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Opinion paper

Testing the feasibility of a guided imagery tobacco cessation intervention delivered by a telephone quitline: Study protocol for a randomized controlled feasibility trial

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A B S T R A C T

Background: Guided imagery (GI) is an evidence-based method that uses the imagination to practice and achieve a desired outcome. Little research has focused on how GI can be delivered to smokers using remote or virtual methods, such as a telephone-based intervention. Telephone-based services for tobacco cessation (quitlines) have emerged as standard of care for tobacco cessation. However, quitlines reach only a small fraction of smokers, and men and racial/ethnic minorities are less likely to use quitlines than majority women. GI has the potential to attract underserved minority groups as well as smokers who are looking for an alternative approach to cessation. The present study is designed to test the feasibility and potential impact of a GI tobacco cessation intervention delivered by telephone. This study compares the GI intervention with a standard behavioral (SB) intervention.

Methods: Participants (N = 100) are randomized to either the GI (intervention) or SB (control) condition. Each condition features a 6-week intervention in which participants work with coaches to quit tobacco. Primary outcomes are feasibility related (recruitment, retention, adherence), and secondary outcomes include cessation at 6 months post-intervention (7-day and 30-day abstinence).

Discussion: A GI intervention delivered via quitline would allow for scalability and dissemination, potentially reaching a more representative group of smokers. Results from this study will determine the feasibility of delivering the GI intervention, and describe the reach of the intervention to under-represented tobacco users. If successful, our study results will guide the design and conduct of a future efficacy trial.

1. Introduction

Telephone-based tobacco cessation services (quitlines) are an effective way to reduce cravings for and use of tobacco [1–4]. Quitlines are efficient, highly scalable, and available throughout the United States, yet they are underutilized by smokers. The North American Quitline Consortium reported that 515,000 users, or 1.2% of all smokers, contacted quitlines in 2009, which has remained steady [3,5]. The cost-effectiveness of quitlines has been widely established [1,3,4,6,7]. Despite these findings, many state agencies are cutting funds at a time when there is record utilization of services [8,9]. This situation has prompted many quitlines to focus recruitment on under-represented groups and use alternative intervention approaches in order to increase participant appeal, engagement, reach, and effectiveness [9,10].

One such strategy is the use of guided imagery (GI). GI is a multisensory cognitive process [11] that has been shown to increase motivation and facilitate goal achievement in sport [12] and exercise settings [13]. Using this technique, one imagines pictures, emotions, sounds, tastes, smells, and other sensations associated with the desired outcome. GI can effectively assist tobacco users to quit [14–16]. However, with the exception of our previous work [17], GI interventions have been tested using in-person study methods, which limit their reach and impact. Delivering a GI intervention via a tobacco quitline has the potential to increase disseminability on a population level. GI intervention may also be attractive to those who do not typically utilize quitlines (e.g., men and racial/ethnic minorities). The use of GI among athletes to improve athletic performance may encourage men to try this approach to tobacco cessation. Moreover, the use of GI may appeal to individuals who prefer an alternative or complementary approach rather than an allopathic approach that focuses on the use of cessation medication.

The present study aims to test the feasibility and impact of a telephone-delivered tobacco cessation intervention using GI. Phase 1: We develop the intervention using a rigorous formative process including

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individual interviews, focus groups, and user testing (to be described elsewhere). Phase 2: We conduct a two-group randomized controlled feasibility trial. In this study, customized guided imagery narratives or scripts are created collaboratively with coach and participants over the phone. The use of customized guided imagery scripts has been conducted in other trials [18]. The guided imagery scripts are based on a cognitive and motivational framework that has been supported by psychometric analyses [19] and used in previous studies [13,17].

The randomized controlled feasibility trial (N = 100) gathers preliminary data on the feasibility of delivering a GI tobacco cessation intervention via telephone, and potential impact of the GI intervention on participants' tobacco use. We compare a GI intervention for tobacco cessation with a robust standard behavioral control condition. The primary feasibility outcomes include participant recruitment and retention, adherence to the intervention, use of study materials, fidelity of protocol delivery, collection of salivary cotinine for biochemical verification of tobacco abstinence. Secondary outcomes explore tobacco cessation (self-reported 7-day point prevalence and 30-day prolonged tobacco abstinence measured at 6-months post-enrollment).

2. Materials and methods

2.1. Study design

This study uses a two-group randomized trial design as shown in the Study Flow Diagram (Fig. 1). Participants are recruited through two IRB-approved processes: 1) callers to a state quitline; and 2) targeted community-based recruitment using a Community Advisory Board (CAB), printed materials, and media announcements.

