

**Protocol Title:**

**QuitBet Phase II: A Digital Social Game that Pays You to Stop Smoking**

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## A. SIGNIFICANCE

### **There is a Critical Need to Increase Acceptability and Accessibility of Smoking Cessation Treatment**

Cigarette smoking persists as the leading cause of preventable death in the U.S., annually responsible for more than 480,000 deaths [1] and a total economic burden of over \$300 billion [1, 2]. Most U.S. smokers want to quit and over half try to quit each year [3]. In clinical trials, behavioral and pharmacological treatments each increase the likelihood of achieving long-term abstinence. However, **most U.S. smokers do not use these treatments**. During their quit attempts, <30% of smokers use medication, <10% receive behavioral treatment, and <5% use both [3, 4]. The majority of quit attempts undertaken without the aid of treatment (i.e., unassisted) end in relapse within one week [5, 6]. Only 3-5% of unassisted quit attempts result in long-term (> 6 months) abstinence [5]. Barriers to engaging in behavioral treatment include perceived (and real) costs of treatment, logistical barriers (e.g., transportation, time, scheduling), lack of knowledge of how to access programs, low expectancies of effectiveness, stigma related to seeking counseling, beliefs that professionals may not understand smokers if they have not smoked, valuing lay knowledge from peers over professional help, and the belief that quitting is a personal responsibility that requires only motivation and willpower [7, 8].

### **Delivering Behavioral Treatment Via Digital Technology May Increase Access and Uptake**

Arguably the most significant recent innovation in behavioral treatment for smoking cessation has been the development of treatments delivered via digital technologies. In particular, interest in smartphone applications to aid smoking cessation is growing rapidly. There are hundreds of smoking cessation apps currently available in the Apple and Android app stores [9, 10], and smokers express strong interest in them [11]. However, to date, very few have been empirically validated [9] and they have had limited reach [11-13]. Our company, WayBetter, Inc., has already demonstrated the ability to develop and successfully commercialize a smartphone application targeting a health behavior change [14]. In this study, we will complete the development of and test another new game: **QuitBet. QuitBet will target smoking cessation, for which there is a critical need for innovative industry solutions**. QuitBet is modeled upon and builds upon the commercial success of DietBet and our other games. We recently developed the QuitBet prototype and conducted an initial test game that established proof-of-concept.

All of our games, including QuitBet, consist of two primary components intended to foster inspiration, motivation, friendly competition, and, above all, **fun**: 1) **social gaming elements**, including a digital game activity board with an interface similar to Facebook on which a game host and players can post messages, photos, and videos and view results in real time, and 2) self-sustaining **financial incentives** in the form of a deposit contract, which we call the “bet.”

All games are offered with a range of bet amounts to accommodate players of varying motivation and income levels; a typical bet is \$30 for a 4-week game. All players who achieve their game’s goal are declared “winners” and equally split the pot of money bet at game start. Thus, winners are refunded their entire bet plus receive extra money from the forfeited bets of players who did not meet the goal. We have established systems for objective verification of game outcomes.

### **Traditional Contingency Management (CM) is Very Effective but Not Feasible for the Real World**

The use of financial incentives to motivate and reinforce desired behavior, termed “contingency management” (CM), is an evidence-based intervention rooted in the principles of operant conditioning theory. Extensive research supports the efficacy of CM for smoking cessation [15] and other health-related behavior changes [16-20]. Indeed, CM is one of the **most effective** behavioral intervention approaches for smoking cessation, especially in underserved and treatment-resistant populations, such as pregnant women [21] and smokers with comorbid psychiatric [e.g., 22] and substance use disorders [23]. However, traditional CM as developed and tested in research settings has not been widely implemented in community settings [24, 25].

In 2010, Petry [26] reviewed the **four primary reasons why CM has had limited real world implementation**. The first is that although CM is very effective while the target behavior is being incentivized, high relapse rates are observed when incentives are no longer available [15, 16, 27]. Petry insightfully notes that this criticism is “often directed toward CM” but also applies “equally to other treatments” and “it is unclear why CM should be held to higher standards.” Second, there is some concern that CM could undermine internal

motivation to change, but this concern may be unfounded [28-30]. Third, there are emotional and ethical concerns that reduce acceptability. CM has been viewed as “bribery” or unfair (e.g., why should we “pay people for what they should be doing anyway”?) (see also [31,p. 909]). Therefore, although CM is potentially more cost-effective than other treatments [e.g., 32, 33-35], it has been difficult to obtain funding for the incentives. Finally, there are practical concerns about feasibility [26, 36-38]. Traditional CM for smoking cessation requires daily clinic visits for biochemical verification of abstinence using exhaled breath carbon monoxide (CO) testing. Daily testing is necessary because breath CO only remains elevated for up to about 24 hours after smoking [39]. This schedule is unlikely to be feasible, especially for disabled, rural, or low income smokers who may lack transportation or childcare [37], and given limited clinic hours. Some CM studies have employed testing of cotinine instead of CO, which only requires weekly testing. However, since cotinine testing detects all sources of nicotine, it is not valid if an individual is using nicotine replacement therapy (NRT), an effective treatment [40] that typically costs less per day than smoking [41]. Given these challenges, most CM interventions have been of very short duration ( $\leq 4$  weeks) and have not incorporated NRT use.

### **QuitBet: A Social, Digital Game that Pays You to Stop Smoking**

**We designed QuitBet to overcome all limitations of traditional CM. We believe that QuitBet has the potential to fulfill a critical need to deliver empirically-supported behavioral treatment to the millions of U.S. smokers** who want to quit but are unwilling or unable to access traditional behavioral treatments. Our intention is that QuitBet players, like the players in our other games, will be able to play multiple consecutive games and thereby be incentivized indefinitely until they achieve abstinence. Consecutive games could be played for as long as needed to sustain long-term abstinence.

