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DEVELOPMENT AND USABILITY TESTING OF QUIT4HEALTH, A SMOKING CESSATION SMARTPHONE APPLICATION FOR YOUNG ADULTS

by

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2018

DEVELOPMENT AND USABILITY TESTING OF QUIT4HEALTH, A SMOKING CESSATION SMARTPHONE APP FOR YOUNG ADULTS

by

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DEVELOPMENT AND USABILITY TESTING OF QUIT4HEALTH, A SMOKING CESSATION SMARTPHONE APP FOR YOUNG ADULTS

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School of Public Health, 2018

Thesis Chair: Dr. Ross Shegog, PhD

Introduction: Tobacco use is the leading cause of death in the United States. As of 2016, 23.5% of American 18-25 year olds reported having used cigarettes in the last month compared to 20.2% of adults and only 3.4% of adolescents. Due to the efficacy and widespread general use of mobile technology today, mobile-phone health, or mHealth apps, have become increasingly popular methods of delivering smoking cessation programs. However, there is a lack of evidence in regards to the quality and the effectiveness of using mHealth to deliver smoking cessation interventions to young adults. This study aims to fill this gap to a certain extent by providing evidence for the usability and quality of Quit4Helath, an interactive smoking cessation mobile phone aimed predominantly at young adults.

Methods: Participants were pre-screened and recruited from the Houston Community College Coleman campus. Participants were smokers who were current students between 18-26 years old who owned either an iOS or Android smartphone and could speak and read in English.

Focus groups were held in September and October of 2018 during which participants used the various features within the app before taking the user version Mobile Application Rating Scale (uMARS) to assess usability.

Results: Five participants were analyzed in the final sample. Participants gave Quit4Health a total app quality mean score of 4.26 (SD=.35) out of 5. Engagement was given the lowest mean quality score of 3.8 (SD=.48) whereas Functionality, Aesthetics, and Information received a high quality mean score of 4.4. In the thematic analysis, four broad themes were identified that described these young adult smokers' perceptions of the app's quality and acceptability: Information, Relevance & Relatability, Appeal and Credibility.

Discussion: The Quit4Health app received a high overall app quality mean score similar to the top apps on the market. Participants expressed overall satisfaction with the Quit4Health app. Individual engagement items showed the app to be very interactive but lacking in entertainment. Participants felt that the Quit4Health app could benefit from more credibility and health related information regarding cigarette smoking but found the app to be relatable to themselves and college students in general.

Conclusion: The results of this study indicate that the application is of high quality and meets the needs of young adult community college smokers attending the Houston Community College Coleman Campus and has high usability. However, improvements to the Quit4Health application are needed in order to provide a more entertaining and informative experience. More research is needed in order to discern how to optimize the use of mHealth with smoking cessation interventions for young adult smokers

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BACKGROUND

Tobacco use is the leading cause of preventable death and disease in the United States. It is responsible for every 1 in 5 deaths and continues to impose a substantial financial health burden with more than \$300 billion in annual costs (Centers for Disease Control and Prevention, 2014). In the United States more than 16 million people every year end up living with a tobacco related disease (Centers for Disease Control and Prevention, 2014). The consequences of tobacco use have been known for a very long time. A wealth of evidence gathered over several decades has culminated in the 50th anniversary edition of the Surgeon General's report published in 2014 which outlines in detail the health problems caused by tobacco use that have been discovered and proven in the past 50+ years such as lung disease, cardiovascular disease, cancer in almost every part of the body, diabetes, impotence, stroke, compromised immunity, infertility and more (Centers for Disease Control and Prevention, 2014). Today, long-term smoking causes about 30% of all cancers in the United States and is the leading cause of lung cancer and chronic obstructive pulmonary disease (COPD) causing around 80% of COPD deaths and over 85% of lung cancer deaths (American Cancer Society, 2018; American Lung Association, 2018; Centers for Disease Control and Prevention, 2014). Multiple cancers such as bladder, kidney, larynx, and stomach, are attributable to smoking (Centers for Disease Control and Prevention, 2014). Those who smoke have also been found to have a 30-40% higher risk of developing type 2 diabetes mellitus and have a 2 to 4 times higher risk for coronary heart disease and stroke than those who do not smoke (American Heart Association, 2018; Centers for Disease Control and Prevention, 2014). And yet, in 2016 an estimated 63.4 million people in the United States aged 12 or older reported currently using a tobacco product (Substance Abuse and Mental Health Services Administration, 2017).

Unfortunately, the majority of tobacco initiation occurs during adolescence and young adulthood (Choi & Stommel, 2017). Around 98% of today smokers imitated tobacco use by the age of 26 (Centers for Disease Control and Prevention, 2014). College life, in particular, is a period associated with high sensation seeking and experimentation and is therefore associated with high susceptibility to initiation of substance use in general. The transition from high school to college and managing the responsibilities that come with college life also causes increased levels of depression and anxiety which are triggers for tobacco use (Bares, Dick, & Kendler, 2017). As such, the highest rates of tobacco use in the United States are usually seen among this age group (Lipari, 2013). As of 2016, 23.5% of 18-25 year-olds reported having used cigarettes in the last month compared to 20.2 % of adults and only 3.4% of adolescents aged 12-17 years (Substance Abuse and Mental Health Services Administration, 2017).

Smartphones and mHealth

Smartphones have made it possible for the majority of today's Americans to connect to the world of digital information while "on the go". The earliest devices that could be referred to as "smartphones" emerged in the early 1990s in Japan but did not achieve mass adoption until the end of the 1900s. Even then, smartphone use did not become popular in the United States until the early 2000s. Over the decades smartphone capabilities have rapidly evolved to fulfill a multitude of young adult needs and have now become pocket-sized personal handheld computers that support portable access to the Internet and are able to run a large variety of applications. The majority of modern smartphones offer sleek appealing designs that come equipped with touchscreen technology, high quality color displays, virtual keyboards, virtual assistants, and eye-catching onscreen icons to activate apps. These apps allow for instantaneous access and

direct communication and combined with the mobility of smartphone technology have revolutionized the ways in which health information and healthcare are accessed.

The advent and evolution of smartphones in the last decade has resulted in the rapid rise of medical and public health services being delivered using smartphone technology, otherwise known as mobile health or mHealth. This relatively new field has made health interventions more accessible to today's tech savvy generation of adolescents and young adults especially since smartphone usage in the United States has skyrocketed in the last few years. In 2011, only about 35% of Americans owned a smartphone. As of 2017, around 95% of Americans now own some kind of cellphone 77% of which own a smartphone (PEW Research Center, 2018). Smartphone ownership is especially high among young Americans which makes the use of mobile health interventions an increasingly desirable method for targeting this age group. According to the PEW Research Center, 100% of today's 18-29 year old Americans own a cellphone of some kind, 92% of which own a smartphone (PEW Research Center, 2018). A meta-analysis of mobile phone health app usage in the United States found that the main users of health apps are younger individuals (Carroll et al., 2017). A systematic review in 2017 analyzed 27 SMS systems and mobile apps used as physical and mental health interventions. Of those that used mobile apps, the majority gave positive results and received positive feedback in reference to feasibility, usability, and efficacy of the intervention or treatment (Rathbone & Prescott, 2017). These studies confirm that health apps are an efficient and effective way of reaching today's young adults.

Smartphone Applications for Smoking Cessation among Young Adults

Due to the efficacy and widespread general use of mobile technology today, mobile phone health, or mHealth apps, have become increasingly popular methods of delivering

programs (Krebs & Duncan, 2015). In terms of smoking cessation, they have the potential to give the young adult the ability to receive real-time interactive monitoring and tailored support within the comfort of their own homes as well as anywhere else in their day to day lives. These apps also can be cost effective and wide reaching as many apps have the benefit of being available online and free of charge allowing interventions to be distributed quickly and easily among large numbers of people (Rathbone & Prescott, 2017). It was reported in 2013 that over 700,000 smoking cessation apps for the Android platform are downloaded per month. A recent study among 1000 smokers from the United States and New England found that the majority endorsed the internet (46.7%) and apps (42.7%) as the top platforms that they would use if they wanted to quit smoking in the future (Borrelli, Bartlett, Tooley, Armitage, & Wearden, 2015).

Research and development of smoking cessation apps, however, is still an emerging field of study that is made complex and difficult by constant and rapidly evolving smartphone technologies. An article reported that there are around 400 smoking cessation apps available in the United States, United Kingdom, and Australian market as of 2015 (Alden, 2013). And yet, a very limited number of studies have been done to evaluate these apps. As such, evidence to support the effectiveness of using apps to promote smoking cessation is limited. In a recent systematic review looking at smoking cessation apps available on the App Store, over 150 articles related to evaluating these apps were identified (Haskins, Lesperance, Gibbons, & Boudreaux, 2017). Only six apps among these articles were found to have some level of scientific support. Of these six, only three apps were evaluated using exploratory pilot randomized control trials. Another recent review looked at 224 articles regarding smoking cessation apps. Of those only 8 were identified as being pilot randomized control trials, control trials, or quasi-interventional by design (Regmi, Kassim, Ahmad, & Tuah, 2017). Of those eight,

three studies reported higher smoking cessation/quit rates. *SmartQuit* was evaluated using a double-blind randomized controlled pilot trial among 196 smokers. The app was found to have a quit rate of 13% (95% CI: 6–22%) vs only 8% (95% CI: 3–16%) in the control group (OR = 2.7; 95% CI = 0.8–10.3) (Bricker et al., 2014). *Get with the Program* was evaluated using a single arm pilot study among 84 daily smokers. Fully adherent young adults were over four times more likely to quit smoking (OR = 4.45; 95% CI = 1.13, 17.45; p = 0.032)(Zeng, Heffner, Copeland, Mull, & Bricker, 2016). The third study was observational and involved automated data collection from 1170 participants using an app called *SmokeFree28*. Around 19% (95% CI 16.7-21.1) of young adults were recorded as being abstinent from smoking for 28 days or longer (Ubhi, Michie, Kotz, Wong, & West, 2015).

Some evidence for the effectiveness of smartphones as cessation tools exists, however, none of these app were specifically designed for young adults. Even though the inclusion criteria for these three studies were adult daily smokers aged 18 years and older, the average age of the participants using *SmartQuit* and *Get with the Program* was 40 years old. *SmokeFree28* was the only app that was used mainly by adolescents and young adults. The study reported that 50.43 % of the 1170 participants were 16-29 years old (Ubhi et al., 2015). Smoking cessation trials generally do not seem to focus on young adults but rather pool them together with younger or older participants making it difficult to assess how effective these interventions are for those 18-26 years old. Only one smoking cessation app was found that was specifically designed to meet the needs of young adult smokers. *Crush the Crave* is a theory-and evidence-based app that integrated the opinions of young adults into the design process and was made available on Android and iPhone in 2013 (Baskerville, Struik, & Dash, 2018). A 6-month parallel randomized control trial with 2 arms was conducted in Canada but results have yet to be published

(Baskerville et al., 2015).

The Role of Usability in Smoking Cessation Applications

A key aspect that is crucial to ensuring that smartphone apps are effective in promoting smoking cessation are the use of evidence-based behavioral change techniques (BCTs), such as the processes identified by the Transtheoretical Model of Change (TTM) (Michie et al., 2013). BCTs have been described as the "active ingredients" of interventions designed to bring about behavior change. However, the few studies that have evaluated the content of smoking cessation apps for use of BCTs lack a standardized definition or set of criteria for identifying these techniques. One comparative study had two coders analyze the content of 137 free iPhone apps for the presence of five BCTs identified in a previous study as being effective in aiding smoking cessation. This study found that only 14.6% of the apps used all five BCTs (Ubhi et al., 2016). Another study, however, used the TTM's processes of change to define BCTs and found that out of 100 iPhone apps 78% included at least 7 processes (Paige, Alber, Stellefson, & Krieger, 2017). Despite BCTs being the "key ingredients" of behavior change, the evidence on whether or not BCTs are effectively used in smoking cessation apps is uncertain and lacking.

What is known is that successful exposure to BCTs, which eventually leads to behavior change, relies heavily on smartphone apps being easy to use and engaging. Therefore, high usability and engagement are considered critical to the success of apps that are focused on changing health behaviors (Serrano, Coa, Yu, Wolff-Hughes, & Atienza, 2017). The majority of content analyses that looked at BCTs also looked for features that promoted usability and engagement. Ubhi, et al. found that less than half of the apps used engagement features (45.3%) while ease-of-use features turned out to be very high (94.5%) (Ubhi et al., 2016) Paige, et al. rated the interactivity of 100 IPhone apps on a scale of 0 (min) to 5 (max) and usability on a

scale of 0 (min) to 7 (max). The study found that few usability strategies were used (M = 2.79; SD = 0.95) and even fewer interactivity strategies were used (M = 1.86; SD = 1.27) even though interactivity is considered to be a major component that promotes engagement (Paige et al., 2017).