1) The Arizona Smoker's Helpline (ASHLine), Arizona's state quitline, is a partner in our study to recruit potential participants. From July 2017–June 2018, ASHLine reached about 3% of all adult tobacco users in Arizona, receiving 19,137 calls and enrolling 9034 individuals. Of these, most were White women (79% White, 16% Hispanic, 7% African American, 2% American Indian, and 56% female) [20]. The ASHLine, similar to most national quitlines, utilizes a client-directed, outcome-informed approach based on elements of cognitive behavioral therapy and motivational interviewing. In 2017–2018, ASHLine coaches provided an average of 3.5 calls per enrollee, and facilitated provision of nicotine replacement therapy to eligible clients with an overall tobacco quit rate of 38.3% [20].
2) Underrepresented smokers are recruited using tailored recruitment materials, and targeted recruitment strategies (e.g., swap meets, churches, medical providers, etc.) developed in conjunction with our consultants, and with the assistance of our Community Advisory Board. ASHLine and/or study staff screen participants for eligibility, obtain consent, and administer the baseline survey. Study staff use pre-programmed, stratified (on gender), block randomization using statistical software and uploaded to the Research Electronic Data Capture (REDCap; NCATS/NIH UL1TR000445) system to automatically randomize participants upon survey completion. The study protocol allows enrollment and randomization of a minimum of 100 and maximum of 120 feasibility trial participants with randomization of approximately equal numbers per condition. This trial is guided by the CONSORT reporting standards [21] for randomized controlled trials and the SPIRIT guidelines for reporting clinical trial protocols [22] and has been registered with clinicaltrials.gov (NCT0296831). Ethical approval was obtained from the University of Arizona Institutional Review Board (1607731416).

2.2. Participants and setting

Participants are male and female smokers over the age of 18 who are interested in quitting and call the ASHLine or call study staff in response to our targeted recruitment efforts (e.g., flyers, post cards, rack cards or media announcements).

Participants must meet the following inclusion criteria to participate in this study: (1) Current smokers or those whose primary tobacco product is cigarettes; (2) Be at least 18 years of age; (3) Speak English; (4) Have a valid email address and phone number; (5) Be willing to receive telephone coaching; and (6) Ability to understand and comply with study procedures for the length of the study. Participants are excluded from the study if they meet any of the following criteria at baseline: (1) Serious mental illness; (2) Use of the ASHLine in the past 12 months; (3) Currently receiving any form of tobacco cessation treatment; and (4) Refusal to be randomized to one of the study conditions.

All study staff use the REDCap system to collect and track participant data during the study. These data include dates of contact attempts and method of contact (phone, text or email), eligibility/screening information, oral consent documentation, baseline and randomization information, details from every coaching session (i.e., protocols for both conditions), receipt of nicotine replacement therapy, survey responses, incentive payments and biochemical verification results.

2.3. Screening and enrollment

Screening and enrollment occurs in two sequential phases, each lasting four months:

1) ASHLine Recruitment, Screening and Enrollment. Enrollment staff at the quitline are trained by study investigators on the study's recruitment and screening procedures. Callers to the ASHLine are screened and initial informed consent and baseline data collection are obtained by ASHLine staff. All incoming callers who meet the study eligibility criteria at the time of ASHLine's regular intake process are flagged, and a "pop-up" box is displayed to provide a script describing the study. ASHLine staff read the study description to the caller and offer participation in the study. If the caller agrees, ASHLine staff read an IRB-approved short consent document. Potential participants provide verbal consent, and ASHLine staff collect additional study baseline questions. Upon completion of the baseline survey, the study data is securely transmitted from the ASHLine database to the study's REDCap database. Study staff attempt to contact the potential participant within 48 h. Upon contact, study staff describe the study in greater detail, and confirm consent. Participants are emailed the full-length consent for their records.
2) Targeted Recruitment, Screening and Enrollment. Potential participants responding to targeted community recruitment strategies (e.g. IRB-approved study collateral and advertising) either call, email, or visit the study website. Study staff attempt to contact the potential participant within 48 h. Upon contact, study staff describe the study requirements and screen the potential participants for eligibility. Eligible participants provide verbal consent and study staff complete the baseline survey. Participants are emailed the full-length consent for their records

2.4. Randomization and allocation

The REDCap system then randomizes participants to either the imagery intervention condition (IC) or the active control condition (CC) using a stratified (by gender), block randomization table created by a biostatistician using statistical software who has no contact with the participants. The allocation sequence is automated, unpredictable, and concealed from study staff. Following randomization, study staff assigns the participant to an appropriate study coach who then schedules the first session with the participant.

