randomized trial, this study examined the effectiveness of the avatar led intervention compared to a wait-list control group. It was hypothesized that the intervention would produce higher quit rates (7-day point prevalence) and better smoking related outcomes (i.e., lower number of cigarettes smoked per day, higher smoking cessation self-efficacy and higher intentions to quit), than the control group.

Methods

Research Design

This was a randomized controlled 2-arm clinical trial that compared an avatar-led ACT-based digital intervention for smoking cessation to a wait-list control. This clinical trial was registered at Clinicaltrial.gov (number masked for review). Intervention participants (n=49) completed assessments at pre- and post-intervention (immediately after completing session 6) and 6-month post-intervention follow-up, whereas waitlist control participants (n=35) completed the same questionnaires twice (pre- and post-intervention). Control group participants' timing of questionnaire completion was yoked to the participants in the intervention group. Those in the intervention group completed 6 sessions, each averaging 25-minutes. The assessment and treatment were all completed on-line. Participants were able to complete the program either using a computer or a tablet by entering into the program website (masked for review). Frequency of contact with the program was spaced out over 3 to 30 days, thus the time it took to complete the entire program and post-assessment varied. Given that in order to proceed to the next session the previous one had to be completed, attrition was defined as missing one or more sessions. Although this is more conservative than face-to-face trials that allow for missed sessions, this permitted for session spacing to

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not exceed the 30-day cut off. Participants who failed to log-in, were sent an email after one week and then a second email after two more weeks.

The local National Bioethics Committee, the Ministry of Education, and each participating university approved the study. All participants completed a consent form prior to participation.

Participants & Recruitment

As depicted in Figure 1, 297 university student smokers were recruited from three universities in Cyprus via flyers posted in cafeterias and classroom announcements (during the academic year 2014-2015). Recruitment occurred in two rounds, one in the fall and one in the spring semester. Interested individuals were informed about the study and told that they would not be "forced" to quit and that the main aim was to get their opinion regarding this digital intervention, likes and dislikes, and recommendations for helping other smokers quit. Participants were screened following informed consent. One hundred five smokers (68 females), aged 18-28 years old (M=22.44, SD=2.61) who met inclusion criteria (daily smokers) completed the screening questionnaires. Exclusion criteria included not being a daily smoker, defined as smoking <1 cigarette per day over the past 30 days. Of those completing screening measures, 84 entered the digital intervention and were randomized to either Flexiquit (N=49) or waitlist-control groups (N=35). Participants were blind to allocation until after the completion of pre-intervention measures at which point, they were contacted and informed about the next steps to the study. Participation incentives for completing intervention sessions and questionnaires were extra class credit for university students whose instructors agreed or a raffle entry of small monetary value.

Intervention and Software and Avatar Development

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A website was developed to host the program. The software development used Lightswitch template of Visual Studio Platform, which uses HTML5 and Silverlight technologies. The backend code was developed in C#, deployed on Microsoft Cloud and used the Microsoft SQL server. Two avatars (one male and one female) were created using the Media Semantics Character Builder (see Appendix 1 for a picture of the avatars). Avatar voices were recorded using "Audacity" and incorporated in the program. "Audacity" is a free open-source easy-to-use multi-track audio editor and recorder application (www.audacityteam.org). Each module/component or game was created in HTML5 and javascript and embedded. Videos were created using clips from several sources in iMovie and Final Cut Pro. Finally, questionnaires were created using Tailorbuilder and embedded in the program. Data were sent to Tailorbuilder for storage, subsequently extracted and imported to SPSS. There were both constrained and unconstrained multiple-choice questions used for participants to communicate with the avatar. The avatar was programmed to present limited head and mouth movements, and hand gestures, to match verbal information. To also build rapport, the avatar presented his/her own backstory and teachings regarding smoking. The engine was rules-based with several option paths with pre-recorded answers for each path. Thus, depending on the users' response to the questions posed by the avatar, there was a different continuation to the story, different information, encouragement, skill etc. provided. For example, if the participant responded that they quit smoking, they received a different response than if they stated that they had not yet quit smoking. Sessions were consecutive and participants had to complete them in order.

The digitized "Flexiquit" manual was adapted from ACT for smoking cessation and other protocols [20,23,25]. During the previous smoking cessation trials run by our group targeting this population, participants' ideas and needs were recorded and incorporated in the

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development of this program. The development followed several steps including

brainstorming of ideas, discussions with young smokers about the look of the avatar, realism

to be included, the backstory, and voice preference. Gamification and persuasive technology

principles were utilized in making decisions on program presentations. Gamification utilizes

behavioral principles (e.g., positive reinforcement) along with mechanisms found to make

games addictive and implements these principles in nongame digital situations [19,37,43].

For example, we set up a virtual reward system of earning points for completing tasks and

sessions, along with receiving congratulations, certificates and a virtual graduation from the

program celebration (see Appendix 1 for a picture). Persuasive technology stipulates that for

technology itself to have the capacity of being persuasive (or engaging) the persuasion has to

be intentional, utilized as a medium via which experiences can be created, and follow certain

principles (i.e., provide a sense of trustworthiness, expertise, and credibility) [38]. These

were utilized in the development of this program, where it was made clear which university

was behind this program, what is their expertise, and information regarding the therapy

approach and its empirical support.

Iterations of the program were pilot tested with small groups (2-3 individuals) of

young adult smokers. The program went through two rounds of testing before it was finalized

in its current format. Each of the six exclusively digital sessions was adapted so that

experiential exercises, therapy facilitating metaphors, and other materials, were tailored to

engage young adults [following guidelines of 19; e.g., adapting the content to the interests of

youth, such as including music and sports metaphors] and presented in a digitized way via the

use of pictures, videos, avatar discussions, exercises, games etc. (see Table 1 for session

overview and also a detailed description of the content can be found at [30] and the full

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manual is available from the authors). Each session took approximately 25 minutes to complete.