Tailoring is another major component that promotes usability and engagement. Yet, there is evidence that the majority of apps in fact do not make use of the smartphone's extensive potential to customize and tailor to the young adult's needs. A recent content analyses found the use of tailoring within Android smoking cessation apps to be positively related to app popularity and young adult-rated quality (Hoeppner et al., 2016). The study looked at three types of general tailoring approaches among 225 publically available smoking cessation apps: 1) interactivity defined as input provided by the young adult resulting in specific feedback, 2) proactivity defined as the app reaching out to young adults after they have starting using it, and 3) responsiveness defined as responding to the quit date by having the functionality of the app change after quit day. 44.9 % of apps provided tailored feedback, 10.2% of apps were proactive, and only 2.2% of apps had more than minimal responsiveness (Hoeppner et al., 2016). Despite young adults' preferences for tailored features, the study found that the majority of smoking cessation apps identified provided very little tailoring (Hoeppner et al., 2016).

Rubin and Chisnell, in their *Handbook of Usability Testing*, define usability as that which makes a product truly usable, that is, when "the young adult can do what he or she wants to do the way he or she expects to be able to do it, without hindrance, hesitation, or questions (Rubin & Chisnell, 2008)." The question that often arises is whether current smoking cessation apps available to smokers are effective and meet young adults' needs. In a recent systematic review over 150 articles related to smoking cessation applications were identified (Haskins et al., 2017).

Only six apps among these articles were found to have some level of scientific support. Of those six, only two were found to have pilot studies pertaining to acceptability or usability. Evidence to support usability of smoking cessation apps is limited with few apps having been formally evaluated using actual usability tests. Given the enormous popularity of health app usage among young adults and the lack of available evidence-based smoking cessation apps, there is a growing need to examine and provide evidence for both the quality and the effectiveness of using smartphone technology to deliver smoking cessation interventions to young adults. (Haskins et al., 2017).

Objectives

The objective of this observational study is to examine and analyze the usability of a new multifaceted smoking cessation app for young adults that was developed using prominent evidence-based theories. Quit4Health was designed for young adults and uses interactive strategies such as games, videos, and animations. The app also utilizes multiple tailoring methods to promote smoking cessation such as tailored feedback and daily notifications. The Quit4Health app was developed by MD Anderson Cancer Center in collaboration with Radiant Creative Services. Quit4Health content was developed by a research team at MD Anderson Cancer Center led by Dr. Alexander Prokhorov and software was developed by a team at Radiant led by Jeffery McLaughlin. App development was funded by a grant from the Small Business Technology Transfer (STTR) program under the National Institutes of Health (NIH). Usability testing for Quit4Health will be conducted among a small group of young adult smokers in order to assess the quality and acceptability of this novel app.

METHODS

Recruitment & Participant Eligibility

This research study was approved by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center Institutional Review Board at Houston as HSC-SPH-18-0576 [see Appendix K] as well as the Houston Community College Institutional Review Board [see Appendix A - B].

Participants were recruited from the Houston Community College Coleman Campus from September to October of 2018. In order to be eligible for the study, participants had to be current students at the Coleman campus. The main study regarding the effectiveness of the Quit4Health app will be conducted with Houston Community College students. The Coleman campus was chosen in order to avoid contamination as it is not one of the campuses included in the main study. In addition, participants had to be between the ages of 18-26, to be able to speak English, and had to be smokers who owned an Android or iOS smartphone with access to the internet. Being a smoker was defined as having smoked at least one cigarette in the past 30 days. Participants were recruited on site at a recruitment table and flyers were distributed throughout the campus [see Appendix F]. A pre-screening questionnaire was administered to interested students at the recruitment table to ascertain their eligibility [see Appendix D]. Once eligibility was confirmed, contact information was collected and recorded on a sign-up sheet [see Appendix E]. Eligible students were also asked to provide their availability to allow the researcher to schedule the focus group on a day that worked best for the students. The eligible students were then contacted via phone/email regarding the location and time of the prearranged focus group. The usability testing of the Quit4Health application took place in a classroom located at the Houston Community College Coleman campus.

Development of Quit4Health

Quit4Health is a tobacco cessation and prevention application program available on both Android and iOS platforms that is targeted towards smokers and non-smokers 18-26 years of age. The application was developed by a team of researchers at the University of Texas MD Anderson Cancer Center led by Dr. Alexander Prokhorov, the leading expert in adolescent and young adult smoking prevention. The primary goal of the application is to move smokers through the stages of behavior change by educating them about the harms of tobacco-use, equipping them with various coping skills, and eventually guiding them through cessation. The secondary goals are to educate non-smokers about 1) the harms of tobacco-use and 2) how to support and assist friends and family members who are trying to quit. The application accomplishes this through mini-activities that are given to the young adult to complete. Quit4Health is considered Phase II of a previous research study done on the Houston Community Campus using AppSPIRE, a prototype application that was developed in 2013. Quit4Health is an updated version of AppSPIRE with brand new graphics, animations, and activities added. The original content has also been rewritten and updated to reflect the current scientific literature and the most recent young adult preferences.

The application was developed using the Transtheoretical Model (TTM), a theory created around cigarette smokers which posits that quitting is not an event but rather a process consisting of several stages (Prochaska, Redding, & Evers, 2015). The TTM lists six different stages of change that a smoker goes through during the quitting process. The application guides the young adult through the first four stages, Precontemplation, Contemplation, Preparation, and Action, which are respectively defined within the application as "Not There Yet", "Thinking About It", "Getting Ready", and "Ready". The initial stage that a young adult is placed in is determined by

a staging questionnaire that the young adult takes when creating their profile [see Figure I]. The activities the young adult is given to complete within the application are determined by the stage that they are placed in [see Figure II].

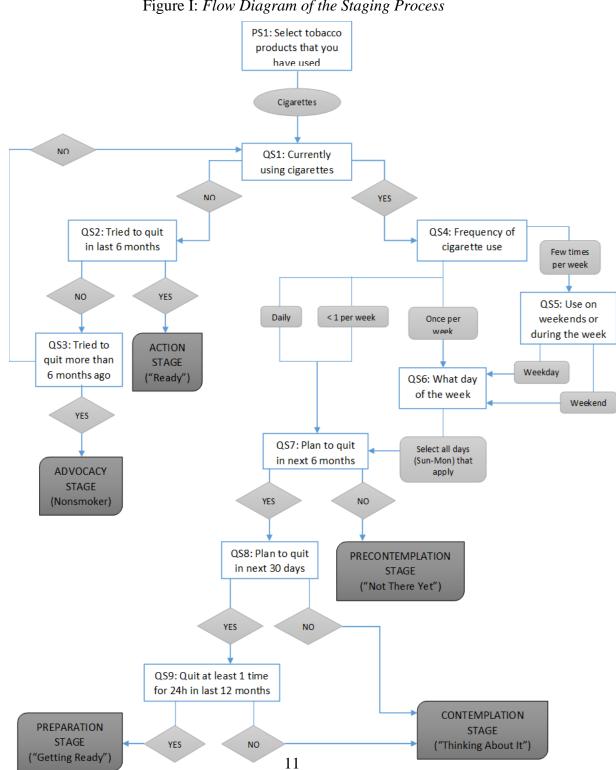
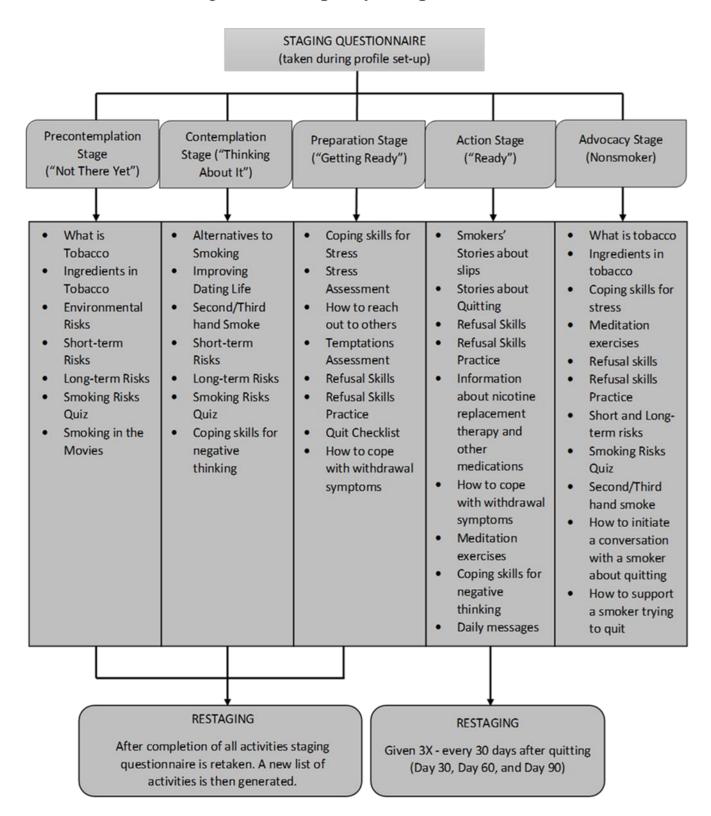


Figure I: Flow Diagram of the Staging Process

Figure II: Flow Diagram of the Stage Activities

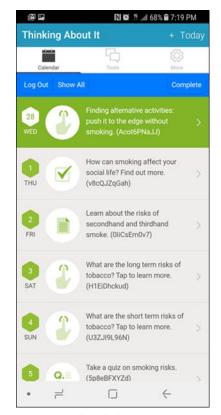


After all activities within the stage are completed, the young adult is taken through the restaging questionnaire. Depending on the young adult's answers, the young adult may move forward to the next stage in the quitting process, stay within their current stage, or move back to a previous stage. There is no reframed messaging within the list of activities associated with movement between stages. The list of activities within each individual stage remain the same, therefore, young adults will go through the repeat the same activities until they are ready to move forward into the next stage. Young adults in the Action/Ready stage are the only exception to this. Young adults in the Action/Ready stage are going through cessation and therefore are prompted every 30 days to retake the restaging questionnaire. Young adults that do not use cigarettes are placed in the "Advocacy" track which is separate from the cessation track. Young adults in Advocacy are given activities that instruct nonsmokers in how to support and assist a family member or friend trying to quit.

The main application screen consists of pages that the young adult can switch between using tabs located at the top of the screen [see Figure III]. The Calendar is the program's home page and the first thing the young adult sees upon logging in. The calendar provides the list of mini activities that are given to the young adult to complete. There is also a Tools page where the young adult will find a calculator to calculate the cost of cigarettes, a quit contract to complete, a milestones page where achievements are unlocked, meditation videos to watch, a tool to measure nicotine addiction levels, and a panic button which can be used to access strategies when faced with temptations. The "More" tab provides access to a settings page with a customizable profile screen. The calendar and its activities are the main part of the application and the ultimate goal is to have young adults go through and complete every activity that is given to them. There are two types of activities within the application. The first are simple reading activities where graphics

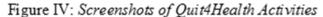
Figure III: Screenshots of Quit4Health



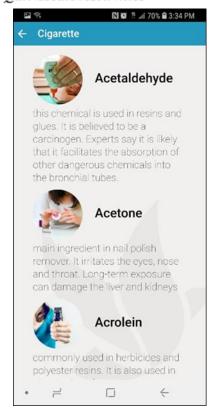


A: Splash Screen

B: Calendar







and information are given. The second are interactive point and click mini-games where information is provided in an entertaining format. Examples of these activities can be seen in Figure IV.

Young adults going through the quitting process in the Action/Ready stage are additionally monitored using daily in-app check-ins and are given support and advice through tailored notification messages delivered on a daily basis. Check-ins ask young adults to report their mood as well as their craving, stress, and confidence levels once per day during their quit attempt. The mood is selected from a list of twelve different facial icons six of which are emotionally positive and six of which are negative. Craving, stress, and confidence is reported on three 0 to 10 sliding Likert scales with 0 denoting no stress, confidence, or craving at all and 10 denoting extremely high levels. Two notifications, one tailored to the results and one motivational, are then delivered to the young adult. Young adults are also asked to report if they relapsed, slipped, or are still a nonsmokers during the check-in. If a slip is reported three times the young adult is considered to have relapsed and is restaged accordingly.

In order to encourage both daily check-in completion during Action and general usage of the application among all stages, reminders are sent in the form of phone notifications. These reminders are scheduled to be sent at certain intervals of time in the event that prolonged inactivity is detected and are tailored to the stages. The initial reminder is sent after 24 hours of inactivity and the second after 48 hours. If inactivity still persists after that, then reminders are sent every five days for a full month. Reminders will cease automatically once activity within the application is detected. The full details regarding the effectiveness and impact of the application on young adult smoking cessation will be provided in subsequent papers.

