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Questions About Quitting (Q²): Design and Methods of a Multiphase Optimization Strategy (MOST) Randomized Screening Experiment for an Online, Motivational Smoking Cessation Intervention

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Abstract

Effective interventions are needed to improve smokers' motivation for quitting, treatment utilization, and abstinence rates. The Internet provides an ideal modality for delivering such interventions, given the low cost, broad reach, and capacity to individually tailor content, but important methodological questions remain about how to best design and deliver an online, motivational intervention to smokers. The current paper reports on the intervention, study design and research methods of a randomized trial (called Questions about Quitting) designed to address some of these questions. Using a Multi-phase Optimization Strategy (MOST) screening experiment, the trial has two key aims: to examine the impact of four experimental intervention factors (each evaluated on two levels) on smokers' subsequent treatment utilization and abstinence, and to examine select moderators of each sub-factor's effectiveness. The experimental factors of interest are: navigation autonomy (content viewing order is dictated based on stage of change or not), use of self-efficacy based testimonials (yes vs. no), proactive outreach (reminder emails vs. no emails), and decisional framework (prescriptive vs. motivational tone). To our knowledge, this is the first application of the MOST methodology to explore these factors or to explore the optimal design for a motivational intervention targeting smokers not actively trying to quit smoking. The rationale for the experimental factor choice, intervention design, and trial methods are discussed. Outcome data are currently being collected and are not presented, but recruitment data confirm the feasibility of enrolling smokers at varying stages of readiness to quit.

Keywords

smoking cessation; Internet-based treatment; treatment tailoring; MOST; behavioral research

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1. Introduction

Smoking remains one of the leading preventable causes of death and illness in the US, affecting one in five US adults [1]. While effective treatments for nicotine dependence exist [2], these programs are typically designed for smokers who are ready to quit and seeking treatment. Unfortunately, the majority of smokers have no interest in quitting smoking in the near future [3, 4] and only a small proportion of all smokers (<17%) actively seek treatment each year [5]. Thus, effective interventions are needed that target those smokers who are not actively thinking about quitting or seeking treatment to motivate them to want to quit and to take advantage of existing treatment programs.

The Internet provides an ideal venue for delivering population-based, motivational interventions for smoking cessation since nearly 80% of U.S. adults are Internet users [6]. Internet-based programs also have many advantages including: broad reach (content can be accessible on a population level), reduced cost (after the program is developed, cost of delivery is minimal compared to in-person screening and counseling), privacy (the program can be accessed in the privacy of one's home), and content can be personalized, which in turn, can potentially increase the effectiveness [7]. However, more research is needed to inform the optimal design of Internet-based motivational interventions for smoking cessation. That is, what are the optimal strategies for presenting content? Should people have full access to all intervention materials at once, or should content access be dictated based on one's readiness to change? Should people receive prompts or reminders to return to the intervention website periodically, or would doing so be an annoyance? Do testimonial stories designed to model appropriate self-efficacy skills enhance outcomes as theorized [8]? Are the answers to these questions the same for everyone, or do they vary by important individual characteristics (e.g., age, education, gender, need for cognition, etc), which suggests that different strategies should be used for different people? Finally, should the tone of the content be prescriptive (i.e., explaining to people what to do and how to do it), as is typical in public health interventions, or motivational (i.e., providing support and encouragement to help people make their own informed decisions about what they should do and how) as has been recommended by others [9] and is considered by some to be more patient-centered? These are just a few of the questions that the Questions about Quitting (Q²) study aims to address in the context of an online smoking intervention.

This paper describes the design, rationale, methods, and experimental intervention of the Q² study. Recruitment data is also presented; however, since the study is ongoing, outcome data are not presented. Ultimately, results from this research will inform whether each of the four experimental factors described below is important for intervention outcome (cessation treatment utilization and abstinence) in the current study, and for whom. Findings could advance our understanding of how to design maximally effective motivational interventions for smoking cessation. The study design and results also have applicability to other online health behavior change interventions.

2. Methods

In this paper we refer to Q² as both the name of the randomized trial and the name of the experimental intervention website. The experimental intervention was designed by researchers at the Group Health Research Institute (GHRI) and University of Michigan's Center for Health Communication's Research (CCHR) with funding from the National Cancer Institute. Below we describe the experimental study design, primary analytic aims, and intervention content.