2.5. Intervention and control conditions

Table 1 details the weekly activities and topics for both the IC and

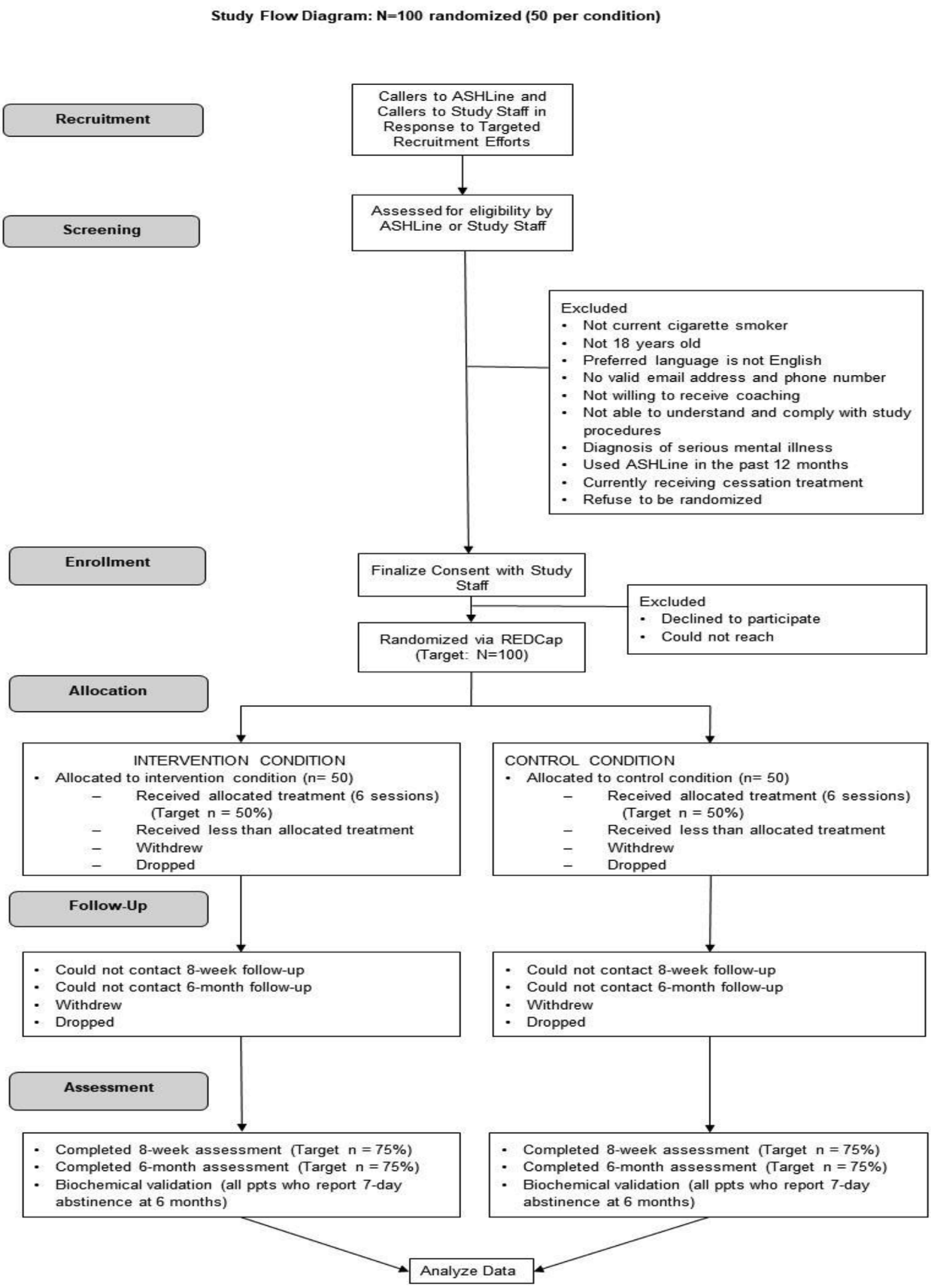

Fig. 1. Study flow diagram.

Table 1
Session goals by condition.