Parent Study - ASPIRE

Project ASPIRE (A Smoking Prevention Interactive Experience) is an interactive, individually tailored CD-ROM-based smoking prevention and cessation program for high school students designed and developed by Prokhorov et al. in the 2000s (Prokhorov et al., 2010; Prokhorov et al., 2008). ASPIRE was created using Intervention Mapping®, a systematic stepped intervention development framework, combined with theoretical concepts taken from the Social Cognitive Theory and the Transtheoretical Model of Change (Eldredge, Markham, Ruiter, Kok, & Parcel, 2016; Kelder, Hoelscher, & Perry, 2015; Prochaska et al., 2015). The result is a strong theoretical framework that is operationalized through rigorous program development and inspired multimedia strategies. The program features individualized assessment and tailored feedback on critical determinants of smoking behavior (i.e., readiness to quit or start smoking, depression, nicotine dependence, and susceptibility to smoking) as well as several other interactive components. An animated coach in the form of an older, experienced peer provides guidance to the learner on his/her journey to cessation which is done by climbing up the left side of Mount ASPIRE, an animated metaphorical mountain that represents the various stages that a smoker must go through in order to quit. The right side of the mountain represents the pitfalls that a nonsmoker must overcome in order to avoid becoming a smoker. Numerous interactive games cognitively challenge the learner regarding critical self-management concepts and approximately 2 hours of high-quality video featuring peer opinions, expert facts, and modeled real-life scenarios are provided. The program delivers these components using appealing animations and a cast of recurring characters to simultaneously excite, educate, and entertain adolescents. This has made ASPIRE a leader in tailored, interactive, computer-based interventions for smoking cessation and prevention.

The ASPIRE curriculum program was evaluated among 16 Houston-area, urban high schools comprising 1,608 students. This 4-year, nested cohort, group-randomized, controlled trial compared the effect of the CD-ROM based ASPIRE intervention to a standard-care intervention among high schoolers and was one of the first studies to report positive longer-term outcomes of such a school-based interactive smoking prevention program (Prokhorov et al., 2010; Prokhorov et al., 2008). Smoking cessation showed changes in the right direction, however, the study had limited power to detect smoking cessation change therefore the results didn't reach significance. Due to the success of the program, an Internet version of ASPIRE available to the public through the MD Anderson website was created to supplement the classroom curriculum during the after-school hours (University of Texas MD Anderson Cancer Center, 2007). The key modules of the original ASPIRE curriculum were enhanced with several new multimedia pieces and then reconfigured into five unique sessions tailored towards the player's smoking status and intentions to quit. Even though ASPIRE has now enjoyed almost two decades of success evolving technologies, new research, and emerging tobacco products have resulted in the severe need for an upgrade in both content and technology.

Phase I – AppSPIRE Prototype

To create a new generation of the ASPIRE curriculum that is quickly and easily accessible by the general public, a prototype using smartphone technology was designed and developed in 2013. This prototype leveraged the host of opportunities and resources offered by sophisticated smartphones for a more personal, accessible, appealing and, potentially effective program. The strong theoretical framework of ASPIRE was translated to the smartphone platform and was enhanced through the use of mobile-centric design strategies. The resulting smartphone application was named AppSPIRE, an intervention that used updated versions of

ASPIRE's existing media and technologies, incorporated game mechanics and new interactive features, and provided updated research findings on the various tobacco products. AppSPIRE was built upon the content, structure and tailoring algorithm of the ASPIRE internet version, and incorporated additional features, including social network integration and game mechanics. The application was assessed for feasibility using a randomized controlled trial in 2014-15 among 14 cessation participants and 16 prevention participants recruited from the Central and West Loop Houston Community College campuses. 86% of cessation participants attempted to quit 3 times during the study and 1 successfully quit without relapsing. In the prevention arm 58% of prevention participants felt that AppSPIRE would help them assist others in quitting smoking. In 2016, this prototype was used as the basic framework upon which Quit4Health was developed and became its predecessor. Old content was rewritten and updated, new activities were added, and graphics and animations were completely redone in order to produce a high quality interactive application that was appealing to young adults.

Setting and Recruitment

Recruitment of students from Houston Community College Coleman campus took place in September and October of 2018 using selective sampling. The usability testing was done in a classroom on the Coleman campus and lasted around an hour. Students who were interested in participating in the study were pre-screened at a recruitment table using a short 8 question screening survey to ensure that they met the eligibility requirements [see Appendix D]. Students had to answer "Yes" to the first 7 questions. If a potential participant answered "No" to the final question "Do you smoke 1 or more cigarettes a day?" then they were probed by the recruiter for further information. Students were recruited only if they clarified that yes they had smoked cigarettes at least once in the last 30 days.

Usability Testing Procedure

After giving informed written consent, participants were asked to fill out a demographics survey [see Appendix C and G]. They were then given a link to the Quit4Health download webpage and instructions on how to download the application onto their smartphones. A researcher provided a brief introduction on how the profile set-up process and how the application works. The young adults were instructed to create their account using the unique study ID provided by the researcher and a password of their own creation. Participants were then given the opportunity to explore the various aspects of the Quit4Health application for around 15-20 minutes. After taking some time to navigate through the various features, participants were asked to fill out a series of questions regarding their smoking status and then concluded the written portion of the study by completing the uMARS scale [see Appendix H]. All surveys and questionnaires were filled out on paper. At the conclusion of the study, participants were given 15-20 minutes to vocally express their opinions and feelings regarding their experiences with the application in an open discussion. The researcher facilitated the discussion with prepared interview questions [see Appendix J]. The entire group session was recorded for research purposes. After completing the focus group, each participant was given a \$25 Target gift card and lunch in the form of pizza and soft drinks as compensation for their time.

Measures

The usability and acceptability of Quit4Health was tested using the user version of the Mobile Application Rating Scale (uMARS) [see Appendix H]. The benefit of using the uMARS over the original 23-item MARS is that the user version is simpler and does not require training or expertise in order to administer it (Stoyanov et al., 2015). Both the MARS and the uMARS have been previously assessed and validity is supported. The uMARS consists of six subscales

which have been shown to have excellent internal consistency (alpha = 90) and good test-retest reliability (Stoyanov, Hides, Kavanagh, & Wilson, 2016).

The first subscale of the uMARS revolves around perceived impact. This scale will be used to gather information on the perceived impact of the application on the young adult's knowledge, attitudes and intentions related to the target health behavior. The Perceived Impact subscale contains 6 items rated on a 5-point Likert scale from 1. "Strongly Disagree" to 5. "Strongly Agree". The next four uMARS subscales cover four areas of objective quality: engagement, functionality, aesthetics, and information. The App Quality mean score generated by the uMARS is acquired by calculating the mean score of all four of these subscales (Engagement, Functionality, Aesthetics, & Information) summed together. The Engagement subscale contains 5 items that will evaluate how fun, interesting, customizable, and interactive Quit4Health is. The 4-item *Functionality* subscale will evaluate the application's functionality, ease of learnability, navigation, flow logic, and the gestural design. The Aesthetics subsection has 3-items that will evaluate the application's overall visual appeal, colour scheme, graphic design, and stylistic consistency. The 4-item *Information* subscale will determine whether or not the application contains high quality information from credible sources. The uMARS also contains a subscale for subjective quality. The Subjective Quality subscale contains 4 items that asks the young adult to rate whether or not they would pay for the application, recommend it, etc. The items of these five subscales on subjective and objective quality are answered using a 5point Likert scale with the scaled answers tailored toward each specific item.

During the qualitative portion, participants were asked a series of interview questions and probes by the researcher to facilitate the direction of the discussion. Questions were developed in order to perceive participants' past experiences with smoking cessation apps as well as their

overall views of the Quit4Health app including appeal, barriers to use, and relevance. Questions asked participants to describe what they enjoyed the most as well as the least about the app and why. The researcher also probed to better understand what participants would change about the app and why. Eight items with potential probes were developed by the researcher and approved by an independent reviewer (see Appendix J).

Statistical and Qualitative Analysis

Descriptive analysis and analysis of measures of central tendency were conducted using STATA IC 15 software (StataCorp LLC, 2018). Qualitative analysis of the transcribed audio recordings were conducted using NVIVO 12 software (QSR International Pty Ltd, 2018).

RESULTS

Participants

Of the 31 students who were pre-screened 11 were recruited. The other 20 students were found to be ineligible mostly due to either being above the age limit or using other tobacco products, such a cigarillos and hookah pipes, rather than cigarettes. Initially, only 21 students were pre-screened out of which 8 were found to be eligible and subsequently recruited. The date and time of the focus group was selected after carefully reviewing recruited students' availability. Five of the students confirmed that they would attend the focus group either by phone or by email. Two of the students declined to participate after being contacted and one was unreachable by phone and never responded to any emails. Of the five who confirmed, only two students attended and completed the actual focus group. Due to low participation the researcher

had to facilitate an individual interview with a group of two people instead of the intended focus group.

The students who didn't attend were contacted again and the majority were confirmed as still willing to participate. Therefore, a second focus group was scheduled with the pre-screened students who didn't attend the first focus group. After receiving the invitation for the second focus group, two of the students confirmed attendance, two declined to participate, and the remaining two were unreachable by phone or email. On the day of the actual focus group, none of the students attended so the focus group was cancelled.

Due to the many declines and difficulties with getting into contact with the original prescreened students, recruitment was restarted in October of 2018. An additional ten students were pre-screened and pf those three were found to be eligible. These three participants, along with the original six pre-screened students who never attended the previous focus groups, were all invited to the next focus group. Of the nine students who were invited, five declined to attend, one was unreachable by phone and email, and two confirmed attendance. The two students who initially confirmed did attend and complete the focus group, however, one of the participants was late and arrived at the end of the focus group. Due to the circumstances, the intended focus group instead became two separate individual interviews.

In order to obtain as much data as possible, one final focus group was scheduled with the remainder of the pre-screened students. Recruitment continued up to the day of the focus group but no new students could be found who were interested in participating. Of the remaining seven pre-screened students who were invited to the last focus group, two confirmed attendance over the phone, two declined to attend, and two were unreachable by phone or email. On the day of

the last focus group one of the students who confirmed attendance remitted by phone after the focus group began. Only one student actually attended and completed the final focus group.

The original intent was to hold a single focus group with up to eight participants. However, due to low participation rates and difficulties getting into contact with eligible students, the focus groups were turned into four individual interviews. Of the 31 students in total who were prescreened 11 met the eligibility criteria. Of those 11, only five attended and completed the usability testing. Therefore, the final sample that was analyzed consisted of five participants.

The average age of the participants in the final sample was 22.8 years old (SD = 3.27) with the youngest being 19 years old and the oldest being 26 years old. Participants were mostly male (80%) with there being only one female in the group. 40% were African American, 40% were Asian, and 20% were White. There were no participants of Spanish/Hispanic/Latino ethnicity. The majority were full time students who worked part time and were of low socioeconomic status.

Table I: Demographics of students who completed the usability testing

	(N=5)
Age	
18-20 years old	2
21-23 years old	1
24-26 years old	2
Gender	
Male	4
Female	1
Ethnicity	
Spanish/Hispanic/Latino	0
Not Spanish/Hispanic/Latino	5
Racial Background	
American Indian/Alaska Native	0
Asian	2

Native Hawaiian/Other Pacific Islander	0
Black/African-American	2
White	1
Student Classification	
Associates Degree	3
Workforce/Certification Program	1
Prerequisite Classes for Bachelor's	0
Degree Unsure/Undecided	1
Enrollment Status	
Full-time	4
Part-time	1
Financial Status	
Live comfortably	1
Meet your needs adequately	2
Just meet basic expenses	$\frac{-}{2}$
Cannot meet basic expenses	0
Work Status	
Full-time employee	0
Part-time employee	3
Volunteer/intern	1
Not working at this time	1

Smoking Status

In terms of smoking status, only 20% of participants reported being daily cigarette smokers that is having smoked a cigarette at least once every day for the last 30 days. Forty percent reported smoking around 15-29 days in the last month and 40% reported to be social smokers that is having smoked around 1 to 14 days in the last month.

After taking the initial staging questionnaire within the Quit4Health application during profile set-up, 80% of the participants went into the Action stage indicating that 80% of participants were ready to try quitting cigarettes. The only participant who didn't go into the Action stage was the daily smoker. The daily smoker was placed in the Precontemplation stage

which indicates that they were not ready to quit and had no intentions to quit in the next 6 months.

Objective Quality

The App Quality mean score reported in Table II is the mean of all five participants' App Quality scores summed together. Using the criteria set forth by the uMARS, participants gave the Quit4Health smoking cessation application an overall App Quality Mean score of 4.26 out of a total of 5. Among the individual subscales, participants gave the Quit4Health application an almost equal score among Functionality, Aesthetics, and Information. Functionality was given the highest score among the subscales with a mean score of 4.44 out of 5 which was only slighter higher than Aesthetics and Information both of which received an equal score of 4.40 out of 5. Engagement was the subscale where participants gave the lowest score of 3.80 out of 5. An analysis of the individual items within the Engagement subscale shows that 100% of participants reported the application being very interactive. However, 80% of participants gave the application an average rating in terms of entertainment reporting that the application was fun enough to entertain them but only for a very brief time.

