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Research Plan - R34 application to NIDA		
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RESEARCH STRATEGY

A. Background and Significance

Tobacco use and heavy drinking

Cigarette smoking is the single most important preventable cause of morbidity, mortality, and excess health cost in the United States (US), accounting for 443,000 premature deaths each year.[5, 12] Although the prevalence of cigarette smoking has declined among adults in the US since 1983, smoking among young adults aged 18–25 years has remained stable, with past month cigarette use rates as high as 31% in 2013.[13] A large majority of smokers (88%) report starting before the age of 18 years,[14] and 2100 US youth and young adults become daily cigarette smokers each day.[14, 15]

Heavy episodic drinking (HED), also referred to as "binge" drinking, is defined as 5+ standard drinks in a row for males and 4+ drinks for females.[16] HED is most common among young adults than any other age group, with 38% reporting binge drinking in the past month in 2013.[17] HED is a known risk factor for injury, violence, accidents, and unprotected sexual intercourse, especially among younger drinkers.[18-21] In the US, the cost of hospitalizations of underage drinkers is estimated to be 755 million dollars a year.[22] **Reaching the US public health goals of cutting the smoking rate to no higher than 12% and binge drinking to 24% by 2020[23] will require novel approaches to reach and intervene with young adults who engage in these health risk behaviors.**

There are strong links between alcohol use and smoking in the general population.[24-27] For example, the prevalence of smoking among individuals with alcohol use disorders ranges between 80 and 90;[28] in fact more alcohol-dependent patients die of tobacco-related death than alcohol-related causes.[29] The co-occurrence of smoking and drinking is extremely common and detrimental in young adults. National survey data showed that in 2013, more than three quarters of young adult smokers had at least one binge drinking episode in the prior month.[30] Weitzman and Chen[31] found that 98% of student smokers drank alcohol and that 44–59% of drinkers smoked cigarettes, with co-occurrence risk highest among students who reported greater alcohol consumption, having a drinking problem, or using drinking to cope with their problems. Koopmans et al. found that alcohol and tobacco use among young adult twins could be attributed primarily to genetic risk.[32] Among drinkers, the odds of "drinking to get drunk" were more than 2.7 times greater for smokers than nonsmokers. Alcohol complicates occasional or light smoking in young adults, and it often plays a powerful catalyst role in facilitating and maintaining smoking.[33] Young adults report that alcohol increases the enjoyment of and desire for cigarettes,[34] and tobacco enhances the desired effect of alcohol.[35, 36] The co-use of cigarettes and alcohol has been described as like "milk and cookies" or "peanut butter with jelly."[37] Use of both cigarettes and alcohol is associated with greater likelihood of a dependence diagnosis on either substance in adulthood,[1, 2] and increases the risk for certain cancers (e.g., mouth, throat, esophagus, upper aerodigestive tract).[38-40] Further, co-use makes it more difficult to quit either substance.[41-45] **The combined tobacco use and heavy drinking among young adults clearly poses a serious health threat.**

Intervention for tobacco and heavy drinking among young adults

Tobacco Programs. US Clinical Practice Guidelines[5] recommend tailoring smoking cessation interventions to readiness to quit smoking, combining counseling and pharmacotherapy, and using strategies including Motivational Interviewing for those not ready and cognitive and behavioral counseling strategies for those who are ready to quit. However the guidelines note the relative lack of effective interventions targeting the young adult population. Compared to other age groups, young adults are less likely to use behavioral or pharmacotherapy interventions for smoking cessation,[46] and report little intention to use common approaches to smoking cessation.[47] Studies of tobacco treatment have reported great challenges in recruiting young adults.[48, 49] Online smoking cessation strategies (e.g., websites designed to help people quit smoking) reach large samples of smokers[50] but tend not to have a personalized approach to smoking cessation or to have follow-up treatment contacts.[51] Young adults are less likely to take advantage of these cessation resources, and studies of web-based smoking cessation programs have been associated with large drop-offs in engagement of smokers throughout the course of participation.[52-55] Websites directly targeted to young adults have promise with respect to feasibility and short-term outcomes, but have typically focused on college students[56, 57] who are less likely to smoke than less well-educated young adults.[58, 59] For example, a study (*N* = 35) evaluating Kick It!, a web-based intervention including graphics, quizzes, and other features, provided initial support for its acceptability and feasibility with college students.[60] Although the 6-month follow-up quit rate of 25.7% was nearly equal to the self-quit rate of 24.8%, 94.1% reported they would consider future participation in web-based programs, supporting the feasibility of this modality of intervention. Obermayer, Riley, Asif, and Jean-Mary[61] developed a smoking cessation program combining web assessment with

individually tailored smoking cessation messages delivered via text messaging to a participant's cell phone. Among those who completed the study (*n* = 29), the 6-week quit rate was 28%, and there was a significant reduction in cigarettes smoked per week among those who did not quit. Thus, there is limited efficacy for tobacco interventions targeting young adults and those that exist mostly target college populations.

Alcohol Programs. For young adults, prevention and treatment interventions for drinking incorporating motivational interviewing, cognitive–behavioral skills (e.g., alcohol-related skills training), and personalized normative feedback have received considerable empirical support for efficacy, and are more efficacious than purely educational interventions or no intervention.[62-64] As with smoking, college students have been the focus of alcohol interventions. The Brief Alcohol Screening and Intervention for College Students (BASICS),[65] an empirically supported intervention for college student heavy drinking, incorporates personalized feedback about drinking behavior with components of cognitive–behavioral treatment, including education regarding the effects of alcohol, skills training, risk awareness, expectancy information, and suggestions for less risky drinking habits. A meta-analysis of 18 studies showed that after approximately 12 months of follow-up, students receiving BASICS showed a significant reduction in alcohol consumption (difference between means=-1.50 drinks per week) and alcohol-related problems (difference between means=-0.87) compared to controls.[66] A Smartphone app delivering brief intervention for alcohol use to university students showed no difference in frequency of drinking occasions per week compared to a control condition, and suffered from high drop-out.[67] **Strategies are needed to expand available treatments to those beyond the college student population and to increase demand for and sustained engagement in digital health interventions for young adults.**