Second, QuitBet players, like the players in our other games, fund all of the incentives themselves. Therefore, there should be no concerns about the fairness of or source of the incentives. Our deposit contract [35, 42-45] procedure is rooted in loss aversion theory, which posits that people are more motivated to avoid losses than to obtain equivalent gains [46]. Deposit contracts for smoking cessation are not new and were tested as early as the 1970s. Early studies found that deposit contracts were effective, but, as with reward-only CM, relapse was observed during post-treatment follow-up [42, 45, 47]. As noted above, we address the problem of post-treatment relapse by allowing for game play to be extended as long as needed. More recently, the efficacy of deposit contracts has been compared directly to traditional, reward-only CM. A study conducted by Consultant Dallery and colleagues found no significant difference in abstinence rates between participants who paid a \$50 deposit that was earned back for abstinence (plus additional incentives once the deposit was recouped) vs. a group who earned incentives for abstinence but did not pay a deposit [48]. A trial [44] that included over 2500 participants revealed that deposit contract programs in which participants could earn back a \$150 deposit plus additional rewards for quitting smoking had significantly lower abstinence rates overall than reward-only programs (10.2% vs 15.7% abstinent at 6 month follow-up). However, this outcome was attributable to a difference in program acceptance rate. Whereas 90% of those who were randomized to a reward-only program enrolled in it, only 14% of those randomized to a deposit program made the deposit and enrolled. Among those who enrolled in their programs, 6-month abstinence rates were **17.1% in the reward-only programs vs. 52.3% in the deposit programs**. After adjusting for lower willingness to enroll in the deposit programs, the deposit programs were found to have an abstinence rate 13% higher than the reward-only programs. The deposit programs were “superior to rewards even if we assumed that participants who would accept deposits had up to 12.5 times greater underlying propensities to stop smoking than participants who would accept rewards only.” (p. 5). Our take-away from this study is that **\$150 is likely to be an unacceptably high deposit amount for many smokers**. Our \$30 deposit should be more acceptable [49].

Third, QuitBet is more feasible than traditional CM because it is delivered entirely via the Internet. We believe that digital CM (DCM) has even greater potential to reach low income populations, who have the highest rates of tobacco use [50], than traditional clinic-based behavioral treatments given the convenience and growing ubiquity of Internet-connected smartphones capable of recording video and because this technology eliminates barriers to access that disproportionately affect the underserved (e.g., transportation, childcare, costs). In 2017, the smartphone ownership rate among U.S. adults was 77% (92% for age 18-29 and 88% for age 30-49) [51]. Rates did not differ by race or ethnicity [51] and continue to increase toward complete saturation [52], including among low income individuals. In two recent studies [12, 53] involving over 700 U.S. smokers, the smartphone ownership rate was consistent with general U.S. population data (70-80%).

Finally, QuitBet is not just CM. It incorporates novel social gaming elements intended to foster social support, internal motivation to change, and a sense of fun. Group treatments are theorized to work in part by

instilling hope, universality, altruism, group cohesion, and modeling [54]. One might predict that QuitBet players would act as adversaries given that they stand to win more money if more players are unsuccessful. However, our experience with DietBet has shown that, in contrast, our players are extremely supportive of each other. They are having FUN while losing weight. Group smoking cessation treatments have a long history in the U.S. Some have been commercialized (e.g., Smokenders, American Lung Association's Freedom from Smoking). However, these programs have had limited reach and have not been recently evaluated [55]. More recent evaluations of group-based treatments available primarily from the Stop Smoking Services in the United Kingdom suggest that group-based treatments are at least as effective, and may be even more effective, than individual treatments [55]. Nevertheless, in the U.S., there remain significant challenges to making group-based treatments readily available in clinical settings [56]. In contrast, QuitBet will be much more accessible, representing a viable alternative or adjunct to other treatment options such as quitlines.

### **Digital Contingency Management (DCM) for Smoking Cessation Has Established Efficacy**

**Consultant Dallery** and his colleagues pioneered the use of DCM for smoking cessation [36, 37]. DCM has already been tested for rural smokers [57, 58], smokers with PTSD [59], and homeless veteran smokers [60], with demonstrated feasibility and efficacy. In these studies, participants were mailed a professional CO testing device (value \$500+) and other necessary equipment (e.g., web camera) for remote verification of smoking abstinence, which eliminated the need for daily clinic visits. Dallery and colleagues recently demonstrated the feasibility, acceptability, and efficacy of a DCM program that included a \$50 deposit contract [49]. Given the cost of the CO testing device, only a small number of participants could be accommodated in these studies and participants had to mail back the device at the end of the study, which limited the potential for real-world dissemination and scalability. In QuitBet, participants test their CO using the **Bedfont iCO Personal Smokerlyzer**. The iCO, released in 2015, is the first low-cost (\$60) CO monitor intended for personal use by an individual consumer (it cannot be sanitized for use by multiple individuals). The iCO connects to the user's personal smartphone via a free application that can automatically transmit the results via email (e.g., to a clinician or research team). It has a range of 0-100 parts per million (ppm) with a sensitivity of 1ppm, an operating life of about 200 tests or 3 years, and a 6-month warranty.

### **Summary of Significance**

We believe that, like our other games, **QuitBet** will be broadly appealing, produce clinically meaningful outcomes, and have the potential for **very large** reach, thereby having a significant positive impact on public health. Furthermore, we did not design QuitBet as a replacement for or competitor to medication or other behavioral treatment. Rather, QuitBet should be compatible with virtually all other cessation treatment options.