Table II: Results of the Objective Quality subscales of the uMARS

Individual Scales	Mean Score (SD)
Engagement	3.80 (.49)
Functionality	4.44 (.57)
Aesthetics	4.40 (.28)
Information	4.40 (.45)
App Quality Mean Score	4.26 (.35)

Perceived Impact

Of the six perceived impact items, Attitudes, Help Seeking, and Behavior Change were given the highest ratings. The majority of participants strongly believed that the application changed their attitudes towards smoking (4.4; SD = .8366) and that it encouraged them to seek further help to quit smoking if they needed it (4.4; SD = .8944). The majority of participants also strongly agreed that using the Quit4Health application would help them quit smoking (4.4; SD = .5477). However, the majority of participants felt that the application was lacking in knowledge and did not believe that the application significantly increased their knowledge or understanding of cigarette smoking (3.8; SD = .8366).

Table III: Results of the Perceived Impact subscale of the uMARS

Individual Items	Mean Rating (SD)
Awareness	4.2 (.84)
Knowledge	3.8 (.84)
Attitudes	4.4 (.89)
Intention to Change	4.2 (1.09)
Help Seeking	4.4 (.89)
Behavior Change	4.4 (.55)

Subjective Quality

When asked if they would recommend the Quit4Health application to others who might benefit from it, the majority of participants reported that that they would recommend the Quit4health application to many people. When asked how many times they would use the application in the next 12 months, 20% answered that they would use it 10-50 times and 40% answered that they would use it more than 50 times. Participants gave the Quit4Health

application an overall average rating of 3.8 stars out of 5 but most reported that they would not be willing to pay for it.

Thematic Analysis

After completing all surveys participants were asked to express their experiences with the Quit4Health application in a short open-ended discussion. A thematic content analysis was conducted and four broad themes were identified that described how these young adult smokers perceived the application's quality and acceptability: Information, Relevance & Relatability, Appeal and finally Credibility.

Theme 1- Information: Information was the first theme and the most prevalent among this group. This broad theme describes the types of information that participants viewed as greatly important when quitting yet thought missing from the stage within the application that they were placed in. Participants expressed differing views on what factor was of the greatest importance when attempting to quit smoking. However, three subcategories of information could be detected among their responses.

The first and most frequent was *Health Risks*. Multiple participants expressed that they would prefer to see more information regarding the health effects of using tobacco such as long and short term risks, the chemicals in tobacco, and the psychological effects of smoking:

"You should also have some diagrams of whatever it affects the most, you know, heart, lungs. Because I did a conference where they showed you black lungs what it looks like – if its like this or like that – you know just different stages because when you give somebody a visual of something and then they can actually see like "oh no I don't want to look like that" then that'll help . . . so that's one thing I was saying more of visuals of what it affects and how it affects over time to the body."

- (Female, 26 years old, African American)

"Like add stuff like . . . why we shouldn't have cigarettes and how bad they were, what chemicals were included, how you know, how does it affect and stuff like that."

- (Male, 19 years old, Asian)

The majority of participants were placed in Action stage within the application which denotes that they are ready to quit. Participants were informed that activities intended to educate the user about the various health risks of tobacco were accessible in the Quit4Health application but only to those in earlier stages who defined themselves as not ready to quit at all. However, the majority of participants responded that it would be more beneficial to them to have these activities within the Action stage as well:

"I think the person who's like really addicted they don't care. They'll be like . . . "Either I'm gonna die of cancer either I'm gonna die naturally, it doesn't matter to me." But the person who's thinking about [quitting], they're gonna do the research. They want to get to know more. Like what's in [cigarettes]."

- (Male, 19 years old, Asian)

The second subcategory was *Alternatives to Smoking*. Many participants discussed how important it is for those trying to quit to find ways to distract themselves:

"Like most people were saying that if they were busy or talking to somebody else then they wouldn't smoke or, you know, they wouldn't take any drugs. I think that's true because like when I'm at work I'm mostly working by myself. And like in the afternoon and in the morning I don't have no customers. And that's the time when I when I get myself busy."

- (Male, 19 years old, Asian)

"So it's kinda like you know if you can't [smoke] you can't but what can you do in the meantime to just calm yourself down?"

- (Female, 26 years old, African American)

As with the Health Risks subcategory, participants felt that young adult smokers would be more likely to quit smoking if this type of information was present in the Action stage and not just in previous stages.

The third subcategory that emerged was the concept of *Dual-Use* that is, using more than one type of tobacco product. Participants believed that the Quit4Health application should focus not

just on quitting cigarette use but on aiding young adult smokers in quitting other tobacco products as well. Participants' perceptions were that dual use was very common among their peers and therefore should be addressed within the application:

"And a lot of you know students in college specially they don't just use cigarettes, like they don't just smoke cigarettes. They do more than that."

- (Male, 19 years old, Asian)

"Because like I'm just saying it because a lot of my friends they're on vaporizers."

- (Male, 23 years old, Asian)

Participants believed that the information presented to them was helpful but felt young adult smokers who were ready to quit would have a greater chance of succeeding if the Action stage presented them with a larger variety of information. *Health Risks, Alternatives to Smoking*, and *Dual-Use* were the subcategories of information missing in the Action stage that participants gave the most importance to.

Theme 2 - Relevance & Relatability: Relevance & Relatability was the second theme and is defined as the relevance of the information presented in the Quit4Health application to the young adult smoker and how relatable it is to the circumstances and situations of the participants. The majority of participants expressed satisfaction in terms of relevance and relatability. They felt that the application was relatable both to themselves, to other college student smokers, and to young adult smokers in general as well:

"Yes, just like college students would like they would get a kick out of this . . . So great."

- (Male, 23 years old, Asian)

"Very relatable."

- (Female, 26 years old, African American)

Participants described two aspects, or subcategories, that they believed added most to the relevance and relatability of the application, that is, the accuracy of the information presented to them and the series of fictional stories designed to be read as testimonies from ex-smokers or smokers going through multiple quit attempts. Participants believed that these aspects strongly increased the relatability and relevance of Quit4Health:

"Basically, it gave, uh like real life experiences, like stories. That's probably what was the what was the best part because you can relate to you know real life."

- (Male, 20 years old, African American)

Theme 3 - Appeal: The third overarching theme was Appeal that is how attractive or interesting participants perceived the Quit4Health application to be. Comments made by participants during the discussion generally fell into two subcategories: positive sentiment and negative sentiment. Participants expressed more than five time the number of positive sentiments than they did negative sentiments.

Positive sentiments expressed by participants revolved around either the application overall, the information provided within the application, or the general functionality of the application. Statements made about the application overall included sentiments such as "helpful", "pretty cool", "really pretty", "very happy with it", "interesting", and "compelling". Positive sentiments regarding the information within the application included statements such as "really captured the audience", "covered more than I was expecting", "very informational", "sounds like pretty smart", and "interesting to read". Positive sentiments regarding the functionality of the application included statements such as "easily able to locate what you want to do", "got a nice layout", "pretty simple", and "a lot of different sections you can go into".

A very small number of negative sentiments were expressed by participants in terms of functionality and interactivity. Some participants experienced issues and commented on how the application "had some bugs" or how the download process was slow. Only one participant expressed that they found some of the interactive features within the activities to be "repetitive" and "kind of boring". The majority of the sentiments expressed by participants were positive therefore for the most part participants enjoyed using the application and perceived the application to be attractive and interesting.

Theme 4 - Credibility: The last theme that emerged among this group was Credibility which was defined as the participants' ability to believe in and trust that the information provided in the Quit4Helath application is authentic and/or comes from a trustworthy source. Participants' comments regarding this theme revolved around two subcategories that is the authenticity of the testimonies, called "stories" in the application, and the references from which the information in the application came from. In regards to the testimonies, some participants asked the interviewer about the authenticity of the testimonies and learned that they were fictional. These participants seemed to view the use of fictional testimonies in a negative light and commented on how it detracted from the credibility of the application:

"The fact that you actually made them up and made them to where they're like okay different scenarios of people going through you know whatever they're going through and using you know cigarettes which was helpful but to get a real life individual to actually say something credible . . ."

- (Female, 26 years old, African American)

Some participants also viewed the lack of references displayed in the application to detract from credibility as well. The content of the Quit4Health application was developed after gathering the most recent published research from credible peer-reviewed journals. Participants commented that adding more of these references to the application's content for users to visually see where

the information within the various activities is coming from would significantly strengthen the credibility of the application:

"Like some of [the content] had,, like what is it, the reference to the information which was, which was amazing like oh it was from the ICC or something. I was like "Oh, that's great". Another ones didn't have that. I mean every single entry does not shouldn't have to have a reference but like like some people might be sticklers about that and it's be nice to have like that."

- (Male, 23 years old, Asian)

Overall, participants believed most of the information provided in the application to be accurate and interesting but felt the Quit4Health application overall to be somewhat lacking in credibility.

DISCUSSION

The purpose of this study was to examine and analyze the usability of a novel smoking cessation application, Quit4Health, among young adult cigarette smokers between the ages of 18 and 26 in order to understand whether or not the application meets the needs of these young adults. Participants gave the application a high app quality mean score of 4.26 out of 5 points which was higher than the average 3.8 out of 5 stars that participants gave when asked to rate the application. The star rating is a subjective score and may be biased whereas the app quality mean is an objective number calculated by having participants carefully analyze various aspects of the application. Therefore the app quality mean score is a more accurate evaluation.

Very few evaluations of smoking cessation applications have been published most of which are content analyses and systematic reviews (Ferron et al., 2017; Haskins et al., 2017; Hoeppner et al., 2016; Regmi et al., 2017) Only two studies could be found that utilized the Mobile Application Rating Scale (Patel et al., 2015; Thornton et al., 2017). Thornton et al. analyzed the app quality of 112 smoking cessation apps available in Australia using the original Mobile

Application Rating Scale (Thornton et al., 2017). The mean MARS overall quality total score of these apps was 2.88 (SD=.83) indicating that the majority of these apps are poor in quality. Petal et al. also found that the majority of apps did not perform well against the various criteria including the MARS and were of limited quality (Patel et al., 2015). Of the 112 smoking cessation apps that were rated by Thornton et al. only six achieved a high app quality score that is an average mean total score of 4 or higher. Among these apps were SmokeFree28 and SmartQuit (Bricker et al., 2014; Ubhi et al., 2015). There was also SmokeFree Baby for pregnant smokers developed by a research group in the United Kingdom (Tombor et al., 2018). The other three were developed by various governmental agencies and included Singapore's HPB I Quit, Australia's My Quit Buddy, and QuitStart developed by the United States' National Cancer Institute in collaboration with the US Food and Drug Association. Among these top ranking apps, My QuitBuddy was found to be the highest quality app with a mean score of 4.9 followed by SmartQuit with a mean score of 4.6 (Thornton et al., 2017). However, Quit4Health scored higher on the uMARS than SmokeFree28 (MARS mean score = 4.1), HPB I Quit (MARS mean score = 4.2), and $SmokeFree\ Baby$ (MARS mean score = 4.2). The application was also almost equal in quality with QuitStart which received a MARS app quality score of 4.3 (Thornton et al., 2017). The results show Quit4Health to be among the few high-quality smoking cessation applications that exist and perhaps one of the only high quality apps designed specifically for young adult smokers.

Based on the objective quality mean score generated by the uMARS, participants expressed overall satisfaction for the information, functionality, and aesthetics of the Quit4Health application. The application received the lowest score in terms of engagement. Participants believed the application to be very interactive but lacking somewhat in entertainment. Some

viewed the interactivity within a few of the activities as slightly repetitive. Others expressed their desire to see more images and informative visuals within the application. Interactivity is seen as a significant source of usability in mHealth but does not always seem to ensure entertainment as such more research is needed to better understand which aspects of interactivity will lead to greater entertainment. The results of this study, however, indicate that these young adult smokers seem to need a great amounts of variety and visual appeal to feel entertained for long periods of time.

The four broad themes using thematic content analysis were identified that is Appeal, Relevance & Relatability, Credibility, and finally Information (Hsieh & Shannon, 2005). Participants found the application greatly appealing and highly relevant to their situations. They believed the Quit4Health application to be very relatable to both themselves and to other college students in general. However, many participants felt that the application was lacking in credibility and in health related information regarding cigarette smoking. They believed that including such information would increase the user's chances of successfully quitting. This is consistent with the perceived impact score given by participants when asked if the application increased their knowledge and understanding of cigarette smoking (3.8; SD = .8366) which received the lowest score among the perceived impact items. An explanation for this could be because the majority of participants were placed in the Action stage during the initial staging process and therefore were not exposed to the knowledge based activities which are primarily in earlier stages. This low scoring, however, is not consistent with the uMARs app quality rating for the Information subscale which received a high quality mean score of 4.4 (SD = .4541) out of 5. The information subcale items within the uMARS are objective and have a greater focus on how well the existing information is presented which may explain this discrepancy in scoring.