Intervention Condition	Control Condition
Session 1: Intro, Reasons & Benefits **Goals:** Provide basic definition of GI, introduction to breathing and relaxation. Identify participant's primary reason for and benefit of quitting. Develop imagery script related to reasons/benefits of quitting. Set times to practice script. Set quit date.	**Session 1: Intro, Reasons & Benefits** **Goals:** Define and discuss behavioral treatment. Discuss previous quit attempts. Identify participant's primary reason for and benefit of quitting. Develop a plan to review reasons and benefits, and next section of quit booklet. Set quit date.
Session 2: Triggers **Goals:** Review progress and troubleshoot problems. Identify participant's primary trigger, and develop coping strategies. Develop imagery script related to triggers and coping. Set times to practice script.	**Session 2: Triggers** **Goals:** Review progress and troubleshoot problems. Identify participant's primary trigger, and develop coping strategies. Create a plan for practicing coping strategies. Set time to review booklet.
Session 3: Cravings and Withdrawal **Goals:** Review progress and troubleshoot problems. Discuss 2 types of urges (habitual and physiological reaction). Develop strategies to address cravings, create imagery script for dealing with cravings. Explain nicotine replacement therapy (NRT) and order NRT if appropriate. Encourage listening to GI as a new habit. Set times to practice imagery.	**Session 3: Cravings and Withdrawal** **Goals:** Review progress and troubleshoot problems. Discuss 2 types of urges (habitual and physiological reaction). Develop strategies to address cravings, create plan for dealing with cravings. Explain nicotine replacement therapy (NRT) and order NRT if appropriate. Set times to practice behaviors and review next section of booklet.
Session 4: Preparing to Quit **Goals:** Review progress and troubleshoot problems. Discuss use of NRT and preparing environment for quitting. Review imagery script and make changes as necessary. Set times to practice imagery; make it a new habit.	**Session 4: Preparing to Quit** **Goals:** Review progress and troubleshoot problems. Discuss use of NRT and preparing environment for quitting. Review strategies to handle withdrawal. Set time to practice strategies and review next section of booklet.
Quit Date (day before or on quit date) Brief call to remind participant of quit date, provide encouragement and answer any questions.	**Quit Date (day before or on quit date)** Brief call to remind participant of quit date, provide encouragement and answer any questions.
Session 5: Relapse Prevention/Recommit to Quit **Goals:** Review progress and troubleshoot problems. Support quitting among those who quit and encourage quitting among those who didn't or who relapsed. Make changes to scripts. Set times to practice script; make it a new habit. Discuss NRT.	**Session 5: Relapse Prevention/Recommit to Quit** **Goals:** Review progress and troubleshoot problems. Support quitting among those who quit and encourage quitting among those who didn't or who relapsed. Set times to practice behavioral strategies; make it a new habit. Review booklet. Discuss NRT.
Session 6: Next Steps **Goals:** Review progress and troubleshoot problems. Prepare participants to be successful on their own. Make plans for staying smoke free or change plans and quit. Make edits or additions to imagery script if desired. Set times to practice script. Discuss continue use of script. Discuss NRT. Provide GI and relaxation resources.	**Session 6: Next Steps** **Goals:** Review progress and troubleshoot problems. Prepare participants to be successful on their own. Make plans for staying smoke free or change plans and quit. Revise behavioral strategies as needed to address issues that came up during the week. Discuss NRT. Provide resources for quitting or staying quit.

CC. Participants in both conditions receive six telephone coaching sessions delivered over six weeks plus a brief "quit call" on or around the participant's quit date; all of which are conducted by trained quit coaches. Coaching sessions range from 15 to 60 min long, with an average length of 30 min. Sessions 1–3 range from 20 to 60 min, and sessions 4–6 range from 15 to 20 min in length. Participants receive at least one text message reminder before each phone session, one text message summary after each session, and occasional, scripted motivational texts from their coach.

Condition-specific quit booklets with sections that correspond to each of the six phone sessions are sent to all participants in hardcopy and available on the study website. The booklets are customized to focus on the definition, use, and applications of guided imagery (in the IC) or evidence-based cognitive-behavioral activities that support tobacco cessation (in the CC). Participants are instructed to log into a condition-specific website to view study materials, testimonials, and additional resources.

Best practices for tobacco cessation treatment include nicotine replacement therapy (NRT) [1,23]. Participants in both conditions who request NRT receive up to four weeks of either nicotine patches or lozenges based on level of nicotine dependence. All participants requesting NRT are screened by trained project staff for usage contraindications, level of dependence, and are informed of potential side effects of using NRT. Participants with any contraindications for use are required to obtain written permission from their physician, upon which NRT is provided.

2.6. Intervention condition (IC)

As shown in Table 1, the first session includes an overview of guided imagery, and focuses on creating a GI script based on the reasons for and benefits of quitting. During this session the coach and participant set a quit date and a guided imagery schedule. Finally, the coach provides instructions for using the website and schedules the next session. Sessions 2–4 focus on creating GI scripts for specific topics (e.g., coping with cravings; see Table 1) and modifying previous or creating new scripts, and include follow-up and review of progress and use of the imagery files. Sessions 5 and 6 focus on either relapse prevention (for those who have quit) or recommitting to quit (for those who have not quit or have "slipped"), and include a review of progress and an opportunity to modify previous scripts. Session 6 creates a plan for continued use of guided imagery, prepares the participant to continue the quitting process on their own, and a debrief of program participation.

