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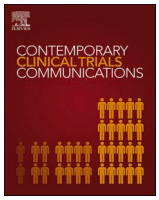

Assessing efficacy of a web-based smoking cessation tool - QuitAdvisorMD: Protocol for a practice-based, clustered, randomized control trial

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ABSTRACT

Background: Smoking remains the leading cause of preventable death, yet physicians inconsistently provide best-practices cessation advice to smokers. Point-of-care digital health tools can prompt and assist physicians to provide improved smoking cessation counseling. QuitAdvisorMD is a comprehensive web-based counseling and management digital health tool designed to guide smoking cessation counseling at the point-of-care. The tool enables clinicians to assess patient readiness to change and then deliver stage-appropriate interventions, while also incorporating Motivational Interviewing techniques. We present the research protocol to assess the efficacy of QuitAdvisorMD to change frequency and quality of smoking cessation counseling and its effect on patient quit rates.

Methods: A practice-based, clustered, randomized controlled trial will be used to evaluate QuitAdvisorMD. Cluster design will be used where patients are clustered within primary care practices and practices will be randomized to either the intervention (QuitAdvisorMD) or control group. The primary outcome is frequency and quality of clinician initiated smoking cessation counseling. Secondary outcomes include, 1) changes in physician knowledge, skills and perceived self-efficacy in providing appropriate stage-based smoking cessation counseling and 2) patient quit attempts. Analyses will be conducted to determine pre- and post-test individual clinician outcomes and between intervention and control group practices for patient outcomes.

Conclusion: Results from this study will provide important insights regarding the ability of an integrated, web-based counseling and management tool (QuitAdvisorMD) to impact both the quality and efficacy of smoking cessation counseling in primary care settings.

1. Introduction

Despite significant reductions in smoking over the past few decades, 11.5 % of US adults still smoke [1]. Smoking remains the leading cause of preventable disease and death, costing over $300 billion each year in both productivity losses ($156 billion) and excess medical expenditures ($170 billion) [2]. Over two-thirds of smokers want to quit, and about half of them try to quit each year, but only 7 % succeed [3].

Primary care settings provide a key opportunity to promote smoking cessation [2,4]. Patients are seen in primary care settings more than any other part of the US health care system [5], and 70 % of smokers visit a primary care provider (PCP) annually. People trust their PCP [6], value their advice [4,5], and change their behaviors as a result of this advice [7–9]. Indeed, clinician advice is one of the most effective ways to promote smoking cessation attempts, making the clinical encounter a critical venue for smoking interventions.

Significant barriers persist to regular delivery of effective smoking cessation counseling in clinical encounters, including time limitations

Abbreviations: MI, Motivational Interviewing; TTM, Transtheoretical Model; 5 A's, (Ask, Advise, Assess, Assist, Arrange); CME, Continuing Medical Education; SP, Standardized Patient; PHS, Public Health Service; EHR, Electronic Health Record; OTC, Over-the-Counter.

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[10–12] and lack of provider knowledge and skills to promote recommended methods [13–15]. Although the majority of smokers are now identified due to widespread implementation of electronic health records, the quality and depth of counseling that smokers receive is questionable [16–18], as only 20 % of smokers report receiving counseling or education, and only 3.8 % report receiving a cessation medication prescription [18]. In addition, while the 5-As approach (i.e., Ask, Advise, Assess, Assist and Arrange) [19] is a recommended strategy to address smoking cessation, PCPs are not using it with the exception of "Asking" about tobacco use [20]. Interventions are sorely needed to increase the frequency and quantity of smoking cessation counseling by healthcare providers.

Digital health interventions can help leverage the limited time PCPs have with their patients and have proven efficacy in multiple trials [21], potentially by facilitating three key areas that enhance the quality of smoking cessation counseling [22]:

1) *Priming patients for smoking cessation discussions (*5-As – *Ask, Assess)*. Utilizing automated digital health interventions prior to the clinical encounter can assess patients' intentions to quit, importance of quitting, and confidence to quit, as well as other important patient characteristics, thereby enabling PCPs to efficiently use the limited time they have with patients [22]. For example, commonly used health behavior risk assessments can be completed by patients prior to the visit. These data can then be incorporated into discussions with the patient about how to promote healthy behavior change [23–26].
2) *Tailoring smoking cessation interventions to the patient (*5-As – *Assess, Assist & Arrange)*. Automated algorithms can enhance intervention relevance and effectiveness by tailoring cessation information based on smokers' characteristics (e.g., interest in quitting, confidence to quit) [27–34]. Compared to generic interventions, tailored interventions more effectively promote health behaviors, particularly preventive behaviors like smoking cessation [35,36].
3) *Ensuring consistency between clinician practices, guidelines and emerging science.* Lack of clinician knowledge and confidence about cessation counseling is a major barrier to clinician-initiated counseling [10, 13–15,37]. Automated digital interventions can deliver up-to-date evidence-based information to clinicians about recommended cessation methods. PCP-patient conversations that follow such interventions and are tailored to patient needs are most effective at promoting abstinence [38] and can build PCP knowledge and confidence for subsequent patient encounters. A computer-based intervention tested in the Henry Ford Health System, guided smoking cessation counseling by clinicians and significantly increased *asking about smoking status* (93 % vs 84 % control arm, $P < .001$) and *assessing willingness to quit* (78 % vs 54 % control arm, $P < .001$). For *ask, assess and arrange,* differences between the intervention and control arms post-implementation were statistically significant ($P = .001$) [39].

To address the need for improved smoking cessation counseling in primary care settings, we developed QuitAdvisorMD; a point-of-care, web-based, interactive counseling and management digital health tool designed to assist clinicians with patient tailored smoking cessation counseling that adheres to evidence-based practice guidelines. Algorithms driving the application are based on the 5-A's framework [19], Motivational Interviewing [40–42], the Transtheoretical Model of Change (TTM) [43,44], and the Public Health Service (PHS) guidelines [19]. Through a point-and-click interface, the tool 1) delivers a scripted interview to assess the patient's readiness to change, 2) provides a scripted motivational interview tailored to the patient's stage of change, 3) provides stage-relevant tools, including: risk calculators (e.g. for lung cancer, cardiovascular disease, etc.), a nicotine dependency assessment, drug information and dosing, abridged information on pertinent clinical guidelines and local and national resources, and 4) tracks clinician behavior during the patient encounter. A QuitAdvisorMD prototype was previously designed and tested through a usability study [45].

2. Specific aims

The primary aim of this study is to assess whether QuitAdvisorMD, a computer-assisted smoking cessation counseling and management tool, increases smoking cessation counseling frequency and quality in the primary care ambulatory setting.

Secondary outcomes will include: 1) differences in clinician knowledge, skills and self-efficacy to provide appropriate stage-based smoking cessation assistance, and 2) differences in number of patient quit attempts.

3. Methods

3.1. Study design

This study will be a practice-based, randomized, controlled trial. Cluster design will be used where patients are clustered within primary care practices. Practices will be randomized to either the intervention (QuitAdvisorMD) or control group. The study was approved by the University of Virginia School of Medicine, University of South Carolina and Palmetto Health System Institutional Review Boards. Fig. 1 depicts the study flow diagram.

3.2. Participants

Primary care physicians and advanced practice providers (APPs) in practices based in Virginia and South Carolina will be targeted for participation. Individuals who smoke and are patients of enrolled clinicians will be eligible for enrollment in the study.

3.2.1. Eligibility criteria

Eligibility criteria for the study include primary care practices in Virginia and South Carolina that provide care for members of a collaborating insurance company/Third Party Administrator (Southern Health, Inc.), and primary care practices in South Carolina that belong to an accountable care organization (Palmetto Health Quality Collaborative). Practices and participating clinicians must have access to a point-of-care computing device (e.g., smartphone or desktop PC) during patient visits. Eligible patients in the above practices include smokers aged 18–65 years. See Table 1 for inclusion/exclusion criteria for clinicians and patients.

3.2.2. Recruitment

We plan to recruit 100 clinicians. Power calculations can be found in sections 3.6 and 3.7 of this paper. Notifications of the study will be placed in clinician newsletters, flyers will be posted in eligible practices, e-mail messages will be sent to eligible practices and clinicians, and we will conduct meetings with practice managers. We also will partner with local payor groups in Virginia and South Carolina to promote participation in the study. Additionally, Dr. Strayer is part of a national initiative (Continuing Education Aimed at Smoking Elimination-CEASE) which conducts numerous CME events in Virginia and South Carolina, and eligible participants at these events will be invited to participate in the study.