The Quit4Health application uses the Stages of Change, the primary concepts of the Transtheoretical Model, to help young adult smokers achieve complete smoking cessation (Prochaska et al., 2015). The TTM model revolves around the premise that behavior change occurs not with any single event but rather is achieved over time by moving through a series of stages. Critical assumptions of this model include emphasizing specific processes of change during specific stages in order for progress through the Stages of Change to successfully occur (Prochaska et al., 2015). The processes of change explain how the behavior changes occur, however, the results of this study suggest that these processes are flexible and may work differently for young adult smokers than for adult smokers. The young adult smokers who rated the Quit4Health application were in the late stages of change yet desired to see more factual information regarding cigarette smoking. This experiential process, consciousness raising, is seen as more effective in the early stages of behavior change rather than in later stages and yet participants expressed dissatisfaction at not being exposed to this process during the Action stage. Further research is recommended to determine whether or not having these experiential processes in later stages of change improves the success of smoking cessation applications in helping young adults quit smoking.

This study is unique in that it provides an in depth look at the usability of Quit4Health by utilizing both <u>qualitative</u> and <u>quantitative</u> data. This study was conducted among young adult smokers and therefore provides the perceptions of a difficult population to reach and those most likely to use mHealth applications. Finally, this research adds to the evidence of the quality and usability of smoking cessation smartphone applications in a field where very little research has been conducted (Thornton et al., 2017). The results presented here can be used to inform the development of future smoking cessation interventions using mHealth in order to produce more

effective high quality applications for young adult smokers.

Limitations

Some limitations of this study need to be taken into account. Young adult cigarette smokers at the Houston Community College Coleman campus proved to be an extremely difficult population to recruit from thus resulting in extremely low participation rates and a small sample size. The small sample size limits interpretation and utility of the results of this study as sampling variability is high. Therefore it may be difficult to generalize the results to the overall population of young adult smokers. There are several reasons as to why this small sample size occurred. The Coleman campus is home to a large number of HCC's medical-based programs. Therefore, the majority of the students attending the college are very health conscious. The fear of social stigma resulted in there being very few students willing to admit to smoking cigarettes. Communication with the pre-screened students was discovered to be extremely difficult to maintain. Students never responded when contacted via email and frequently ignored phone calls. Recruited Coleman students would also frequently confirm participation by phone only to cancel without alerting the researcher resulting in a high rate of unanticipated no shows. This may partly be due to the fact that the majority of these students were part-time workers whose shifts changed on a weekly basis. For future qualitative studies with young adult smokers in community colleges, it is recommended that different avenues of communication, such as text messaging and social media platforms, be explored.

The self-reported smoking status of the participants was not biochemically validated.

Smoking behavior patterns over time were not analyzed in this study and past studies have shown self-reported smoking measures to be reliable and valid. Validation for a small and short study such as this is also not recommended by the Society for Research on Nicotine and

Tobacco's Subcommittee on Biochemical Verification (SRNT Subcommittee on Biochemical Verification, 2002). Therefore, biochemically verifying participants' smoking status was determined to be unnecessary. Also, the Quit4Health smoking application was designed specifically to aid cigarette smokers. The participants of this usability study were cigarette smokers so the results of this study may not be generalizable to other types of tobacco use and behaviors.

Finally, due to the staging process within the Quit4Health application and the limited time frame, participants were exposed to only a small section of the application and were not able to experience all of the various aspects that Quit4Health has to offer. A more comprehensive analysis of the usability of Quit4Health may be obtained by conducting multiple focus groups across the various stages but, unfortunately is beyond the scope of this study.

CONCLUSION

The Quit4Health application was developed with the intention to assist young adults in quitting cigarette smoking. The results of this study indicate that the application is of high quality and meets the needs of young adult community college smokers attending the Houston Community College Coleman Campus. In view of these results, the Quit4Health smoking cessation app is ready to be circulated on the market provided that studies regarding the app's efficacy, which are in process, are able to report higher smoking cessation rates. However, it is recommended that updates to the app be implemented in the near future as improvements to the Quit4Health application are needed in order to provide a more entertaining and informative experience. More research is needed in order to discern how to optimize the use of mHealth with smoking cessation interventions for young adult smokers.

JOURNAL ARTICLE

Development and Usability Testing of Quit4Health, A Smoking Cessation Smartphone Application for Young Adults

JMIR Serious Games

BACKGROUND

In the United States more than 16 million people every year end up living with a tobacco related disease (Centers for Disease Control and Prevention, 2014). Tobacco use is responsible for every 1 in 5 deaths and continues to impose a substantial financial health burden with more than \$300 billion in annual costs (Centers for Disease Control and Prevention, 2014). Unfortunately, the majority of tobacco initiation occurs during adolescence and young adulthood (Choi & Stommel, 2017). Around 98% of today smokers imitated tobacco use by the age of 26 (Centers for Disease Control and Prevention, 2014). College life, in particular, is a period associated with high sensation seeking and experimentation and is therefore associated with high susceptibility to initiation of substance use in general. As such, the highest rates of tobacco use in the United States are usually seen among this age group (Lipari, 2013). As of 2016, 23.5% of 18-25 year-olds reported having used cigarettes in the last month compared to 20.2 % of adults and only 3.4% of adolescents aged 12-17 years (Substance Abuse and Mental Health Services Administration, 2017).

The advent and evolution of smartphones in the last decade has resulted in the rapid rise of medical and public health services being delivered using smartphone technology, otherwise known as mobile health or mHealth. According to the PEW Research Center, 100% of today's

18-29 year old Americans own a cellphone of some kind, 92% of which own a smartphone (PEW Research Center, 2018). A meta-analysis of mobile phone health app usage in the United States found that the main users of health apps are younger individuals (Carroll et al., 2017). Studies confirm that health apps are an efficient and effective way of reaching today's young adults (Rathbone & Prescott, 2017). These apps also can be cost effective and wide reaching as many apps have the benefit of being available online and free of charge allowing interventions to be distributed quickly and easily among large numbers of people (Rathbone & Prescott, 2017).

Research and development of smoking cessation apps, however, is still an emerging field of study that is made complex and difficult by constant and rapidly evolving smartphone technologies. An article reported that there are around 400 smoking cessation apps available in the United States, United Kingdom, and Australian market as of 2015 (Alden, 2013). And yet, a very limited number of studies have been done to evaluate these apps. As such, evidence to support the effectiveness of using apps to promote smoking cessation is limited. In a recent systematic review looking at smoking cessation apps available on the App Store, over 150 articles related to evaluating these apps were identified (Haskins, Lesperance, Gibbons, & Boudreaux, 2017). Only six apps among these articles were found to have some level of scientific support. Of these six, only three apps were evaluated using exploratory pilot randomized control trials. Another recent review looked at 224 articles regarding smoking cessation apps. Of those only 8 were identified as being pilot randomized control trials, control trials, or quasi-interventional by design (Regmi, Kassim, Ahmad, & Tuah, 2017). Of those eight, three studies reported higher smoking cessation/quit rates. Some evidence for the effectiveness of smartphones as cessation tools exists, however, none of these app were specifically designed for young adults.

A key aspect that is crucial to ensuring that smartphone apps are effective in promoting smoking cessation are the use of evidence-based behavioral change techniques (BCTs), such as the processes identified by the Transtheoretical Model of Change (TTM) (Michie et al., 2013). BCTs have been described as the "active ingredients" of interventions designed to bring about behavior change. However, the few studies that have evaluated the content of smoking cessation apps for use of BCTs lack a standardized definition or set of criteria for identifying these techniques (Paige, Alber, Stellefson, & Krieger, 2017; Ubhi et al., 2016). Despite BCTs being the "key ingredients" of behavior change, the evidence on whether or not BCTs are effectively used in smoking cessation apps is uncertain and lacking. What is known is that successful exposure to BCTs, which eventually leads to behavior change, relies heavily on smartphone apps being easy to use and engaging. Therefore, high usability and engagement are considered critical to the success of apps that are focused on changing health behaviors (Serrano, Coa, Yu, Wolff-Hughes, & Atienza, 2017).

The question that often arises is whether current smoking cessation apps available to smokers are effective and meet young adults' needs. In a recent systematic review over 150 articles related to smoking cessation applications were identified (Haskins et al., 2017). Only six apps among these articles were found to have some level of scientific support. Of those six, only two were found to have pilot studies pertaining to acceptability or usability. Given the enormous popularity of health app usage among young adults and the lack of available evidence-based smoking cessation apps, there is a growing need to examine and provide evidence for both the quality and the effectiveness of using smartphone technology to deliver smoking cessation interventions to young adults. (Haskins et al., 2017).

Objectives

The objective of this observational study is to examine and analyze the usability of Quit4Health, a new multifaceted smoking cessation app for young adults that was developed using prominent evidence-based theories. Usability testing for Quit4Health will be conducted among a small group of young adult smokers in order to assess the quality and acceptability of this novel app.

METHODS

Development of Quit4Health

Quit4Health is a tobacco cessation and prevention application program available on both Android and iOS platforms that is targeted towards smokers and non-smokers 18-26 years of age. The application was developed by a team of researchers at the University of Texas MD Anderson Cancer Center led by Dr. Alexander Prokhorov, the leading expert in adolescent and young adult smoking prevention. Computer software was developed by a team at Radiant Creative Services led by Jeffery McLaughlin. The primary goal of the application is to move smokers through the stages of behavior change by educating them about the harms of tobaccouse, equipping them with various coping skills, and eventually guiding them through cessation. The application accomplishes this through mini-activities that are given to the young adult to complete. Quit4Health is considered Phase II of a previous research study done on the Houston Community Campus using AppSPIRE, a prototype application that was developed in 2013. Quit4Health is an updated version of AppSPIRE with brand new graphics, animations, and activities added. The original content has also been rewritten and updated to reflect the current scientific literature and the most recent young adult preferences.

The application was developed using the Transtheoretical Model (TTM), a theory created around cigarette smokers which posits that quitting is not an event but rather a process consisting of several stages (Prochaska, Redding, & Evers, 2015). The TTM lists six different stages of change that a smoker goes through during the quitting process. The application guides the young adult through the first four stages, Precontemplation, Contemplation, Preparation, and Action, which are respectively defined within the application as "Not There Yet", "Thinking About It", "Getting Ready", and "Ready". The initial stage that a young adult is placed in is determined by a staging questionnaire that the young adult takes when creating their profile. The activities the young adult is given to complete within the application are determined by the stage that they are placed in [see Figure I]. After all activities within the stage are completed, the young adult is taken through the restaging questionnaire. Depending on the young adult's answers, the young adult may move forward to the next stage in the quitting process, stay within their current stage, or move back to a previous stage.

Young adults going through the quitting process in the Action/Ready stage are additionally monitored using daily in-app check-ins and are given support and advice through tailored notification messages delivered on a daily basis. Check-ins ask young adults to report their mood as well as their craving, stress, confidence levels and smoking status once per day during their quit attempt.. The full details regarding the effectiveness and impact of the application on young adult smoking cessation will be provided in subsequent papers.

Parent Study - ASPIRE

Project ASPIRE (A Smoking Prevention Interactive Experience) is an interactive, individually tailored CD-ROM-based smoking prevention and cessation program for high school students designed and developed by Prokhorov et al., in the 2000s (Prokhorov et al., 2010;

Prokhorov et al., 2008). ASPIRE was created using Intervention Mapping®, a systematic stepped intervention development framework, combined with theoretical concepts taken from the Social Cognitive Theory and the Transtheoretical Model of Change (Eldredge, Markham, Ruiter, Kok, & Parcel, 2016; Kelder, Hoelscher, & Perry, 2015; Prochaska et al., 2015). The result is a strong theoretical framework that is operationalized through rigorous program development and inspired multimedia strategies. The program features individualized assessment and tailored feedback on critical determinants of smoking behavior (i.e., readiness to quit or start smoking, depression, nicotine dependence, and susceptibility to smoking) as well as several other interactive components. The program delivers these components using appealing animations and a cast of recurring characters to simultaneously excite, educate, and entertain adolescents. This has made ASPIRE a leader in tailored, interactive, computer-based interventions for smoking cessation and prevention.

The ASPIRE curriculum program was evaluated among 16 Houston-area, urban high schools comprising 1,608 students. This 4-year, nested cohort, group-randomized, controlled trial compared the effect of the CD-ROM based ASPIRE intervention to a standard-care intervention among high schoolers and was one of the first studies to report positive longer-term outcomes of such a school-based interactive smoking prevention program (Prokhorov et al., 2010; Prokhorov et al., 2008). However, the study had limited power to detect smoking cessation change therefore the results didn't reach significance. Even though ASPIRE has now enjoyed almost two decades of success evolving technologies, new research, and emerging tobacco products have resulted in the severe need for an upgrade in both content and technology.