## **B. INNOVATION**

Our research is innovative in these important respects:

**1) QuitBet will be the first digital smoking cessation program that employs a self-sustaining, entirely participant-funded deposit contract model of CM.** The use of a deposit contract greatly reduces costs as well as concerns about the fairness of incentives and identifying funding sources.

**2) QuitBet will be the first digital smoking cessation program to combine a deposit contract with novel social gaming components intended to increase engagement and internal motivation to change.** The purpose of "serious games" is to apply game elements (competition, prizes, social interaction) to serious health issues [61], and make the process of behavior change engaging and fun. Thus, gaming is thought to have serious potential for health behavior change [61, 62]. Previous studies have demonstrated the efficacy of: 1) group-based DCM for smoking cessation that included opportunity for communication among teammates (3-4 per team) [e.g., 63] and 2) "competitive" deposit programs [44]. Also, recent studies have evaluated video games for: 1) preventing tobacco use among youth [64], 2) coping with urges to smoke during a quit attempt [65], and 3) promoting smoking cessation with video game-based rather than monetary rewards [66, 67]. However, to our knowledge, no studies have yet examined the impact of an evidence-based serious game for smoking cessation with our deposit contract model. Novel social gaming components of QuitBet include crowdsourced verification of CO test results and a game host. The host facilitates and encourages player discussions and provides content that integrates evidence-based education about the process of and treatments for smoking cessation with fun activities.

**3) The research will be conducted entirely via the Internet.** We will recruit smokers from throughout the U.S. They will play QuitBet on our established digital platform, which can accommodate a virtually unlimited number of “players.” If shown effective, QuitBet will be scalable and commercializable.

## C. APPROACH

### Previous Study: QuitBet Phase I Pilot Trial

Our goal for Phase I was to achieve the following **three milestones**:

- 1) Complete development of the QuitBet smartphone application, which will be adapted from the applications for our other games and include a custom iCO application with the capability to record CO tests on video. We will develop content and links to resources for the game host to post on the game activity board that are consistent with best practices for smoking cessation [40, 89] and are intended to promote internal motivation to change, engagement with QuitBet, and **fun**.
- 2) Demonstrate that QuitBet is feasible; that is, that there is consumer demand for Quitbet.
- 3) Demonstrate that QuitBet is acceptable (pilot trial players are engaged, satisfied, and can be retained).

Our secondary aim for Phase I was to demonstrate preliminary effectiveness of QuitBet. However, this pilot trial was not designed or powered for a formal evaluation of effectiveness.

### Phase II Study Design Overview

Our first step for Phase II is to make minor revisions to the QuitBet program and study procedures based on the feedback provided by Phase I participants. There will be no human subjects involved in this portion of the project.

Then, **we will conduct a randomized controlled trial (RCT)** to examine the effectiveness of QuitBet compared to an alternative version of QuitBet (QuitBet-NS) consisting of a \$30 deposit contract only (no social gaming elements). In Phase II, all players will be offered the opportunity to play a second QuitBet game at the end of their first game. All Phase II participants will complete follow-up surveys at the end of their first and second games (regardless of whether they choose to play the second game) and at 1 and 4-months after the second game is over.

**Bedfont iCO Personal Smokerlyzer.** CoVita, the USA distributor of the iCO, informed our study team after the Phase I pilot trial ended that the original iCO has been discontinued. A new updated model, called the iCOquit, will be used for Phase II. Whereas the original iCO used a cord to connect to smartphones via the headphone jack, the new iCOquit is cordless and uses a Bluetooth connection instead. Otherwise, the two devices appear and operate in a nearly identical manner. Also, the new iCOquit has a longer battery life (lasts for 500-1000 tests instead of 200) and an upgraded free companion app with more features. We will update the QuitBet app so that it is compatible with the new iCOquit for Phase II. Detailed information about the new iCOquit may be found here: <https://www.icoquit.com/us/>. As in Phase I, we will allow participants who experience technical difficulties with taking or submitting their CO tests in the QuitBet app to use the free (updated version) of the iCOquit app instead to submit a screenshot of their results.

In general, the Phase II RCT procedures including recruitment, enrollment, game play, surveys, and retention strategies will be similar to the Phase I pilot trial.

**Participants.** We will recruit a total of approximately 550 participants in Phase II. Phase II participants will be recruited in cohorts. We are aiming for approximately 50 participants per cohort, but the number of participants in each cohort may vary with no minimum or maximum limit. We will continue to recruit cohorts until we reach our goal of a total of N = 550 participants.

**Eligibility Criteria.** The official eligibility criteria for Phase II will be as follows:

#### Phase II eligibility criteria:

- 1) Sufficient English fluency to complete study procedures
- 2) at least 21 years of age
- 3) U.S. resident of any state
- 4) currently smokes at least 5 cigarettes per day
- 5) has an email address they check regularly
- 6) has a mailing address at which they can receive packages
- 7) owns an Internet-connected Apple iPhone or Android smartphone that is compatible with QuitBet (Phase I was restricted to Apple; Phase II will include Apple and Android)
- 8) willing to deposit \$30 (QuitBet "bet") via PayPal or a credit card
- 9) willing to receive financial incentives earned during QuitBet via PayPal or in a paper check sent by mail

Notes about eligibility changes from Phase I: For Phase II, we will include Alaska and Hawaii residents. We also eliminated the exclusion for current pregnancy or planning to become pregnant within one year. We realized it was not necessary to exclude pregnant women as this protocol poses no additional risk to them and pregnant women are highly encouraged to quit smoking. Furthermore, many previous studies have shown beneficial effects of financial-incentive based interventions for smoking cessation among pregnant women. Current clinical guidelines indicate that there is not sufficient evidence to recommend that pregnant women use over-the-counter nicotine replacement therapies or other smoking cessation medications but that use may be considered under a physician's supervision. Therefore, the game rules as well as education about cessation medications provided during the game by game hosts will always include a disclaimer that pregnant women should consult a healthcare professional before using these medications.