Intervention for combined use of tobacco and other drugs

Addressing tobacco and other substance use simultaneously can lead to better outcomes than addressing each substance separately. Smoking cessation interventions delivered in the context of alcohol or drug treatment do not impede recovery,[68] and may actually reduce alcohol and other substance use with adults[69-71] as well as teens.[72-74] School-based prevention interventions such as those based on the Transtheoretical Model of Change[75] and Project Towards No Drug Abuse[76] have demonstrated that targeted multiple substances simultaneously can have positive outcomes. As directly applied to tobacco use and heavy drinking, Toll et al. showed that in adults who use tobacco and drink heavily, adding an alcohol component to tobacco quitline counseling resulted in significantly greater tobacco abstinence at 7 month follow-up (13.5%) compared to tobacco counseling alone (10.3%).[77] For young adults, Ames and colleagues showed that integrated treatment addressing both risk behaviors would be acceptable to young adults and, compared to standard tobacco treatment, resulted in more participants biochemically confirmed abstinent from tobacco at 3 month follow-up (but no differences in drinking outcomes between groups).[78] A subsequent pilot trial showed that participants who received integrated intervention were more likely to have biochemically confirmed abstinence from tobacco, consumed fewer drinks per month ($p<0.05$) and had fewer binge drinking episodes per month ($p<0.05$) than those who received standard treatment at 6 months follow-up.[79] **Thus, there is potential for an integrated intervention to result in better tobacco and alcohol outcomes for young adults than treating tobacco alone. Extending an integrated intervention to a digital environment could maximize reach and utility for young adults.**

To our knowledge only one previous study has tested the effectiveness of a digital health intervention jointly targeting smoking and HED in young adults.[80] Compared to a minimal assessment control condition, a 14-day mobile feedback intervention based on the BASICS curriculum resulted in a decrease in the number of cigarettes smoked, but did not reduce HED or concurrent smoking and drinking at the 1 month follow-up. There were no significant differences between the mobile BASICS intervention and a mobile assessment control condition. **More research is needed to determine how best to harness digital tools to target tobacco use and HED in young adults.**

The Promise of Social Media

Given that almost all (97%) young adults in the US use the Internet, and young adults are the age group most likely to go online,[81] digital tools are promising to engage young adults in intervention for smoking and HED. However, most online tools have either targeted only one substance or have shown limited engagement and efficacy with young people.[67, 80] Social media tools (e.g., Facebook) represent a promising strategy to reach and deliver evidence-based treatment for smoking and HED to young adults. Social media are widely popular among young adults (89% of 18 to 29 year olds online)[3] and can be harnessed to influence a broad range of behavioral and emotional changes including smoking cessation.[82-85]

Facebook remains the most widely used social media tool by young adults in the United States. With 87% of US online young adults reporting an account and 70% of those using daily in 2014,[3] there is promise to use this platform to deliver public health intervention programs to young people. Previous evaluations using Facebook to change health risk behavior have shown promising results with respect to feasibility as measured by participant's engagement and satisfaction with the interventions and Facebook delivery.[86-94] However, trials examining social media intervention have shown limited or no effects on health behavior change (e.g., physical activity).[95] **There is a need to harness social media to promote lasting health behavior change and to focus on addictive disorders, which has not been sufficiently addressed in the extant literature.**

The PI has developed the *Tobacco Status Project (TSP),* an intervention with young adult smokers showing engagement and promising initial smoking quit rates.[6] No trial has used social media to target multiple substances, compared social media intervention for substance use against an active control, or coupled a social media intervention with medication for smoking cessation given its influence on smoking quit rates.[96]

The present study brings together a strong, interdisciplinary and well-establish collaborative team to test the current version of the TSP against a version targeting both tobacco and alcohol (TSP+ALC). Our group brings expertise in the design of Facebook-delivered smoking cessation, alcohol interventions, and social media analytics. Given the high rate of tobacco use and HED in young adults and extent of social media use in the population, **young adults should be a priority population for digital substance use interventions funded by the NIH.** Results from this trial will provide an evidence-base from which to disseminate a low-cost intervention worldwide.

B. Innovation

This will be the first study to design and test the feasibility of implementing a Facebook-delivered intervention targeting smoking and heavy drinking among young adults. Particularly novel facets of this research are: 1) the delivery of addiction treatment over social media; and 2) the application of social media intervention to multiple substances (tobacco and alcohol). Social media offer significant potential as delivery mechanisms for health behavior change due to their reach (high number of users and high frequency of use), their ability to bring people together who share similar experiences, and their level of engagement in the lives of its users; yet they are vastly understudied.[97, 98] An additional novel aspect of the research design includes the intervention itself. We propose to use social media to deliver both automated messages (study posts) and counselor-delivered intervention (The Dr. Is In Sessions), as well as harness the social connection among individuals who are matched on substance use and readiness to quit tobacco. Many digital health tools only use one or even two of these tools without using all three. Additionally, we propose to use social media analytics to evaluate relationships among user activity, substance use profiles, and tobacco and alcohol outcomes from the intervention. Our combined Facebook and secure survey data will allow for an unprecedented examination of the relationship between communication patterns and health behavior, informing digital health tools across populations and health risk behaviors.

C. Approach

C.1. Investigative Team

We bring together the strengths of investigators seasoned in using social media to understand and treat substance use disorders in traditionally hard-to-reach populations. **Dr. Danielle Ramo,** Principal Investigator, is an addiction researcher who has experience in designing and conducting social media interventions to promote smoking cessation among young adults. **Dr. Derek Satre**, Co-Investigator, brings expertise in alcohol intervention among patients in mental health service settings, and Motivational Interviewing to reduce alcohol and drug use. He currently leads a large NIAAA U01 alcohol intervention study in an HIV primary care clinic, using a computerized intervention model. His work has also shown the detrimental effect of smoking on 5 year alcohol outcomes[99] **Dr. Kevin Delucchi,** Co-Investigator, has expertise in biostatistics for substance abuse clinical trials, including those conducted over social media, and serves as Co-Mentor on Dr. Ramo's K23 award research. **Dr. Judith Prochaska,** Co-Investigator, has expertise in conducting clinical trials to treat tobacco use and other health risk behaviors in special populations, including young adults[100] and using Twitter to prevent relapse to tobacco use.[101] She has been primary mentor to Dr. Ramo through postdoctoral fellowship and career development award research. **Dr. Sandra Brown,** Collaborator for Alcohol Intervention, brings leadership and expertise in alcohol and drug intervention with youth and young adults. She helped lead NIAAA's effort to establish national screening guidelines for youth, directs the National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA), and was Dr. Ramo's thesis advisor in the SDSU/UCSD Joint Doctoral Program in Clinical Psychology. Especially relevant to the current application is her work in alcohol intervention for youth,[102] and patterns of alcohol involvement among youth.[103] **Dr. Nicolas Sheon**, Qualitative Data Consultant[104, 105], uses qualitative methods to design anti-tobacco messages[106-108] and consults on qualitative study design for the UCSF Clinical and Translational Sciences Institute. **Dr.**

Christopher Yang, Social Media Analytics Consultant, brings expertise in data analytics and social network analysis to evaluate health behavior interactions and interventions. **Dr. Johannes Thrul**, Postdoctoral Scholar, has served as interventionist for the TSP and led analyses and presented results using TSP data since July 2014.