Phase I – AppSPIRE Prototype

To create a new generation of the ASPIRE curriculum that is quickly and easily accessible by the general public, a prototype using smartphone technology was designed and developed in 2013. This prototype leveraged the host of opportunities and resources offered by sophisticated smartphones for a more personal, accessible, appealing and, potentially effective program. The strong theoretical framework of ASPIRE was translated to the smartphone platform and was enhanced through the use of mobile-centric design strategies. The resulting smartphone application was named AppSPIRE, an intervention that used updated versions of ASPIRE's existing media and technologies, incorporated game mechanics and new interactive features, and provided updated research findings on the various tobacco products. AppSPIRE was built upon the content, structure and tailoring algorithm of the ASPIRE internet version, and incorporated additional features, including social network integration and game mechanics. The application was assessed for feasibility using a randomized controlled trial in 2014-15 among 14 cessation participants and 16 prevention participants recruited from the Central and West Loop Houston Community College campuses. 86% of cessation participants attempted to quit 3 times during the study and 1 successfully quit without relapsing. In the prevention arm 58% of prevention participants felt that AppSPIRE would help them assist others in quitting smoking. In 2016, this prototype was used as the basic framework upon which Quit4Health was developed and became its predecessor. Old content was rewritten and updated, new activities were added, and graphics and animations were completely redone in order to produce a high quality interactive application that was appealing to young adults.

Setting and Recruitment

This research study was approved by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center Institutional Review Board at Houston as HSC-SPH-18-0576 as well as the Houston Community College Institutional Review Board. Students who were interested in participating in the study were pre-screened at a recruitment table using a short screening survey to ensure that they were eligible. In order to be eligible for the study, participants had to be current students at the Coleman campus, between the ages of 18-26, be able to speak English, and had to be smokers who owned an Android or iOS smartphone with access to the internet. In addition, participants had to be smokers defined as having smoked at least one cigarette in the last 30 days. Recruitment of students from Houston Community College Coleman campus took place in September and October of 2018 using selective sampling. The usability testing was done in a classroom on the Coleman campus and lasted around an hour.

Usability Testing Procedure

After giving informed written consent, participants were asked to fill out a demographics survey. They were then given a link to the Quit4Health download webpage and instructions on how to download the application onto their smartphones. Participants were instructed to create an account using the unique study ID provided and a password of their own. Participants were then given the opportunity to explore the various aspects of the Quit4Health application for around 15-20 minutes. After taking some time to navigate through the various features, participants were asked to fill out a series of questions regarding their smoking status and then concluded the written portion of the study by completing the uMARS scale. All surveys and questionnaires were filled out on paper. At the conclusion of the study, participants were given 15-20 minutes to

vocally express their opinions and feelings regarding their experiences with the application in an open discussion. The researcher facilitated the discussion with prepared interview questions. The entire group session was recorded for research purposes. After completing the focus group, each participant was given a \$25 Target gift card and lunch in the form of pizza and soft drinks as compensation for their time.

Measures

The usability and acceptability of Quit4Health was tested using the user version of the Mobile Application Rating Scale (uMARS) [see Appendix H]. The benefit of using the uMARS over the original 23-item MARS is that the user version is simpler and does not require training or expertise in order to administer it (Stoyanov et al., 2015). Both the MARS and the uMARS have been previously assessed and validity is supported. The uMARS consists of six subscales which have been shown to have excellent internal consistency (alpha = 90) and good test-retest reliability (Stoyanov, Hides, Kavanagh, & Wilson, 2016). The Perceived Impact subscale contains 6 items rated on a 5-point Likert scale from 1. "Strongly Disagree" to 5. "Strongly Agree". The next four uMARS subscales cover four areas of objective quality: engagement, functionality, aesthetics, and information. The App Quality mean score generated by the uMARS is acquired by calculating the mean score of all four of these subscales (Engagement, Functionality, Aesthetics, & Information) summed together. The Subjective Quality subscale contains 4 items that asks the young adult to rate whether or not they would pay for the application, recommend it, etc. The items of these five subscales on subjective and objective quality are answered using a 5-point Likert scale with the scaled answers tailored toward each specific item.

During the qualitative portion, participants were asked a series of interview questions and probes by the researcher to facilitate the direction of the discussion. Questions were developed in order to perceive participants' past experiences with smoking cessation apps as well as their overall views of the Quit4Health app including appeal, barriers to use, and relevance, etc. Eight items with potential probes were developed by the researcher and approved by an independent reviewer (see Appendix J).

Statistical and Qualitative Analysis

Descriptive analysis and analysis of measures of central tendency were conducted using STATA IC 15 software (StataCorp LLC, 2018). Qualitative analysis of the transcribed audio recordings were conducted using NVIVO 12 software (QSR International Pty Ltd, 2018).

RESULTS

Participants

Of the 31 students who were pre-screened 11 were recruited. The other 20 students were found to be ineligible mostly due to either being above the age limit or using other tobacco products, such a cigarillos and hookah pipes, rather than cigarettes. The original intent was to hold a single focus group with up to eight participants. However, due to low participation rates and difficulties getting into contact with eligible students, the focus groups were turned into four individual interviews. Of the 11 recruited students only five attended and completed the usability testing. Therefore, the final sample that was analyzed consisted of five participants.

Demographics are presented in Table I.

 $\textbf{Table I:} \ Demographics \ of \ students \ who \ completed \ the \ usability \\ testing$

testing	(N = 5)
Age	(21 3)
18-20 years old	2
21-23 years old	1
24-26 years old	2
	_
Gender	_
Male	4
Female	1
Ethnicity	
•	0
Spanish/Hispanic/Latino Not Spanish/Hispanic/Latino	5
Not SpaniswHispanic/Latino	
Racial Background	
American Indian/Alaska Native	0
Asian	2
Native Hawaiian/Other Pacific Islander	0
Black/African-American	2
White	1
Witte	1
Student Classification	
Associates Degree	3
Workforce/Certification Program	1
Prerequisite Classes for Bachelor's Degree	0
Unsure/Undecided	1
Enrollment Status	
Full-time	4
Part-time	1
1 ur-time	1
Financial Status	
Live comfortably	1
Meet your needs adequately	2
Just meet basic expenses	2
Cannot meet basic expenses	0
Work Status	
Full-time employee	0
Part-time employee	3
Volunteer/intern	1
Not working at this time	1
Smoking Frequency	
(during last 30 days)	
0 Days	0
1 – 7 Days	1
8 – 14 Days	1
15 – 20 Days	1
21 – 29 Days	1
30 Days	1
In-App Staging	_
Precontemplation	1
Contemplation	0
Preparation	0
Action	4

Objective Quality

Using the criteria set forth by the uMARS, participants gave the Quit4Health smoking cessation application an overall App Quality Mean score of 4.26 out of a total of 5. Among the individual subscales, participants gave the Quit4Health application an almost equal score among Functionality, Aesthetics, and Information. Functionality was given the highest score among the subscales with a mean score of 4.44 out of 5 which was only slighter higher than Aesthetics and Information both of which received an equal score of 4.40 out of 5. Engagement was the subscale where participants gave the lowest score of 3.80 out of 5. An analysis of the individual items within the Engagement subscale shows that 100% of participants reported the application being very interactive. However, 80% of participants gave the application an average rating in terms of entertainment reporting that the application was fun enough to entertain them but only for a very brief time.

Table II: Results of the uMARS

Mean Score (SD)
3.80 (.49)
4.44 (.57)
4.40 (.28)
4.40 (.45)
4.26 (.35)
Mean Rating (SD)
4.2 (.84)
3.8 (.84)
3.8 (.84) 4.4 (.89)
` ′
4.4 (.89)

Perceived Impact

Of the six perceived impact items, Attitudes, Help Seeking, and Behavior Change were given the highest ratings. The majority of participants strongly believed that the application changed their attitudes towards smoking (4.4; SD = .8366) and that it encouraged them to seek further help to quit smoking if they needed it (4.4; SD = .8944). The majority of participants also strongly agreed that using the Quit4Health application would help them quit smoking (4.4; SD = .5477). However, the majority of participants felt that the application was lacking in knowledge and did not believe that the application significantly increased their knowledge or understanding of cigarette smoking (3.8; SD = .8366).

Subjective Quality

When asked if they would recommend the Quit4Health application to others who might benefit from it, the majority of participants reported that that they would recommend the Quit4health application to many people. When asked how many times they would use the application in the next 12 months, 20% answered that they would use it 10-50 times and 40% answered that they would use it more than 50 times. Participants gave the Quit4Health application an overall average rating of 3.8 stars out of 5 but most reported that they would not be willing to pay for it.

Thematic Analysis

After completing all surveys participants were asked to express their experiences with the Quit4Health application in a short open-ended discussion. A thematic content analysis was conducted and four broad themes were identified that described how these young adult smokers

perceived the application's quality and acceptability: Information, Relevance & Relatability, Appeal and finally Credibility.

Theme 1- Information: Information was the first theme and the most prevalent among this group. This broad theme describes the types of information that participants viewed as greatly important when quitting yet thought missing from the stage within the application that they were placed in. Participants expressed differing views on what factor was of the greatest importance when attempting to quit smoking. However, three subcategories of information could be detected among their responses.

The first and most frequent was *Health Risks*. The second subcategory was *Alternatives* to *Smoking*. Many participants discussed how important it is for those trying to quit to find ways to distract themselves. The third subcategory that emerged was the concept of *Dual-Use* that is, using more than one type of tobacco product. Participants believed that the Quit4Health application should focus not just on quitting cigarette use but on aiding young adult smokers in quitting other tobacco products as well.

"And a lot of you know students in college specially they don't just use cigarettes, like they don't just smoke cigarettes. They do more than that."

- (Male, 19 years old, Asian)

Theme 2 - Relevance & Relatability: Relevance & Relatability was the second theme and is defined as the relevance of the information presented in the Quit4Health application to the young adult smoker and how relatable it is to the circumstances and situations of the participants. The majority of participants expressed satisfaction in terms of relevance and relatability. Participants

described two aspects, or subcategories, that they believed added most to the relevance and relatability of the application, that is, the *accuracy of the information* presented to them and the *series of fictional stories* designed to be read as testimonies from ex-smokers or smokers going through multiple quit attempts. Participants believed that these aspects strongly increased the relatability and relevance of Quit4Health:

"Basically, it gave, uh like real life experiences, like stories. That's probably what was the what was the best part because you can relate to you know real life."

- (Male, 20 years old, African American)

Theme 3 - Appeal: The third overarching theme was Appeal that is how attractive or interesting participants perceived the Quit4Health application to be. Comments made by participants during the discussion generally fell into two subcategories: positive sentiment and negative sentiment. Participants expressed more than five time the number of positive sentiments than they did negative sentiments. Positive sentiments expressed by participants revolved around either the application overall, the information provided within the application, or the general functionality of the application. Statements made about the application overall included sentiments such as "helpful", "pretty cool", "really captured the audience", "covered more than I was expecting", "easily able to locate what you want to do", and "got a nice layout". A very small number of negative sentiments were expressed by participants in terms of functionality and interactivity such as the activities being "repetitive" and "kind of boring". The majority of the sentiments expressed by participants were positive therefore for the most part participants enjoyed using the application and perceived the application to be attractive and interesting.

Theme 4 - Credibility: The last theme that emerged among this group was Credibility which was defined as the participants' ability to believe in and trust that the information provided in the Quit4Helath application is authentic and/or comes from a trustworthy source. Participants' comments regarding this theme revolved around two subcategories that is the authenticity of the testimonies, called "stories" in the application, and the references from which the information in the application came from. In regards to the testimonies, some participants asked the interviewer about the authenticity of the testimonies and learned that they were fictional. These participants seemed to view the use of fictional testimonies in a negative light and commented on how it detracted from the credibility of the application:

"The fact that you actually made them up and made them to where they're like okay different scenarios of people going through you know whatever they're going through and using you know cigarettes which was helpful but to get a real life individual to actually say something credible . . . "

- (Female, 26 years old, African American)

Overall, participants believed most of the information provided in the application to be accurate and interesting but felt the Quit4Health application overall to be somewhat lacking in credibility.