**Recruitment and Enrollment Process.** Participants will be recruited from throughout the continental U.S. We will recruit using the marketing strategies that we use for our other games: advertising throughout the U.S. on social media, emails sent to our database of registered subscribers, and messages posted within the feeds of our other games and in our social media accounts. Additionally, we will advertise on other websites that allow postings about research studies, on email lists that we have access to (e.g., professional society listservs for tobacco researchers and clinicians), by emailing our professional networks and encouraging them to share the study information with their colleagues and clients/patients, and by hanging paper flyers in public locations. All advertisements will indicate an opportunity for smokers to participate in a research study testing QuitBet, a quit smoking game that is modeled upon DietBet and our other games. We acknowledge that many people who are exposed to QuitBet marketing will be current or former WayBetter game players and may not be smokers; therefore, we will encourage sharing the information about QuitBet with friends and family members who smoke. Additional advertising methods will include: 1) contracting with companies that specifically offer services to help researchers recruit participants for studies and other marketing agencies, 2) using social media influencers to help promote the study, and 3) advertising on other websites.

WayBetter, Inc. has previously enlisted social media influencers and celebrities to promote their games. During Phase II, we will identify influencers who willing to promote QuitBet by posting about the study on their social media accounts, following procedures in our previously Advarra-approved Social Media Influencer Plan.

We will streamline the enrollment process for Phase II to make it easier for people to find out about the study and enroll. For Phase II, the QuitBet app will be publicly available in the App Stores. People who are interested may find this app by searching directly in the App Store (e.g., they might search for "quit smoking" apps) or by seeing a link to the app store page in a study ad or on the study website ([www.quit.bet](http://www.quit.bet)). Anyone may download the QuitBet app for free. Upon downloading the app, they will proceed through the study enrollment process. Upon opening the app for the first time, they will see a screen that provides a brief description of QuitBet and the study eligibility criteria (we have eliminated the formal screening survey), as well as links to the full game rules and the consent form. The consent form will be a page on the QuitBet website. This page will be accessible to participants throughout the study (on the website and within the app) and they may request a copy via email (pdf). They will click a box that says "sign up with email" and be asked provide their name, email address, and a password to create a QuitBet account. The screen will indicate that by providing this information and creating an account, they are acknowledging that they meet the eligibility criteria, have read the game rules, and have read the consent form and consent to participate in the study. After their

account has been created, they have the option to join a QuitBet game, which requires that they pay the \$30 bet.

After paying their bet and joining a game, participants will complete a baseline (pre-game) survey and a contact information form (in a Google Form or Alchemer survey) that includes their mailing address for the purpose of sending them an iCOquit and a baseline (pre-game) survey. This form and survey will be displayed in the QuitBet app upon joining a game or a link will be sent to the participant via email and/or text message. Upon completing this form and survey, we will send the participant an iCOquit in the mail that will arrive prior to the game start date.

Their iCOquit package will include instructions for how to operate the iCOquit and take a CO test within the QuitBet app. We will encourage participants to take a practice test prior to the game start date to ensure their iCOquit is working properly. Participants are permitted to request a refund of their \$30 bet until the end of Day 1 of the game. No refunds will be offered after Day 1 but we may make exceptions for unusual circumstances, consistent with WayBetter's policy for all WayBetter games. At any time, we can remove players from the game (with or without also refunding their \$30 bet) if they request to be removed, if they have not completed the requirements for participation (e.g., did not complete baseline survey), or if they violate a WayBetter policy.

**Randomization.** The first QuitBet game in Phase II will be considered a test game and will be fixed to include the social feed and leaderboard. Each subsequent cohort will be randomly assigned to QuitBet (with the social feed and leaderboard) or an alternative version of QuitBet (QuitBet-NS, "no social" - details below) by a statistician who has no direct contact with participants nor any access to any data that could identify a participant. Participants will be informed of which version their game is after they pay their \$30 bet and join the game. This information will be displayed in the app inside their game. Therefore, there will be no bias or influence of group assignment knowledge on recruitment or on participants' decisions to enroll or their decisions to provide the deposit, as all of these events will occur prior to randomization. Randomization will be conducted using a permuted block randomization scheme, using small, random sized blocks. We will ensure that an approximately equal number of cohorts are assigned to each condition (QuitBet or QuitBet-NS) and that the total number of participants in each condition is approximately equal (e.g., approximately 225 per condition).

### QuitBet Components

- 1) Social Gaming Features.** Consistent with our other games, the QuitBet smartphone application will feature a link to the QuitBet website with a detailed description of the game rules, a Frequently Asked Questions (FAQ) page, and a game activity board on which players may post their CO test videos for crowdsourced verification, view game results in real time, and interact by posting messages and other photos and videos. The game activity board will have an interface and communication functions that are similar to Facebook (e.g., where users can "like" and post comments, photos, and videos). The host serves as a game moderator and also posts discussion topics and other activities. We will complete the development of host content for QuitBet based on the content in the QuitBet test game (see Table 1). However, we expect that if QuitBet were commercialized, game hosts could develop additional content.

