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An Investigation of SMART Recovery: protocol for a longitudinal cohort study of individuals making a new recovery attempt from alcohol use disorder

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ABSTRACT

Introduction

Alcohol use disorder (AUD) remains one of the most pervasive of all psychiatric illnesses conferring a massive health and economic burden. In addition to professional treatments to address AUD, mutual-help organizations (MHOs) such as Alcoholics Anonymous (AA) and newer entities like SMART Recovery play increasingly important salutary roles in many societies. While much is known about the positive effects of AA, very little is known about SMART Recovery. Hence, this study seeks to estimate real-world patterns of utilization and derived benefit from SMART Recovery as well as explore for whom (moderators) and how (mechanisms) SMART may confer recovery benefits.

Methods and analysis

Naturalistic, longitudinal, cohort study (N=368) of individuals with AUD initiating a new recovery attempt who self-select into one of four groups at study entry: 1. SMART Recovery; 2. AA; 3. SMART+AA; 4. Neither SMART nor AA; (stratified by DSM 5 severity markers), with assessments conducted at intake, and 3-, 6-, 9-, 12-, 18-, and 24-months. Primary outcomes are: Frequency of SMART and AA meetings attendance; Percent Days Abstinent (PDA) and percent days heavy drinking (PDHD). Secondary outcomes include: psychiatric distress; quality of life and functioning. Moderator variables include sex/gender; race/ethnicity; spirituality. Mediational variables include: social networks; coping skills; self-efficacy; impulsivity. Multivariable regression with propensity score matching will test for patterns of attendance and effects of MHO participation over time on outcomes and test for mechanisms and moderators.

Ethics and dissemination

This study is approved by the Mass General Brigham Institutional Review Board. Results will be published in peer-reviewed journals and presented at relevant conferences.

Registration

This is a non-randomized, naturalistic, longitudinal, cohort study, and thus was not registered in advance. Results stemming from the study, therefore, should be considered exploratory. The study was funded by the US National Institute of Alcohol Abuse and Alcoholism (NIAAA; 5R01AA026288).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will be one of the first rigorous, real-world, evaluations of the addiction recovery mutual-help organization, SMART Recovery, providing objective estimates of patterns of utilization and recovery benefits, and will explore the moderators and mechanisms of behavior change to determine who benefits from SMART Recovery participation and why.
- Individuals (N=368) with primary alcohol use disorder who self-select into either SMART Recovery, Alcoholics Anonymous (AA), both SMART and AA, or neither, will be compared over time on addiction recovery processes and outcomes.
- Participant characteristics, changes processes, and outcomes will be measured prospectively at study intake, and again at 3-, 6-, 9-, 12-, 18-, and 24-months later.
- Primary outcomes will be: number of SMART and AA meetings attended per week at each follow-up; percent days abstinent (PDA); percent days heavy drinking (PDHD); alcohol use disorder remission status; alcohol/drug related consequences. Secondary outcomes include quality of life and functioning psychiatric distress, self-esteem, happiness.
- Due to COVID-19, the majority of study visits are being conducted remotely, meaning that substance use outcomes will be provided exclusively by participant self-report without biochemical verification.

INTRODUCTION

Alcohol and other drug use disorders confer a prodigious burden of disease, disability, and premature mortality in most middle- and high-income countries globally. To help alleviate this burden, most countries provide an array of professionally delivered addiction treatment services. Yet, despite these efforts, such services are often unable to meet both acute care and long-term relapse prevention needs of the millions or tens of millions affected annually. In response, most countries also possess an array of informal community-based peer recovery support services which can provide ongoing assistance for individuals suffering from these disorders [1]. The oldest and largest of these are the 12-step mutual-help organizations (MHOs), such as Alcoholics Anonymous (AA). Rigorous research evidence has now demonstrated that when AA is subjected to the same scientific standards as other addiction focused interventions it does as well on most outcomes measures, is better at sustaining abstinence and remission over time, and is highly cost effective [1].

A limitation of the current standard of care, however, borne out of a limitation in available empirical data, is the fact that referral oftentimes focuses solely on spiritually-oriented 12-step organizations, such as AA, which is the only empirically-supported MHO continuing care referral option. Not everyone chooses AA as a pathway to recovery for various reasons, and alternative MHO options - although much newer and smaller - are growing and may contain many of the same positive therapeutic elements and dynamics possessed by AA [2, 3]. These therapeutic pathways include adaptive social network changes, increases in social abstinence self-efficacy, and reducing negative affect. Indeed, some preliminary evidence suggests such organizations may confer similar benefits for those who self-select into them [4].

The largest and possibly most well-known of these newer alternative MHOs is Self-Management and Recovery Training (SMART) Recovery. There are approximately 1,200 SMART groups nationwide and another 1,000 internationally. SMART also has a strong online support presence including online meetings, forums, and chat rooms. Unlike AA, SMART is founded upon cognitive-behavioral principles and practices and is led by trained facilitators. It focuses on enhancing and maintaining motivation to abstain or (more recently) reduce use to non-problematic levels, coping with urges, problem solving, and lifestyle balance [5]. It also advocates for appropriate use of professional psychosocial and pharmacological treatments. A compelling aspect of SMART as an MHO is, because it is itself based on empirically-derived CBT principles, it provides a philosophically compatible recovery resource that is aligned with cognitive-behavioral treatment principles, which make up a large majority of national and international evidence-based treatments [6]. Consequently, SMART is appealing to many individuals with SUD [5], yet due to the lack of empirical evidence supporting its effectiveness, clinicians remain less likely to discuss or refer patients to SMART [7, 8]. This has hindered its growth and prevented many the opportunity to learn about and try SMART.

Compared to the dozens of high-quality studies examining 12-step MHOs [9-12], there have been just a handful of studies on SMART. We conducted a systematic review of this research [13] and found that only 12 studies exist (4 of which are unpublished dissertations) that have focused on SMART Recovery and used any kind of formal measurement. Most of these (8 out of the 12) are cross-sectional with mixed results and suffer from considerable biases as they possess substantial methodological limitations making it difficult to draw firm conclusions [14-16]. For instance, these studies have rarely assessed mental health status or its severity, despite the high rates of comorbidity between AUD and mental health. Two recent high-quality studies

examining SMART Recovery, however, have been conducted, one in a criminal justice context, the other examining its effect on heavy alcohol use in an RCT.