Data Collection and Measures

Participants who screened eligible (n=105) and consented, were invited to complete pre-intervention measures. Twenty-one people did not complete this step. Eighty-four completed pre-intervention measures and were randomly allocated using computer-generated allocation with oversampling for the treatment condition (randomizer.com). After completing each session, an automated email thanked them for participating, provided session handouts, and reminded them about homework assignments. Following completion of session 6, participants completed the post-treatment questionnaires on-line.

Waitlist-control group participants received the pre-treatment questionnaires concurrently with the intervention group. Timing was yoked at post-intervention, such that for every participant in the intervention group that completed the sixth session and received an email to complete the post-treatment questionnaires, one participant from the control group received the post-treatment assessment. Waitlist-control participants were then invited to enter the program, but no intervention data were collected on these participants.

Assessments were completed three times on-line: at pre- and post-intervention, and 6-month post-intervention follow-up for the intervention group only. These included:

Demographics and smoking history, assessed age, gender, weekly allowance/income, smoking history and current smoking patterns (e.g., number of cigarettes smoked per day).

Quit status, 7-day point prevalence abstinence. Since the point prevalence is the most common cessation outcome in smoking cessation effectiveness trials and it makes the comparison of effectiveness across trials easier [29], participants were given the question

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"Did you smoke, even a puff, in the last 7 days?" and were required to give a "yes" or "no" answer.

Fagerström Test of Nicotine Dependence (FTND [24]; Greek validation [25]**)** is a 6-item self-report instrument of nicotine dependence. Higher total scores indicate higher levels of dependence. It is one of the most frequently used measures of nicotine dependence with adequate internal consistency; 14 studies showed Cronbach's α coefficient range of 0.55 to 0.74 [26]. Also, 8 studies found a range of 0.65 to 0.91 for its test-retest reliability [26]. Cronbach's α for this sample was 0.81.

Smoking Self-Efficacy Questionnaire (SSEQ; adapted from [27]; Greek adaptation [24]**)** contains 12-items assessing self-efficacy in resisting smoking in specific situations, on a Likert-type scale ranging from 1=I'm sure I won't smoke to 7=I'm sure I will smoke. Lower scores indicate higher self-efficacy in resisting temptation. It showed good internal consistency and test-retest reliability, with Cronbach's α coefficients of .95 and .94 respectively [27]. For this study Cronbach's α=.93.

Contemplation Ladder [28] is a one-item ordinal measure assessing intention/readiness to quit smoking and was used to determine participants' stage of change. It consists of a 0-10 scale, where higher scores indicate higher levels of motivation/readiness to quit smoking. Researchers reported good concurrent and predictive validity and suggested that this measure is a good predictor of smoking cessation [28].

End-of-Session Satisfaction Questionnaire (completed at the end of each session- total 6 times), was based on the Modified Client Satisfaction Questionnaire [44] and adapted for the purposes of this study. It assessed participants' satisfaction with each treatment session and its components and helpfulness in quitting, using a Likert-type scale (0=not at all and

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10=very much satisfied). Areas assessed included: session quality, effectiveness, interesting, helpful, accurate, useful in quitting smoking, and ease of use (see [30] for more details).

Data Analysis

In order to test group equivalence prior to the intervention, demographic variables, smoking variables, self-efficacy, intention to quit, and baseline variables were compared between the two groups (treatment vs. control) using two-tailed t-tests for continuous variables and chi-square tests for categorical variables. These same analyses were repeated, comparing completers (all who completed the post-assessment) to non-completers (those who completed at least one session of treatment but not the post-assessment) on baseline measures to ensure that demographics or smoking characteristics at baseline did not predict drop out from the study.

To determine whether abstinence rates (self-reported 7-day point-prevalence) at post-treatment differed between groups, logistic regressions were conducted, as this was a binomial outcome. A logistic regression was also conducted on an intent-to-treat (ITT) basis, where non-completers were considered smokers at the time of assessment.

Mixed factor ANOVAs evaluated group changes from pre- to post-treatment quit rates and smoking outcomes. One-way repeated measures ANOVAs compared the effects of time separately for each of the outcome variables (FTND, SSEQ, CL) pre- and post-intervention, and at 6-month follow-up (calculated from post-intervention) only for the Flexiquit condition since wait-list participants were offered the intervention after the post-treatment point. All statistical analyses were conducted using SPSS (IBM SPSS version 22).

Results

Demographics

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Table 2 presents the demographics in the treatment and control groups. More female smokers were included than males, which reflect the proportion of genders attending university in social science majors (from where the sample originated). Most participants (90%) were Greek Cypriots, 4% were Greeks and the rest reported "other" as their ethnicity. Participants reported having smoked their first cigarette between 11 and 23 years old (*M*=16.36 years, *SD*=2.34). Participants reported smoking on average 9.41 (*SD*=6.93) cigarettes per day (range=1-27 cigarettes per day) during the past week. Thirty-four percent of participants also experimented with other drugs (e.g., marijuana, cocaine). On average participants took 44.07 days to complete (session 1-6) the program (*SD*=22.60; *mode*=22). Most participants (65.45% overall; 78.78% in Flexiquit and 53.57% in control) were in pre-contemplation or contemplation stages of change suggesting that they were not interested in quitting smoking (Table 3).

Baseline Measures: Assessing Group and Completer Equivalence

There were no statistically significant differences in any of the demographic, smoking-related, or outcome variables between the treatment and control groups or between treatment completers and non-completers (see supplementary Table 1).

Attrition

Attrition within the intervention group was 42.86% (21 of 49 participants). Attrition in the wait-list group was 20% (7 of 35 participants). One participant's post-treatment data was lost due to technical problems (crashing of the website without saving the data). Some other isolated technical problems reported by participants included: "crashing" of the website or the pause button getting "stuck" resulting in the need to repeat parts of the session again, and lack of program responsiveness [for more details see 30].