**Table 1. Content of Host Messages in QuitBet Test Game**

Day	Content	Day	Content
1	Welcome - share your reasons for quitting	15	Education about "non-smoker" CO levels (i.e., will fluctuate, 1ppm not is "better" than 3ppm)
2	Share anticipated benefits of quitting	16	Was a holiday - wished everyone a safe and fun holiday
3	General quitting tips from the Truth Initiative (link)	17	Share how much money you have saved
4	Helpful tips for using the iCO app	18	Share what you will do with money saved
5	Smokefree.gov resources (link)	19	"Funny Friday" - share a song title that describes how you're "breaking up" with cigarettes
6	Encouragement for upcoming quit date, share what you're doing to prepare	20	Share tips for getting back on track after a slip and for coping with weekend cravings
7	Quit date (day 8) reminder	21	Relapse prevention tips from webmd.com (link)

8	Quit Day! Provided basic education about duration of nicotine withdrawal	22	Quitting on Mondays is most popular (The Monday Campaigns link)
9	Congrats to everyone who quit and thanks for sharing your tips	23	Share how you successfully coped with a temptation to smoke
10	10 ways to cope with cravings from the Mayo Clinic (link)	24	Share benefits of quitting so far; website about benefits (American Lung Association link)
11	Share benefits of quitting so far; posted image from smokefree.gov about benefits over time	25	Share a helpful app or website you've found
12	"Funny Friday" - share a funny meme or gif that describes your quitting experience so far	26	"Funny Friday" - share a funny meme or gif about your overall quitting experience
13	Share tips for coping with weekend cravings	27	Share how you will stay smoke-free after QuitBet
14	Halfway reminder of game rules and general encouragement	28	Last day - congrats to the winners!

**2) Deposit Contract.** The Phase II game bet (\$30) and length (28 days) will be identical to the QuitBet test game and Phase I pilot trial. The "warm-up" period will be shortened from 1 week (7 days) to 1 day, such that the quit day will be day 2 of the game instead of day 8 as in Phase I. We will eliminate the \$1/day incentive for each day that a "negative" CO test of  $\leq 6$ ppm is submitted. Phase I participants indicated that this \$1/day incentive did not promote continued participation or quit attempts as we had hypothesized. The criteria to be a winner for Phase II will be as follows: winners must submit a CO test of  $\leq 6$ ppm on at least 24 of the 26 days (2 slip or missed days allowed) between day 3-28. All winners will split the grand prize pot equally. As noted above, Phase II participants will not receive any other incentives for abstinence (we will not provide \$1/day for each individual day of abstinence as in Phase I). However, consistent with Phase I, the quit day (day 2), will not count toward winning because it can take up to 24 hours for CO to drop to 6ppm or lower after quitting. All participants within each game who submit a CO test on at least 75% of game days (at least 21 tests in total), regardless of the test results ( $\leq 6$ ppm or  $\geq 7$ ppm), will be entered into a raffle to win a \$75 Amazon.com gift card. The purpose of this raffle is to replace the \$1/day incentive from Phase I as a way to encourage continued participation in the game and continued efforts to quit smoking even after a participant has 2 or more slip days and is no longer eligible to be a winner.

**QuitBet-NS.** Participants randomized to QuitBet-NS (no social) will receive an alternative version of QuitBet (QuitBet-NS) that does not include any social interaction with other players or game hosts. QuitBet-NS will include: 1) the deposit contract, with identical rules to QuitBet for being a winner, 2) the \$75 raffle for submitting 21 CO tests, 3) a display of the participant's daily CO test results that is updated in real time, and 4) a game feed on which only the game host has the ability to post. Players will not be able to post on this feed or respond to the host's posts. At the beginning of the game, the host will post limited information, including the game type (i.e., QuitBet "Individual") and a list of smoking cessation resources (e.g., links to websites such as smokefree.gov, information about medications and counseling). This resource list will include some of the content that game hosts will be posting in QuitBet. QuitBet-NS will not include any other social features. That is, the QuitBet-NS app will not include the social feed (QuitBet-NS participants will be unable to communicate other game players or a game host within the app) or the leaderboard (QuitBet-NS participants will not see any information about other players' CO test submissions during the game). The QuitBet-NS app will otherwise have an appearance that is identical to QuitBet (same general design and colors, etc) other than the missing features (no social feed or leaderboard). QuitBet-NS will include the same capabilities as QuitBet to take CO tests, record these tests on video, and submit these videos to WayBetter.

**Second Game.** At the end of their first game, all participants (QuitBet and QuitBet-NS) will be offered the opportunity to play a second game for an additional bet of \$30. The second game will be the same version and have rules identical to their first game (i.e., QuitBet or QuitBet-NS). Given that we have eliminated the warm-up week based on Phase I participant feedback, such that in Phase II, all participants will quit right away in their first game (i.e., on day 2), we decided not to split the second game into separate standard and Maintainer versions according to smoking status at the end of the first game. All players within a cohort who decide to play the second game will be grouped together for the second game regardless of their smoking status at the end of their first game.



**Assessment Procedures.** Phase II assessments will consist of brief ( $\leq 15$  min) online surveys administered at baseline (before the first game), after the first game (1-month post-quit date), after the second game regardless of whether they participated in it (2 months post-quit date) and at 1 and 4 months after the second game (i.e., 3 and 6 months after the original quit date). Additionally, all participants will be asked to submit a CO test after completing each survey.

Phase II survey questions will be mostly the same as in Phase I, with some slight differences and some additional questions added. As in Phase I, Phase II participants will receive a prize with a value of \$10 (e.g., an Amazon.com gift card, a water bottle, or portable charging bank) for completing each survey (total up to \$50). Participants will not have the ability to choose which prize they receive. Physical prizes for Phase II surveys will be shipped directly from the retailer (e.g., Amazon.com). As of September 2022, we have discontinued physical prizes and all participants will receive a \$10 Amazon.com gift card for each survey.