The criminal justice study was a large quasi-experimental study of criminal offenders in Australia [17]. It compared a group of individuals participating in SMART Recovery and/or a criminal justice intervention (called "Getting SMART") designed to link offenders with SMART meetings following prison release, to a group of control participants who did not interact with any SMART materials or attended meetings, but who were matched on various other relevant characteristics through the use of propensity scores. The study found that participation in Getting SMART by itself, and Getting SMART + SMART Recovery meeting attendance, was associated with a reduced overall rate of reconviction with rates of reconviction reduced by 19 and 22%, respectively. For violent reconvictions, rates were reduced by 30% for Getting SMART participation and 42% for Getting SMART + SMART Recovery. While an important and promising set of results in their own right, unfortunately, the authors did not examine or report any alcohol/drug use outcomes [17].

There has been only one small, randomized trial evaluating SMART Recovery, which randomized people to (a) "Overcoming Addictions" (OA) - a SMART Recovery web application, (b) SMART Recovery meeting attendance, or (c) OA + SMART Recovery meeting attendance combined. The study found participants from all groups benefitted equally with respect to alcohol outcomes [18]. This finding underlines the promise of SMART Recovery to provide recovery support. Unfortunately, however, this trial did not include a control group, who did not have any exposure to SMART materials. Given, however, that all groups participated in SMART, it is not clear if observed benefits were simply naturally occurring improvements in alcohol outcomes, or really a function of SMART participation. Another limitation is that it only enrolled subjects with heavy drinking problems and excluded participants with more severe forms of AUD, who more typically enroll in formal treatment and are thus in need of referral options for continuing care.

A more recent study examined participation among individuals with alcohol use disorder recruited from various online and community venues with varying lengths of sobriety who self-selected into one of four different types of MHOs: Alcoholics Anonymous, LifeRing Secular Organization, SMART Recovery, and Women for Sobriety[4]. This study found that SMART Recovery participants had as good alcohol outcomes at 6- and 12-month follow-ups as those attending other MHOs. Again, however, the study did not include a control group with no MHO involvement.

These results provide some preliminary information about real-world benefits related to SMART Recovery participation. There is very little, if any, information regarding how involved they become or the mechanisms of behavior change through which SMART may help individuals attain AUD remission and recovery (e.g., via social changes, coping skills, recovery motivation, abstinence self-efficacy; reduced impulsivity). SMART has the potential to be a secular MHO alternative to 12-step MHOs for those preferring the secular and cognitive-behavioral foundation of SMART, yet in order to increase clinical confidence and referrals, more systematic research is needed. This study will be one of the first rigorous, real-world, evaluations of SMART providing objective estimates of recovery benefit (e.g., abstinence, AUD remission, quality of life, psychosocial functioning), and will explore the mechanisms (e.g., social network changes, self-efficacy, decreased impulsivity) and moderators (e.g., sex, race/ethnicity, addiction severity, psychiatric co-morbidity) of behavior change to determine how SMART Recovery may help its affiliates achieve and maintain remission from addiction and who seems to benefit most.

To this end this study has the following specific aims: 1. Characterize and describe professional and non-professional recovery support service participation choices, migrations, and pathways using group trajectory analyses over a two-year period for individuals (N=368) starting a new AUD recovery attempt. More specifically in this regard, we will investigate the real-world effectiveness of SMART Recovery by comparing outcomes of AUD individuals making a new recovery attempt (N=368) pursuing either a SMART Recovery pathway (online or face-to-face; N=184) or a non-SMART recovery pathway (N=184). Because, according to SMART Recovery's annual survey data, roughly half of SMART participants also attend AA, we will use a stratified design to enroll persons with AUD making naturally occurring continuing care choices vis-à-vis participation in MHOs in a balanced fashion and follow them prospectively across a 24-month period. This stratified design will allow us to compare the outcomes of persons choosing to participate in SMART Recovery vs. not (balanced by AUD severity), while accounting for simultaneous choices regarding AA or neither AA or SMART MHO participation. 2: Explore moderators and mechanisms of behavior change. Exploration of factors that may help uncover who (i.e., moderators) and why (i.e., mechanisms) SMART affiliates benefit from participation will be investigated. Moderators will include sex and gender, addiction severity, psychiatric distress; and mechanisms will include social network changes, recovery motivation, cognitive-behavioral coping, abstinence self-efficacy, and impulsivity.

METHODS AND ANALYSIS

Study overview

This study is a naturalistic, prospective, longitudinal cohort study of 368 individuals making a new recovery attempt from AUD with seven assessments over a 24-month follow-up period. Following the baseline assessment, research staff will conduct additional follow-up assessments at 3, 6, 9, 12, 18, and 24 months after study enrollment. Assessments include both self-reports by participants using online surveys, and staff-administered assessments, conducted via phone and/or Zoom. Baseline visits were conducted from February 2019 to February 2022. Follow-up visits are ongoing and will continue until approximately February 2024. The study was fully reviewed and approved by the Institutional Review Board at Mass General Brigham, Boston, MA USA.

Sample size determination

The primary outcome variables are percent days abstinence (PDA) and percent days heavy drinking (PDHD; NIAAA-defined). Secondary outcomes include quality of life and psychosocial functioning. To estimate a plausible effect size to be expected in PDA as a function of mutual help organization (MHO) utilization, we examined the PDA outcomes in Project MATCH [19] for persons utilizing AA vs. not. Effects were surprisingly consistent across time, with patients with any AA utilization reporting a higher average number of PDA than patients with no AA involvement (d=0.45, 0.39, 0.38, 0.42, and 0.39 at 3-, 6-, 9-, 12- and 15-month follow-up respectively). Thus, conservatively, we are powering this study to detect an effect size of d=0.35. Using SAS proc power we determined that n=130 per group are necessary to detect d=0.35, leading to a combined sample size of n=260 (equally balanced, due to stratification, in terms of AA utilization and addiction severity). With a conservatively estimated retention rate of 75%, we would need to enroll n=347 to retain n=260. Given our stratified design (i.e., 2 [SMART vs. not] x 2 [12-step vs. not] x 3 [mild vs. moderate vs. severe AUD] design = 12

stratification cells), we proposed to enroll a final sample size of n=348 (i.e., n=29 per cell). In addition, 20 further participants were enrolled to increase representation of individuals attending SMART Recovery and to account for participants who withdrew, were terminated from the study, were found ineligible, or were otherwise no longer participating (e.g., death unrelated to the study).