2.1 Overview of Aims and Experimental Design

The Q² study has two key aims: to examine the impact of the four experimental intervention factors described below on smokers' subsequent treatment utilization and abstinence and to examine select moderators of each sub-factor's effectiveness which could inform future intervention tailoring. Results will inform planning for a subsequent randomized comparative effectiveness trial to evaluate an 'optimized' intervention design based on the study results against a usual care control website.

Q² uses a relatively new methodological framework called the Multiphase Optimization Strategy (MOST) [10–14]. The MOST methodology, rooted in engineering, agriculture, and behavioral science, is a principled and comprehensive framework for optimizing and evaluating behavioral interventions [11]. MOST uses a multiphase strategy consisting of a series of screening, (optional) refining, and confirmatory experiments to identify, fine-tune, and confirm effective intervention factors [10–14]. The first two of these phases typically use a factorial or fractional factorial design, allowing one to explore main effects and important interactions among factors [15]. In the final experimental phase, the 'optimized' intervention, based on the findings from the initial phases, is compared against a control intervention. Thus, this experimental strategy allows both the identification of important intervention components, as well as a standard test of the comparative effectiveness of the complete, optimized intervention versus a usual care or control program.

A chief advantage of the MOST methodology is greater experimental efficiency, resulting in fewer overall resources than would be necessary to answer the experimental questions using a traditional approach to intervention development [11, 12]. In the traditional approach, a multi-component intervention is evaluated in a randomized trial, and if it is effective, additional studies may be conducted to disarticulate the intervention components and test their individual effectiveness. If done in a systematic and controlled manner, the effective treatment components can emerge. However, this follow-up process rarely happens systematically. Interventions that are not significant often get shelved or discarded rather than investigators seeking to identify individual components that may have undermined treatment effectiveness. The same can be said when interventions are shown to work. It is rare that additional effort is expended to identify the selected 'active ingredients' versus 'inactive' or extraneous components. This level of understanding is needed to advance the science of creating online and tailored health behavior change interventions.

The types of factors examined in a MOST screening experiment can vary, but they should be guided by important theoretical questions as to which variables, or level of certain variables, are necessary to increase effectiveness. For online interventions, key variables for investigation include content and presentation factors (e.g, how content is presented and how often). These can be rooted in theory or have an empirical basis, but it is unknown how effective that factor will be when delivered online or with a new target population. This is the purpose of Q² -- to evaluate the effectiveness of the four experimental factors in the context of an online motivational intervention for smoking cessation.

While there are distinct advantages to the MOST multiphased approach to intervention design, there are also disadvantages. A chief limitation is that the factors chosen for the screening and refining experiments must be distinct from one another, so that each can be evaluated independently. If the exposure or dose of one factor is crossed with another (i.e., a participant is exposed to each at the same time or in an inextricable manner), then it is not possible to evaluate the effects of each factor. This is an important consideration in choosing which intervention factors to pair with one another in the experimental design. Readers interested in a more thorough review of the MOST methodology are referred to several papers by Collins and colleagues [11–13, 16].

2.2 Experimental Factors and Planned Comparisons

In this initial MOST ‘screening experiment’, four experimental factors are being evaluated, each on two levels. The result is a 16-arm factorial design (see Table 1). Each of the factors is described below and detail on how each factor level is implemented is described in section 2.5. We had originally planned to include a fifth factor (gain versus loss framed risk/benefit messaging), but this factor was dropped during content development after we concluded that it was not possible to present only gain vs. only loss framed risk messages without compromising the integrity of the other factors. In writing the treatment content we realized that risk and benefit messages needed to be included in two other factors (testimonials and decisional framework), which would later prevent our ability to examine the independent effects of these factors. Thus, we elected to drop gain/loss message framing as an experimental manipulation.

Navigation Autonomy—An important empirical question is whether it is better to dictate what content smokers are exposed to and the presentation order of that content, or allow them to choose content based on what they feel is most relevant to them. Dictating content order could ensure that smokers are exposed to content deemed theoretically most relevant to them and, therefore, be more effective. This is the rationale for stage-matched interventions (i.e., those in which the content is matched to people’s stated motivation and readiness to quit smoking). Allowing people to choose the content they review, however, may result in people being exposed to a greater breadth of information, and could increase program satisfaction and engagement, thereby improving outcomes.