**Phase II Survey Platform.** During Phase I, surveys were administered via SurveyMonkey. During Phase II, we will use Alchemer (this company was formerly called SurveyGizmo; they recently changed their name to Alchemer) instead of SurveyMonkey. Alchemer is a company that is a direct competitor to SurveyMonkey and their survey platform has very similar features including the appearance of the surveys and data security. Our primary reason for switching to Alchemer for Phase II is that Alchemer has superior capabilities for sending survey links via text messages using automated processes (i.e., can schedule in advance to send both emails and text messages containing survey links at designated times, whereas SurveyMonkey only allowed advance scheduling of emails and text messages had to be sent manually). This advance scheduling function for text messages will save the study team a significant amount of labor time. Screenshots of the surveys as they appear in SurveyGizmo/Alchemer were previously submitted to Advarra.

## Phase II Data Analysis

**Power Analysis and Sample Size Justification.** Sample size was calculated to have sufficient power ( $>80\%$ ) to detect a 10% difference between QuitBet and QuitBet-NS, which we consider clinically meaningful, with respect to the primary outcome (CO-verified 7-day point-prevalence abstinence, PPA, rates at follow-ups). In Consultant Dallery's recent DCM study [90], in which the DCM was similar to our proposed QuitBet-NS, the abstinence rates were 40% at 3-weeks, 29% at 3 months, and 23% at 6-months post-quit date [112]. Some features differ between our proposed QuitBet-NS and Dallery et al.'s DCM (e.g., eligibility criteria, total incentives available, intervention duration), but we believe these differences would balance out with regard to effects of abstinence rates. Therefore, we believe 23% is a reasonable estimate for the QuitBet-NS abstinence rate at 6-month follow-up. Furthermore, 23% abstinence at the final follow-up is typical for a smoking cessation trial, even when the intervention does not include financial incentives for abstinence [40]. Therefore, we have powered for an estimated absolute difference of 10% in abstinence rate between QuitBet-NS (23%) and QuitBet (33%). If the actual abstinence rates are lower, we will have more than adequate power as a smaller sample size would be required (e.g., detecting 10% vs. 20% requires fewer participants than 23% vs. 33%). Thus, given an odds ratio of 1.65 for the longitudinal effect across follow-ups (i.e., 3- and 6-month post-quit follow-ups) with hypothesized 7-day PPA rates of 23% in QuitBet-NS and 33% in QuitBet at the 6-month follow-up and an alpha level of 0.05, a total sample size of 550 participants is required to have sufficient (80%) power to test the longitudinal effect on the intent-to-treat (ITT) 7-day PPA.

**Preliminary analyses.** As a preliminary step, we will assess potential between-group differences in baseline characteristics (demographics, smoking history, nicotine dependence, etc.) using graphical methods, non-parametric and parametric tests as appropriate (e.g., Wilcoxon rank-sum test for skewed data, t-tests for normally distributed continuous data, and chi-squared tests for categorical data). Any variables not balanced by randomization will be controlled for as covariates in subsequent analyses.

**Data Analysis Plan.** Consistent with the **Phase II Aim**, we will estimate the effect of the interventions on CO-verified 7-day PPA at 1, 3 and 6 months after original quit dates [113, 114] using a single repeated measures regression model implemented with generalized estimating equations (GEE) with robust standard errors. Specifically, we will regress smoking status on intervention group (QuitBet vs. QuitBet-NS) and potential covariates (e.g., medication use, other variables not balanced by randomization) using binomial errors, a logit link function, and a working unstructured correlation to accommodate within-subject correlation.

Subsequently, using a longitudinal mixed effects model, we will explore the effects of QuitBet vs. QuitBet-NS on secondary outcomes, including smoking heaviness (treated as a continuous variable) at follow-ups. Specifically, we will regress mean cigarettes per day during the past week at each follow-up on baseline cigarettes per day, intervention group, time, group\*time and potential confounders (including those variables not balanced by randomization). Models will include a participant-specific intercept to adjust for repeated measurements within participant over time. Using a similar modeling approach as for 7-day PPA, we will assess group effects on medication use over time.

Finally, we will explore the roles of engagement and satisfaction as mediators of intervention effects on abstinence using a product of coefficients approach with bootstrapped standard errors (5000 samples with replacement) [115]. We will estimate the path coefficients (e.g., a path: effects of intervention on changes in engagement and b path: effects of engagement on 7-day PPA at 6-month follow-up), as well as the indirect effect of intervention (ab path: effect of intervention on 7-day PPA at 6-month follow-up through engagement). Interest is in estimating the path coefficients, effect sizes, and confidence intervals.

**Missing data approaches.** We will censor the data at the point of loss for drop-outs. Our analyses will focus on the ITT sample, meaning that all participants randomized will be included in the analysis. Analysis will use estimating equations and maximum likelihood (ML) approaches to produce estimates of the regression parameters. One advantage of a ML approach is that it makes use of all available data without requiring imputation of missing values. ML estimates have been shown to be consistent when missing data is related only to covariates and observed values of the outcome [116]. As it is possible (although not testable) that missingness may be related to the missing outcome itself (e.g., not random), we will run a sensitivity analysis to explore the robustness of our findings to other assumptions of the missing data.

## **PROTECTION OF HUMAN SUBJECTS**

### **Human Subjects Involvement, Characteristics, and Design**

Participants are adults who meet the eligibility criteria specified in **Human Subjects and Clinical Trials Information section 2.2. Eligibility Criteria.**

Males and females of all racial and ethnic backgrounds who meet inclusion and exclusion criteria and are continental U.S. residents will be eligible. We will target our nationally distributed advertisements in areas with high populations of racial and ethnic minorities, with a goal for our sample to be consistent with recent estimates (2012-2014) of U.S. smoker demographics [111]: at least 20% non-Caucasian and at least 10% Hispanic.