Controlled Differences on Quit Rates and Smoking Outcomes

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As hypothesized, with completer case analysis, at post-intervention the treatment group had statistically significantly higher self-reported quit rates (7-day point-prevalence abstinence) than the control group (51.90% vs. 14.30% respectively; OR=6.46, 95% CI=1.76–23.71, p=.005; see Table 3). Intent-To-Treat (ITT) analysis also showed increases in odds of quitting; however, this increase was non-significant (28.57% vs. 11.43% respectively; OR=3.10, 95% CI=0.92-10.41, p=.067). A comparison at 6-month follow-up was not possible as participants in the control group entered treatment after the waiting period (i.e., post time-point).

There was a statistically significant interaction between time and group on participants' average number of cigarettes smoked per day, $F(1,53)$=9.61, p=.003, η^2=.15; a significant main effect of time, $F(1,53)$=16.92, p<.001, η^2=0.24, with higher number of cigarettes smoked per day at pre than at post-intervention (see Table 3 and Figure 2). Statistically significant differences between the two groups were found only at post intervention, ($F(1,53)$=8.80, p=.005, η^2=.14) with lower number of cigarettes smoked by individuals in the treatment group compared to control. Table 3 presents all means, standard deviations and denotes where statistically significant group differences were found.

There was a statistically significant interaction between time and group on participants' FTND scores, $F(1,53)$=6.78, p=.01, η^2=.11 (see Table 3). There was a significant main effect of time, $F(1,53)$=10.42, p=.002, η^2=.16, with FTND scores at pre being higher than at post-treatment. Single degree of freedom interaction contrasts showed that the differences driving the interaction were those between the two groups at post-intervention ($F(1,53)$=4.51, p=.04, η^2=.08), with the treatment group presenting with lower levels of nicotine dependence compared to control.

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Similarly, there was a statistically significant interaction between time and group on participants smoking self-efficacy scores, $F(1,53)=22.64$, $p<.001$, $\eta^2=.30$. There was also a significant main effect of time, $F(1,53)=32.32$, $p<.001$, $\eta^2=.38$. Single degree of freedom interaction contrasts showed that the differences driving the interaction were those between the two groups at post-intervention ($F(1,53)=13.11$, $p=.001$, $\eta^2=.20$), where individuals in the Flexiquit group presented lower scores (higher self-efficacy) compared to controls.

There was a statistically significant interaction between time and group on participants' intention to quit smoking scores (CL), $F(1,53)=22.29$, $p<.001$, $\eta^2=.30$. There was also a significant main effect of time, $F(1,53)=17.06$, $p<.001$, $\eta^2=.24$. Single degree of freedom interaction contrasts suggest that the differences driving the interaction were the statistically significantly higher intention-to-quit scores of the treatment group compared to the control group at post-intervention, $F(1,53)=19.01$, $p<.001$, $\eta^2=.26$.

Time differences from pre to post to follow-up for Flexiquit group only

One-way repeated measures ANOVAs compared the effects of time separately for each of the outcome variables (FTND, SSEQ, CL) pre- and post-intervention, and at 6-month follow-up only for the Flexiquit condition, since wait-list participants were offered the intervention after the post-intervention point (see Figure 2). There was a statistically significant effect of time on FTND, Wilks' Lambda=.58, $F(2,12)=4.27$, $p<.05$, $\eta^2=.42$, with pre FTND scores ($M=2.50$, $SD=2.25$) being significantly higher than follow-up scores ($M=.93$, $SD=1.33$). Similarly SSEQ scores significantly decreased across time, Wilks' Lambda=.34, $F(2,12)=11.77$, $p<.001$, $\eta^2=.66$; from pre ($M=60.43$, $SD=13.83$) to post ($M=36.93$, $SD=16.92$) to follow-up ($M=31.93$, $SD=18.91$). Regarding CL scores, there was a significant quadratic effect across time, Wilks' Lambda=.58, $F(2,12)=4.27$, $p<.05$, $\eta^2=.69$, with scores increasing from pre ($M=5.21$, $SD=2.36$) to post ($M=9.00$, $SD=1.66$) but

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significantly decreasing from post to follow-up (*M*=3.43, *SD*=3.53) at similar levels as pre-intervention.

Post-hoc analysis of number of cigarettes smoked per day among non-quit participants

Repeated measures ANOVAs (group x time) was carried out only for those individuals who did not quit smoking at the post assessment point (13 in Flexiquit and 24 in control). There was a statistically significant interaction $F(1,35)=3.97$, $p=.05$, $\eta^2=.05$; driven by a significant decrease in the number of cigarettes smoked per day by the Flexiquit group pre to post intervention, ($F(1,35)=6.48$, $p<.05$, $\eta^2=.16$), whereas no such decrease was found in the control group ($F(1,35)=.09$, $p>.05$).

A logistic regression was performed to ascertain the effects of pre-intervention motivation to quit on the likelihood first on dropout and then on quit success. Neither model was statistically significant, suggesting that pre-intervention motivation levels were not predictive of dropout or quit success.

Additional information on the percent of individuals who quit and for those who continued to smoke, the number of cigarettes smoked per day by stages of change (from pre-contemplation to action) for the two groups is found in the supplementary Table 2.

Satisfaction with treatment

Participants satisfaction, interest, engagement, acceptability and helpfulness of the program were found to be highly positive for the intervention. Specifically in terms of quality, the average mean score across all sessions was 8.17 (SD=0.35); the average mean for effectiveness across sessions was 8.03 (SD=0.60); on average across sessions the mean for how interesting the sessions were, was 8.09 (SD=0.29); the average mean of how helpful the sessions were, was 8.02 (SD=0.58); in terms of usefulness of material presented, the average mean across sessions was 8.06 (SD=0.59); and the average mean for ease-of-use was 8.70

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(SD=0.28). See [30] for a detailed description of this assessment and findings. This paper

also presents a comparison between completers and non-completers, where no statistically

significant differences were found between these groups.