In this study, we will test which form of program exposure and navigation is more important to our treatment outcome. Participants are randomized to either receive content in a dictated order, chosen based on their self-reported stage of readiness to quit, or they have autonomy to access all program content in the order that they choose, regardless of their present stage of change. Studies assessing the use of print-based stage-matched materials have shown these materials to be effective at promoting abstinence compared to no intervention [17]; however, studies comparing the effectiveness of stage-matched to mismatched interventions across health behaviors have yielded mixed results [18–24]. Thus, the evidence is not clear whether dictating content in this way necessarily leads to greater behavior change. We believe Q² is the first study that will examine this issue in the context of an online intervention.

Testimonials—In our previous research, we found that highly-tailored narrative testimonials (e.g., vignettes presented from the standpoint of a fellow smoker or ex-smoker addressing relevant issues such as reasons for quitting, how to quit, and relapse prevention) were associated with higher abstinence rates at 6 month follow-up among motivated quitters using an online treatment program [25]. In Q², we will compare participants who receive highly-tailored testimonials designed to enhance self-efficacy for quitting smoking and staying abstinent versus those who receive no testimonials to see if the inclusion of this content improves outcomes when smokers are not actively seeking treatment to stop smoking.

There are several explanations why narrative testimonials focused on self-efficacy should be effective. Narrative testimonials can evoke emotion [26], impact beliefs [27], and teach new behaviors [28]. They are also particularly well-suited for challenging strong attitudes which are otherwise resistant to change [29] and can be effective as a means of modeling behavior and influencing perceived self-efficacy [8]. Put simply, people learn from watching, listening to, or even reading about others. In this way, others’ experiences can inform one’s perceived outcomes for behaviors (i.e., what will happen if I do that?) and whether or not it

is something they can do (i.e., do I have the skills and knowledge to do that?). Social Cognitive Theory posits that these outcome and efficacy expectations, in turn, influence the extent to which a person will engage in a behavior and how hard they will persist at trying to succeed in the face of difficulty. Shaping these expectations is generally considered a critical component of motivational interventions. We will test this assumption in the current intervention.

Proactive outreach—Another unknown for this type of intervention is the extent to which proactive outreach is important or detrimental to program engagement and treatment outcome. For example, we presume that viewing the program content on a single occasion may not provide adequate motivation for most people to want to quit smoking and seek treatment, let alone make a successful quit attempt. If true, then continued proactive outreach via email could help support this process. Emails could be used to push content to participants emphasizing relevant tips and information about quitting, providing supportive messages, etc. On the other hand, continued emails could be seen as annoying and deter people from returning to the website or wanting to quit.

Decisional Framework (aka, message tone)—Public health interventions tend to be prescriptive in nature. It is particularly common for smoking cessation messages and interventions to take a prescriptive tone, advising smokers that they need to quit smoking and instructing them how to do this. However, this approach does not recognize smokers' preferences or needs in the decision making process, and it can be off-putting to smokers who are ever-deluged with messages about the risks and offensiveness of smoking and increasing social stigma. For these people, prescriptive messages may lead to greater resistance and avoidance, rather than motivating cessation.

A contrasting technique used to motivate behavior change is motivational interviewing (MI) [9]. According to recent meta-analyses, MI can be effective for promoting change across a range of health risk behaviors [30–35]. While the full complement of MI counseling techniques is impossible to implement in an online program, we hypothesized that an intervention designed around the basic principles of MI (using a non-confrontational approach, recognizing and accepting one's ambivalence for change, developing discrepancy, creating a sense of collaboration, and honoring one's autonomy in the decision making process) would be more acceptable to smokers, result in greater program engagement, and therefore result in greater motivation for quitting, treatment utilization, and abstinence.

Planned Comparisons—We will compare the independent effects of each of the four experimental factor levels as described above. In addition to exploring main effects, Q^2 is also designed to assess the effect of interactions between the factors. We will evaluate the effect of all two way interactions between the factors on outcomes. Select treatment moderators and mediators will also be explored (see further discussion below).