3.2.3. Screening, enrollment and randomization

Upon receiving calls, e-mails or other sign-up information from potential practice participants, the study coordinator will ensure eligibility and obtain informed consent from participating clinicians and a practice representative. All participating practices will be asked to sign a data sharing agreement. Participants will be told that the purpose of the investigation is to study smoking cessation counseling by physicians and APPs. Clinical providers also will be informed that they will be visited by standardized patients (SPs) and these visits will be audio-recorded, but

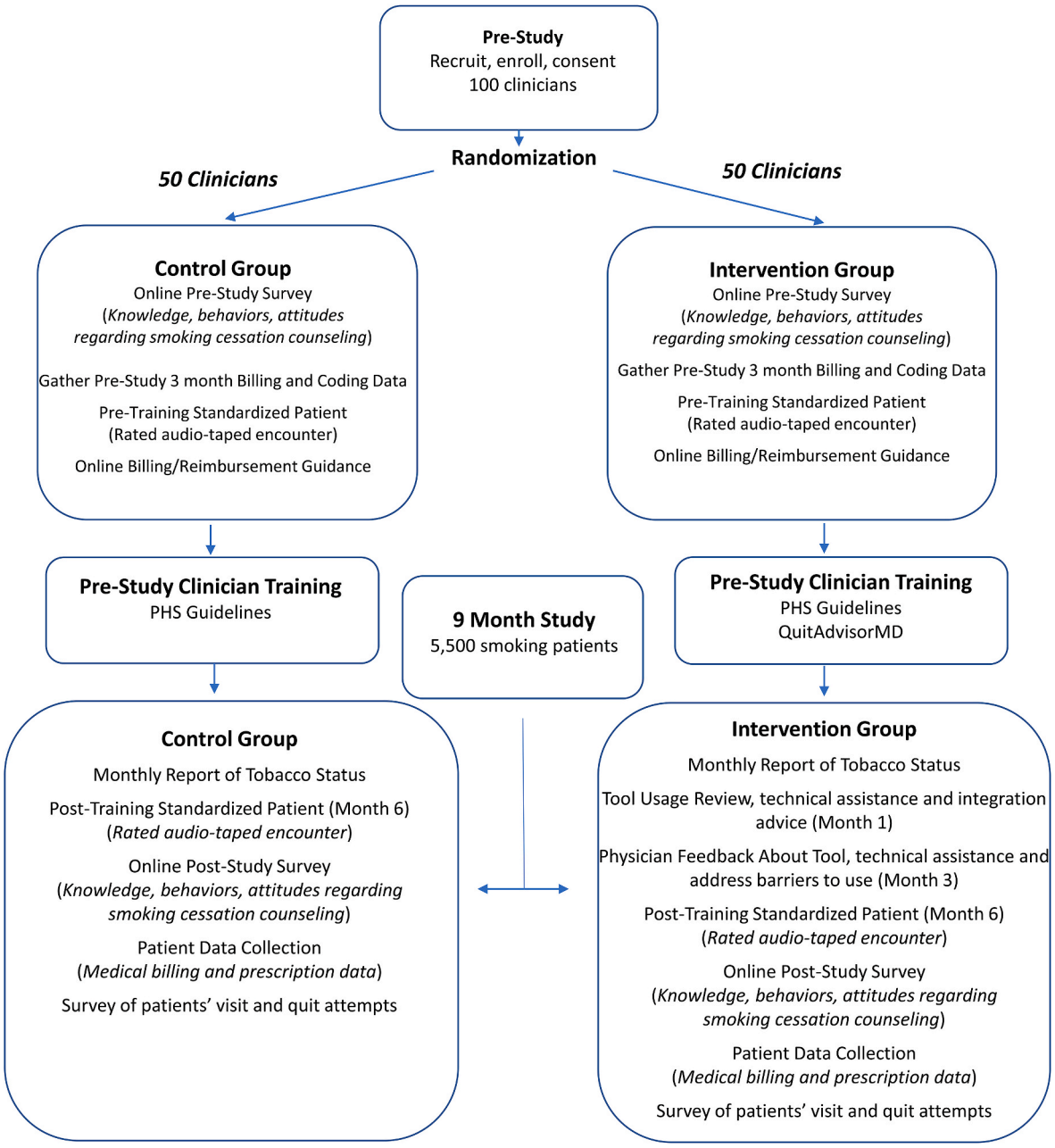

Fig. 1. Trial flow diagram highlighting pre-study, training, and study components in control and intervention groups.

they will be blinded to timing of the actual visit. Clinician participants will be recruited in waves to accomplish enrollment, pre-training SP visits and training requirements prior to starting the study. Following informed consent, practices will be randomized via computer generated randomization to either the intervention group or control group. Both groups will be scheduled for a separate initial group meeting where training and initial survey and baseline billing and coding data will take place (see Intervention 3.3). The initial SP visit will occur prior to the training sessions but after informed consent is given.