Discussion

This study demonstrated how a digital virtual coach intervention based on state-of-

the-art theory increased odds of quitting smoking in the traditionally hard-to-reach population

of young adult smokers. Results were consistent across all stages of readiness to change

(from pre-contemplation to action) and, importantly, even among those who were not yet

motivated to quit prior to the intervention. Furthermore, a statistically significant decrease for

cigarettes smoked per day was reported among those individuals who did not fully quit at

post-treatment assessment.

The program was built using gamification [37] and persuasive technology concepts

[38] as well as an empirically supported theory of behavior change (i.e., ACT) [19]. This

program directly addressed participants' values, goals and deep-seated dreams as a means of

cultivating appetitive motivation. The intervention targets values as a type of appetitive

motivation to stand in opposition to one's motivation to avoid the aversive aspects of the

quitting process (i.e., cravings, fear of weight gain, etc). In other words, the intervention

provided a powerful individual reason to give up an otherwise "pleasurable" habit. It is

believed that once appetitively motivated, young adult smokers are more likely to engage

with the other active parts of the program that provided the skills necessary to cease smoking

(e.g., tolerance of discomfort and cravings). Based on the complete-case analysis, the

probability of quitting was six times as high among completers compared to those in the

control group. Quit rates remained quite high in the ITT analysis (probability of quitting was

three times as high among Flexiquit group participants [28.57%] than control group

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[11.43%]). In comparison, previous young adult smoking cessations studies reported only as high as double the self-reported quit rates at post-treatment compared to controls [6,10,13], a lower rate than the outcomes of the present study.

Nicotine dependence levels of young adults in this sample were relatively low to moderate at pre-treatment. Such levels are consistent with those of dependence in other samples, likely due to a shorter smoking history than older adult smokers [32]. Irrespective of individuals' levels of nicotine dependence at pretreatment, more decreases were observed from pre- to post-treatment in Flexiquit than the control group. Importantly, the mean number of cigarettes smoked per day also statistically significantly decreased in the Flexiquit compared to control group even among those individuals who did not quit smoking at post-intervention. Therefore, even for participants who did not manage to fully quit at post, there was a trend towards decreasing the amount of cigarettes smoked per day in the intervention group, potentially bringing this group closer to completely quitting in the future [39,40].

Similar to previous smoking cessation research, this study observed an increase in participants' self-efficacy and readiness-to-quit (e.g. [33]). Importantly, this study observed this same phenomenon in individuals who had little interest to make a quit attempt prior to the intervention (65% were at the pre-contemplation or contemplation stages of change). We believe that one of the areas where ACT deviates from previous treatments and has potential to be particularly helpful may be in providing meaning to the quit attempts and thus motivating individuals. This is accomplished by putting smoking into a larger context (e.g., of valued living) and specifically aiding individuals to move through the stages of change, with increased quitting self-efficacy and translating this into actual behavior change. Future studies should also explore the preventive value of such an approach in preventing adolescents and young adults from picking up smoking.

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Attrition rates among young smokers are usually quite high for general face-to-face programs (e.g., up to 77% dropout [6]) and is a substantial problem plaguing all types of digital interventions [19]. The attrition rate of the treatment group in this study was 42.86%, which is in line with previous face-to-face smoking cessation studies in young adults [6]. This is particularly promising for this program, as this was a digital intervention where one would expect higher attrition rates and given the low interest in quitting prior to the study (only moderately motivated to quit smoking). However, there was a higher proportion of female smokers than males, potentially suggesting that males were even less likely to be interested in quitting or entering such a cessation program. This is in line again with research suggesting that males are less likely to engage with digital interventions and more likely to dropout compared to females [19,34]. Finding ways to deal with attrition should be of concern to future digital intervention studies and measures are needed to improve user engagement and adherence, especially among young adult male smokers. Further, there was more retention of participants in the wait-list control group and this may have been an artifact of the contingencies provided, as participants in the wait-list were told that they would receive course credit or a chance to enter the raffle drawing after completing the intervention. Further, curiosity of trying out the digital program may have led to higher retainment in this group, however this was not specifically tested.

This study had several limitations. First, it relied exclusively on self-reported abstinence in all cessation outcome variables. It is possible that young adults over-report quitting. However, given that no incentives were provided for quitting and that from the beginning participants were told that they would not be "forced" to quit but instead the focus was placed on testing the intervention and providing feedback regarding likeability and helpfulness of the approach, we believe there was less of a demand for participants to over-

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report quitting. Given the advent of technological means of biochemical verification, future studies should attempt to assess quitting, if not for all participants, at least to assess a random sample for abstinence. Further it would be important to assess smoking cessation at each session so as to examine when changes in smoking behavior occur during the intervention. Second, in order to accommodate participants, spacing between sessions was allowed to range from three to 30 days, thus the resulting time to completion of the program varied among participants (22-94 days). This heterogeneity might have affected findings in that not all participants received the same temporal intensity of intervention. Future programs may consider a more fixed schedule of session completion so as to decrease the heterogeneity, however this comes with the risk of increasing drop-out if individuals are unable to complete the sessions for non-therapy related reasons (e.g., due to time pressures at school or work). Cross-contamination between conditions is possible as the participant pool originated from similar environments, however this was not specifically assessed. Future studies should take this into consideration as this may actually impact the findings (possibly exaggerate outcomes in the control group). Additionally, we were not able to assess in this trial whether treatment was delivered as intended as background metrics were not incorporated into the development of the program (e.g., time to completion of each session) and participants were not required to upload their homework for verification of task completion. Future programs should ensure the gathering and reporting of background metrics and participants' homework. Also, some technical problems were reported by participants that resulted in some data loss (e.g., post-treatment questionnaires) or difficulties. Technical problems were more evident during session 1 (some problems were fixed for later sessions), which may have resulted in higher attrition at the beginning of the intervention (see also [30]). The comparison condition chosen in this study was a wait-list control group, as there was no other

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"standard of care" equivalent intervention available against which to compare Flexiquit for this population. Future studies should aim to directly compare the Flexiquit program to other active (digital) interventions to further isolate non-specific effects. Further, the sample in this study comprised of university based young adults with possible generalizability limitations. However, an epidemiological study of young adults in Cyprus showed similar smoking rates among working and community dwellers, and university students [31]. Future studies should also examine this program with additional populations and larger samples.