Motivational imagery includes detailed images about the participants' reasons for quitting and future-focused imagery about how their life will be improved when they are smoke-free. Cognitive-Behavioral imagery includes specific strategies to use during the quitting process such as ways to cope with cravings and urges and setting and writing down a quit date. The IC coach helps participants contextualize the guided imagery scripts in a way that maximizes each individual's challenges, barriers, and overall life circumstances by embedding both cognitive and motivational messages.

The IC coach works with the participant to create scripts rich with multi-sensory images that produce affect. For instance, in Session 1, the coach asks participants to share their specific reasons for and benefits of quitting. The coach elicits the participants' sights, sounds, smells, tastes and emotions related to their reasons and benefits. The coach then crafts the participants' input into cohesive narratives which are read to the participants. Participants may suggest edits as desired until a final version is created. The IC coach then records the narrative with peaceful background music as a digital audio file and sends it electronically to the participant. The coach encourages participants to listen to their guided imagery audio file at least once each day and more often if possible. This procedure is repeated during sessions 2 to 4 with the development of new narratives and audio files (see Table 1).

Table 2
Measures by assessment point.

Both Conditions	Baseline	8 Weeks	6 Months	Other
Demographics	✓			
Tobacco Use	✓	✓	✓	
Dependence	✓	✓	✓	
Cravings	✓	✓	✓	
Self-Efficacy	✓	✓	✓	
Expectancy/Credibility	✓	✓	✓	
Biochemical Validation			✓	
Consumer Satisfaction		✓		
Website Use				**Daily**
Intervention Only				
Imagery File Use		✓		**Weekly**
Imagery Experiences and Credibility		✓		**Weekly**

2.7. Control condition (CC)

The CC sessions are matched on topics and length to the IC sessions (Table 1). Session 1 includes an introduction to cognitive behavioral telephone coaching, and focuses on the reasons for and benefits of quitting. During Session 1, the coach describes the quit booklet, and engages in two activities in the booklet to identify and rate participants' reasons for and benefits of quitting. The coach then works with the participant to set a quit date and a schedule for using the booklet between sessions. Sessions 2–4 focus on specific topics (e.g., cravings; Table 1), and the coach reviews progress and engages in problem-solving and planning activities with the participant using the booklet. Sessions 5 and 6 focus on quitting issues and relapse prevention strategies (also using the booklet to complete activities). Session 6 also prepares the participant to continue the quitting process on their own and includes a debrief of program participation.

2.8. Intervention fidelity

Several steps ensure intervention fidelity. 1) Study coaches are trained in the content and delivery of the intervention as well as cognitive behavioral theory and motivational interviewing [24–26]. They are also provided with background information on tobacco statistics, the physiology of tobacco and tobacco cessation. 2) Coaches are assigned to only one condition to avoid contamination between the two approaches. 3) All coaches are independently rated by two of the investigators using rating sheets. The rating sheets contain rigorous criteria including items for assessing general interpersonal and specific intervention skills. Each criterion is rated on a scale of 1–5 (low to high) with specific metrics required for each numerical rating. Coaches must achieve competency (be rated at least 4) by two investigators prior to working with participants. 4) The coaches use the REDCap system during sessions and are prompted to complete each step of the protocol. 5) All sessions in both conditions are audio recorded. The study PI or co-investigators listen to call recordings monthly to assess competency and fidelity. Appropriately tailored intervention fidelity checklists for each condition are used to provide direct and structured feedback about each week's telephone calls. The fidelity checklists include general skills important for both study conditions (e.g., active listening, use of motivational interviewing, knowledge about tobacco use, and empathy) along with condition-specific information (e.g., definition of guided imagery, developing guided imagery scripts for each session or use of cognitive behavioral strategies). Coaches meet weekly with the PI for supervision until reaching saturation, at which time supervision occurs at least monthly or on an as-needed basis.

2.9. Assessment procedures

Assessments occur at baseline, 8 weeks and 6 months post-enrollment. Baseline assessments area conducted by ASHLine and study staff, and occur via ASHLine and REDCap systems. Follow-up assessments occur at 8 weeks and 6 months post-enrollment via a REDCap online survey or by phone for non-responders. Participants receive $10 for completing the baseline survey, $15 for completing the 8-week survey, and $25 for completing the 6-month survey, for a total of $50. All participants who report 7-day abstinence at the 6-month assessment are invited to participate in biochemical verification. Participants who are reached and agree to biochemical verification receive a NicAlert salivary cotinine test kit in the mail and join a video chat with study staff in approximately one-week post-assessment. During the video chat, study staff instruct the participant in and monitor the collection of saliva and reading of the test strip. Participants are offered $25 for completing the saliva assessment.