3.3. Intervention

3.3.1. Training

Participants in both the intervention and control groups will receive training on billing procedures for smoking cessation counseling within their health system via a brief online presentation. Each group will also attend separate initial training meetings that will cover current Public Health Service (PHS) smoking cessation guidelines. During this training meeting, the intervention group will also receive instruction regarding the content and utilization of QuitAdvisorMD. Functionality of QuitAdvisorMD will be introduced through a PowerPoint and live demonstration by a clinician. Each participant will be instructed on how to access the tool and technical support staff will be available to answer questions. To facilitate active utilization of QuitAdvisorMD during training, participants will be presented with a scripted example of a clinical scenario with a study member posing as a hypothetical patient. Participants will utilize the tool during the scenario to demonstrate sufficient understanding of the tool's features. Once the training has been completed, participants will be instructed to use QuitAdvisorMD as they see fit in their practice for the next nine months. Meetings for both the control and intervention groups will consist of 5–10 physicians from the same geographical area or practice and will be designed so that licensed providers receive continuing education credit.

Table 1
Inclusion and exclusion criteria.

Clinician Inclusion Criteria	Clinician Exclusion Criteria
English speaker	Clinicians who do not meet the inclusion criteria
Licensed, practicing MD, DO or APP in primary care	Clinicians in practices that do not agree to the data sharing terms in the practice agreement letter
Access to point-of-care web-accessible computer device during visits	
Providing care for members of a collaborating insurance company/ third party administrator	
Patient Inclusion Criteria	**Patient Exclusion Criteria**
Adults age 18–65 years	Have not met the inclusion criteria
Patient visit with their provider during the study period	Have not smoked at least 100 cigarettes within their lifetime
Smoke at least one cigarette within the past 6 months	

3.3.2. Quit advisor tool

QuitAdvisorMD is a web-based counseling and management tool designed to influence smoking cessation at the point-of-care. It includes elements from PHS guidelines [19], basic components of MI [38–40], TTM [43,44], and 5-A's framework [19] that our team has previously combined in primary care settings [46]. QuitAdvisorMD enables clinicians to assess patient readiness to change, and then deliver stage-appropriate interventions using MI techniques. As illustrated in Fig. 2, QuitAdvisorMD is a bimodal instrument that consists of, 1) an algorithmic scripted interview and 2) a clinician's reference that provides deeper explication of the underlying theories. Additionally, the reference section contains up-to-date pharmacologic interventions as well as local and national support resources such as the national DHHS 1-800-QUIT NOW number and the www.smokefree.gov website. The QuitAdvisorMD platform is demonstrated in Fig. 3 and Video 1.

3.4. Retention

Retention strategies for participating clinicians will include the following: 1) We will provide a phone number and email contact to access any technical support needs or difficulties providers might encounter during implementation. Providers will be given access to extensive web-based training materials developed to support them, including step-by-step instructions for using the QuitAdvisorMD tool, how to interact with patients who smoke and how to assist patients in changing their smoking behaviors; 2) At one month, intervention group providers who have not used the tool will be sent a reminder and an offer of technical assistance and/or advice on integrating QuitAdvisorMD into their daily practice procedures; 3) At three months, intervention group clinicians will be contacted to ascertain initial use experience, satisfaction and concerns. Any additional technical or other barriers will be addressed at that time. Any clinicians who have not had the opportunity to use the tool will be offered a practice patient visit with a study team member; 4) All clinician participants will receive monthly feedback on the percentage of patients with tobacco use status reported. Tobacco use documentation rates will be determined by the following formula: rate = number patients with tobacco status indicated in billing/number of patients seen * national smoking rate. Physicians with a low <50 % use of the patient tobacco-use status codes will receive an extra reminder notice of the importance of accurate billing data; 5) Upon completion of the post-test questionnaire, clinicians will be sent $200 for their participation and an additional $175 for maintaining at least 80 % compliance with tobacco use status reporting; and 6) QuitAdvisorMD users will receive CME credit based on tool usage.