DISCUSSION

The purpose of this study was to examine and analyze the usability of a novel smoking cessation application, Quit4Health, among young adult cigarette smokers between the ages of 18 and 26 in order to understand whether or not the application meets the needs of these young adults. Participants gave the application a high app quality mean score of 4.26 out of 5 points. Very few evaluations of smoking cessation applications have been published most of which are

content analyses and systematic reviews (Ferron et al., 2017; Haskins et al., 2017; Hoeppner et al., 2016; Regmi et al., 2017) Only two studies could be found that utilized the Mobile Application Rating Scale (Patel et al., 2015; Thornton et al., 2017). Thornton et al. analyzed the app quality of 112 smoking cessation apps available in Australia using the original Mobile Application Rating Scale (Thornton et al., 2017). The mean MARS overall quality total score of these apps was 2.88 (SD=.83) indicating that the majority of these apps are poor in quality. Of the 112 smoking cessation apps that were rated by Thornton et al. only six achieved a high app quality score that is an average mean total score of 4 or higher. However, Quit4Health scored higher on the uMARS than at least three of these apps. The results show Quit4Health to be among the few high-quality smoking cessation applications that exist and perhaps one of the only high quality apps designed specifically for young adult smokers.

Based on the objective quality mean score generated by the uMARS, participants expressed overall satisfaction for the information, functionality, and aesthetics of the Quit4Health application. The application received the lowest score in terms of engagement. Participants believed the application to be very interactive but lacking somewhat in entertainment. The results of this study, however, indicate that these young adult smokers seem to need a great amounts of variety and visual appeal to feel entertained for long periods of time.

The four broad themes using thematic content analysis were identified that is Appeal, Relevance & Relatability, Credibility, and finally Information (Hsieh & Shannon, 2005). Participants found the application greatly appealing and highly relevant to their situations. They believed the Quit4Health application to be very relatable to both themselves and to other college students in general. However, many participants felt that the application was lacking in credibility and in health related information regarding cigarette smoking. They believed that

including such information would increase the user's chances of successfully quitting. This is consistent with the perceived impact score given by participants when asked if the application increased their knowledge and understanding of cigarette smoking (3.8; SD = .8366) which received the lowest score among the perceived impact items. An explanation for this could be because the majority of participants were placed in the Action stage during the initial staging process and therefore were not exposed to the knowledge-based activities which are primarily in earlier stages.

The Quit4Health application uses the Stages of Change, the primary concepts of the Transtheoretical Model, to help young adult smokers achieve complete smoking cessation (Prochaska et al., 2015). The TTM model revolves around the premise that behavior change occurs not with any single event but rather is achieved over time by moving through a series of stages. Critical assumptions of this model include emphasizing specific processes of change during specific stages in order for progress through the Stages of Change to successfully occur (Prochaska et al., 2015). The results of this study suggest that these processes are flexible and may work differently for young adult smokers than for adult smokers.

This study is unique in that it provides an in depth look at the usability of Quit4Health by utilizing both qualitative and quantitative data. This study was conducted among young adult smokers and therefore provides the perceptions of a difficult population to reach and those most likely to use mHealth applications. Finally, this research adds to the evidence of the quality and usability of smoking cessation smartphone applications in a field where very little research has been conducted (Thornton et al., 2017). The results presented here can be used to inform the development of future smoking cessation interventions using mHealth in order to produce more effective high quality applications for young adult smokers.

Limitations

Some limitations of this study need to be taken into account. Young adult cigarette smokers at the Houston Community College Coleman campus proved to be an extremely difficult population to recruit from thus resulting in extremely low participation rates and a small sample size. The small sample size limits interpretation and utility of the results of this study as sampling variability is high. Therefore it may be difficult to generalize the results to the overall population of young adult smokers. In addition, the self-reported smoking status of the participants was not biochemically validated. Also, the Quit4Health smoking application was designed specifically to aid cigarette smokers. The participants of this usability study were cigarette smokers so the results of this study may not be generalizable to other types of tobacco use and behaviors. Finally, due to the staging process within the Quit4Health application and the limited time frame, participants were exposed to only a small section of the application and were not able to experience all of the various aspects that Quit4Health has to offer. A more comprehensive analysis of the usability of Quit4Health may be obtained by conducting multiple focus groups across the various stages but, unfortunately is beyond the scope of this study.

CONCLUSION

The Quit4Health application was developed with the intention to assist young adults in quitting cigarette smoking. The results of this study indicate that the application is of high quality and meets the needs of young adult community college smokers attending the Houston Community College Coleman Campus. In view of these results, the Quit4Health smoking cessation app is ready to be circulated on the market provided that studies regarding the app's efficacy, which are in process, are able to report higher smoking cessation rates. However, it is

recommended that updates to the app be implemented in the near future as improvements to the Quit4Health application are needed in order to provide a more entertaining and informative experience. More research is needed in order to discern how to optimize the use of mHealth with smoking cessation interventions for young adult smokers.

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APPENDICES

Appendix A: Signed Letter of Support



Dr. Phillip Nicotera

President

HCC Coleman College

Texas Medical Center
1900 Pressler Street, Suite 285

Houston, Texas 77030

August 2, 2018

Katrina Czerniak UT School of Public Health

Dear Ms. Czerniak,

I am writing this letter in support of your master thesis project investigating the usability of a novel smoking cessation smartphone application for young adults. The smartphone application described in the proposal was built on a strong foundation built on evidence-based research and behavior theory. Tobacco use among college students is high and is a concern. Therefore, it would be highly beneficial to offer a smartphone application resource such as the one described in the proposal.

If approved, please contact me. Our campus would like to have the opportunity to have our students participate in the study. We approve the use of our facilities and our supportive of championing tobacco cessation in the HCC system.

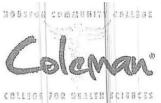
Sincerely,

Phillip Nicotera, M.Ed., M.D.

President, Coleman College for Health Sciences

Houston Community College

Appendix B: Approval Document from Houston Community College Coleman Campus



Student Event/Activity Review Form

Event: <u>Doctorate Degree Pres</u> Reviewer: <u>Dr. Phillip Nicoter</u> of	entation	Submission date: 4 18 208
Reviewer: Dr. Polittip Nilote Po	1	Date: 4 9 2018
Location/Date and Time/Attendance Comments/notes:		
Budget/Projected Expenses Comments/notes:		
Other Comments/notes:		
Approved Declined Incomp	olete	Date: 4/27/15 Updated 04-21-2017, OOP, PBF



M

Coleman Cal	iipus Ei	CITY ACTIVITY		PPRA
COLFFCE LOS REWILM SCIENCES	<u> </u>	RECEIVED F	4/2	3/18
Instruction Checklist: PLEASE READ - All requests must be submitted at leas - Attach confirmation e-mail from College	THE INSTRUCTION st two (2) weeks prion ge Operations for the	to the date of the event.	an 1:04:28	APR 72018
Program/Event Information			Ĉī.	SP SP
Name of Program/Department	Other (please	specify below)]	
Other ,	University of	exas School of Public Health]	
Submitted by:	Amanda Salir	as (Behalf of MD Anderson Study)	
Event/Activity Title:	Development	and Testing of Quit4Health.		
Date: Start Time:	End Time:	Room:		
Total Number of Attendees:				
* Please complete, HCC online event re * Audio Visual Equipment is free of cha Purpose of Event (Detailed explanation	rge but must be rese	rved through Coleman Computer	Center.	
Study-Need authorization for Institution	nal Review Board App	Dication		
Projected Budget Summary Estimated Expenses List all expenses being requested (attach qua	ote(s))			
Budget number	0			
Food (please include vendor name)	0			
Printing	0			
Decorations	0			
Special equipment (please specify)	0			
Other expenses (please specify)	0			
Total Expenses	\$0.00	•		

Appendix C: Informed Consent Document



Development and Usability Testing of Quit4Health, a Smoking Cessation Smartphone App for Young Adults

INFORMED CONSENT TO TAKE PART IN RESEARCH

HSC-SPH-18-0576

INVITATION TO TAKE PART

You are being invited to take part in a research project called *Development and Usability Testing of Quit4Health, A Smoking Cessation Smartphone App for Young Adults* conducted by Katarzyna Czerniak, MLA. University of Texas Health Science Center at Houston. Your decision to take part is voluntary and you may refuse to take part, or choose to stop taking part, at any time.

You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committees for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-SPH-18-0576. Please take your time to make a decision.

PURPOSE

The purpose of this research is to analyze the acceptability and usability of Quit4Health, a novel interactive smartphone application designed to help young adults quit smoking, in order to determine whether or not the application meets the needs of young adult smokers.

PROCEDURES

If you agree to take part in this study, you will participate in a $\underline{1 \text{ to } 1\frac{1}{2} \text{ hour}}$ focus group. You will test a new smoking cessation application for smartphones that is designed to assist young adults in quitting smoking. This testing will be conducted in a classroom at the Houston Community College Coleman Campus.

You will be asked to fill out a demographics survey and then will be given instructions on how to download the app onto your smartphones. A researcher will provide a brief introduction on how the app works and then you will be given the opportunity to explore the Quit4Health app for around 15-20 minutes. After taking some time to navigate through the various features, you will be asked to take the usability questionnaire. You will first answer questions regarding your smoking status and then will answer the 26-item uMARS scale. Afterwards, you will be given 15-20 minutes to express your opinions and feelings in a group discussion regarding your experiences with the app.

TIME COMMITMENT

The focus group which consists of using the app, answering two questionnaires, and a group discussion will take about 1 to $1\frac{1}{2}$ hours to complete.

BENEFITS

Other than learning about a new cessation smoking app that you may use to help you quit smoking, there will be no other benefits.

RISKS AND/OR DISCOMFORTS

Risks to using the Quit4Health smartphone application and providing information about its content and function are minimal. Others may find out about your smoking status and participation in the study if they see the app on your phone. Provision of any information is voluntary. Information you provide will not be identified with you but will be assigned a unique identification number for study purposes.

STUDY WITHDRAWAL

You may withdraw from this study at any time. If you withdraw, any information collected from you during the study will not be used. Withdrawing from the study will not cost you anything.

COSTS, REIMBURSEMENT, AND COMPENSATION

At the end of the study, you will be compensated for your participation with a \$25 gift card and lunch in the form of free pizza and soft drinks. Taking part in the study will not cost you anything.

CONFIDENTIALITY

Any personal information about you that you provide will remain confidential to every extent of the law. Data collected in the app is not linked to any medical record system and will be only accessible to study staff. Survey data will be both confidential and anonymous and stored with a study code. Please understand that representatives of the Committee for the Protection of Human Subjects and the primary investigator of this research may review your research for the purposes of verifying research data and will see personal identifiers. You will not be personally identified in any reports or publications that may result from this study.

QUESTIONS

Ms. Czerniak will be glad to answer any questions regarding the study at any time. Contact information: Katarzyna Czerniak (713-792-1647).

SIGNATURES

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at Houston (713) 500-7943. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Study ID
Signature of Subject	Date/Time
Printed Name of Individual Obtaining Consent	
Signature of Individual Obtaining Consent	Date/Time

CPHS STATEMENT:

This study (HSC-SPH-18-0576) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713-500-7943).

Appendix D: Quit4Health Screening Survey

Thank you for your interest in Quit4Health. Please answer the following questions and the check the box that completes your response.

1. How old are you?		
2. Are you enrolled in at least one class and plan to continue at HCC this year?	YES	NO
3. Do you speak English?	YES	NO
4. Do you own a smartphone?	YES	NO
5. Do you have access to the internet?	YES	NO
6. Can you provide contact information?	YES	NO
7. Do you currently use tobacco?	YES	NO
8. Do you smoke 1 or more cigarettes a day?	YES	NO

Appendix E: Sign-Up Sheet

Quit4Health Usability Study: Focus Group Sign-up

	Name	Date	Primary Phone Number	Alternate Phone Number	E-mail Address	Alternate E-mail Address	Available Days & Times
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Have an IPhone or Android smartphone?

Come check out Quit4Health!

Quit4Health is a brand new smartphone app designed to help smokers quit. The University of Texas Health Science Center at Houston is looking for smokers to help test it out! Volunteers will participate in a focus group during which they will:

- Download the app and briefly go through some of the activities
- Give opinions about the app and rate it
- Receive compensation for their time



To learn more please contact Katarzyna Czerniak at Katarzyna.W.Czerniak@uth.tmc.edu or call (713) 792-1647



Appendix G: Quit4Health Demographics Instrument

Demographics

Welcome and thank you for participating in the Quit4Health Usability Study. Please answer the following questions about your demographics.

- 1. How old are you? _____
- 2. Do you consider your gender to be:
 - o Male
 - o Female
- 3. Which of the following best describes your ethnic background?
 - o Spanish/Hispanic/Latino
 - Not Spanish/Hispanic/Latino
- 4. Which of the following best describes your racial background?
 - American Indian/Alaska Native
 - o Asian
 - Native Hawaiian or Other Pacific Islander
 - o Black/African-American
 - o White
- 5. What is your student classification?
 - Associates Degree (with text box)
 - Workforce/Certification Program (with text box)
 - o Prerequisite Classes for Bachelor's Degree
 - o Unsure/Undecided
- 6. What is your enrollment status?
 - o Full-time
 - o Part-time
- 7. How would you describe your current financial situation?
 - o Live comfortably
 - Meet your needs adequately
 - Just meet basic expenses
 - Cannot meet basic expenses
- 8. What is your work status?
 - o Full-time employee
 - o Part-time employee
 - Volunteer/intern
 - Not working at this time

Appendix H: User Version Mobile Application Rating Scale (uMARS) for QuitHealth

Thank you for using Quit4Health. Please fill out the following questionnaire to the best of your ability.