2.2 Setting and Population

This study is a collaboration between Group Health Research Institute and the University of Michigan Center for Health Communications Research. Participants were recruited from Group Health, a large, regional non-profit health plan in the Pacific Northwest. All research materials (intervention materials, surveys, and protocols) were approved by the institutional review boards at Group Health and the University of Michigan. The study is registered with clinicaltrials.gov (NCT00992264).

2.3 Recruitment, screening, randomization, and enrollment

Recruitment occurred from May 2010 through November 2011. Adult likely smokers were identified from automated health plan records and were mailed a study invitation letter including a brief description of the study, the URL for the study website, a unique access code for each person, and a \$2 bill pre-incentive. Interested smokers were instructed to visit the website to learn more about the study and be screened for eligibility. People were eligible if they were 18 or older, a current member of Group Health, had smoked 100 cigarettes in their lifetime, smoked even a puff in the last 7 days, averaged at least 5 cigarettes per day, were not currently enrolled in a smoking cessation program or taking medication to stop smoking, had access to the Internet for personal use, were willing to check their email at least once a week, were comfortable reading and writing in English, had no visual impairments that prevented reading text on a computer screen, and were comfortable using a computer and the Internet.

People who were eligible reviewed the consent form online and provided consent by typing in their name and clicking a box that read “I agree.” An electronic copy of the consent form was available for people to read online or download throughout the study period. After consenting, individuals set up an account by providing their phone number, email address, and mailing address. Participants had to click on a link in an automated email to activate their account. This ensured that valid email addresses were provided for all participants. Upon account activation, participants completed a baseline assessment online and were then randomized to treatment (see Table 1), stratified by their baseline readiness to quit smoking (in the next month, in the next 6 months, or not at all). Participants were immediately able to access their personalized intervention program following the baseline assessment.

2.4 Intervention

2.4.1 Overview of Design and Layout—Consistent with Social Cognitive Theory, the Q² program is designed to enhance motivation for quitting by increasing positive outcome expectations for quitting, increasing self-efficacy for seeking treatment and quitting, and reducing perceived barriers to behavior change. Content includes material addressing the risks (e.g., withdrawal, cravings, etc.) and benefits of quitting smoking (e.g., health, financial, social, etc.), perceived barriers to treatment, perceived barriers to quitting (e.g., stress relief, weight concerns, enjoyment), strategies for reducing smoking, how and where to seek treatment, how to quit, what treatments are shown to be effective, and how to remain abstinent once quit.

The intervention content is organized in three main sections based on various stages of readiness to quit smoking: not ready to quit, ready to quit, and already quit (see Figure 1). Each section contains a drop down menu and content relevant to people at that stage of readiness. Content in each section is consistent across participants with the exception that it varies based on random assignment to the four experimental factors (described further below) and within each randomization arm, content is individually tailored based on each participants' demographic, smoking history and psychosocial data (e.g., stage of change, self-efficacy, motivation, values, perceived risks and benefits) collected at baseline. Prior research has shown that smokers react more positively to intervention materials when they believe content has been tailored to them personally [36]. For this reason, most pages also contain a text box at the top of the page summarizing key information about the individual that was used to tailor content on that page. Upon each return visit, participants are asked to indicate their current readiness for quitting (not ready to quit, ready to quit, have already quit). Content on the site is then updated to reflect each person's current motivation, or readiness to quit smoking.

Additional untailored content is included in a fourth content section called, ‘Special Features.’ In this section, participants can access information on a range of health topics of relevance to smokers, but not necessarily focused on quitting smoking (e.g. stress management, alcohol, weight gain, physical activity) and printable worksheets and tracking logs for monitoring one’s behavior. This content is included to increase the program’s relevance to smokers not ready to quit and encourage ongoing use of the Q² website.

2.4.2 Implementation of Experimental Intervention Factors—Each participant’s intervention is influenced by their assigned experimental factors, which further dictates what content is provided, how it is presented, and whether or not participants are prompted to return to the site after their initial visit. Implementation of each factor is discussed briefly below.