Innovative modes of treatment delivery, such as digital programs like Flexiquit, are promising with respect to reducing or stopping smoking among young adults. Advancements in computer software and the gaming-world in terms of graphics, interactivity, avatar personifications and anthropomorphisms, contribute to the flow of information and user experience [19]. If these state-of-the-art technologies are applied outside the gaming world and adapted to state-of-the-art therapeutic interventions, this will inevitably improve the attractiveness, engagement, and effectiveness of digital interventions [19]. Such interventions may be appealing and attractive to young adults who are comfortable and familiar with digital means of information exchange and play.

Overall, Flexiquit provides promise for the delivery of smoking cessation interventions to young adults who may otherwise be hard-to-reach or not interested in engaging in a face-to-face smoking cessation. This is especially encouraging given that digital interventions have the advantage of being cost-effective, easy to disseminate, convenient, and sustainable. As such, digital interventions that prove their efficacy have the potential to impact public health at higher rates than other treatments [36]. Therefore, we are optimistic of the promise of such programs in dealing with the smoking epidemic, especially among young adults.

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Table 1.

Digital Acceptance and Commitment Therapy Sessions Goals, Techniques used and Homework Assignments

Sessions	Goals	Techniques used	Homework Assignment
Session 1	• Introduction of the Avatar and the program/approach • Session overview • Values clarification[1]	• Avatar videos • Testimonials from participants who previously successfully quitted • Values-Game of life[2]	• Values exercise[3]
Session 2	• Session overview & homework check-in • Control as the problem • External and Internal smoking triggers • Mindfulness of triggers[4]	• Interactive discussion of triggers (open-ended questions, graphs, pictures, experiential exercises & metaphors) • Inevitability of control of internal smoking triggers[5] discussion & "don't think about…." metaphor • "Wrap around method" [6] video • Mindfulness of triggers exercise	• Use "wrap around method" • Practice mindfulness of triggers
Session 3	• Session overview & homework check-in • Difficulty in controlling thoughts, emotions, cravings • Problem with placing too much emphasis on words/ Cognitive defusion[7]	• Cognitive Defusion interactive and experiential metaphors[8] • "Lie detector" metaphor video[9] • Experiential exercises (e.g., "hands as thoughts" exercise)[8]	• Link values to smoking cessation & practice values-based action • Practice cognitive defusion • Choose to decrease number of cigarettes smoked per day (recommendation to decrease by half)
Session 4	• Session overview & homework check-in • Cognitive defusion[7] • Recognize excuses as obstacles to valued living • Learn techniques to get "unstuck" from thoughts & excuses	• Open ended questions about obstacles faced in homework completion • Cognitive Defusion interactive and experiential metaphors & exercises (e.g., "musical thoughts")[8] • Choosing a quit date & planning for values-based actions in the face of obstacles	• Link values to smoking cessation & practice values-based action • Practice cognitive defusion techniques
Session 5	• Session overview & homework check-in	• Open & close-ended questions about obstacles	• Practice learned skills to quit

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		faced in homework completion	smoking or remain quit
	• Learn to reward ourselves for succeeding • How to deal with failure or lapses • Learn about willingness[10] & choices • Relapse prevention[11] • Linking together all learned skills	• Willingness interactive and experiential metaphors & exercises (e.g., "mountain" metaphor)[12] • "Demons on the boat" metaphor video[13] • Relapse prevention skills exercises • Values based choices in the face of difficulties exercises	
Session 6	• Session overview & homework check-in • Summary of learned concepts & skills • Integrate the techniques learned from the previous sessions and evaluate whether they are living a life based on their values	• Open & close-ended questions about obstacles faced in homework completion • Relapse prevention skills exercises • "Waves" videos about relinquishing control[14] • Avatar recap of sessions	• Completion of post-intervention questionnaires

Note: Each session took approximately 20-30 minutes to complete. All sessions were created to last approximately an equal amount of time and videos ranged from 2-3 minutes in duration.

[1]Values clarification (Hayes, Strosahl & Wilson, 2011): This is defined as clarification of and living based on deeply meaningful chosen values as opposed to being confused about what is meaningful and/or living life in incongruence to what is really important for the person (i.e. being confused about what is of value, behaviour discrepant from one's values).

[2]Values-Game of life: This is a game adapted and digitized from Hayes & Ciarrochi (2015), where participants explore different values and are asked to choose the 5 that best represent them and what they would like their lives to be about.

[3]Values exercise homework. Created for purposes of this study. This exercise helps the person record whether behaviors engaged in that were in accordance to expressed personal chosen values. Available from the authors.

[4]Mindfulness of triggers: Mindfulness refers to flexible attention to the here and now, as opposed to loss of contact with the present moment or being on an "autopilot" mode of functioning (Hayes, Strosahl & Wilson, 2011). Mindfulness of triggers refers to applying mindfulness skills to observe and attend to smoking triggers when they show up at the time when they show up.

[5]Inevitability of control of internal smoking triggers exercise. This exercise was designed to help participants recognize the inevitability of attempts at controlling thoughts and cravings related to smoking (internal smoking triggers) and how attempts at control may paradoxically increase the intensity of thoughts and cravings and lead to smoking behaviors.