Using this design, we will be equally well powered to test the main effect of 12-step participation. In terms of conducting pair-wise comparisons between the four possible combinations of using SMART Recovery and/or 12-Step, this sample size would enable us to detect pairwise differences of medium effect size (d=0.50). Improvements over our conservatively estimated retention rate would increase power (e.g., could detect d=0.46 with 85% retention).

Recruitment

Participants were recruited through SMART Recovery meetings, inpatient and outpatient treatment programs, and a variety of commercial recruitment sources during the recruitment period (January 2019 to January 2022).

Flyers and postcards for the study were distributed around buildings of Massachusetts General Hospital, particular around inpatient and outpatient SUD clinics. SMART facilitators were asked to advertise the study at SMART meetings and were provided with recruitment postcards and flyers. The study was also advertised on the SMART San Diego website. Additional recruitment methods included ResearchMatch, PeRC, TrialFacts, Rally for Recruitment, the Metro Newspaper, radio advertisements, MBTA advertisement, Facebook, Craigslist, and Reddit. For radio, MBTA, Facebook, and Craigslist advertisements, this study was advertised along with another ongoing R01 study of individuals making a new recovery attempt from AUD with similar eligibility criteria. Monthly meetings were also held with regional SMART Recovery MHO group facilitators to provide them with updates and inquire if there was anything we could provide to help facilitate study recruitment from online SMART resources or SMART meetings.

Interested individuals called the study-specific phone line, emailed the study-specific email address, or filled out an online screening form. Individuals were then able to participate in a brief 10–15-minute phone screen, during which eligibility criteria were confirmed. If the individual was eligible to participate, the baseline visit was scheduled and contact information for two locator contacts who can assist research staff in locating participants was collected.

Eligibility

Participants were required to be 18 years or older, living in the New England or San Diego metropolitan area, and willing to travel to Boston, Massachusetts, to complete study visits (for New England residents) or to complete study visits remotely (due to COVID-19 and for the San Diego participants). The geographical catchment area eligibility criteria were expanded to include people from the San Diego area in December 2020 to increase the number of SMART participants in the study. Since all visits were conducted remotely beginning in March 2020 due to the COVID-19 pandemic, participants from the New England area would also be considered eligible even if they could not travel to the Boston office for assessments in the foreseeable future.

Participants could be using other drugs but had to report alcohol as their primary substance of concern; they were also required to have a self-perceived alcohol problem, to meet

current criteria for DSM 5 alcohol use disorder (AUD) using semi-structured interview; to have consumed alcohol in the past 90 days and report currently engaged in a new recovery attempt defined as "a serious effort to abstain from drinking or to drink without problems in the past 90 days or planning to make one in the next 14 days."

Additionally, participants were required to provide locator contact information for two close friends/family members in case we were unable to contact the participant directly; provide their social security number for reimbursement or be willing to not receive reimbursement; provide a urine sample and breathalyzer (for in-person visits) or remote saliva test (for remote visits) for biochemical verification; and provide a stable home address and contact information. These initial bioassay requirements were not required following the start of COVID-19 lock-downs which began in March 2020.

Methods

All assessments were initially conducted (prior to COVID) with a study research coordinator in person at our downtown Boston offices at the MGH Recovery Research Institute. Each assessment consisted of staff-administered and self-administered surveys, which were completed via REDCap (a secure, web-based application designed to support data capture for research studies), a computerized task to assess impulsivity (Go/No-Go task), and biochemical verification tests of abstinence (breathalyzer, urine) for all participants at all time points. For in person visits, the baseline and follow-up assessments lasted for approximately 3 hours. At the end of the first visit and every follow-up visit, the next follow-up was scheduled.

Due to the COVID-19 pandemic, all assessments were transitioned to be conducted remotely beginning in March 2020. During remote visits, the computerized task and urine and breath biochemical verifications of abstinence were not completed. A web-based version of the computerized task was tested, but the effects of internet speed on results made data unreliable. In lieu of the urine and breathalyzer tests, saliva tests were implemented for remote visits from March 2021 to May 2021 but were discontinued due to documented inconsistent results. Relative to in-person assessments, remote assessments were shorter with assessments lasting approximately 1.5 hours (for baseline) or 45 minutes (for follow-ups) on the phone and approximately 1 hour for participants to complete surveys individually.

All participants (in-person and remote) agreed to provide their phone numbers and email information and that of two locator contacts so that they may be contacted for follow-up assessment reminders. Research staff contacted and confirmed the contact information of the locator contacts as needed if research staff loses touch with the participant. Participants indicated their preferred method of contact (phone call, email, or text message) for receiving automated reminders throughout the project period. In keeping with a validated research follow-up protocol for maximizing retention in clinical addiction research, after the baseline assessment, research staff proactively reached out to participants for reminders and to check if there were any changes to their contact information. Check-ins occurred 1 month, 14 days, 7 days, and 24 hours before the next scheduled visit. These messages are automated and sent with Twilio, which is an approved REDCap module by Mass General Brigham.

Participants are compensated $45 for completing the baseline visit and $55, $60, $65, $70, $75, and $85 for completing the 3-, 6-, 9-, 12-, 18-, and 24-month follow-up visits, respectively. Payment for each timepoint is broken up into payment for the staff-administered surveys, self-administered surveys, and travel reimbursement. During remote visits due to

COVID-19, all participants were still paid the travel reimbursement to maintain the same payment structure used for in-person assessments.

Measures

Staff-administered measures assess the following: substance use history, AUD and SUD status and severity, tobacco use, treatment utilization for physical health problems and alcohol/drug use problems, anti-craving and anti-relapse medications (alcohol and opioids), mental and emotional health diagnoses, hospitalizations, treatment history, and psychiatric medication use, social networks, 12-step/MHO attendance history, online resource utilization, SMART involvement, 12-step MHO involvement (MM-HAS), recovery/abstinence time, recovery support services and formal treatment program utilization, substance use change over the past year (YES), impulsivity (Go/No-go cognitive task), and biochemical verification of substance use (breathalyzer, urine drug screen).