C.2. Preliminary Studies

While preliminary work is not necessary for a Planning Grant application (R34), our team has pilot data and expertise that is directly relevant to this application.

Development, feasibility and efficacy of the Tobacco Status Project (TSP). During her postdoctoral fellowship, Dr. Ramo led a mixed-methods study to determine how young adult smokers would like to use Facebook to help change smoking behavior. About a third (31%) of survey respondents reported they would want to quit smoking using Facebook, and interest was greater among those more motivated to quit, who had made a quit attempt in the past year, and had previously used the Internet for assistance with a quit attempt (all $p<0.01$). In qualitative interviews, social support and convenience were identified as strengths of a Facebook intervention, while privacy was the main concern.[4]

Dr. Ramo is currently funded with a five-year K23 career development award from NIDA to develop and test the feasibility and efficacy of Tobacco Status Project, combining Facebook contacts tailored to participants' readiness to quit smoking with a 12-week cessation program consisting of 7 state-of-the-art group cognitive-behavioral sessions occurring over Facebook text chat. A feasibility trial enrolled 79 young adults who formed 7 Facebook groups. Follow-up rates were 84% and 72% at 6 and 12 months, respectively, and reported 7-day abstinence was 21% at 6 months (9% biochemically-verified) and 18% at 12 months (9% verified).[6, 7] From baseline to 12-months, there was a significant increase in the proportion prepared to quit (13% to 46%, p<.001), 35% reduced their cigarette consumption by 50% or greater, and 67% reported a 24-hr quit attempt. Engagement in the intervention was high, with 92% participation in the full 3 month intervention and 61% commented on at least one post, with more commenting among those randomized to receive a personal monetary incentive.[109] Participants reported reading most of the Facebook posts (mean usability rating=3.3/4) and interactions from counseling sessions (3/4), thinking about what they read (3/4) and would recommend the program to others (3.3/4). Given low participation in CBT sessions (7 of 79 participated) but extremely high engagement (6/7 sessions attended on average) we incorporated the sessions directly into the Facebook groups for a larger efficacy trial currently underway.

In a 3-year controlled trial, we are randomizing 480 young adult participants to either TSP or referral to the National Cancer Institute Smokefree.gov website (control). In 34 weeks, we have randomized 309 young adult smokers, consistent with the proposed timeline, 19% were ready to quit smoking in the next 30 days, and the TSP group has 19 groups actively running or completed. Among TSP participants in groups that have completed the 3-month intervention (n=66), 73% commented at least once to their Facebook group. At 3 month follow-up (treatment end), follow-up rate is 71%, biochemically-verified 7-day point prevalence abstinence among completed cases is 7.1% in the TSP group and 0% in the control group. A majority of participants in both groups reported a 24 hour quit attempt during the 3-month intervention period (62% TSP; 60% control). More participants in the TSP group reported intention to quit smoking in the next 30 days (43%) than those in the control group (35%). At baseline 68% of the sample drank alcohol in the past month and 51% of all drinkers reported current HED. Although promising, there is a need to determine whether expanding the intervention to address multiple substance use will yield maximal effectiveness. **This pilot work will directly inform the present study.**

Facebook Recruitment. Drs. Ramo and Prochaska's research has previously found social media to be an efficient and affordable source of recruitment for young adult smokers. A survey study (N=1987) reported a cost of $4.28 per valid completed online survey, far more affordable and targeted than other online recruitment methods.[110] The TSP feasibility trial, discussed above, reported a cost of $8.80 per eligible consented young adult smoker into our Facebook intervention.[111] Gender and ethnicity have differed by online recruitment source in our work (e.g., Craigslist, Facebook, survey sampling), suggesting the utility of combining recruitment methods.[112.] **Our experience with social media recruitment will inform recruitment in the present study.**

Multiple substance use among young adults. Dr. Ramo has led studies examining multiple substance use among young adults, including reports of a project evaluating patterns of tobacco and marijuana use among young adults (N=1987) surveyed online. We showed that marijuana use was more prevalent than previously reported among young adult smokers,[113] that co-users of tobacco and marijuana used tobacco more heavily and had a lower likelihood of wanting to quit tobacco compared to marijuana,[114] and that co-users showed marked differences in motivation and thoughts about abstinence toward marijuana compared to

tobacco.[115] Studies of multiple health risk behaviors among our group have shown that alcohol use is common among young adult smokers[116] and smokers in mental health treatment.[117]

Analyses of Social Media Data. Dr. Christopher Yang's group has used social network analysis to examine patterns of substance use interactions on social media.[109, 118-121] In an analysis of the TSP feasibility trial data, Ping, Yang, and Ramo found that a monetary incentive was associated with "any" engagement (commenting on Facebook posts) in TSP for those not ready to quit, while an incentive was associate with extent of engagement among those commenting at least once in all readiness to quit groups.[109] Another study using Facebook data, Zhang and Yang analyzed the content of posts and comments in an online forum for smoking cessation (Quitnet).[122] They identified dominant patterns of social support including "initiated support" that was offered voluntarily and "invited support" that was offered in response to requests and most prevalent. In an effort to tie patterns of social interactions to smoking cessation outcomes, Zhang and Yang examined features of posts and users that were related to engagement on QuitNet.[123] Posts that received the most and the fastest comments from Facebook users tended to ask for responses of user motivations, methods, experiences and emotions of smoking abstinence. Users in the maintenance stage of smoking cessation were more active (made comments more frequently and immediately) than those at the early action stage of readiness to quit smoking. Personal communications and advice were the most popular types of informational support. **This work forms the basis for incorporating an incentive into our intervention, and informs analytic strategies with Facebook data to accomplish Specific Aim 3.**

Summary. Numerous studies, including ours, have shown high rates of tobacco and alcohol co-use among young adults; yet this population is less likely to present for formal treatment than those of other age groups. Our group has demonstrated that we have the capability to recruit young adults throughout United States using online strategies, collect biochemical verification of tobacco abstinence, and retain participants in our longitudinal studies. Our Tobacco Status Project Facebook intervention shows great promise for helping young adults quit smoking. The next essential step in this line of research is to subject this intervention to a more rigorous test of efficacy and determine whether multiple substances should be targeted for maximum effectiveness.