[6]Wrap around method is a commonly used method in smoking cessation protocols, where a piece of paper is wrapped around a cigarette packet. In the adapted exercise here, the person needs to remove the piece of paper in order to open the cigarette packet with the aim to break down the automaticity of the smoking behavior and for the person to consider their choice of whether to smoke or not the cigarette in conjunction with previously stated values. The video explaining this exercise is available from the authors upon request.

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[7]Cognitive Defusion refers to the act of separating ones' thoughts from behaviors, allowing the thoughts to come and go without struggling to get rid of them or getting "caught up" in them or allowing them to dictate behavior (Hayes, Strosahl & Wilson, 2011).

[8]Cognitive Defusion Interactive and experiential metaphors and exercises. A variety of metaphors and exercises were used, which were adapted and digitized for purposes of this study. For example, one exercise includes asking the participants to sing their craving thoughts to the music of the "happy birthday song." This exercise helps the person to relate to their thoughts in a different way, become unstuck/defuse from them. The exercises and metaphors originated from various books and Acceptance and Commitment Therapy protocols (e.g., Gifford, Kohlenberg, Hayes, Antonuccio, Piasecki, Rasmussen-Hall, Palm (2004); Harris (2007); Hayes & Ciarrochi (2015); Hayes, Strosahl & Wilson (2011); 1st author (2010))

[9]"Lie detector" metaphor video was created by the authors (available upon request) based on a metaphor originally described by Hayes, Strosahl & Wilson (2011). The metaphor helps someone experience how difficult it is to control thoughts and urgers – especially unwanted ones.

[10]Willingness in ACT refers to the choice of being "open" to have uncomfortable thoughts, feelings, sensations and smoking cravings in this case and at the same time choosing to act in accordance to chosen values (Gifford, Kohlenberg, Hayes, Antonuccio, Piasecki, Rasmussen-Hall, Palm (2004)

[11]Relapse prevention utilized traditional skills as those proposed by Marlatt and colleagues (2008) which normalize and anticipate difficulties and combined with links to values-based actions and choices in accordance with the ACT approach.

[12]Willingness interactive and experiential metaphors & exercises. A variety of metaphors and exercises were used, which were adapted and digitized for purposes of this study. For example, via the "mountain" metaphor the person comes to explore their choices of either being willing to have cravings and not smoke for the purpose of living a valued life vs. give into the craving and smoke and be on a different values path than the one chosen.

 These originated from various books and Acceptance and Commitment Therapy protocols (e.g., Gifford, Kohlenberg, Hayes, Antonuccio, Piasecki, Rasmussen-Hall, Palm (2004); Harris (2007); Hayes & Ciarrochi (2015); Hayes, Strosahl & Wilson (2011); 1st author (2010))

[13]"Demons on the boat" metaphor video (Oliver & Harris, 2009). In this video participants' thoughts, emotions and all internal events that may get in the way of not smoking are likened to demons that may appear on a boat that one is traveling on (representing our life's journey) and via the video the person comes to see the futility of struggling to get rid of the demons and the outcomes of this struggle (i.e., the boat is left ungoverned and the person gets lost at sea). The alternative shown is that person makes space for the demons on the boat and takes control of the wheel and drives the boat to the desired path.

[14]"Waves" video about relinquishing control of internal events (e.g., cravings) was created by the authors (available upon request) and is based on the idea of learning to "ride the wave" of cravings instead of unnecessarily fighting with the waves only to have them "break" on you which will hurt more.

References for terms, exercises and metaphors

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Table 2.
Demographics, smoking related and outcome variables between the treatment and control groups

	Flexiquit		Wait-list Control	
	M	**SD**	**M**	**SD**
Age (years)	22.50	2.56	22.31	2.73
Age at 1st cigarette	16.47	2.23	16.14	2.57
Gender	**%**		**%**	
Female	64.30		65.70	
Male	35.70		34.30	
Year of study (%)				
1st	4.30		11.40	
2nd	21.40		17.10	
3rd	22.90		11.40	
4th	24.30		28.60	
Post-graduate	27.10		31.40	
Ambition (%)				
Want to finish college/university	24.30		14.30	
Want to complete post-graduate studies	75.70		85.70	
[1]Weekly Allowance/Income (%)				
<50 euro	34.30		25.70	
51-100 euro	37.10		28.60	
>101 euro	28.60		45.70	
Number of cigarettes smoked per day on average (%)				
1-10 cigarettes	55.70		55.20	
11-20 cigarettes	37.10		36.20	
21-30 cigarettes	7.10		8.60	

Note[1]: Allowance for these students does not include room and board.

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Table 3.
Group by Time Comparisons of Study Outcomes

	Flexiquit				Wait-list Control				Comparison	
	Pre		Post		Pre		Post			
% Quit (ITT analyses)	51.90% (28.57%)				14.30% (11.43%)				OR=6.46, 95% CI=1.76–23.71** (OR=3.10, 95% CI=0.92–10.41)	
	M	SD	M	SD	M	SD	M	SD	Interaction F (1,53)	η^2
Mean number of cigarettes per day										
All participants	9.68	6.55	2.89[a]	4.01	8.89	7.72	7.61[b]	7.26	9.61**	.15
For those not quit at post[1]	9.00	5.76	6.00	3.83	8.96	7.30	8.87	7.09	3.97*	.10
For those who quit at post[2]	8.00[a]	7.71	0	0	5.00[b]	5.66	0	0		
FTND	3.19	2.09	1.37[a]	1.86	2.91	2.02	2.57[b]	2.30	6.78**	.11
SSEQ	62.13	15.10	39.22	18.25	58.29	17.89	57.04	18.23	22.64***	.30
CL	4.86	2.68	8.63	2.26	5.63	3.42	5.50	3.00	22.29***	.30
CL-Stages of change	%		%		%		%			
Pre-contemplation	31.40		3.70		34.30		28.60			
Contemplation	45.70		14.80		20.00		35.70			
Preparation	10.00		14.80		20.00		17.90			
Action	12.90		66.70		25.70		17.90			

Note[1]: Flexiquit N=13, Control N=24.
Note[2]: Flexiquit N=14, Control N=4.
Note: FTND= Fagerstrom Test of Nicotine Dependence; SSEQ= Smoking Self Efficacy Questionnaire; CL= Contemplation Ladder.
Note: *** $p<.001$; **$p<.01$, *p<.05; [a] significantly different from [b].