2.10. Measures

All of the measures proposed for use in this study have been used successfully used in our previous work [17,27]. Baseline surveys include demographics, tobacco use, self-efficacy for quitting, cravings, imagery expectancies and imagery use, and use of NRT and other forms of cessation treatment. Follow-up assessments include all of these items except for demographics, plus measures of their experiences with the coaches, program materials, and website. (See Table 2).

2.10.1. Demographics

At baseline, we collect gender, age, race/ethnicity, level of education, insurance, prior use of tobacco cessation resources (including quitline and medication) and guided mental imagery experience.

2.10.2. Tobacco use

Measured during every telephone session, plus 8-weeks and 6-months post-enrollment. We collect tobacco use status using a series of questions that have been standardized and employed in previous studies [17,28–30], and level of dependence using the 6-item Fagerström Tolerance Nicotine Dependence scale [31]. To test feasibility of biochemical verification of abstinence in this population, we will conduct a salivary cotinine assay using the NicAlert test kit on all participants who report 7-day abstinence at the 6-month assessment and agree to perform a saliva test. As all participants are current smokers, there is no need for biochemical testing at baseline.

2.10.3. Self-efficacy for quitting

Items from the 15-item version of the Condiotte & Lichtenstein Confidence Questionnaire [32] are used.

2.10.4. Cravings

All participants are asked to rate their experience with withdrawal symptoms and cravings using items from the 5-item Shiffman rating scale at each baseline and each follow-up assessment [33].

2.10.5. Imagery use, expectancies and credibility

We include two items to assess the frequency of guided imagery use and use of other forms of relaxation (e.g., meditation, mindfulness, breathing) used in our previous study [17]. We include two items adapted from the Borokov and Nau Treatment Credibility Scale [34] and used in our on-going guided imagery mobile app study to measure expectancies and perceived credibility of guided imagery for tobacco cessation [17,34].

2.10.6. Consumer satisfaction measure

At 8-week follow-up, participants complete a consumer satisfaction survey adapted from Tullis' and Stetson's 10-item adaptation [35] of Brooke's widely used System Usability Scale [36] that we have used in our previous research [17,30,35,37] consisting of 8 items (using a 5-point Likert scale), measuring overall satisfaction with the program, perceived usefulness and relevance of the information, likeability, level

of interest, ease of use, and whether they would recommend the program to others.

2.10.7. Website use

We collect usage data and can analyze use of all components of the website. Data most likely related to outcome will include, but not be limited to: (a) the length of time participants interact with the site; (b) the number of pages they visit within the site, and (c) the number of links they click on while using the site.

2.10.8. IC condition only

Imagery is measured during each IC session by asking participants the number of times they listened to imagery files and if they modified or created their own file. Ratings of imagery vividness and controllability are measured weekly via the coach in order to verify compliance with the protocol using a modification from Marks' instrument [38] that has been employed in previous investigations [13,17,39].

2.11. Outcomes

The primary outcomes are related to feasibility. Our feasibility outcomes include the following: 1) At least 50% of participants will complete the 6-session intervention program; 2) At least 50% of the IC participants will report listening to the guided imagery audio files at least 5 times per week; 3) At least 50% of all participants will use the website at least one time; and 4) At least 75% of participants will complete both follow-up assessments. In addition, we will explore the demographics of study participants to assess how they may differ from the general population of ASHLine callers, and compare the participants recruited through ASHLine versus those via targeted recruitment activities.

The cessation outcomes of interest are self-reported tobacco abstinence measured using 7-day point prevalence and 30-day prolonged abstinence at the 6-month follow-up assessment. Other tobacco-related outcomes include increased number of quit attempts, reduced tobacco use (for non-quitters), increased self-efficacy for quitting and reduced nicotine cravings.

2.12. Sample size

Because this is a feasibility study, our primary objective is to assess feasibility and acceptability of a guided imagery tobacco cessation intervention and compare its effects with a rigorously designed comparison condition. A minimum sample size of 50 participants per group will yield a margin of error (95% confidence interval half-width) of no more than 10% for all binary outcomes, such as feasibility outcomes (% completing the 6-session intervention program; % listening to the guided imagery audio files at least 5 times per week, tobacco use, and dropout rates. This sample size is large enough to reasonably estimate, in conjunction with sensitivity analysis, relevant variance components, recruitment, and dropout rates for use in a future definitive trial [40,41]. This sample size will also help us to assess the potential efficacy of the intervention, by giving 80% power to detect a difference in cessation rates of 30%, (chi-square test) and large effects for continuous outcomes (standardized effect size 0.7) assuming a type I error rate of 0.05 and a dropout rate of 20% (two-sample *t*-test). We will use clinically meaningful effect sizes (not pilot effect sizes) to estimate the future definitive trial's sample size.