C.3. Overview of Design

The proposed 3-year research plan will target young adults who smoke cigarettes and also have HED in two phases (**Fig. 1**). **Phase I** consists of formative work to adapt the existing Tobacco Status Project Intervention (TSP) to include a component targeting alcohol (TSP+ALC) and will also conduct online usability testing with the target population. **Phase II** is a pilot randomized trial (N=160) testing the efficacy of TSP+ALC compared to TSP on smoking and drinking outcomes. Participants will be young adults who have smoked 100+ cigarettes in their lifetimes and smoke at least 4 days per week on average, have had at least one heavy drinking episode in the past month (5+ for men, 4+ for women), and use Facebook on 4+ days per week. Primary outcome will be biochemically verified 7-day abstinence from smoking. Secondary outcomes will be days of HED, sum of days using either tobacco or alcohol in the past 30 days, and dependence symptoms, quit attempts, motivation, and thoughts about tobacco and HED abstinence.

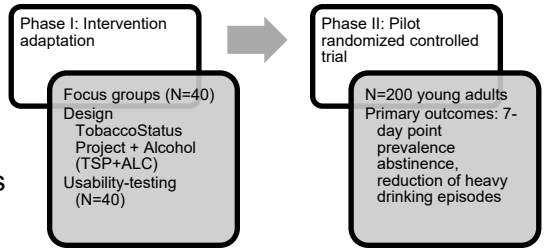

Figure 1: Study design

C.4 Formative work: Focus groups

Focus groups will be used to inform the design of a Facebook intervention targeting tobacco use and HED among young adults (TSP+ALC). During this Phase, investigators will seek consultation services from **Dr. Nicolas Sheon** through the UCSF Clinical and Translational Sciences Institute Study Design Consultation Service**,** to help develop qualitative interview questions and conduct data analysis.

Participants. Participants will be 20 young adult men and women who: 1) read English; 2) are between 18 and 25 years of age; 3) indicate they use Facebook "most" (≥ 4) days per week; 4) have smoked ≥100 cigarettes in their lives and currently smoke at least 1 cigarette per day on 4 or more days of the week; 5) have had at least one heavy drinking episode (5+ for men, 4+ for women) in the past month. Smoking criteria are based on those used in the National Health Interview Survey[12] and are liberal based on smoking patterns most common in young adults and to include ethnic/racial minority populations, who tend to smoke fewer cigarettes per day than Caucasians.[12]

Procedure. Participants will be recruited through Facebook and Craigslist advertisements, using a design and targeting strategy used successfully by the PI with young adult smokers.[110-112] Eligibility and consent will be evaluated online through a Qualtrics survey housed on UCSF secure servers. Once consented, participants will be invited to join a focus group, through a private event conducted on Facebook.

Each of two focus group will contain 10 participants, given general consensus that 6-12 participants is ideal for most focus groups.[124, 125] A structured guide for the focus groups will be developed with the consultation of **Dr. Sheon**. Two 90-minute focus groups will be led by Dr. Ramo (with previous mixed-methods research experience[4]) and Dr. Thrul, a postdoctoral fellow mentored by Dr. Ramo. During focus groups, participants will be asked some initial questions about their demographics, smoking, and drinking characteristics (quantity/frequency of use, age of first use, readiness to quit, whether they have made any past year quit attempts). They will then be asked open-ended questions about patterns and motivations of tobacco and alcohol co-use (e.g., "To what extent do you use tobacco and alcohol at the same time?" "When do you tend to use tobacco and alcohol together?"), and their receptivity to a combined tobacco and alcohol intervention on Facebook (e.g., "Would you want posts to address tobacco and alcohol together or just one substance?" "What images do you think would be most/least impactful?" "What do you think would be most/least helpful about interacting with a counselor on Facebook about tobacco and alcohol use?") With time in the research plan allotted to recruit 20 participants, it is expected that adequate amount of feedback will be garnered to determine how best to incorporate alcohol content into the TSP intervention. Upon completion of focus groups, participants will be sent via email a $20 giftcard to their choice of Amazon or BestBuy.

Analysis of focus group data. All focus group data will be extracted from the Facebook application programming interface (API) by Dr. Ramo. Data (from Facebook comments) will be entered into Dedoose[126] qualitative analysis software along with relevant descriptor data on demographics, and substance use to aid in analyses. Initial qualitative analyses will use Grounded Theory[127, 128] to identify themes in each focus group. To develop a coding scheme, 20% of the focus group content will be independently coded by two research staff, and coding will be compared using the intercoder agreement tools in Dedoose. Differences in the application of codes will be discussed until consensus is reached and the coding scheme will be iteratively revised during bi-weekly meetings with the investigative team and consultant. The initial coding scheme will be based on our research goals and interview questions and will incorporate unexpected themes emerging from the data analysis. We will then analyze subsequent waves of interview transcripts and examine patterns in the sequence, distribution, and co-occurrence of codes using Dedoose's visualization tools and test hypotheses by comparing the responses of participants categorized by quantitative descriptors. Dedoose was chosen because its robust mixed-methods, intercoder reliability, and collaborative analysis features will permit all members of our investigative and consultation team to analyze and interpret qualitative data.

C.5 Treatment Conditions

Tobacco Status Project (TSP). The TSP is a smoking cessation intervention implemented entirely through "secret" (Facebook's word for entirely private) Facebook groups. The intervention has two main features. First, evidence-based strategies have been used to design Facebook posts to be delivered each day for 90 days to intervention groups on Facebook. Posts are based on the US Clinical Practice Guidelines for smoking cessation[5] and the Transtheoretical Model (TTM) of behavior change,[129] both recommending treatment be tailored to participants' readiness to quit. Interventions based on TTM principles have demonstrated efficacy for quitting smoking in adults,[130-134] and adolescents.[135-138] Further, tailoring treatments is the most promising method available for smokers not immediately ready to quit, as demonstrated by mixed-methods formative work with young adult smokers led by Dr. Ramo.[4] For those not ready to quit in the next month, posts are based on Motivational Interviewing (MI), a directive patient-centered counseling intervention recommended by the Clinical Practice Guidelines.[5, 139] There is evidence that MI is effective in increasing future quit attempts among smokers unmotivated to quit including young adults [140-145] and has shown initial efficacy when delivered in an online format to adolescents.[146, 147] Posts elicit clients' motivation and importance of changing tobacco use, problems associated with use, and using open-ended questions to elicit "change talk" (a client's mention of desire, ability, reason, or commitment to change) through using the 5-R's: relevance, risks, rewards, roadblocks, and repetition, shown to increase likelihood of tobacco quit attempts.[140, 148] For those ready to quit in the next month, posts incorporate skills from cognitive behavioral therapy, found effective for long-term smoking cessation,[149] as well as the TTM processes of self-liberation (e.g., making a commitment to quit), stimulus control (e.g., removing smoking paraphernalia from the home), and counter conditioning (e.g., engaging in alternative behaviors). Posts also encourage setting a quit date and making a detailed quit plan. Facebook posts include a combination of images, videos, text and polls designed to reflect the experience of young adults and all elicit a response from participants. Posts may suggest that participants use their FB or real social networks for support with alcohol or tobacco reduction. However, they are not required to share any information about substance use on social media. **See Appendix for sample posts.**

The intervention also incorporates weekly "The Dr. Is In" live sessions with a postdoctoral counselor (using FB commenting features), during which a counselor provides some limited content for discussion and participants can ask questions and get supplemental support. Content for sessions is tailored to readiness to

quit tobacco and is based on Motivational Interviewing (MI) and cognitive behavioral coping skills for smoking cessation. Dr. Johannes Thrul, who has been trained by the PI in delivery of MI (including core techniques of expressing empathy, rolling with resistance, supporting self-efficacy, and developing discrepancy)[139] and CBT skills to address tobacco use, has served as counselor on the current RCT of TSP (N=480). This strategy has been successful in yielding participation in interactive discussion, and setting of goals related to quitting tobacco.[6] As needed, links to more intensive treatment in a participant's' area will be available.