Self-administered measures assess the following: demographics, criminal justice involvement, religiosity and spirituality (RBBS, religious and spiritual intensity, DSES), stress and psychiatric distress (PSS-4, K6), coping (CSS), self-efficacy (A-DSES-20, single item self-efficacy), alcohol/other drug craving (PADCS-5), commitment to sobriety (CSS-5), substance use consequences (SIP-2R), recovery status (questions about recovery, drinking goal), recovery capital (BARC-10), behavioral addictions, medical marijuana use, medication attitudes, impulsive behavior (SUPPS-S), quality of life and psychosocial functioning (TPS, Q-LES-Q, EQ5D3L, EUROHIS-QOL, self-esteem, happiness, and satisfaction with life), and physical health (PSQI, pain VAS, IPAQ, meals).

All measures were administered at each timepoint except for the Year End Summary (YES), SUD DART, and Questions about Recovery, which were administered at baseline, 12-months, and 24-months. Detailed descriptions of measures are available in Supplement 1.

COVID-19 impact

The COVID-19 pandemic significantly affected the conduct of study assessments as all assessments were transitioned to fully remote visits beginning in March 2020. As previously noted, this shift to remote assessments meant that we were unable to conduct the Go/No-go cognitive measure, breathalyzer, or urine screen. Due to these changes, all substance use outcomes are self-reported. Self-administered saliva tests were used briefly as a replacement, but inconsistent results (e.g., false negatives, partial results, no results) made data collected from these tests unreliable and this strategy was stopped.

Additionally, recruitment was halted as the study team transitioned to remote assessments and many previous recruitment methods were no longer viable (e.g., recruitment from outpatient clinics, advertisements on Boston area trains). It was particularly challenging to recruit individuals attending SMART as meetings were halted, then moved to virtual-only. To address these challenges, we expanded the recruitment area to San Diego, where there is a large SMART Recovery MHO participation community. We also maintained contact with SMART facilitators throughout the recruitment period to encourage them to share the study with meeting attendees and solicit feedback on how to best improve recruitment of SMART participants.

To capture potential changes in recovery resource utilization due to the COVID-19 pandemic, we added a staff-administered measure related to use of online recovery resources and social network site use. In addition, a supplemental study focusing on the impact of COVID-19 was conducted, consisting of both quantitative measures and a qualitative interview with a sub-

group (n=80) of study participants selected at random from the SMART, AA, SMART+AA, and neither cohorts (n=20 from each group).

Patient and public involvement

No patient or public involvement.

Data analysis plan

Aim 1 Effectiveness. We will use multiple linear regression analyses to determine whether our primary stratification factor of interest (predictor: SMART vs. no SMART) is associated with alcohol outcomes (primary dependent variables: PDA; PDHD) at 24-month (primary end-point), and 3-, 6-, 9-, 12- and 18-month (secondary) follow-ups, while controlling for other confounding variables using propensity score matching methods that we have used successfully in prior work. We will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity. We will also test longitudinal models to investigate the dynamic relationship of these various recovery pathways over time (e.g., using hierarchical linear modeling as we have done previously [20]).

Aim 2a. Mechanisms and Moderators. We will use mediational modeling, using the product-of-coefficients approach [21, 22] to test how SMART Recovery confers benefit (or fails to do so). The independent variable will be stratification group (i.e., SMART vs. no SMART), and the outcome variables will be PDA (primary), PDHD, AUD remission, quality of life, and measures of psychosocial functioning. The mediators will be our theorized mechanisms of change (e.g., social network changes, recovery motivation, coping, self-efficacy, impulsivity), which we will quantify as change since baseline in these constructs as measured via REDCap administered scales prior to the outcome (e.g., change in craving observed from baseline to 3-month would be used to predict 6-month ultimate outcomes). We will use multiple mediation to determine the relative impact of each mechanism, and moderated multiple mediation to identify differences in mechanisms across (moderator) subgroups (e.g., males vs. females, severe AUD addiction severity vs. moderate/mild), similar to our prior approach in delineating mechanisms of behavior change in AA [23-25].

Aim 2b. Dose-response relationship of SMART Recovery. Using only data from participants in the stratified SMART group, we will use linear regression (primary outcome: PDA) to test if the level of SMART involvement, as measured by the SMART Involvement Scale, is related to PDA at 24-month (primary endpoint) and other follow-up points over time. We will use basic model building practices to determine if such an effect persists after accounting for demographics, other important contextual variables, moderators, and baseline levels of the theorized mechanisms of change. In follow-up analyses, we will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity.

Multiple Testing. We will use the false recovery rate adjustment [26] to control for multiple testing.

Missing Data. Some data will inevitably be missing. We will explore patterns of missingness to determine if missingness is occurring at random (MAR) (i.e., unrelated to the value of the missing observation) or likely to be missing not at random (MNAR). For each analysis, we will use a variety of recommended strategies to address the issue of missing data (e.g., multiple imputation, maximum likelihood estimation)[27]. Consistency in findings across missing data methods will enhance our confidence in the findings. Note that study participation will be completely separate from SMART participation; thus, participants should feel comfortable remaining in the study regardless of whether they continue in SMART or not. Assuming some attrition, we plan to conduct analyses examining predictors of attrition and control for these.

ETHICS AND DISSEMINATION

All study procedures are approved by the Institutional Review Board of Mass General Brigham (approval number: 2017P002029). Written consent was received from all participants following an explanation of the study, including confidentiality and freedom of choice to participate. Results will be published in relevant peer-reviewed scientific journals and presented at conferences.

AUTHORS' CONTRIBUTIONS

JK developed the idea and conceptualized the study design and led the writing of the manuscript. SL contributed to conducting the study and writing the manuscript. BH contributed to study design and development and statistical analysis as well as reviewing and editing final versions of the manuscript.

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COMPETING INTERESTS STATEMENT

None declared.