2.13. Data analyses

Feasibility outcomes, including recruitment and dropout, will be described using frequencies and percentages, and 95% confidence intervals. Surveys will be scored according to developer instructions. Tobacco use outcome measures will use appropriate mixed models (linear for continuous outcomes and generalized linear with a logistic link for binary) using time categorically. Comparisons between the intervention and control group at 8 weeks and 6 months will be carried out using contrasts within these models. These mixed models are robust to missing outcome data (including dropout) and model misspecification, and are consistent with an intention to treat analysis [41–44]. Mixed models will also be used to model self-efficacy, cravings, and consumer satisfaction, and to estimate intervention effects. For outcomes measured in the intervention group (e.g., imagery file use), appropriate descriptive statistics will be computed, including means, standard deviations, ranges and frequencies/proportions. We are underpowered to detect any subgroup effects, but will conduct exploratory analyses in anticipation of the larger trial by including appropriate interactions within the mixed models. We will compare guided imagery use with tobacco outcome measures using linear regression in order to investigate a "dose-response" effect of the intervention. We will examine the number of sessions attended (1–6) and number of times the guided imagery or behavioral exercises are practiced each week (0 to maximum number reported). Demographics will be described with means, standard deviations, ranges and frequencies/proportions and will be explored as correlates for successful tobacco outcomes.

2.14. Data monitoring

An Independent Monitoring Committee consisting of three independent (unaffiliated with the University of Arizona) experts review study reports and data quarterly. One member (University of California, San Diego) has expertise in tobacco cessation interventions delivered via quitlines, one (University of Oregon) has expertise in data collection, management and analysis in behavioral interventions, and one (Penn State University) has expertise in health behavior change interventions.

3. Ethics and dissemination

3.1. Research ethics approval

This study was approved by the University of Arizona Institutional Review Board (UA IRB) (1607731418). The UA IRB approves all protocol changes, informed consent documents, coaching protocols, participant materials and recruitment materials.

3.2. Protocol amendments

Submitted electronically to and approved by UA IRB as needed; investigators and Independent Monitoring Committee notified of amendments. Amendments do not affect previous participants; they are not notified of changes.

3.3. Consent

Trained ASHLine and study staff use IRB-approved script and informed consent documents to obtain consent from study participants. Consent is obtained verbally using an IRB-approved "short version." Verbally-consented participants are emailed the full-length informed consent, which is also available on the study website, to which all participants have access.

3.4. Confidentiality

Efforts are made to keep study-related information confidential by using password-protected computers and data bases for electronic files and locked file cabinets for hard copy documents. There may be circumstances where this information must be released, for example, personal information regarding participation in the study may be disclosed if required by state law. To help protect privacy, we have

obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH).

3.5. Declaration of interests

None.

3.6. Access to data

Physical access to the data center is restricted to authorized personnel. All servers are housed in a locked rack and secured from the Internet and other university departments through the use of a hardware-based firewall and virtual LAN. A host-based firewall is installed and configured on each server as a secondary level of defense from outside intrusion. All servers and computer systems on the network are configured with domain-managed accounts and password controls with audit logs. Access to server resources such as project data are restricted to authorized users only as approved by the project's Principal Investigator.

3.7. Ancillary and post-trial care

There are no provisions for ancillary and post-trial care. Participants are not expected to face any risks, side effects, or discomfort beyond those usually associated with quitting tobacco; however, they are told to discuss any such issues with their study coach. The study coach informs and discusses risks or side effects with the Principal Investigator.

3.8. Dissemination policy

Efforts will be made to present our findings to all stakeholders (e.g., ASHLine, community advisory board, etc.), and to scientists at academic conferences. We will publish the results in high impact journal outlets. All authors must make substantive contributions to the work upon which a manuscript is based, make substantive contributions to the manuscript, give final approval of the version to be published, and be accountable for all aspects of the work described in the manuscript. Authorship of publications will be based on contributions to the manuscript, not role on the study. No professional writers will be used. The protocol will be published in an open-access journal, and stored in the University of Arizona Repository. De-identified data will be made available six years after the study is closed in the University of Arizona Repository.

3.9. Participant timeline

See Table 3 for details regarding the timeline for activities involving participants.