Tobacco Status Project + Alcohol (TSP+ALC). The TSP+ALC intervention design will be informed by results of focus groups (see Section C.4), and the existing TSP intervention. Content targeting heavy drinking will be based on the NIAAA Guides Rethinking Drinking[9] and Guide to Alcohol Screening and Brief Intervention for Youth,[8] recommending use of the 5A's to address alcohol use. Early posts are expected to elicit assessment of alcohol use and give links to normative feedback and risks based on use. Recognizing that ambivalence is part of many young adults' experience with changing substance use behavior, early posts will also incorporate MI[139] strategies, also effective with heavy drinkers unmotivated to quit, including young adults. [65, 150-152] Strategies used in later posts will focus on combining MI with CBT coping skills to empower participants to prepare for reduction or cessation of alcohol use, setting a specific goal, and making a plan for achieving that goal. Skills will be based on "Tips" from the NIAAA Guidelines for youth and adults.[8, 9, 153] Core CBT skills will include coping with life problems, understanding alcohol use patterns among young adults, coping with cravings and urges to drink heavily, managing thoughts about alcohol use, problem-solving, refusal skills, and elective skills topics including planning for emergencies, recognizing seemingly irrelevant decisions, managing negative moods and demonstrating assertiveness. **The number of posts each day, and strategies to combine alcohol and tobacco content in posts will be informed by focus groups.**

TSP+ALC will also include weekly "The Dr. Is In" sessions. Strategies used in the sessions, as in TSP, will be based primarily on Motivational Interviewing and cognitive behavioral coping skills to change both tobacco use and HED. Stimulus material for these sessions will be designed before the intervention is launched and will address use of both substances. Content is expected to differ based on the two types of groups (Ready/Not Ready to quit tobacco), and alcohol content will be similar among tobacco readiness groups. Some content will address the relationship among tobacco and alcohol use (e.g., "What do you guys think is the relationship between smoking and drinking alcohol?"), while other content will address either one substance or the other. **Final content for The Dr. Is In sessions will be informed by the results of the focus groups** and generated by **Dr. Ramo** and **Dr. Satre** with collaboration from **Dr. Sandra Brown**. The Dr. Is In sessions will be delivered by Dr. Thrul, who has also published in the area of alcohol use among young adults,[154, 155] and a fellow in the UCSF Clinical Psychology Training Program who will both be supervised by Dr. Ramo. With approximately 16 groups total (8 in each study condition, 4 Ready, 4 Not Ready, 10 members each on average), each therapist will conduct The Dr. Is In sessions in 8 groups (2 Ready/2 Not Ready in each study condition).

Monetary Incentive for Engagement. Analyses of our TSP feasibility trial showed that a monetary incentive increased engagement in the Facebook intervention for all those who had some basic level of engagement (at least one Facebook comment).[109] In the RCT currently underway, groups are randomized to three different monetary incentive structures (daily, weekly, monthly) or no incentive. Although results are not final, preliminary analyses with 310 participants in the TSP condition in 10 TSP groups complete through 6/5/2015 (3 daily, 3 weekly, 1 monthly, 3 no incentive) indicate that any incentive is associated with higher engagement than no incentive (75% vs. 67% commenting at least once) and engagement is highest among those receiving an incentive in a weekly basis (82%). Thus in the present study, we will tally posts weekly and offer all participants a $20 giftcard at the end of the intervention if they comment on all Facebook posts during the time period.

Nicotine Replacement Therapy (NRT).

We will offer a free 14-day starter pack of nicotine patch to all participants regardless of intervention condition, given findings that smokers receiving a 14-day starter pack showed more satisfaction with a telephone quit line and had higher 7-day quit rates compared to those not receiving patch.[96] In our current trial, at baseline, 88% were daily smokers and participants averaged 11.8 (SD=14.3) cigarettes per day and 2.8 years (SD=.6) of smoking; the sample averaged low to moderate nicotine dependence (FTND score=3.0, SD=1.6) It is anticipated, therefore, that NRT will be necessary and useful for many participants. For those who are not nicotine dependent, we do not anticipate any decrease in the probability of quitting due to nicotine patch availability.[156, 157] Further, NRT use will not be required for study participation. All participants who smoke an average of 5 or more cigarettes per day in the past 30 days and who are still members of a Facebook secret group at the time the group starts will be offered the nicotine patch. The 5 cigarettes per day criterion is based on successful implementation in Dr. Sharon Hall's trial with depressed outpatient smokers[158] and trials

with adolescents and smokers in inpatient psychiatry led by Dr. Judith Prochaska (Co-Investigator).[100, 159] At any time during the three month intervention, participants will be mailed nicotine 21-mg, 14-mg, or 7-mg patches based on smoking rate at intake. Participants in both conditions will be encouraged to discuss use and ask questions during weekly counseling sessions.

C.6 Usability testing

Once TSP+ALC has been developed, the intervention will be usability-tested and feedback will be garnered from 30 young adults who smoke (15 ready to quit, 15 not ready to quit) through Facebook. Participant eligibility and procedures for recruitment will be identical to those for the focus groups. Eligible participants will sign online consent through a Qualtrics website housed on UCSF secure servers. Once consented, initial questions will assess demographics, smoking, and drinking characteristics. Then, participants will be invited to join a Facebook secret group populated by study staff and shown a series of posts from the TSP+ALC intervention and asked to rate posts using Facebook polls on likability (e.g., "How much do you like this post?"; score 1 to 5) and helpfulness (e.g., "How much would this post make you want to change something about your drinking?"). Open-ended feedback will also be garnered for all posts, which is extremely user-friendly through Facebook. Participants will also be shown content of counseling sessions to be used for The Dr. Is In Sessions and be asked for open and closed-ended feedback in a similar fashion as that for daily posts. All participants who complete usability-testing will be sent via email a $20 giftcard.