The **navigation autonomy** factor manipulates whether people can freely access all the content on the website immediately (i.e., content availability and order was not-dictated) or whether they have to first view the content section that matches their current stage of readiness before viewing additional content (i.e., content availability and order were dictated). This restriction is explained to participants when they first visited the intervention website. In addition to the dictated order, other subtle visual cues are used in the ‘dictated’ group. For example, small images of padlocks are placed over the sections not yet available for viewing, available content is numbered in each drop down menu to reflect the correct order of viewing (and out of order viewing was not allowed until all content had been viewed at least once), and progress indicators are included for each section heading to indicate how much of the content had been viewed. These cues are not included in the ‘non-dictated’ group.

Half of participants also receive three highly-tailored **testimonials** designed to promote self-efficacy, while the other half do not receive any testimonials. For participants in the testimonial arm, each of their three drop-down content menus includes a link to a testimonial that is matched to their current stage of readiness. Each testimonial is presented in an interview format using a series of questions and answers from the respondent depicted in the testimonial. Each testimonial focuses on ways of coping with or overcoming barriers to quitting and includes a photo of the respondent matched to the participant’s age, race, and gender.

Participants are also randomized to receive personalized, **proactive outreach** emails on a regular schedule or none at all. All participants receive an initial welcome email and reminders to complete follow-up surveys. Participants in the proactive outreach group, however, also receive approximately 18 additional emails to encourage return visits to the Q² site. These emails are sent every other week for two months, and then once a month for the remainder of the 12-month intervention period. Each includes a brief supportive message or tip about quitting smoking, including encouragement to return to the website for more information. Emails highlight one of the Special Features and are intended to keep people interested in the site, encourage them to come back to the site, and revisit content that might help them quit or stay quit.

Decisional framework (message tone) is the most involved of the four experimental factors. Half of participants receive content that is presented in a tone and style consistent with key principles of MI (express empathy, develop discrepancy, roll with resistance, support self-efficacy) and half receive messages that are written in a prescriptive, didactic tone. For example, regardless of one’s readiness to quit, content presented using the motivational framework recognizes and accepts individual’s potential ambivalence about quitting and their autonomy in making decisions about if, how and when they would quit smoking. In

contrast, prescriptive content clearly recommends quitting smoking and provides guidance on how to accomplish this goal. Different presentation strategies are also used to elicit motivation for quitting in a non-confrontational style (motivational group). For example, participants in this group are presented with open ended questions and encouraged to type in responses to help develop discrepancy and engage them in making an informed decision for themselves. Content is also presented in layers using embedded links which allow one to consecutively drill deeper into a topic rather than viewing all content at once. This technique is used to honor individuals' autonomy to review what information they want to see.

To guide treatment development, we modified the Motivational Interviewing Treatment Integrity (MITI) rating scale [37] to allow us to judge the extent to which each web page is consistent with the core principles of MI (expressed empathy, used affirmations, reflected a spirit of collaboration, shared information without confronting or offering advice, supported autonomy, evoked the participants' own ideas and reasons for change, reflected personal content, remained non-directive, asked permission, and used open ended questions). Two Master's level raters, each trained in MI, independently assessed each content section on each of the dimensions above using a 1–7 rating scale where higher scores reflected more optimal operationalization of MI principles. Results were compiled by a third person and any section or items scored as less than a 5 by either reviewer and/or that were discrepant between reviewers by 3 or more points were revised to increase their alignment with the spirit of MI.

3. Assessment Methods and Outcome Measures

Participants complete a total of four online assessments: a baseline assessment and follow-up surveys at 2, 6, and 12 months post-enrollment. The baseline assessment includes main outcomes and analytic variables, as well as items used to individually tailor participants' intervention content. Variables that are subject to change over time and all main outcomes are reassessed at each follow-up. Table 2 provides a summary of the constructs assessed at each time point. Primary and secondary outcomes are also noted.