3.5. Outcomes and measures

3.5.1. Primary outcome

- Percentage of patients who have tobacco-use status ICD-9 codes indicated (e.g., ICD-9 code 305.1). Number of patients who are diagnosed as smokers and in addition receive billable smoking cessation counseling (to include CPT codes 99406 and 99407 as well as billing data that indicates that time was spent on smoking cessation alone (e.g., Evaluation and Management codes that indicate Tobacco Abuse as a primary diagnosis).
- Number of patients who are diagnosed as smokers, receive billable smoking cessation counseling, and received a prescription for a smoking cessation medication, either prescription (e.g. varenicline) or OTC (e.g. nicotine gum or patches). For drugs that may have more than one indication (e.g. wellbutrin SR, clonidine, nortriptyline), only patients that have tobacco abuse as a primary diagnosis or those that do not have other common indications (e.g. depression) will be included in the analysis.
- Co-morbidities, sex and age for all smoking patients in the study

Medical billing has been used to evaluate efficacy of interventions targeted at improving physician compliance with smoking cessation guidelines [47,48]. However, billing can underestimate content in an encounter [49,50]. Therefore, to address potential underutilization, we will track billing for multiple levels of intervention, including smoking status and train all physicians regarding billing codes when they are enrolled in the study. We will also provide monthly feedback to physicians on their rates of reporting tobacco use status and recording smoking cessation counseling billing codes. Physicians with a low use of the patient tobacco-use status codes and smoking cessation counseling codes (based on patient population size and regional smoking prevalence rates) will receive an extra reminder notice of the importance of accurate billing data to the study. The use of feedback has shown to increase use of tobacco-use status codes from 7.5 % to 82 % [51]. Additionally, the correlation between use of billing codes and actual performance will be determined by conducting chart reviews on a random sample of 30 charts from each participating clinician to determine actual performance.

Data will be extracted from Southern Health reporting of tobacco use

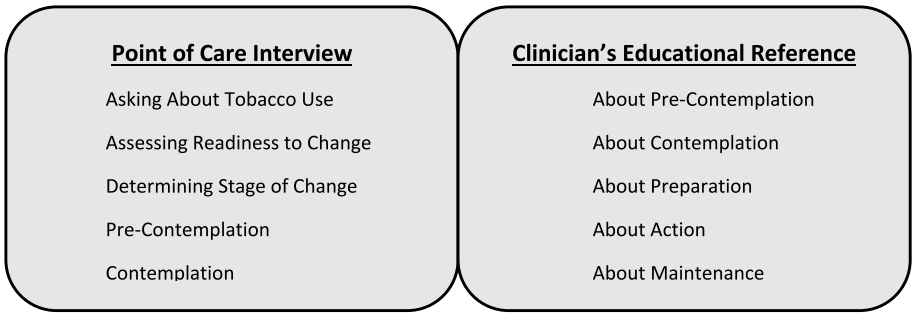

Fig. 2. QuitAdvisorMD bimodal content.