Perceived Impact

Section I: Perceived Impact

Please rate how much you agree with the following statements.

Statement	Strongly Disagree				Strongly Agree
1. Awareness – Quit4Health has increased my awareness of the importance of quitting cigarette smoking.	1	2	3	4	5
2. Knowledge – Quit4Health has increased my knowledge/understanding of cigarette smoking.	1	2	3	4	5
3.Attitudes – Quit4Health has changed my attitudes toward quitting cigarette smoking	1	2	3	4	5
4. Quit4Health has increased my intentions/motivation to quit smoking cigarettes.	1	2	3	4	5
5. Help seeking – Quit4Health encourages me to seek further help to quit smoking cigarettes if I need it.	1	2	3	4	5
6. Behavior change – Using Quit4Health will help me quit smoking cigarettes.	1	2	3	4	5

App Quality Ratings

For the following sections circle the number that you feel most accurately represents the quality that you experienced when using Quit4Health.

Section II: Engagement

- 7. Is Quit4Health fun/entertaining to use? Does it have components that make it more fun than other smoking apps?
 - 1 Dull, not fun or entertaining at all

- 2 Mostly boring
- *OK*, fun enough to entertain young adult for a brief time (< 5 minutes)
- 4 Moderately fun and entertaining, would entertain young adult for some time (5-10 minutes total)
- 5 Highly entertaining and fun, would stimulate repeat use
- 8. Is the app interesting to use? Does it present its information in an interesting way compared to other smoking apps?
 - 1 Not interesting at all
 - 2 *Mostly interesting*
 - *OK*, neither interesting nor uninteresting (would engage young adult for a brief time: < 5 minutes)
 - 4 *Moderately interesting (would engage young adult for some time: 5-10 minutes)*
 - 5 *Very interesting (would engage young adult in repeat use)*
- 9. Does Quit4Health allow you to customize the settings and preferences that you would like to (e.g. sound, content, notifications, etc.)
 - 1 Does not allow any customization or requires setting to be input every time
 - 2 Allows little customization and that limits the app's functions
 - 3 Basic customization to function adequately
 - 4 Allows numerous options for customization
 - 5 Allows complete tailoring the young adult's characteristics/preferences, remembers all settings
- 10. Does Quit4Health allow input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)
 - 1 No interactive features and/or no response to young adult input
 - 2 Some, but not enough interactive features which limits app's functions
 - 3 Basic interactive features to function adequately
 - 4 Offers a variety of interactive features, feedback and young adult input options
 - 5 Very high level of responsiveness through interactive features, feedback and young adult input options
- 11. Is the content of Quit4Health (visuals, language, design) appropriate for young adults?
 - 1 Completely inappropriate, unclear or confusing
 - 2 *Mostly inappropriate, unclear or confusing*
 - Acceptable but not specifically designed for the target audience. May be inappropriate/unclear/confusing at times
 - 4 Designed for the target audience, with minor issues
 - 5 Designed specifically for the target audience, no issues found

Section III: Functionality

- 12. How accurately/fast do the features (functions) and components (buttons/menus) of Quit4Health work?
 - App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
 - 2 Some functions work, but lagging or contains major technical problems
 - 3 App works overall. Some technical problems need fixing, or is slow at times
 - 4 *Mostly functional with minor/negligible problems*
 - 5 Perfect/timely response; no technical bugs found, or contains a 'loading time left' indicator (if relevant)
- 13. How easy is it to learn how to use Quit4Health; how clear are the menu labels, icons and instructions?
 - 1 No or limited instructions; menu labels and/or icons are confusing; complicated
 - 2 Takes a lot of time or effort
 - 3 Takes some time or effort
 - 4 Easy to learn (or has clear instructions)
 - 5 *Able to use app immediately; intuitive; simple (no instructions needed)*
- 14. Does moving between screens make sense; Does Quit4Health have all necessary links between screens?
 - 1 No logical connection between screens at all /navigation is difficult
 - 2 *Understandable after a lot of time/effort*
 - 3 *Understandable after some time/effort*
 - 4 Easy to understand/navigate
 - 5 Perfectly logical, easy, clear and intuitive screen flow throughout, and/or has shortcuts
- 15. Do taps/swipes/scrolls make sense? Are they consistent across all components/screens?
 - 1 Completely inconsistent/confusing
 - 2 Often inconsistent/confusing
 - 3 *OK* with some inconsistencies/confusing elements
 - 4 *Mostly consistent/intuitive with negligible problems*
 - 5 *Perfectly consistent and intuitive*

Section IV: Aesthetics

- 16. Is the arrangement and size of buttons, icons, menus and content on the screen appropriate?
 - 1 Very bad design, cluttered, some options impossible to select, locate, see or read
 - 2 Bad design, random, unclear, some options difficult to select/locate/see/read
 - 3 Satisfactory, few problems with selecting/locating/seeing/reading items
 - 4 Mostly clear, able to select/locate/see/read items
 - 5 Professional, simple, clear, orderly, logically organized
- 17. How high is the quality/resolution of graphics used for buttons, icons, menus and content?
 - 1 Graphics appear amateur, very poor visual design disproportionate, stylistically inconsistent
 - 2 Low quality/low resolution graphics; low quality visual design disproportionate
 - 3 *Moderate quality graphics and visual design (generally consistent in style)*
 - 4 High quality/resolution graphics and visual design mostly proportionate, consistent in style
 - 5 Very high quality/resolution graphics and visual design proportionate, consistent in style throughout
- 18. How good does Quit4Health look?
 - 1 Ugly, unpleasant to look at, poorly designed, clashing, mismatched colors
 - 2 Bad poorly designed, bad use of color, visually boring
 - OK average, neither pleasant, nor unpleasant
 - 4 Pleasant seamless graphics consistent and professionally designed
 - 5 Beautiful very attractive, memorable, stands out; use of colour enhances app features/menus

Section V: Information

- 19. Is the content of Quit4Health correct, well written, and relevant to the goal/topic of the app?
 - 1 Irrelevant/inappropriate/incoherent/incorrect
 - 2 Poor. Barely relevant/appropriate/coherent/may be incorrect
 - 3 Moderately relevant/appropriate/coherent/and appears correct
 - 4 Relevant/appropriate/coherent/correct
 - 5 Highly relevant, appropriate, coherent, and correct
- 20. Is the information within Quit4Health comprehensive but concise?

	2	Insufficient or p	ossibly overwheln	ning		
	3		prehensive or con	-		
	4	Offers a broad	range of informati	on, has some gaps	or unnecessary deta	iil; or has no links
2	4		ation and resource			
:	5	Comprehensive	and concise; cont	ains links to more i	nformation and reso	ources
21.		sual explanation cal, correct?	n of concepts – th	nrough charts/grap	phs/images/videos,	etc. – clear,
	1			ong or necessary b	ut missing	
4	2	Mostly unclear,	confusing/wrong/			
	3	-	nclear/confusing/v	-		
	4		gical/correct with	negligible issues		
	5	Perfectly clear/	logical/correct			
22.	Does	s the information	on within Quit4H	ealth seem to com	ne from a credible s	source?
	1	Suspicious sour	се			
4	2	Lacks credibility				
	3	Not suspicious	but legitimacy of s	ource is unclear		
	4	Possibly comes	from a legitimate	source		
:	5	Definitely come	es from a legitimat	e/specialized sourc	e	
Subj	jectiv	e Quality				
			e rate the Quit4F	Health app		
For t	his nex			Health app		
For to	his nex	xt section pleas Subjective Qu	ality			
For to	his nex	xt section pleas Subjective Qu	ality	Health app	benefit from it?	
For to	his nex	xt section pleas Subjective Qualid you recomm	ality		benefit from it?	5
For to	his nex	xt section pleas Subjective Qualid you recomm	end this app to p	eople who might		5 Definitely
For to	his nex	xt section pleas Subjective Qualid you recomm	end this app to p	eople who might		
For to	his nexon V: Wou	xt section pleas Subjective Qual Ild you recomm 1 Not at all	end this app to p	eople who might 3 Maybe		Definitely
For the Section 19.	his nexon V: Wou	Subjective Quality of the section pleas Subjective Quality of the section pleas I subjective Quality of the section please plea	end this app to p 2 2 you think you w	eople who might 3 Maybe yould use this app	4	Definitely nths if it was
For the Section 19.	his nexon V: Wou	Subjective Quality of the section pleas Subjective Quality of the section pleas I Not at all I many times do yant to you?	eality end this app to p 2 you think you w	eople who might 3 Maybe vould use this app	4 in the next 12 mor	Definitely In this if it was
For the Section 19.	his nexon V: Wou	Subjective Quality of the section pleas Subjective Quality of the section pleas I subjective Quality of the section please plea	end this app to p 2 2 you think you w	eople who might 3 Maybe yould use this app	4 in the next 12 mor	Definitely nths if it was

Minimal or overwhelming

21.	Would	I you pay for this	s app?			
	De	1 efinitely Not	2	3	4	5 Definitely Yes
22.	What i	s your overall (s	star) rating of	the app?		
	1	*	One of the	worst apps I've use	d	
	2					
		* * *	Average			
		* * * *				
	5	* * * * *	One of the	best apps I've used		
Dlags	a lat us	know if you have	a any furthar	comments or feedb	ack about Quit	1Health
rieus	e iei us	Know ij you nave	e any juriner		аск адойг Q ин-	+11euiin.

Thank you for your time!

Appendix I: Tobacco Use and Dependence Questionnaire

Please answer the following questions about your cigarette use.

	1.	During the	past 30 days,	on how man	y days did	you smoke a cigarette?
--	----	------------	---------------	------------	------------	------------------------

0	0	0	15-20
0	1-7	0	21-29
0	8-14	0	30

If the answer is 30 or more then please also answer the following questions:

2. On <u>average</u>, how many cigarettes do you smoke per day?

o 16-20

0	1-5	0	16-20
0	6-10	0	21-30
0	11-15	0	31+

3. Do you smoke more in the morning than during the rest of the day?

- o Yes
- o No

4. How soon after you wake up do you smoke your first cigarette?

- o Within 5 minutes
- O Within 6-30 minutes
- O Within 31-60 minutes
- o After 60 minutes

5. Which cigarette would you most hate to give up?

- o The first cigarette of the day
- o Any other cigarette

6. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., during class, at the library, at the movies, etc.)?

- o Yes, very difficult
- o Yes, somewhat difficult
- o No, not usually difficult
- o No, not at all difficult

7. Do you smoke even if you are so ill that you cannot leave the bed most of the day?

- o Yes, always
- o Yes, often
- o Rarely
- o Never

Appendix J: Focus Group Interview Questions

Interview Questions for Focus Group

- 1. Tell me about any past experiences you may have had with other tobacco cessation apps.
 - a. Probe: How was your past experience with these apps?
 - b. Probe: What aspect of these apps did you like most?
 - c. Probe: What aspect of these apps did you like least?
- 2. Which aspect of the Quit4Health app did you like the most?
 - a. Probe: What about this aspect did you like?
- 3. Which aspect of the Quit4Health app did you like the least?
 - a. Probe: What about this aspect did you not like?
- 4. How relevant/relatable do you feel that the information presented in Quit4Health is to you?
 - a. Probe: To college students in general?
- 5. Tell me about any barriers to using the Quit4Health app (if any).
 - a. Probe: How do you think these barriers might be addressed?
- 6. What would you change about this app?
 - a. Probe: Why would you change this issue?
 - b. Probe: How do you think this issue should be addressed?
- 7. How would you describe your overall experience with Quit4Health?
- 8. What other types of educational information would you like to see included in Ouit4Health?

^{*}Additional probe questions may be used

Appendix K: Committee of the Protection of Human Subjects (CPHS) Approval Letter



Committee for the Protection of Human Subjects

Houston, Texas 77040

Dr. Katarzyna Czerniak UT-H - GEN - Default Department Code

NOTICE OF APPROVAL TO BEGIN RESEARCH

August 14, 2018

HSC-SPH-18-0576 - Development and Usability Testing of Quit4Health, a Smoking Cessation Smartphone App for Young Adults

Number of Subjects Approved: Target: 8 /Screen: 8

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: 08/14/2018 APPROVAL DATE: 08/14/2018 **EXPIRATION DATE:** 07/31/2019

CHAIRPERSON:

L. Maximilian Buja L. Maximilian Buja, MD

Subject to any provisions noted above, you may now begin this research.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT DETERMINATION:

Signed Informed Consent Required

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent,

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA): Exempt from HIPAA: Yes

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent and HIPAA documents if required, in a manner that ensures subject confidentiality.

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