### **Sources of Materials**

Data will be obtained specifically for research and product development purposes. Data will be stored in password-protected electronic files on secure servers or in locked physical files with only code numbers identifying participants. Research materials include (a) electronic surveys administered via SurveyMonkey or Alchemer (note: surveys may be administered via telephone or on paper and transmitted via postal mail to be hand-entered into SurveyMonkey/Alchemer in the event that a participant becomes unable to complete them electronically); (b) video recordings and photos of CO tests for the purpose of verifying smoking abstinence; and (c) participants' logged behavior on the QuitBet/QuitBet-NS application (e.g., time and duration of log-ins, pictures and comments posted). The QuitBet/QuitBet-NS game content will be password-protected and accessible only to authorized WayBetter employees, other members of research team, and study participants. Game content will not be accessible to players in other WayBetter games or to the general public.

### **Potential Risks**

Potential risks include nicotine withdrawal, loss of money, breach of confidentiality and loss of privacy, and perception of coercion to participate in the study.

### **Adequacy of Protection against Risks**

### **Recruitment and Informed Consent**

Participants will be recruited as described above. All advertisements will indicate an opportunity for smokers to participate in a research study in which they will receive financial incentives for quitting smoking. The \$30 deposit and other requirements should strongly discourage minors and non-smokers from attempting

to enroll. We have set 21 years as the minimum age to enroll because in some jurisdictions individuals must be 21 to purchase cigarettes). Nevertheless, it is possible that a highly motivated applicant could lie about age or smoking status. However, lying about age or smoking status can occur in any study, even when traditional written consent is obtained in-person. Furthermore, should a minor and/or non-smoker enroll, there are no additional risks other than those described below.

## **Protection Against Risk**

### **Nicotine withdrawal**

Risks. Participants who quit smoking may experience some nicotine withdrawal symptoms, including anxiety, restlessness, anger, irritability, sadness, problems concentrating, appetite change and weight gain, insomnia, and decreased heart rate.

Minimization. All participants will receive general information about other smoking cessation treatment options including FDA-approved medications. Participants will be permitted to use approved medications that should diminish the overall severity of withdrawal discomfort. Withdrawal symptoms are usually short-lived, with most symptoms abating within 1-2 weeks. Participants will be advised to consult with a health care provider if they have any concerns about withdrawal symptoms and before taking smoking cessation medication. Participants will assume all risks of medication use. Study staff will monitor game activity during business hours, and will contact by phone any participant about whom there is a concern or who is engaging in risky, inappropriate, or offensive behavior. Per WayBetter policy, participants may be removed from their game at any time or a health care provider's note may be required for continued participation.

### **Loss of money**

Risk. There is a risk that participants could lose some or all of their \$30 deposit if they do not quit smoking and therefore do not earn any incentives in their QuitBet/QuitBet-NS game(s) (i.e., forfeit their deposit).

Minimization. We acknowledge that requiring research participants to "pay" to participate in research is unusual. However, there is ample precedent and evidence for the efficacy of deposit contracts, and the deposit contract is a central feature of all WayBetter games. It will be emphasized to all participants that "winners" will earn back their entire \$30 deposit plus additional money from the forfeited deposits of non-winners. In the very unlikely event that all participants within a QuitBet/QuitBet-NS game achieve sustained abstinence (i.e., all players are winners), all participants will receive their full \$30 deposit back but no additional reward. Therefore, winners are guaranteed not to lose money. We will compensate all participants, regardless of whether they quit smoking, for their time and effort in completing survey assessments with prizes that have a value of up to \$50. They will also receive an iCOquit device at no cost that they will keep after the study is over (value of \$65). Participants in this study are likely to be spending at least \$20 per week on cigarettes, given that cigarettes cost ~\$5-10 per pack depending on U.S. state of purchase and all participants are required to be smoking at least 5 cigarettes per day at baseline.

### **Breach of confidentiality and loss of privacy**

Risks. The risk of breach of confidentiality and loss of privacy is judged to be minimal.

Minimization. All study staff, including those who are WayBetter employees, are or will be fully trained in relevant ethical principles and procedures for the conduct of research with human participants, particularly around confidentiality. Breach of confidentiality with regard to the electronic survey assessments is highly unlikely because all electronic surveys will be administered via SurveyMonkey or Alchemer and all data will be stored on password-protected servers. Within SurveyMonkey/Alchemer, participants are identified by their e-mail address and/or their phone number so that we can link a participant's responses to each of the 5 surveys together and match participants' survey responses to their QuitBet game data (e.g., CO test results). For each survey, participants may be asked to enter their email address and/or phone number as a question in the survey or may be sent a custom unique link that is associated with their email address and/or phone number. Only authorized study staff will have access to participant names and contact information (i.e., only those that need this information to carry out study procedures, such as auditing CO test videos, contacting participants to conduct assessments, and preparing data for analysis). Identifying information will be removed from data that is exported from SurveyMonkey/Alchemer prior to analysis. Participant identifying information will not be included in any published reports. The SurveyMonkey Privacy Policy is located here:

<https://www.surveymonkey.com/mp/legal/privacy-policy/>. The SurveyMonkey Security Statement is located here: <https://www.surveymonkey.com/mp/legal/security/>. The Alchemer Privacy Policy is located here: <https://www.alchemer.com/privacy/>.