Analysis of usability data. All survey data will be extracted from the Facebook API by Dr. Ramo. Poll data will be put into an SPSS database. We will calculate mean responses to Likert scale items and any sections with lower than median values will indicate changes should be made before the trial is launched. Qualitative data (from Facebook comments) will be entered into Dedoose[160] and analyzed in a similar fashion as focus group data.

C.7. Incorporation of participant feedback.

Once the usability data have been analyzed, **there is time allocated in the research plan to make any necessary changes to the intervention**. Facebook posts that are not "usable" (i.e., likable, engaging, based on feedback during testing) will be changed or replaced with other posts.

C.8 Efficacy Trial

The efficacy trial will be designed according to Figure 2 and described below.

Participants. Participants will have the same inclusion criteria as those for the focus groups and usability testing procedures.

Sample size and power analysis. The sample N of 160 was set primarily for practical and clinical reasons and not driven by estimated effect sizes or hypothesis testing. We expect to have representation (although not equal) among males and females, and across ethnic groups consistent with our current trial of TSP. We also expect to have representation across levels of smoking and drinking, and readiness to quit using both substances. We anticipate an attrition rate of 30% at 3, 6, and 12 months, yielding a final sample size of 112 (56 in each group), enabling us to compare groups on primary and secondary outcomes at each timepoint. This will also generate an effect size estimate that will be useful for powering a larger trial.

A goal of 6 participants will be recruited per week during the 6-month recruitment period, which is in line with recruitment for our feasibility trial and current RCT.[111]

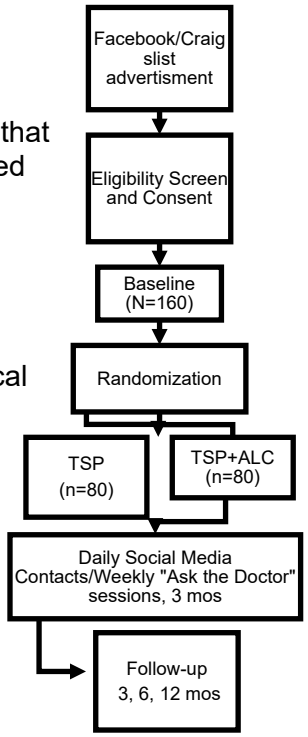

Figure 2. Participant flow through the study

Procedures. Participants will be recruited through Facebook and Craigslist advertisements, using a similar strategy to that of focus group and usability-testing. All advertisements will provide a link to the study's website, with eligibility questions. If respondents are eligible, then they will be taken to the informed consent webpage. Participants consenting to participate in the study will be asked to verify age by sending proof through email or social media, a process used successfully in Dr. Ramo's previous research. Verified participants will be emailed a baseline assessment. Those completing the baseline assessment will be randomized to either TSP, or TSP+ALC, stratified based on readiness to quit smoking (Ready in the next 30 days, Not Ready in 30 days) and smoking pattern (daily vs. non-daily), variables known to be related to outcomes and addressed by the intervention.[161] A stratified random assignment program will be developed in consultation with Dr. Delucchi, and used currently in Dr. Ramo's RCT of TSP. All participants will then be assigned to a secret group tailored to their condition and readiness to quit tobacco. Groups will begin when there are approximately 12 participants enrolled, as that has been deemed the optimal number based on analyses of engagement in our previous work.[109, 162] Groups will receive one social media post daily for 90 days and weekly "The Dr. Is In" counseling sessions managed

through the study's private group pages. If participants wish to have private study interactions with study staff they can do so at any time. Three-month follow-up assessments will be emailed to participants upon completion of treatment.

Informed consent, baseline and 3, 6, and 12 month assessments will be delivered using the online survey program Qualtrics, which is HIPAA-compliant, has been used often in medical research, and is being used successfully by Dr. Ramo for her current Facebook intervention study. Verification of non-smoking status will be conducted for all participants reporting no smoking in the past 7 days at the post-test assessment using mailed saliva cotinine test kits and verified online as described in the **Measures** section. Participants will receive their choice of Amazon or Best Buy gift cards in the amount of $20 for each 20-30 minute online survey**,** and a bonus $20 for completing all assessments, for a total of $100 possible compensation for participation. Amazon and Best Buy were chosen as retail outlets given their overwhelming popularity among a large choice of retailers given in Dr. Ramo's previous studies with young adult smokers.[4, 111] Assessments will not be considered complete until staff receives verification of abstinence.

Measures.

Primary outcome (tobacco):

- **Biochemically-verified 7-day point prevalence abstinence from all tobacco products** will be assessed at 3, 6, and 12 months. Participants reporting no smoking in the past 7 days will be coded as abstinent from cigarettes. Those reporting 7-day abstinence will be mailed a saliva cotinine test kit, and record two pictures: one giving a saliva sample, and another of the test result. Participants with a salivary cotinine level <11 ng/ml, indicating nonsmoking,[163] will be considered confirmed nonsmokers**.** Biochemical verification is recommended in randomized trials with sample sizes under 500,[164] saliva cotinine test kits have been successfully mailed to participants in previous studies,[165] and Dr. Ramo is using this method successfully in her K23 Facebook smoking cessation RCT with young adults (to date, 50% reporting 7-day abstinence have successfully completed biochemical verification). If participants indicate use of an electronic nicotine delivery-system to aid in smoking cessation, saliva cotinine and reported ENDS use will be recorded and reported separately from biochemically verified abstinence.

Secondary outcomes (tobacco):

- **Reduction of cigarette consumption by 50% or more (y/n)** between baseline each follow-up will be calculated from the number of cigarettes smoked in the past 7 days at each time point.
- **Tobacco quit attempt** (y/n). A *Follow-up Smoking Questionnaire* will assess the presence and number of 24 hr quit attempts since the last assessment, used to calculate presence of at least one quit attempt in the assessment time period. This questionnaire has good internal consistency and construct validity, and is routinely used in smoking treatment research.
- **Readiness to quit tobacco** will be assessed using the *Stages of Change Questionnaire*,[129] categorizing participants into five stage categories at each timepoint (precontemplation, contemplation, preparation, action, and maintenance), and predictive of quit attempts and cessation.[166]
- **Desire to quit, abstinence self-efficacy, perceived difficulty of quitting and abstinence goal** will be assessed with the 4-item *Thoughts About Abstinence Form,*[167] measuring each construct on a scale from 1 ("least") to 10("most"), and categorizing goal as no goal, intermediary goal (e.g., reduced smoking), or total abstinence.