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Supplement 1 – Measures

Table 1 (staff-administered measures)

Measure	Description
Substance Use History	Participants answered a series of questions about 15 substances/classes of substances (hereafter simply referred to as substances) from the Global Appraisal of Individual Needs (GAIN-I; (Dennis et al., 2002)): 1) Alcohol, 2) Marijuana, 3) Heroin, 4) Methadone, 5) Buprenorphine and its formulations (e.g., suboxone), 6) Other opioids (e.g., pharmaceutical opioids), 7) Cocaine, 8) Amphetamines (including MDMA), 9) Methamphetamine, 10) Benzodiazepines, 11) Barbiturates, 12) Hallucinogens, 13) Synthetic drugs (e.g., synthetic cannabinoid like "K2" and synthetic cathinones such as "bath salts"), 14) Inhalants, and 15) Steroids, as well as "Other" (specified by participant). At baseline, participants reported which of these substances they used 10 or more times in their life. Then for each substance endorsed, they provided information on the following from the Form-90 (Miller & Delboca, 1994): a) Age of first use; b) If they had ever used the substance regularly (i.e., at least once per week) (yes/no) and if so, the age of first regular use; c) Whether they had used the substance in the past three months (yes/no), and if so how many days out of the past 90 they used the substance and d) If they had not used the substance in the past 3 months, the date of their last use. For follow-ups, the questionnaire assessed if participants had used these substances in any capacity in the past 3 months, if they had used the substances regularly over the past 3 months, and out of how many of the past 90 days they used the substance. Participants then chose their primary substance ("drug of choice") and secondary substance from the substances they had used (lifetime use for baseline assessment, past 3 month use for follow-ups). Finally, participants were asked for how many of the past 90 days their use of alcohol/drugs interfered with their functioning, and how many out of the past 90 days they got drunk at all or high for most of the day.
Alcohol Use Disorder DART	Participants were asked this validated semi-structured interview to capture AUD status (AUD severity and withdrawal symptoms). Participants were first asked if they had consumed alcohol in the past 3 months. If the participant answered 'yes', the DART would pertain to the past 3 months. If the participant answered 'no', they would be asked if they consumed alcohol during the past 12 months, and the DART would pertain to the past 12 months. If the participant answered 'no' to both the questions, they would only be asked if they experienced strong urges or cravings to drink.
Substance Use Disorder DART	Participants were asked about the recreational drugs/medications they used in the past 12 months. They then ranked the substances in the order that they caused problems for them. The DART was administered for the top 3 substances that caused the most problems for participants.
NIH PhenX Toolkit	Participants reported on lifetime use of cigarettes, e-cigarettes, or another tobacco/nicotine product (specified by participant). For those who smoked cigarettes, they reported on the following: 1) Age of first regular use; 2) Of how many of the past 30 days they smoked cigarettes 3) Average number of cigarettes smoked per day in the past 30 days 4) Whether or not they had ever made a serious attempt to quit smoking. This was asked pertaining to 'lifetime' for the baseline visit and for the past 90 days in the follow-up visits. If participants had made a serious quit attempt either in their life (baseline) or in the past 90 days (follow-up), they reported how old they were when they most recently quit smoking, the number of quit attempts in the past 90 days, the longest length of time they had quit smoking for, as well as on psychosocial smoking cessation resources. If not currently still smoking, participants reported the age when they stopped smoking, as well as psychosocial smoking cessation resources used in their most recent quit attempt. Finally, regarding smoking cessation, all participants answered a single item with four multiple choice options to gauge attitudes toward inclusion of smoking cessation in AOD treatment (e.g., "Services that help people stop smoking…should be automatically included in addiction treatment.").

	(National Cancer Institute, 2009; National Institutes of Health & U.S. Food and Drug Administration, 2013; Prorok et al., 2000).
Treatment for Injuries or Physical Health Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for health problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Treatment for Alcohol and Drug Use Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for alcohol or drug use problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Anti-craving and Anti-relapse Medications (Alcohol and Opioids)	At baseline, participants reported whether they had ever been prescribed a medication to prevent them from drinking alcohol or using opioids. At follow-up visits, participants were asked if they had been newly prescribed any medication to prevent them from drinking alcohol or using opioids in the past 3 months. If participants responded yes to either item, participants reported lifetime (baseline), past 3 months (follow-up) and current (baseline and follow-up) use of specific medications from the Form-90, including both generic and brand names (Miller & Delboca, 1994). Participants were also asked to rate what proportion of the time they used each medication as medically indicated.
Mental and Emotional Health: Diagnoses, Hospitalizations, Treatment History	Participants reported whether they had ever been told that they had a mental health condition by a doctor, nurse, or counselor, including agoraphobia, anorexia nervosa, bipolar disorder, bulimia nervosa, delusional disorder, dysthymic disorder, generalized anxiety disorder, major depressive disorder, obsessive-compulsive disorder, panic disorder, personality disorder, post-traumatic stress disorder, schizoaffective disorder, schizophrenia, social anxiety disorder, specific phobia, substance use disorder, and other. For each diagnosis endorsed, participants indicated whether this had been a problem for them in the past 12 months. Participants reported treatment in an emergency room and admissions to a hospital for at least one night for mental, emotional, behavioral, or psychological problems. Participants reported for both lifetime and past 3 months. Participants also reported the number of times they had seen a mental health doctor in an office or outpatient clinic (including telehealth) in the past 3 months, on how many of the past 90 days they had been bothered by mental, emotional, behavioral, or psychological problems, and on how many of the past 90 days these problems had kept them from meeting their responsibilities or made them feel like they could not go on (Dennis et al., 2002; Miller & Delboca, 1994).
Mental and Emotional Health: Psychiatric Medication Use	Participants were asked if they had ever been prescribed medication by a physician or medical practitioner to help them with a mental health condition (lifetime use). If they said yes, they were asked which medication they had ever been prescribed with the options antidepressants, anti-anxiety medication, anti-psychotics, mood stabilizers, stimulants, painkillers, medications for sleep and other (to be specified). Participants were then asked if they were still taking the medicines they indicated. If participants were still taking the medicines, they were asked what proportion of the time they take the prescribed medication as medically indicated. At follow-up visits, participants were asked if they were still using any medication that they had been using at the prior study visit, whether they had been newly prescribed any medication to help with a mental health condition, and if yes, what type of medication. For each medication endorsed, participants reported what proportion of the time they used the medication as medically indicated (Dennis et al., 2002; Miller & Delboca, 1994).
Social Support Questionnaire (SSQ)	Participants were asked to list the initials of up to 5 family members, up to 5 friends, and up to 3 other important people in their life who they felt close to. For each person, they listed their initials, relationship, alcohol use pattern, drug use pattern, days per month they had