With regard to the use of the QuitBet/QuitBet-NS application and the uploading and posting of CO test videos on the social feed, participants will assume the same risks and agree to the same Privacy Policy and Terms of Use as all WayBetter players. The Privacy Policy and Terms of Use will be available within the application and on the QuitBet website. Participants will be required to indicate that they have reviewed these policies as part of the informed consent process. WayBetter employs the use of encryption, firewalls, and hashing to protect players' privacy, including secure socket layer (SSL) technology during information transmission. For the Phase II RCT, anyone may download the QuitBet app but only individuals who indicate that they have read the consent form and agree to participate in the study, created an account with an email address and password, and paid the \$30 bet (i.e., enrolled study participants) will be allowed to join a game and view game information. Participants have the option to receive payments by submitting the e-mail address of their PayPal account or by requesting a paper check that will be sent to their mailing address. Only WayBetter employees who need access to a player's personal information can access it. Participants may delete their QuitBet account if they no longer wish to participate. Study games will not be visible on any public website. All participants assigned to QuitBet will have the option to display their first name or select a "nickname" that will be visible to other players. Participants may be removed from their game at any time for violations of the Terms of Use (e.g., inappropriate or offensive behavior).

### **Perception of coercion to participate in the study**

Risks. Issues related to coercion are judged to be minimal given the use of reactive recruitment strategies.

Minimization. Advertisements will not specify the amount of compensation, and the amount of compensation is not judged to be overly coercive. Based on the outcomes of the QuitBet test game, we expect a maximum abstinence rate in the pilot trial of 40-50% and therefore we expect that game winners will receive at least 2x their original \$30 deposit (\$60, a \$30 net gain). In typical CM studies, participants can often receive much larger incentives for abstinence (i.e., hundreds of dollars) [44, 49]. Informed consent must be obtained from each participant prior to entering the study. The informed consent document will explain in simple terms, before the participant is entered into the study, the risks and benefits to the participant. The informed consent document will contain a statement that the consent is freely given, that the participant is aware of the risks and benefits of entering the study, that the participant is free to withdraw from the study at any time (although the \$30 deposit is non-refundable once the game begins), and that the choice to participate will not affect participants' current or future standing (i.e., future treatment or employment) with any of the organizations or institutions at which the investigators are located/employed. Also, study participation will not affect participants' ability to join other WayBetter games, with the exception that if they are removed from a game for inappropriate or offensive behavior, WayBetter may also choose to ban them from joining other WayBetter games.

### **Potential Benefits of the Proposed Research to Human Subjects and Others and Importance of Knowledge to be Gained**

The risks to participants are judged to be acceptable relative to the anticipated benefits. All participants should benefit from the smoking cessation treatment provided. Additionally, all participants will be assessed on various factors related to their cigarette smoking, thereby potentially increasing their knowledge of their cigarette smoking and related issues. Given the minimal risks to participants (about half of smokers make a quit attempt each year and most have made at least 1 quit attempt in their life; therefore, quitting smoking is an experience that is commonly encountered in everyday life outside of research contexts) and the likelihood of benefit from the treatment provided (and from the additional assessment contacts) and the even greater possibility of benefits to the larger population of smokers, the risk/benefits ratio seems favorable.

### **DATA AND SAFETY MONITORING PLAN**

The PI will have overall responsibility for monitoring the integrity of the study data and participant safety. The PI will be in frequent contact with study staff. Potential risks as described in Protection of Human Subjects include nicotine withdrawal symptoms, loss of money, breach of confidentiality and loss of privacy,

and perception of coercion to participate in the study.

We believe that the risks associated with participating in the proposed research are considered to be minimal, especially given that we are not providing any medications and there are no invasive procedures. However, if any adverse events (AEs) should occur, they will be documented and reported to the PI. All AEs will be assessed by the PI to determine if they meet criteria for a serious adverse event (SAE). All AEs will be followed to the point of a satisfactory resolution. We do not expect any SAEs to occur in this study that are related to study involvement. However, if any AEs meet criteria for serious adverse event (SAE), as defined by the FDA, they will be systematically evaluated at each visit and treated in a similar fashion as AEs with regards to monitoring and reporting. SAEs will be reported to the IRB of record (Advarra) in accordance with their policy for reporting SAEs. The report of SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event and whether all enrolled participants should be notified of the event.

Participants may upload videos of their CO tests to the social feed within the QuitBet/QuitBet-NS application and may also post other text-based messages and photos. These videos, text-based messages, and photos are considered part of the study data. Game activity will be subject to WayBetter's standard Privacy Policy and Terms of Use. The Privacy Policy and Terms of Use will be available in the QuitBet application for players' reference at all times. Players will also have to agree to these policies as part of the informed consent process. Surveys (baseline and post-QuitBet) will be administered and managed using SurveyMonkey or Alchemer. Exported data from SurveyMonkey/Alchemer will be stored on a password-protected server. We will implement cleaning routines that will be used on all data in order to identify miscoded or duplicate variables, mismatched assessment dates, and out-of-range values. Discrepancies will be presented to PI Rosen who will make final decisions about coding.

All data files that contain information that could identify a participant will be stored on cloud-based servers managed by WayBetter. Study staff will be able to access identifying information as needed by logging in remotely to a WayBetter server and accessing this information in Google Docs on a secure cloud-based server managed by WayBetter. Study staff will communicate with participants using WayBetter phone numbers and email addresses.

A data safety and monitoring board has been assembled for the phase 2 trial. It will consist of 3 reserachers with expertise in digital health interventions and/or smoking cessation. The study biostatistician will be a non-voting member of the board. The board will meet annually to review the safety and integrity of the study, or more frequently, if the board deems it necessary.

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