These smoking measures demonstrated significant improvement from Baseline to 12 months in the TSP feasibility trial,[7] and have demonstrated validity for use with young adult smokers online.[168, 169]

Secondary outcomes (alcohol):

- **Days of HED**. Past 30 day HED episodes, defined as 4+ drinks in an occasion for women and 5+ drinks for men, consistent with the NIAAA definition[16] will be assessed with the *Timeline Followback* (TLFB). The TLFB has good reliability and validity for tobacco and alcohol and administered online.[170-173] Past 30 day use is a commonly-used assessment timeframe,[174] and self report measures such as the TLFB can be accurate,[175-177] and are the most common outcome measures for clinical trials.[178]
- **Number of drinks per week** assessed by the *TLFB.*
- **Misuse of alcohol in the past year** will be assessed by the *Alcohol Use Disorders Identification Test-C* (AUDIT-C; 3-items; range: 0-12).[179-181] Used widely in the literature, cut-off scores of 3 in women and 4 in men have demonstrated good sensitivity and specificity compared to longer clinical interviews.[182]
- **Alcohol quit attempt** (y/n). A *Follow-up Drinking Questionnaire* will assess the presence and number of 24 hr quit attempts since the last assessment, used to calculate presence of at least one quit attempt in the assessment time period.

- **Readiness to change alcohol use** will be assessed with a single-item **Readiness Ruler**, developed and validated for use with young adult heavy drinkers participating in brief intervention.[183, 184] and the alcohol item from the **Staging Health Risk Assessment (S-HRA)**[185, 186] to compare stage of change across tobacco and alcohol use.
- **Desire to quit HED, abstinence self-efficacy, perceived difficulty of quitting and abstinence goal** will be assessed with an adapted *Thoughts About Abstinence Form* for HED.
- **Thoughts about alcohol** will be assessed the *Thoughts About Abstinence* form, adapted for alcohol.

Secondary outcome (combined days using tobacco or alcohol):

- *TLFB* data will be used to calculate the sum of days using any tobacco or binge drinking in the past month.

Additional measures.

- **Demographics.** Age, gender, ethnicity, parental and personal education, work/school status, military involvement, parental status, and other personal characteristics will be assessed at baseline with a *Demographic Questionnaire* used in our prior research with young adults.[169]
- **Smoking History.** The *Smoking History Questionnaire*[158] at baseline will assess age of initiation and years of smoking; prior quit attempts and cessation strategies; other nicotine (e.g., electronic nicotine delivery systems) and tobacco use (e.g., cigars); nicotine dependence using the 6-item *Fagerström Test of Cigarette Dependence (FTCD);*[187, 188] and social smoking with 3-items used with young adults.[189, 190]
- **Alcohol Use history.** We will assess age of first drink and first heavy drinking episode, prior attempts to change HED, and change/cessation strategies.
- **Combined alcohol and tobacco use.** Two items assessing subjective effects of smoking while drinking (estimated overlap and pleasure), previously used with college students,[34] will be given at baseline.
- **Drug Use Severity.** The *Drug Abuse Screening Test-10* (DAST; 10 items),[191] will assess misuse of drugs in the past year. Used widely in the literature, a cut-off score of 2 has demonstrated good sensitivity and specificity compared to longer clinical interviews.[192]
- **Other health risk behaviors.** The 34-item *Staging Health Risk Assessment (S-HRA)*[193, 194] will screen and assesses readiness to change for 11 health risk behaviors including tobacco, alcohol, and illicit drug use, poor sleep quality, sedentary behavior, poor diet, depression, and high risk sexual behavior. The staging algorithms for the health behaviors have been well studied and have strong predictive validity over 6, 12, 18, and 24 months.[185, 186, 195-198] This measure will be used to characterize other health risk behaviors in this substance using sample with potential to evaluate the effect of each intervention on multiple health risk behaviors other than tobacco use and HED.
- **Feasibility Measures.** *Advertising statistics* available online through Facebook and participant characteristics will be used to track costs and recruitment over time at each study stage (e.g., study interest, meeting criteria, signing consent, and entering the study). *Retention* will be evaluated by the proportion of participants that completes the 3, 6, and 12-month assessments. *Engagement* will be measured by the total number of "likes" and comments each post/counseling session receives.
- **Usability measure.** A *usability measure*, adapted from our previous research,[6, 7] will assess ease, comprehension, helpfulness, and likability of TSP and TSP+ALC interventions at 3 months.

C.9 Data Analysis.

Analysis for Specific Aim 2: Feasibility. Although we do not expect problems in implementing this intervention given our prior work with social media,[7] we are evaluating feasibility outcomes to ensure feasibility of the TSP+ALC intervention.

Feasibility analyses will examine four areas: **(1) Recruitment Efforts:** We will evaluate (a) length of time to recruit N=160 participants to enroll in the pilot trial, and (b) demographic, smoking, and drinking characteristics of those eligible and who enroll; **(2) Usability:** We will calculate mean responses to Likert scale items of the usability measure and any sections with lower than median values will indicate changes should be made before future investigations take place. **(3) Implementation of biochemical verification of tobacco abstinence:** We will determine the proportion of participants in each condition reporting 7-day point prevalence abstinence at 3-month follow-up that completes a saliva cotinine test and the rate of discordance between saliva cotinine results and self-report. **(4) Attrition:** We will track the number and proportion of participants that completes each follow-up assessments and compare these numbers to previous Internet cessation trials (attrition as high as 75%[52, 53, 199-201]).

Analyses for Specific Aim 2: Preliminary efficacy.

Descriptive statistics will summarize sample characteristics and the extent of intervention delivery in each group. We will examine treatment condition and baseline descriptive characteristics as predictors of

attrition at trial end (month 3) and propose to control for predictors of attrition as covariates in model testing. Missing data will be minimized through online assessment. When subjects do not complete online assessments, they will be re-contacted through Facebook or email to obtain missing information. For each test related to smoking, two sets of outcome analyses will be conducted - one with all participants who are maintained in the study, and another based only on biochemically verified smoking abstinence rates to allow for direct comparison of findings with the research literature.

Primary outcome: To test for the effects of treatment condition on smoking abstinence at 3- through 12-months, we will estimate and test a mixed-effects logistic regression model. Abstinence status will be examined as 7-day point prevalence. The independent variables are TSP versus TSP+ALC plus variables that are related to abstinence such as cigarettes per day, differ by condition at baseline or predict attrition. We will use multiple imputation procedures to impute missing data.