	contact with this person over the past 3 months (including contact via phone/text), how much they value their relationship on a scale of 1 (*not at all*) to 10 (*a great deal*) and how helpful they are in their recovery efforts on a scale of 1 (*not at all helpful*) to 10 (*a great deal*) (Zywiak et al., 2009).
12-step/MHO Attendance History	At baseline, participants were asked about lifetime attendance to help with their AOD problem at 12 different MHOs, with an "other" option specified by participant (Kelly et al., 2011): 1) Alcoholics Anonymous (AA); 2) Narcotics Anonymous (NA); 3) Marijuana Anonymous (MA); 4) Cocaine Anonymous (CA); 5) Crystal Methamphetamine Anonymous (CMA); 6) SMART Recovery; 7) LifeRing Secular Recovery; 8) Moderation Management; 9) Celebrate Recovery; 10) Women for Sobriety; and 11) Secular Organization for Sobriety (S.O.S.).; 12) Dual Diagnosis Anonymous (DDA); and 13) Other. Other options were examined for possible inclusion in existing categories, and recategorized as appropriate. At follow-ups, participants reported attendance for the past 3-months. For each MHO attended, participants reported a) Whether they attended regularly (at least once per week), b) Number of meetings in the past 3 months, and c) Whether they had ever attended a meeting online.
Online Resources and Social Network Sites	For each MHO that a participant had attended online (as noted in "12-step/MHO Attendance History"), participants reported how many meetings they had attended online in the past 3 months, how they accessed these meetings (video, audio only, telephone, etc.), and how helpful they felt the online meetings were on a scale of 1 to 10. Participants also reported whether they used any online or mobile technologies to support their AOD problem resolution or recovery in their lifetime (baseline) and in the past 3 months. Potential online and mobile technologies included recovery-focused social network sites (e.g., InTheRooms.com), general social network sites (e.g., Facebook), and mobile smartphone applications. For each online or mobile technology endorsed, participants indicated how many of the past 90 days they had used the technology for recovery and how helpful they found it on a scale of 1 to 10. Participants were also given the opportunity to provide any other information or comments on their use of online or mobile recovery resources.
SMART Involvement	Questions about SMART involvement were asked for participants who had attended SMART Recovery. Participants were asked how long they have been attending SMART Recovery, how they heard about SMART Recovery, whether they consider themselves to be a current member of SMART Recovery (*yes/no*), how many times they have attended SMART recovery in their lifetime (*numerical value*) and if another member of SMART Recovery served as a personal mentor or guide to them in the past 3 months (*yes/no*). The participants were asked questions about their participation in SMART meetings in the past 3 months to gauge the frequency of the use of SMART meetings, tools, website, and web-application 'Overcoming Addictions.' Participants were also asked four questions about their level of engagement in SMART meetings.
Recovery/Abstinence time	Participants were asked to report in years and months how long they had been either 1) Sober (not using any alcohol/drugs) or 2) Drinking/using drugs without problems.
Multidimensional Mutual-Help Activity Scale (MM-HAS)	Questions from the MM-HAS were asked for participants who had attended meetings of any of the following MHOs: Alcoholics Anonymous, Narcotics Anonymous, Marijuana Anonymous, Cocaine Anonymous, Crystal Methamphetamine Anonymous, and Dual Diagnosis Anonymous. For each organization, participants were asked if they currently considered themselves to be a part of the MHO, their activities as part of the MHO in the past 3 months (sponsor, contact with sponsor outside a meeting, contact with other members outside a meeting, read 12 step literature outside of a meeting, shared or talked during meetings, helped with setting up/running a meeting), and the number of steps out of the 12 step program that they completed while participating in the MHO in the past 3 months. Participants were then asked to rate the helpfulness, enjoyability, and safety of the

	MHO from a scale of 1 (*not at all helpful, do not enjoy at all,* or *not at all safe*) to 10 (*extremely helpful, enjoy a great deal,* or *completely safe*) (Kelly et al., 2013; Kelly et al., 2011).
Recovery support services and formal treatment programs (RSSTX)	The questionnaire assessed history of participation in nine psychosocial treatment and recovery support services: 1) Sober living environment; 2) Recovery high school; 3) College recovery program/community 4) Recovery community center (RCC); 5) Faith-based recovery services (e.g., a recovery group provided by a church, synagogue, mosque, etc.); 6) State or local recovery community organization (RCO); 7) Outpatient addiction treatment; 8) Alcohol/drug detoxification services; 9) Inpatient or residential treatment. If they responded yes to any treatment service (7, 8 or 9), they reported the number of times they used the service (i.e., number of treatment episodes) in their lifetime (baseline) and the past 3 months (baseline and follow-up). (Dennis et al., 2002; Miller & Delboca, 1994).
Year End Summary (YES)	At baseline, 12-month follow-up, and 24-month follow up, participants were asked if they felt like they were better off now than they were 12 months ago in terms of their alcohol and drug problems (worse off, same, better off). Participants were then asked to elaborate on the reason for that answer. Participants were asked if their substance use had changed or stayed the same in the past 12 months (changed for the better, changed for the worse, stayed the same). If participants reported 'stayed the same', they were asked what factors they thought were most responsible for their substance use staying the same.
Timeline Follow Back (TLFB)	Participants provided specific dates for alcohol use, substance use, MHO attendance, inpatient and outpatient addiction treatment, inpatient and outpatient mental health treatment, and incarceration for the past 3 months (baseline, 3-, 6-, 9-, and 12-month follow-ups) or 6 months (18- and 24-month follow-ups) (Miller & Delboca, 1994). For alcohol use, participants were asked to report the number of standard drinks consumed on each drinking day. For MHO attendance and outpatient treatment for addiction and mental health, participants were asked to report whether services were in-person or online. During in-person study visits, a printed calendar was used to facilitate the TLFB. For remote visits, study staff prompted participants with potentially memorable dates within the timeframe (e.g., holidays).
Go/No-Go Cognitive Measure*	The Inquisit Go/No-Go Cognitive Measure is a computerized task used to assess impulsivity. The Inquisit script implemented the Go/No-Go Task as described in Fillmore et al. (2006). Participants were asked to press the spacebar when they see a green rectangle (*go*) but refrain from pressing the spacebar when they see a blue rectangle (*no-go*). The blue and green rectangles could be vertical or horizontal. The vertical rectangle had a high probability (4:1) of being green (*go*) and the horizontal rectangle had a high probability (4:1) of being blue (*no-go*). Participants were given information about the orientation of the rectangle shortly before the color of the rectangle was revealed. Participant response times and error rates were recorded. For remote visits, a web-based version of the Go/No-Go Task was tested, but due to the effect of internet speed on results, this measure was not included.
Breathalyzer*	Breathalyzer tests were used to establish a baseline level of substance use for participants at the first assessment and to ensure that data was not collected from participants who were impaired due to alcohol use. Breathalyzer tests were performed at baseline and all follow-up time points prior to starting each assessment. If a participant's BAC was above .02, study staff did not conduct the study visit; instead, study staff either waited with the participant until their BAC dropped to .02 or lower or attempted to re-schedule the participant's visit. If a participant's BAC was above the legal limit (.08), and the participant had driven to their assessment, study staff asked to hold the participant's car keys while waiting for their BAC to drop below the legal limit. If the participant insisted on holding their car keys and/or driving, or if the participant did not stay with study staff until their BAC dropped below .08, study staff called security as a safety precaution. Study staff also offered to arrange and pay for a cab to transport the participant home. If a participant had driven to the appointment