4. Discussion

This study addresses two current gaps in the field of tobacco cessation. First, it investigates the feasibility of delivering a guided imagery cessation intervention via telephone, and explores the impact of that intervention compared to a standard cognitive-behavioral intervention. Second, it explores whether a guided imagery intervention increases the reach of quitlines to men and under-represented populations of tobacco users who are less likely to utilize a quitline. Our study uses a novel tailored intervention that has potential to reduce tobacco-related health disparities.

This project is the first to develop and evaluate a guided imagery-based intervention delivered via tobacco quitlines. While guided imagery and mindfulness interventions have been successfully used for tobacco cessation, these interventions have mainly utilized in-person or self-help approaches that are often time and resource intensive. This cognitive skill has been shown to improve abstinence rates with smokers in in-person trials, but more disseminable, cost-effective approaches are needed. If shown to be effective, this model could be easily disseminated to quitlines around the U.S., and other English-speaking countries that employ the quitline model.

The GI intervention in this study utilizes an integrative, acceptance-based approach, combining the structure of a cognitive-behavioral intervention (i.e., focusing on evidence-based skills necessary for successful abstinence) with a multisensory visualization which both prepares for and reinforces behavior change. Like mindfulness, GI is based on acceptance of the physiological, psychological, and emotional nature of tobacco addiction. The use of GI serves as a way to maintain motivation during the quitting process and “mentally rehearse” cessation skills.

The intervention in the active control condition is based on behavioral programs delivered by quitlines throughout the United States. We utilize an active control condition that enables us to compare the GI intervention with best practices in the field (i.e., standard of care). However, our control condition intervention is matched to the GI intervention and consists of a six-session protocol with sessions ranging from 15 to 30 min in length. Therefore, program duration is greater than many quitlines and is a very robust comparison condition. Ultimately, the robustness of the control condition may make it less likely to observe differences in quit rates across conditions.

Men and racial/ethnic minorities underutilize quitlines nationally. Therefore, we recruitment both via the ASHLine and in the community, via targeted messaging and partnerships with community organizations. The ASHLine's demographics reflect callers who are mostly White/non-Hispanic/Latino (84.8% White, 79% non-Hispanic/Latino) and female (56%) [20]. A recruitment script, including messaging about guided imagery, aims to appeal to the men and racial-minorities and encourage study participation. Community recruitment uses study materials vetted by a community advisory board, and targets recruitment sites suggested by study participants. Future studies should make particular efforts to recruit these types of participants.

In summary, an effective guided imagery intervention delivered via telephone quitline would allow for scalability and dissemination, potentially reaching a larger, more representative group of smokers. The program also provides online links to resources aimed at tobacco cessation, which extends the reach of these services to smokers who might not otherwise have access to care. The program also allows for tailoring to the individual user, which cannot be accomplished in most self-help GI interventions. In addition, procedures, training, implementation, and assessment protocols will facilitate a future randomized efficacy trial. Results from this study will determine the feasibility of delivering the guided imagery intervention via a quitline model, and describe the reach of the intervention to under-represented tobacco users. If successful, our feasibility and exploratory cessation outcomes will guide the design and conduct of a future efficacy trial.

Declaration of interests

We received funding from the National Center for Complementary and Integrative Health to conduct this study. We have no other interests to declare.

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Table 3
Participant timeline.

Table 3. Participant Timeline													
		Study Period											
	Enrollment	Allocation	Post Allocation										Close out
Time Point	**4//23/18-12/31/18**	**0**	**S-1**	**S-2**	**S-3**	**S-4**	**S-5**	**S-6**	**8-Wks**	**6-Mos**	**8-Mos**	**Auto**	**Aug 2019**
Enrollment	X												
Eligibility Screen	X												
Informed Consent	X												
Confirm consent	X												
Allocation		X											
Interventions													
Imagery			♦	———	———	———	———	———	———	♦			
Active Control			♦	———	———	———	———	———	———	♦			
Assessments													
Baseline Variables													
Demographics	X												
Tobacco use	X		X	X	X	X	X	X	X	X			
Self-efficacy	X								X	X			
Guided-imagery	X								X	X			
Practice			X	X	X	X	X	X					
Use of website			X									X	
Outcome Variables													
# Recruited											X		
% Males											X		
% Race/Ethnicity											X		
% Retained									X	X			
% Completed Tx											X		
% Completed cotinine assay											X		
Other Variables													
% Abstinent 7-day									X				
% Abstinent 30-day									X	X			
# of times listened to GI			X	X	X	X	X	X	X	X			
% used website 1+ times													
Satisfaction									X	X			
Coach fidelity			X	X	X	X	X	X			X		
Coach competency			X	X	X	X	X	X					

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