Our first primary outcome, utilization of a comprehensive treatment program for smoking cessation at any point in the 12-month follow-up period and available to all participants through their health insurance, will be assessed using automated claims data. As such, it will be available for all participants regardless whether they complete the follow-up assessments. Our primary outcome for smoking cessation will be self-reported point prevalent abstinence measured at 12 months after baseline. This measure is recommended in trials like Q² where participants may not be actively trying to quit smoking [38]. Biochemical confirmation of smoking status is also not considered necessary in large, population-based trials with little to no face to face contact and when there are low demand pressures for people to misreport abstinence [39], as in the Q² trial. Moreover, attempting to collect biospecimens to determine smoking status in trials of this nature can inappropriately bias outcomes, since failure to provide biospecimens by mail is often related to patient factors other than smoking status (e.g., moved, deceased). As such, we will not attempt to biochemically confirm reports of not smoking. Per convention, we will code non-responders as smokers for our primary analysis; however, given the inherent potential bias of this method [40], we will perform a respondent only analyses in the event of high attrition.

Although failure to participate in the follow-up surveys will not impact the data available for the two primary outcomes analysis, it could pose challenges for secondary analyses. Study retention is a known problem with longitudinal online interventions. To promote retention, participants receive a combination of mail and email reminders prior to each follow-up assessment and a \$10 incentive following completion of each assessment. Despite these

efforts, retention rates appeared to be trending lower than expected (< 75% at each time point) mid-study, so we introduced a lottery drawing for a \$100 gift card and phone follow-ups to boost retention at 6 and 12 months. All participants who complete the follow-up surveys are entered into the one time lottery drawings, which will occur following completion of data collection. Participants who do not respond to email or mail prompts are also contacted by phone to assess main outcomes.

4. Sample Size Considerations and Overview of Planned Primary Analyses

The study is powered to detect a difference of 5% between each contrasting factor level for each of the primary outcomes using a two-sided test comparing two sample proportions with alpha set at 0.05. We expect the overall 12 month abstinence rate will be 15%. This appears reasonable based on prior meta-analyses demonstrating abstinence rates are approximately 10.5% for minimal self-help intervention, to 14.6% for behavioral counseling alone, and can range from 21.8% to 32.5% when counseling is combined with medication (depending on the intensity of the counseling) [2]. In the current study all participants receive an active intervention plus referral to a comprehensive treatment program which includes counseling and medication, if participants choose to use it. However, we expect only about 15% will utilize the additional treatment based on our prior research evaluating other motivational interventions targeted to smokers at all stages of readiness to quit [41, 42]. Under these assumptions we will have 85 percent power to detect significant differences with our enrolled sample of 1865 participants. The power for detecting 2-way interactions is 85 percent for differences of 7.0%.

We will use logistic regression to estimate the main effects and two-way interaction effects for each of the factors on our two primary outcomes, controlling for stage of change and other baseline demographic factors. First, we will test the main effects of each of the four factors. For each main effect half of the study population will have been randomized to one level of the factor and half will have been randomized to the other level of the factor; thus, the full sample size can be used to test each the main effects. After testing for main effects we will then test the six two-way interactions. If intervention utilization rates are low, we will perform a modified intent-to-treat analysis [43, 44] as a secondary analysis to estimate the main effects and two-way interactions on the primary outcomes in those individuals who were exposed to a minimum level of the intervention, based on automated utilization data. Additional subsequent analyses will explore differences in secondary outcomes of interest including quit attempts, motivation for quitting, and self-reported use of any best practice smoking cessation treatment. Finally, we will explore potential moderators of any main effects on our primary outcomes using baseline characteristics such as demographics, stage of change [45], nicotine dependence [46], perceived risk, and need for cognition [47]. Data on select mediators of outcome (e.g., Q² program utilization, satisfaction, self-efficacy) are also being collected and will be explored. For example, we expect utilization will be particularly important for navigation autonomy. Participants who must view content in a dictated order may have less overall exposure to the treatment content than people who are given free access to view any of the web pages at any time and in any order and thus, worse outcomes. Similarly, the effect of decisional framework (message tone) may be mediated by one's satisfaction with the intervention. Ultimately, we expect any significant effects will be mediated by an increase in participant's self-efficacy for quitting smoking.

5. Results on Recruitment and Baseline Characteristics

A total of 47,675 people were invited to visit the Q² website and be screened for study eligibility. The recruitment flow is included in Figure 1. Characteristics of the final enrolled sample (n = 1,865) are provided in Table 3.