	and decided to take a cab home, the participant could return to pick up their car keys during business hours when their BAC was below .08. For remote visits, study staff were unable to perform breathalyzer tests and instead asked participants to verify that they had not used alcohol or other drugs prior to the assessment via self-report.
Urine Drug Screen*	Urine drug screens were used to establish baseline substance use at baseline and to verify self-reported estimates of alcohol and other drug use. For remote visits, study staff were unable to perform urine drug screens.
Saliva Test	Self-administered saliva tests were implemented in March 2021 as an alternative method of biochemical verification during remote visits. Participants were contacted prior to their assessment to confirm willingness to participate in the saliva test, what address the test would be mailed to, and whether the visit would be conducted over Zoom or on the phone. During the assessment, participants were able to self-administer the saliva test with study staff guidance. If participants completed the assessment over Zoom, participants showed the test results to the research coordinator who screenshotted the test and uploaded it to REDCap. If the participant completed the assessment over the phone, they uploaded images of the test to REDCap or, if unable to upload images, self-reported the results. Due to inconsistencies in saliva test results (no results, partial results, and false negatives), saliva test use was discontinued in May 2021.

* = not administered during remote visits

Table 2 (self-administered measures)

Measure	**Description**
Demographics Background	Participants reported the following: gender, race, ethnicity (whether participants were Hispanic/Latino), where they were living for the majority of the past 3 months (with family or other relatives, with group of friend(s) or non-family members, alone in own dwelling, homeless, hospital rehabilitation facility or nursing home, jail, prison or other correctional facility, other), current marital status (single, married, living with someone as if married, in a relationship, engaged to be married, legally separated, divorced, widowed), sexual orientation, left or right handed, highest level of schooling completed, highest level of schooling completed by either parent, whether they held a job in the past 3 months, (if yes) nature of employment (odd jobs, part time, full time), (if no) reason for unemployment, major source of financial support, total annual household income, type of health insurance, and financial well-being of their family. Numerical values were collected for the following in the past 3 months: unplanned absences from work/school, times disciplined on the job/at school, times your job/school has been in jeopardy, times you were suspended or fired from work/school (Dennis et al., 2002; Miller & Delboca, 1994).
Criminal Justice Involvement	The questionnaire used adapted items about criminal justice involvement from the Form-90 (Miller & Delboca, 1994). Participants reported on their current legal status (none, on probation only, on parole only, on probation and parole, awaiting charge, trial or sentence, outstanding warrant, case pending, other). At baseline, participants reported whether they had ever been arrested (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in their lifetime, and how many times for other reasons in their lifetime. At follow-up visits, participants reported whether they had been arrested in the past 3 months (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in the past 3 months, and how many times for other reasons in the past 3 months. At baseline, participants reported whether they had ever stayed in jail or prison overnight or longer (yes/no). If yes, they reported how many times in their lifetime and how many times in the past 3 months. At follow-up visits, participants only reported the number of times in the past 3 months.

Religious Background and Behaviors (RBBS)	At baseline, the questionnaire assessed if the participant considered themselves to be part of a religious group (No/none, Baptist, Buddhist, Catholic, Evangelical, Hindu, Jewish, Lutheran, Methodist, Mormon, Muslim, Presbyterian, Other Protestant, Shinto, Native American Church, Traditional Native American, Christian, Some other group). For all timepoints participants were asked which of the following describes them at this time: atheist, agnostic, unsure, spiritual, religious. Participants were asked how often they participated in religious activities in the past 3 months on a 7-point Likert scale (*never, rarely, once a month, twice a month, once a week, twice a week, almost daily, more than once a day*) and, at baseline, how often they participated in certain religious activities in their lifetime on a 3 point-Likert scale (*never, yes, in the past but not now, yes, and I still do*) (Connors et al., 1996).
Religious and Spiritual Intensity	The questionnaire included four items assessing participants' religiosity and spirituality. Participants reported the extent to which they considered themselves religious/spiritual on a Likert scale from *not religious/spiritual at all* (1) to *very religious/spiritual* (4). Participants reported the extent to which their religious/spiritual practices and beliefs help them with resolving an alcohol/drug problem on a scale from *do not help at all* (1) to *make all the difference* (5) (Idler et al., 2003).
Twelve Promises Scale (TPS)	This questionnaire assessed participants' current psychosocial state and attitudes towards drinking and using drugs. Participants rated how true each item was for them at the current time on a scale of *never true* (1) to *true most of the time* (5) (Kelly & Greene, 2013).
Perceived Stress Scale (PSS-4)	This questionnaire assessed participants' level of stress over the last month. Participants rated each item on a scale from *never* (1) to *very often* (5) (Warttig et al., 2013).
Kessler 6 (K6)	This six-item scale assessed psychiatric symptoms (also referred to as psychological distress). On a scale from *all of the time* (1) to *none of the time* (5), participants are asked how often they felt: nervous, hopeless, restless or fidgety, so depressed that nothing could cheer you up, that everything was an effort, and worthless (Kessler et al., 2003).
Coping Strategies Scale (CSS)	Participants were asked to select how often they used a variety of coping strategies or thoughts in the past 3 months to help them not use alcohol or drugs. Participants rated each item on a scale from *never* (1) to *frequently* (4) (Litt et al., 2003; Prochaska et al., 1988).
Alcohol and Drug Abstinence Self Efficacy (A-DSES-20)	Participants were asked about their feelings of confidence to not drink or use drugs in various situations in the past week. Participants rated their level of confidence for each scenario on a scale of *not at all confident* (1) to *extremely* (5) (Diclemente et al., 1994).
Penn Alcohol and Drug Craving (PADCS-5)	This questionnaire assessed the frequency and strength of cravings to use alcohol and other drugs during the past week. Participants reported how often they thought about drinking/using drugs, how strong the craving was at its most severe, how much time they have spent thinking about drinking/using drugs, how difficult it would have been to resist drinking/using drugs, and then rated their overall alcohol/drug craving with options ranging from *never thought about drinking/using drugs and never had the urge to drink/use drugs* to *thought about drinking/using drugs nearly all of the time and had the urge to drink/use drugs nearly all of the time* (Flannery et al., 1999).
Commitment to Sobriety Scale (CSS-5)	In this questionnaire, participants were asked 5 questions about their commitment to not using alcohol/drugs. Participants rated the extent to which they agreed with these statements on a scale from *strongly disagree* (1) to *strongly agree* (6) (Kelly & Greene, 2014).
Drinking Goal	In this questionnaire, participants chose one goal that was the most true to them currently from the 5 options: 1) Total abstinence; never use again; 2) Total abstinence; but realize a slip is possible; 3) Occasional use when urges strongly felt; 4) Temporary abstinence; or 5) Controlled use.