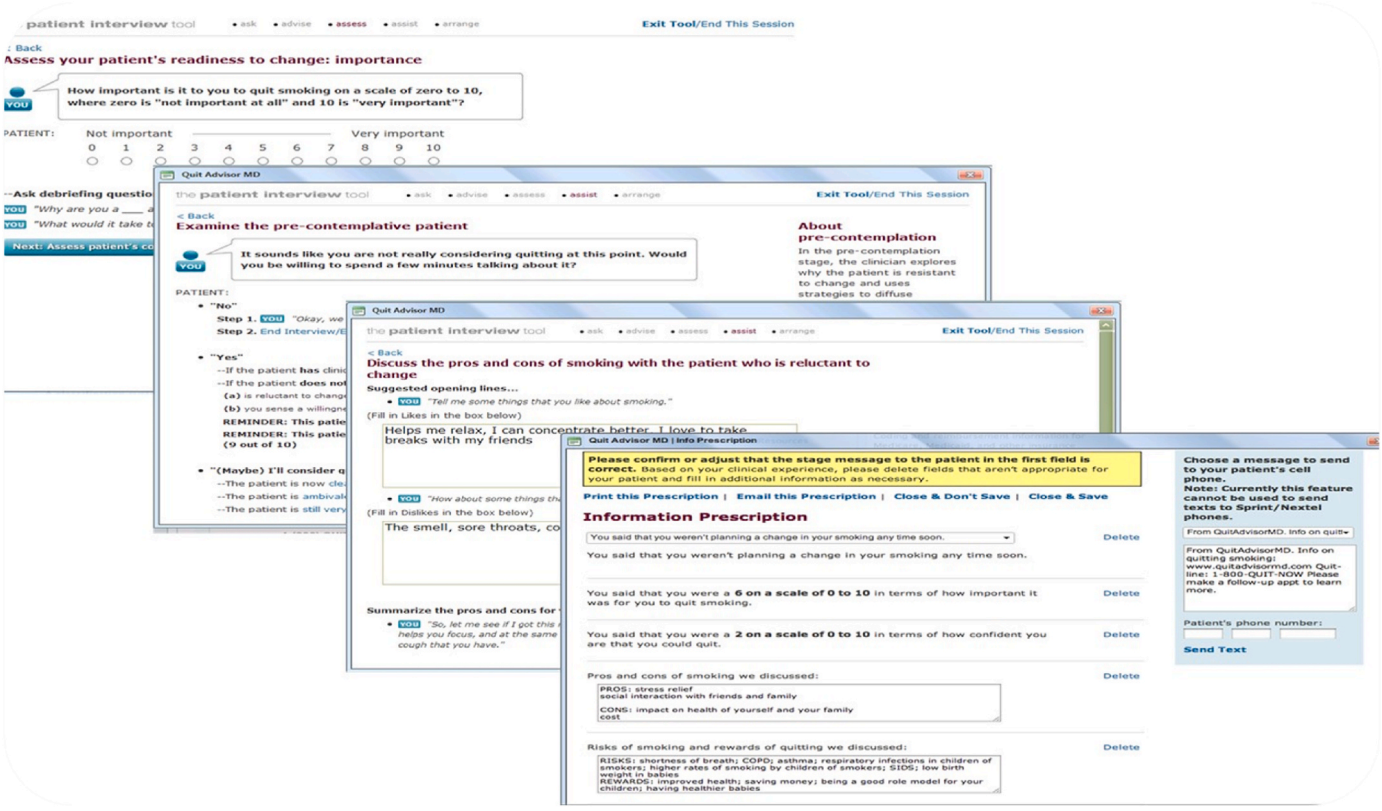

Fig. 3. Sample screen shots from QuitAdvisorMD.
https://www.dropbox.com/scl/fi/wnz3gv1cqzoy6qpesk4vk/QuitAdvisor-usability-video.avi?rlkey=xkwv4ckvmq7hmb0vtz68z7wpb&dl=0

status (Virginia participants) and electronic health record (EHR) reports from Palmetto Health physicians (South Carolina participants). Baseline data will be collected prior to the study and will pertain to the three-month period prior to each clinician's enrollment date. Outcome data will be gathered over the nine-month study period.

3.5.2. Secondary outcomes

Evaluate differences in appropriate stage-based smoking cessation counseling interventions between clinicians in the intervention and control groups. The differences in appropriate stage-based smoking cessation assistance will be measured by mean differences in practices using QuitAdvisorMD and clinicians in the control group through trained assessor reviews of standardized patient encounters using a previously validated MI-based smoking cessation counseling assessment tool [46].

Additional survey-based measurements (previously validated clinician survey on behavior, self-perceived efficacy and comfort, knowledge and attitudes [52], and patient survey of 5-A's performed during physician visit and satisfaction with visit) will include: mean pre- and post-test difference in the change in knowledge, attitudes, self-perceived efficacy and comfort, self-reported smoking cessation counseling behaviors (e.g. 5-A's), and number and quality of patient reported smoking cessation interventions by clinicians in practices using QuitAdvisorMD and clinicians in the control group.

Differences in patient quit attempts will be measured by the mean difference in the number of prescription and OTC smoking cessation products prescribed to patients of clinicians in practices using QuitAdvisorMD and patients of clinicians in the control group. Patient quit attempts from personal reports in phone surveys of 1000 patients who are identified as smokers in the billing records will also be measured. These surveys will provide detailed follow-up on quit attempts and successes for patients of clinicians enrolled in the trial (see sample size calculations in section 3.7.3 below).

3.6. Sample size calculations for primary outcome

Billing data from ~5500 patients who smoke will be used to understand differences in smoking cessation counseling among intervention and control practices. Correlation among smoking patients within the same practice will be taken into account using intra-cluster correlation at the practice level. Assuming the intra-cluster correlation ranging from 0.03 to 0.20, with the 2750 smoking patients per arm, the minimum detectable effects (%) using a one-sided 0.05 significant level at 80 % power for the range of cessation rates are shown in Table 2. Thus, this study will be powered to detect effect size ranging from 5.8 % to 15.6 % with 80 % power.

3.7. Sample size calculation for secondary outcomes

3.7.1. Clinicians

Clinician smoking cessation counseling behaviors, self-perceived efficacy and comfort, knowledge and attitudes will be measured via pre-test and post-test questionnaires. A total of 100 clinician surveys (50 intervention/50 control) will be used to measure differences in these

Table 2
Intra-cluster correlation and smoking cessation counseling rate (%) associated effect sizes.