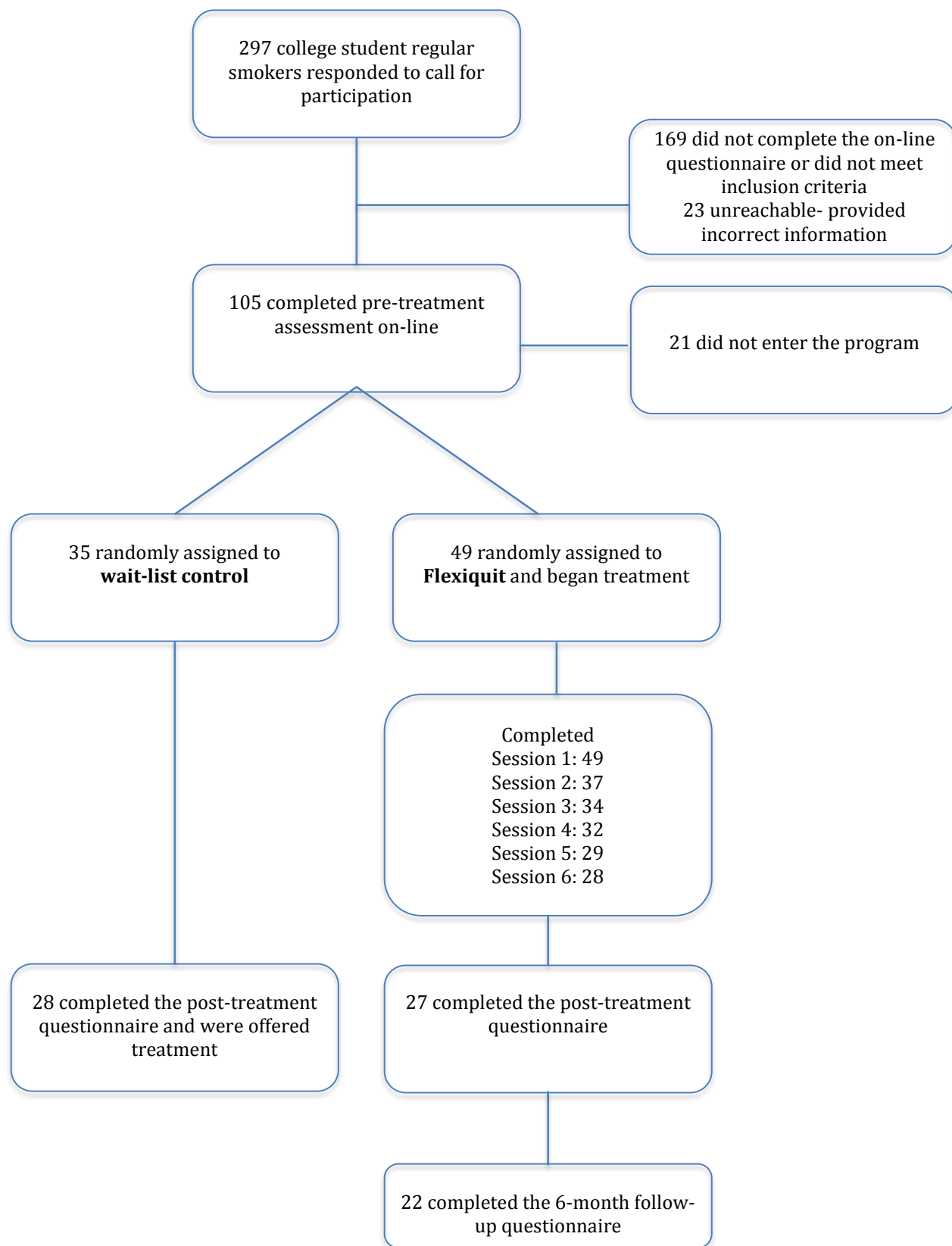Effectiveness of an Avatar-led Smoking Cessation Intervention

Figure captions

Figure 1: CONSORT flow diagram

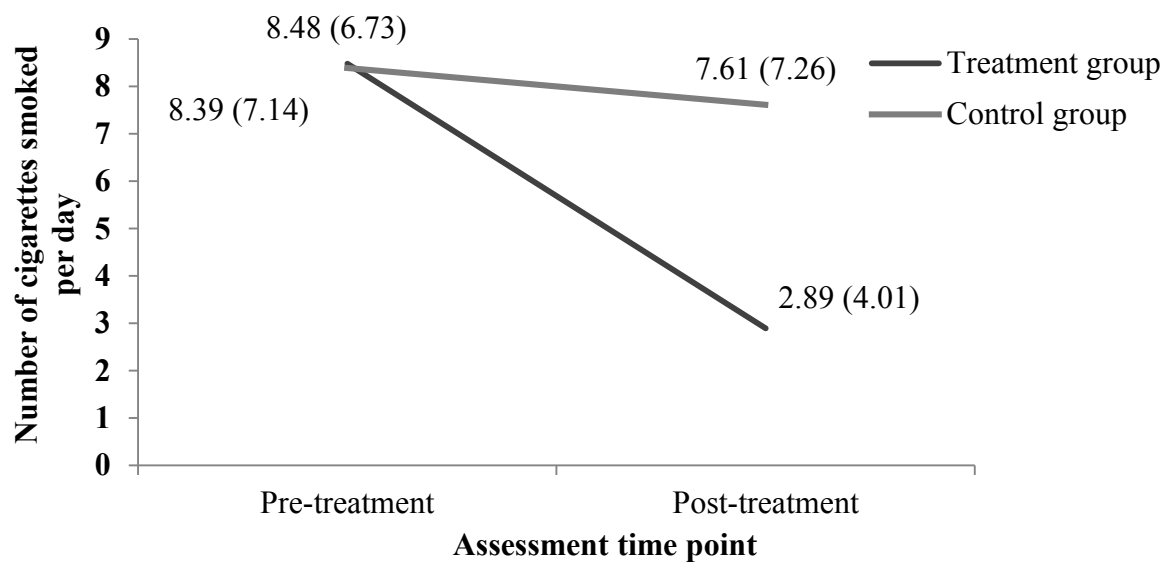Figure 2: Group by Time Interaction on Number of Cigarettes