Secondary outcomes: For secondary outcomes we will estimate and test mixed effects logistic and multinomial regression models for longitudinal ordinal response data to model secondary outcomes for tobacco use and alcohol use across time (3, 6, 12 months): 1) reduction of cigarettes by 50% or more (y/n), 2) tobacco or alcohol quit attempt (y/n; 2 models), 3) readiness to quit tobacco and alcohol (Precontemplation, Contemplation, Preparation, Action/Maintenance; 2 models); and 4) commitment to abstinence (no goal, intermediary goal, complete abstinence). In parallel, mixed effects linear regression models will model the following continuous outcomes over time: 1) past 30 day HED; 2) average number of drinks per week in the past 30 days, 3) severity of alcohol use (AUDIT-C score); 4) desire to cut down tobacco and alcohol use (1 to 10; 2 models); and 5) sum of days using either tobacco or alcohol in the past 30 days. Independent variables in all models will be treatment condition, abstinence status, and covariates identified as relevant to smoking characteristics in the literature.

Analyses for Specific Aim 3 (Engagement and Patterns of Social Interaction). Analyses will use Facebook data extracted from the private groups we develop on Facebook using the Facebook API. All data will be de-identified and transferred to **Dr. Chris Yang**, expert on social media analytics at Drexel University, for analysis. The data will include the content of the posts and comments, the activity of each participant (e.g., number, content, and time of all comments), and interactions among participants. We will determine patterns of engagement, type of posts that are most “engaging” to participants, and relate engagement to smoking and drinking outcomes using three main analyses: **(1) Patterns of engagement:** Total number of “likes” and comments to Facebook groups over the 3 month intervention period will be tallied for each group (TSP, TSP+ALC), and the non-parametric Kruskal-Wallis ANOVA will compare likes and comments in each intervention and include covariates of baseline characteristics (readiness to quit tobacco/alcohol, daily/non-daily smoking status, gender) and group membership; a social network analysis will examine the interaction patterns among different types of users with which participants engage in each intervention; a content analysis will evaluate the content of comments within each group and observe differences among the two groups; **(2) Success of specific posts**: To evaluate which posts are most successful at engaging participants, Drs. Ramo and Yang will collaborate on coding posts based on content type (e.g., alcohol/tobacco, Motivational Interviewing, specific CBT skills). Specific codes will be determined upon design of the TSP+ALC intervention). ANOVA will then be used to examine likes and comments by post type within each group (TSP, TSP+ALC) **(3) Engagement and outcomes**: We will compare TSP and TSP+ALC groups on the relationship between intervention engagement (FB comments) and primary tobacco and alcohol outcomes (abstinence, heavy drinking days) at the end of the 3 month intervention period. Logistic regression will be used to analyze tobacco abstinence, and linear regression for days of heavy drinking at 3 months, controlling for any baseline differences in treatment groups. Kruskal-Wallis tests will evaluate the effect of incentive condition (personal, altruistic, no incentive) on comments to the Facebook group, in both the full sample and only those who made at least one comment to the group to address likely skewed data.

C.10 Data management plan.

Data will be collected through Qualtrics software that is housed in the UCSF MyResearch environment. Qualtrics is a secure, HIPAA-compliant online survey software that is used by over 1,300 universities. It transmits data to and from secure, firewalled data centers using Transport Layer Security (TLS) encryption, the successor to Secure Sockets Layer (SSL) encryption. MyResearch is a HIPAA-compliant desktop environment that is hosted on highly secured and locked servers at a UCSF data center. The MyResearch environment utilizes VM Ware View Virtual Desktop, which must be logged into using UCSF Active Directory credentials. The dataset will stored in Dr. Ramo’s group network folder in the MyResearch environment, where only the research team will be able to view the datasets; this access is audited. Any identifying information will be kept separately from other data. Any data transferred to Drs. Prochaska, Yang, or Sheon will be de-identified.

C.11. Limitations and Difficulties

Choice of Facebook. Facebook is still by far the most widely used form of social media by young adults in the United States compared to Twitter, Pinterest, LinkedIn, and Instagram; 87% of online young adults used Facebook in 2014,[3] up 4% from 2013. Given that social media is increasingly accessed via mobile technology, and its use among those online does not differ by income, it is a particularly good option to deliver intervention to diverse groups of young adults who smoke and exhibit hazardous drinking throughout the US.

Choice of control condition. In this pilot trial, we chose to compare TSP+ALC to TSP targeting only tobacco. We are currently conducting a trial comparing TSP to a website referral control with promising results (7% vs 0% biochemically-verified abstinence, 64% data collection**)**. Thus it seemed wasteful of resources to incorporate a standard treatment control in the present pilot trial. TSP+ALC results in better tobacco or alcohol outcomes than TSP, we plan to submit an R01 application to test TSP+ALC on tobacco and alcohol outcomes against a control condition that more closely approximates standard treatment (e.g., a website referral).

Retention. Attrition in Internet smoking cessation trials can be high **(**up to 75% for other online intervention studies),[52, 53, 199-201] however the drop-out rate in the TSP feasibility study was only 16% at 6 months. Further, by using Facebook to deliver the intervention, we will increase the likelihood that participants will be readily reachable for assessment contacts.

Privacy. Social media, by nature, is a public forum for interaction, and there is potential for unintended sharing of information. **All intervention components will be administered entirely through private groups that will not be visible beyond the participants in the groups.** Participants will be given detailed information about the intervention in the consent process, including notice that all groups are private. However, some participants may have additional concerns about the security of their information. Study investigators will ensure that any concerns are directly addressed with potential participants before they enroll. The exchange of information, including health behavior information, is increasingly being conducted through Facebook, and there is great potential to use this space to help people make positive life changes with the support of an intimate support network. Additionally, Dr. Ramo has successfully obtained Federal Certificates of Confidentiality from the NIH for her previous work and will apply for one for this project.

C.12. Three-year Timeline

	Year 01						Year 02						Year 03					
Month	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Phase I: Intervention adaptation, usability-testing, and revision																		
1. Recruit, hire & train support staff; study preparation																		
2. Program online assessments																		
3. Conduct online focus groups (N=20)																		
4. Analyze focus group data																		
5. Design TSP+ALC from focus group data and TSP																		
6. Online usability-testing (N=30)																		
7. Analyze usability data																		
8. Revision based on usability-testing																		
9. Write-up Aim 1 manuscript (development/usability)																		
Phase II: Efficacy Trial (N=160)																		
1. Study recruitment and baseline assessment																		
2. Intervention period (90 days)																		
3. 3 mo FU																		
4. 6 mo FU																		
5. 12 mo FU																		
6. Data cleaning, data analysis, manuscript submission Aim 3 (FB data)																		
7. Data cleaning, data analysis, manuscript submission Aim 3 (pilot trial)																		
8. Prepare and submit R01 application for RCT																		

C.13. Future Plans

The proposed Project fits within the research team's program of research focused on using social media to reduce substance use. Based on the results of the pilot randomized trial to be conducted here, anticipated next steps include submission of an application for a randomized controlled trial powered to detect differences across groups in both tobacco and alcohol outcomes.