Rate (%) in Control Group	Intra-cluster correlation				
	0.03	0.05	0.10	0.15	0.2
50 %	6.89	8.44	11.4	13.68	15.59
45 %	6.9	8.47	11.47	13.8	15.76
40 %	6.84	8.42	11.43	13.78	15.77
35 %	6.71	8.27	11.27	13.62	15.62
30 %	6.5	8.03	10.98	13.31	15.29
25 %	6.21	7.68	10.54	12.82	14.77
20 %	5.8	7.2	9.93	12.12	14.02

outcomes. With two groups of 50, ($\alpha = 0.05$, $\beta = 0.2$, two-sided), this study will be powered to detect a difference of 0.280 units for knowledge scale (total scale score range = 0–5), 1.730 units for behavior scale (total scale score range = 0–27), 0.733 units for attitude scale (total scale score range = 4–28), and 1.385 units for physician comfort/self-efficacy scale (total scale score range = 4–28).

3.7.2. SP encounters

Appropriate stage-based smoking cessation counseling will be measured by SP encounters. A total of 100 clinician encounters (50 intervention/50 control) will be used to evaluate any differences between intervention and control clinicians. Assuming the intervention rate in the control group ranging from 40 % to 80 %, using a two-sided 0.05, this study will be able to detect group differences ranging from 22 % to 27 % with 80 % power.

3.7.3. Patient quit attempts and satisfaction

Patient quit attempts and satisfaction with the clinical encounter will be measured by the UVA Center for Survey Research (CSR). The CSR will contact 1000 patients, by phone, who are identified as smokers via billing data and who visit participating clinicians during the study period. These patients will be contacted at one, three, and six months after their visit. We expect ~1000 smokers to be approached and 60 % to participate. With 600 patients we will have 80 % power to detect differences in smoking quit rates between groups ranging from 6.21 % (assuming 5 % quit rate in the control group) to 8.38 % (assuming 12 % quit rate in the control group).

3.8. Statistical analyses

3.8.1. Primary outcome

The primary outcome defined at the patient level will be whether smoking patients receive cessation counseling. Because data from smoking patients seen in the same practices may be more correlated, we will use the generalized estimating equation approach and a generalized linear mixed-effects model to assess the intervention effect while taking this clustered structure into account. The response variable will be the log odds of receiving smoking cessation counseling and the independent variable will be the indicator variable for intervention. Since patient characteristics may not be perfectly balanced between the two groups, the adjusted intervention effect will be examined in the same models with patient characteristics included as covariates. The odds ratio will be used to interpret the intervention effect, and in addition, intra-cluster correlation will be estimated.

3.8.2. Secondary outcomes

3.8.2.1. Evaluate differences in clinician smoking cessation counseling behaviors, perceived self-efficacy and comfort, knowledge and attitudes. The distribution of scores will be generated for each group and examined for substantial departures from normality, as well as for measures of central tendency and dispersion. Depending on the extent to which the data are normally distributed, the intervention and control groups will then be compared on the subscale scores (behaviors, self-perceived efficacy, comfort, knowledge and attitudes) using an appropriate parametric or non-parametric test. We will conduct repeated measures analyses of variance using both pre- and post-test self-efficacy scores, in order to detect any additional effect in the intervention group using QuitAdvisorMD, whether additive or multiplicative. Because we have no a priori estimate of the likely correlation of pre-to post-scores, this will be an exploratory analysis, and the primary test will be between groups on post-scores.

We will conduct an Analysis of Covariance (ANCOVA) if there is need to adjust for covariates that may differ between the two groups. The dependent variable will be the post-test score and the independent variables will include the indicator variable for the intervention group, value of pre-test score and additional covariates including physician age, gender and specialty. The difference between two groups will be on post-scores while adjusting for pre-test scores and clinician covariates.

3.8.2.2. Evaluate appropriate stage-based smoking cessation counseling using SP encounters. The appropriateness of clinician stage-based smoking cessation counseling will be addressed through the standardized patient visit. To be classified as having met the criteria, clinicians have to: 1) assess the patient's readiness to quit smoking, 2) advise patients to quit smoking, including personalizing risks, and 3) assist patients with smoking cessation through stage-appropriate counseling, including exploring decisional balance. In addition, clinicians must not have provided assistance clearly inappropriate for the pre-contemplation stage. Each of the 5-A's will be classified as having been met or not. Trained assessors will evaluate the audio-recordings of these interviews using a standard form and guide to evaluate achievement of these objectives.