Effectiveness of an Avatar-led Smoking Cessation Intervention

Figure 1.
CONSORT flow diagram

Effectiveness of an Avatar-led Smoking Cessation Intervention

Figure 2.
Group by Time Interaction on Number of Cigarettes

Effectiveness of an Avatar-led Smoking Cessation Intervention
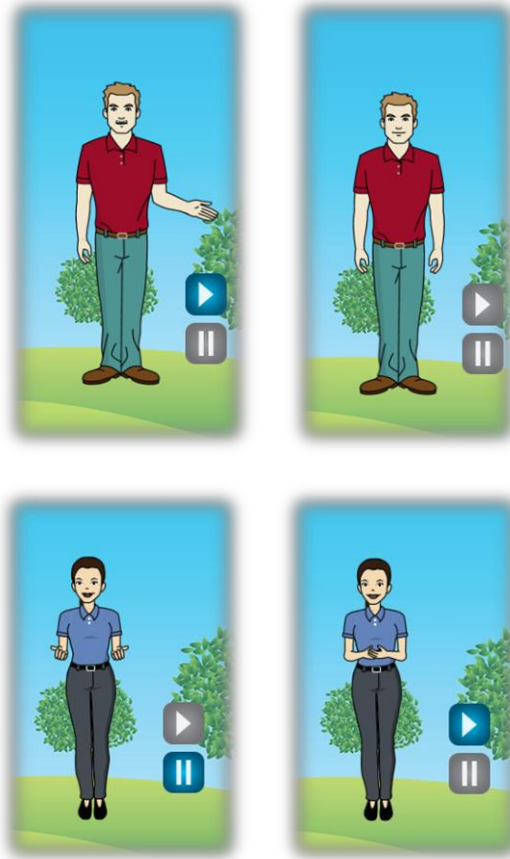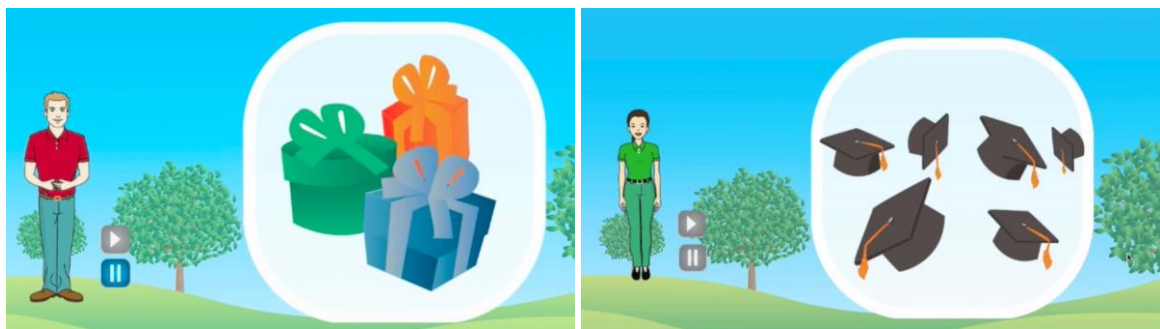
Appendix 1

Flexiquit Avatars

Illustration of Gamification principles utilized in FlexiQuit

Table 1

Comparison of Smoking Characteristics and Study Outcomes for Treatment Completers and Non-Completers at Pre-Treatment

	Completers (N=55)		Non-completers (N=29)		Comparison	
	M	SD	M	SD		p
Age at 1st cigarette	17.04	2.47	16.12	2.01	t = 1.70	.09
Number of previous quit attempts	2.89	1.81	2.74	1.47	t =.35	.73
Average number of cigs / day	8.48	6.73	10.43	6.40	t = -1.22	.23
Tried drugs? (%)						
Yes	25.9		32.6		χ^2 =.35	.60
No	74.1		67.4			
FTND	3.04	2.35	3.28	1.93	t = -.47	.64
SSEQ	62.15	14.83	62.12	15.43	t = .01	.99
CL	4.89	2.42	4.84	2.86	t = .08	.94

Note. FTND=Fagerstrom Test of Nicotine Dependence; SSEQ=Smoking Self-Efficacy Questionnaire; CL=Contemplation ladder.

Supplementary Table 2

Number of cigarettes smoked by stage of change for each group for treatment completers only.

Stages of change		Flexiquit					Control			
	N	Smoke # of cigarettes per day (%)			Quit (%)	N	Smoke # of cigarettes per day (%)			Quit (%)
		<10	11-20	>21			<10	11-20	>21	
Pre-contemplation	8	3(37.57)			5 (62.50)	9	5(55.60)	2(22.20)	1(11.10)	1 (8.30)
Contemplation	13	5(38.50)	1(7.70)		7 (53.80)	6	2(33.30)	2(33.30)	2(33.30)	
Preparation	4	3(75)			1 (25)	7	5(71.40)	1(14.30)		1 (14.3)
Action	2	1(50)			1 (50)	6	4(66.70)			2 (33.30)