6. Discussion and conclusions

This study attempts to advance the field in two significant ways - it is the first study we are aware of designed to identify components of an online intervention that enhance motivation for quitting among non-treatment seeking smokers or to use the MOST methodological framework for this purpose. Enrollment is complete and long term data collection ongoing. We successfully recruited smokers at various stages of readiness to quit smoking; nearly two-thirds of participants had no plans of quitting in the near future at baseline assessment and many had no plans of quitting at all. This is an important and encouraging finding, demonstrating our ability to reach a critical segment of smokers. Among persons who initially visited the study website in response to the study invitation letter, interest in the program was also high. Ninety-one percent chose to be screened for eligibility and 83% of those who were eligible enrolled in Q². This is consistent with previous research, which found that 63% to 85% of eligible smokers proactively contacted and invited to participate in treatment did so [42, 48–51].

Future study results will inform to what extent each experimental factor increased utilization of subsequent smoking cessation treatment or abstinence at one year. Subgroup analyses will explore for whom each factor level is most effective, which will inform the personalization of tailored interventions in the future. This manuscript provides an overview of the Q² design and methods and may be useful to other researchers developing web-based treatment programs or considering the MOST methodological framework for their research.

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Figure 1.
Recruitment Flow

^a Reasons for ineligibility are not mutually exclusive.

Table 1

16-arm Randomization Scheme

Arm	Decisional Framework	Self-efficacy Testimonials	Proactive Emails	Navigation Autonomy
1	Prescriptive	On	Yes	Yes
2	Prescriptive	On	Yes	No
3	Prescriptive	On	No	Yes
4	Prescriptive	On	No	No
5	Prescriptive	Off	Yes	Yes
6	Prescriptive	Off	Yes	No
7	Prescriptive	Off	No	Yes
8	Prescriptive	Off	No	No
9	Motivational	On	Yes	Yes
10	Motivational	On	Yes	No
11	Motivational	On	No	Yes
12	Motivational	On	No	No
13	Motivational	Off	Yes	Yes
14	Motivational	Off	Yes	No
15	Motivational	Off	No	Yes
16	Motivational	Off	No	No

Table 2

Key assessment constructs and timing

Assessment Constructs	Role ^d	Baseline	2 month	6 month	12 month
Demographics		X			
Medical history		X			
Social support and family smoking status		X			
Coping strategies		X			
Perceived competence		X			
Preferences for physician interaction		X			
Need for cognition		X			
Importance of quitting		X	X	X	X
Self-efficacy for quitting smoking		X	X	X	X
Barriers to quitting smoking		X	X	X	X
Perceived risks & benefits of smoking & quitting		X	X	X	X
Outcome expectations of smoking		X	X	X	
Nicotine dependence		X	X	X	X
Q2 utilization and exposure ^b					
Abstinence	Primary & Secondary Outcome ^c	X	X	X	X*
Cessation treatment utilization	Primary & Secondary Outcome ^d	X	X	X	X*
Motivation for quitting	Secondary Outcome	X	X	X	X
Cigarettes per day	Secondary Outcome	X	X	X	X
Readiness to change/motivation for quitting	Secondary Outcome	X	X	X	X
Quit attempts	Secondary Outcome	X	X	X	X
Program evaluation measures	Secondary Outcome		X	X	X

^a Most constructs were used in tailoring intervention content at baseline. Constructs assessed at follow-up and not designated as primary or secondary outcomes will be explored as potential moderators or mediators of treatment outcome, as appropriate.

^b Q2 utilization will be tracked using automated data on the frequency and duration of website visits.

^c Primary outcome assessed at 12 months. Secondary outcomes assessed at 2 and 6 months.

^d Assessed via automated health plan data at 12 months (primary outcome) and self-report at follow-up (secondary outcome).

Table 3

Participant Characteristics at Baseline

Variable	n	%
Gender		
Female	1,177	63.1
Male	688	36.9
Age		
18–34	558	29.9
35–54	767	41.1
55 - older	540	29.0
White, non-Hispanic		78.2
Employed	1287	69.0
Stage of Change		
Precontemplation	234	12.6
Contemplation	1086	58.2
Preparation	545	29.2
Never tried to quit smoking	227	12.7
No quit attempts in past year	664	35.6
	Mean	SD
Cigarettes per day	15.4	7.4
Nicotine dependence ^a	4.2	2.2

^aFagerstrom Test of Nicotine Dependence, score range 0 – 10.