The proportion of clinicians offering correct stage-based assistance to the standardized patient will be contrasted in the intervention and control groups. The proportion achieving correct assistance will be calculated for each group and differences will be analyzed using a chi-square test. Two-sided 95 % confidence intervals will be calculated for each group estimate. Appropriate regression models will be used to control for variables such as: level of experience, gender, age, pre-intervention self-efficacy, etc. Parallel tests will be used to assess other outcomes: proportion making correct stage identification, assessing, advising, assisting and arranging. We will also conduct subgroup analyses, comparing the frequency of device use among those who provide correct assistance to the frequency among those who provide incorrect assistance. These tests will use two-group independent sample comparisons. Non-parametric versions of independent samples tests will be used.

3.8.2.3. Patient quit attempts and patient satisfaction will be evaluated by telephone-based surveys. To examine quit rates and quit attempts between the intervention and control groups in follow-up surveys at 1, 3 and 6 months, we will use a generalized linear mixed-effects model which accommodates clustered data structure (patients clustered within physicians) [53]. In analysis of smoking quit, the response variable is a binary indicator of 1 for quit and zero otherwise while in analysis of quit attempts, the binary response is 1 for quit attempt and zero otherwise. The model includes the random effects for clinician effects and fixed effects for intervention group, the time variable (class variable) for three time points (1, 3, and 6 months), and the interaction term of time and group variables, and additional covariates for patient demographics and co-morbidities. The differences in rates of smoking quit (with the same for rates of quit attempts) between the two groups will be evaluated at each of three time points.

4. Conclusion

Despite 50 years of progress since the first Surgeon General's report on smoking, 28.3 million people in the US continue to smoke [1]. The most recent U.S. Preventive Services Task Force guidelines on smoking cessation recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration approved pharmacotherapy for cessation to adults who use tobacco [19].

However, providers in primary care settings struggle to address patient needs in the time available and they may lack specific knowledge or training to provide effective smoking cessation counseling. Digital health interventions such as QuitAdvisorMD may help to bridge these gaps. QuitAdvisorMD has the potential to facilitate significant health impact yet the effort would remain low as clinicians will be guided

through an intuitive interface that is based on up-to-date clinical guidelines. The software also includes ready access to important tools, including: risk calculators, a nicotine dependency assessment, drug information and dosing, as well as local and national resources for smoking cessation.

The proposed pre-study training sessions and ongoing technical support will enable physicians to become comfortable with the QuitAdvisorMD platform and develop technical competency with the tool. This type of support has been identified as an important component to the success in our previous studies that involved digital health interventions with clinicians [46,52,54,55]. Study methodology incorporates a range of retention strategies, including reminders, opportunity for practice, feedback and incentives. In particular, feedback has shown to increase use of tobacco-use status codes from 7.5 % to 82 % [51].

In addition, the efficacy of QuitAdvisorMD will be assessed comprehensively in order to gain insight into both the provider and patient outcomes, including pre- and post-test clinician surveys, patient surveys, SP interviews and medical billing data. Since billing data can underestimate content in an encounter [50], we will track billing for multiple levels of intervention, including smoking status and train all clinicians regarding billing codes when they enroll in the study.

Results from this study will provide important insights regarding the ability of a clinic-based, integrated, web-based counseling and management tool to impact both the quality and efficacy of smoking cessation counseling. QuitAdvisorMD could easily be scaled up for delivery through patient portals before patient visits (e.g., via myChart). This tool can also be updated as scientific understanding of the public health impact of the array of novel nicotine products evolves. This, in turn, has the potential to significantly impact the health of the public by decreasing smoking and the significant morbidity and mortality associated with it.

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CRediT authorship contribution statement

Scott M. Strayer: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Austin Barnhardt:** Writing – review & editing. **Lisa K. Rollins:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Writing – review & editing. **Karen Ingersoll:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Writing – review & editing. **Guofen Yan:** Data curation, Formal analysis, Funding acquisition, Methodology, Validation, Writing – review & editing. **Kurtis S. Elward:** Conceptualization, Funding acquisition, Investigation, Methodology, Supervision, Writing – review & editing. **John B. Schorling:** Conceptualization, Funding acquisition, Investigation, Methodology, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Strayer is an inventor of the QuitAdvisor software platform. There is a copyright that is held by the University of Virginia Patent Foundation. If this software is commercialized, there is a possibility that he could receive royalty payments from the Patent Foundation. The remaining authors declare that they have no known competing financial interest or personal relationships that could have appeared to influence the work reported in the paper.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101253.

Video 1QuitAdvisorMD Usability Video

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