Short Inventory of Problems (SIP-2R)	This questionnaire assessed how often participants had experienced various problems during the past 3 months because of their drinking/drug. Participants indicated how often they had experienced each problem on a scale of *never* to *daily or almost daily*. Participants were also asked to indicate whether they had had an accident while drinking or intoxicated in the past 3 months (Miller et al., 1995).
Questions about Recovery	This questionnaire assessed recovery identity, definition, and what participants believe are the factors helping them resolve their problem with alcohol/drugs at baseline, 12-month follow-up, and 24-month follow-up. Participants selected a statement that best applied to them from whether they consider themselves to be *in recovery*, *seeking recovery* or *not in or seeking recovery*. If participants chose that they were 'in recovery', they were asked to provide the date they use to mark the beginning of their recovery. Participants were asked to provide their definition of recovery in one sentence (free response) and to select one of three statements that best fit their definition of recovery: 1) Abstinence from all drugs/alcohol; 2) Abstinence from only those drugs/alcohol with which they had a problem; or 3) Non-problematic/moderate use of drugs/alcohol, including those with which they had a problem. Participants were then asked to list the top 3 things that have helped or are helping them to resolve their problem with alcohol/drugs.
Brief Assessment of Recovery Capital (BARC-10)	The BARC-10 (Vilsaint et al., 2017) is a 10-item, abridged version of the Addiction Recovery Capital Scale (Groshkova et al., 2013). The BARC-10 measures personal (e.g., "I take full responsibility for my actions"), social (e.g., "I get lots of support from friends"), physical (e.g., "I have enough energy to complete the tasks I set for myself"), and environmental resources (e.g., "My living space has helped to drive my recovery journey") used to initiate and sustain recovery. Participants rated their agreement with each statement on a scale from *strongly disagree* (1) to *strongly agree* (6).
Behavioral Addictions	The questionnaire used items adapted from Laudet et al. (2015) to assess whether individuals ever had a problem with one or more other behaviors apart from AOD use in their lifetime (baseline) and currently, including 1) Eating disorder; 2) Sex/love addiction; 3) Gambling; 4) Video gaming addiction; 5) Compulsive shopping; 6) Internet addiction (for issues not assessed by other choices); 7) Compulsive exercise; 8) Internet pornography addiction; 9) Self-harm/injury and 10) Other (specified). "Other" options were examined for possible inclusion in existing categories, and recategorized as appropriate. Participants were asked if any reported behavioral addictions had been a problem for them in the past 3 month and if so, how many days out of 90. If reporting more than one, participants indicated which behavior had been the most problematic.
Medical Marijuana Use	Participants were asked if they had ever been recommended to use marijuana for medical reasons. If yes was indicated, participants were asked how many days out of the past 90 marijuana was used for medical reasons and to list up to three medical reasons for using marijuana.
Medication Attitudes	This questionnaire assessed participant attitudes toward medication for an alcohol problem, opioid problem, any kind of alcohol/drug problem, and emotional problem. Participants rated their agreement with the use of medication for these problems on a scale of *strongly disagree* (1) to *strongly agree* (6).
Impulsive behavior (SUPPS-S)	This questionnaire assessed impulsivity. Participants rated their agreement with 20 items describing situations or feelings related to impulsivity on a scale of *agree strongly* (1) to *disagree strongly* (4) (Coskunpinar et al., 2013).
Quality of Life (Q-LES-Q)	This measure of quality of life was used to assess satisfaction related to physical health, mood, relationships, activities, and economic status. Participants rated their satisfaction with

	each item during the past week on a scale of *very poor* (1) to *very good* (5) (Endicott et al., 1993).
Quality of Life (EQ5D3L)	This measure of quality of life was used to assess physical and mental health states. Participants rated their current mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Participants also rated their current overall physical and mental health states using a visual analogue scale with options between 0 (*worst*) and 100 (*best*) (Devlin & Brooks, 2017).
Quality of Life (EUROHIS-QOL)	This measure of quality of life is a widely used eight-item measure of quality of life, adapted from the World Health Organization Quality of Life – Brief Version (WHOQOL-BREF) (Schmidt et al., 2006). Participants rated each item on a 5-point Likert scale from 1 (*very poor, very dissatisfied,* or *not at all*) to 5 (*very good, very satisfied,* or *completely*) (da Rocha et al., 2012).
Pittsburgh Sleep Quality Index (PSQI)	This questionnaire assessed quality of sleep. Participants reported how many hours of sleep they got on average per night over the past month. Participants then rated their quality of sleep on a scale from *very good* (1) to *very bad* (4) (Buysse et al., 1989).
Pain Visual Analogue Scale (VAS)	This measure assessed physical pain. Participants rated the current severity of their pain using a visual analogue scale with options between 0 (*no pain*) to 100 (*very severe pain*) (Wewers & Lowe, 1990).
International Physical Activity Questionnaire (IPAQ)	This questionnaire asks participants about their level of physical activity over the past seven days. Participants indicate how many days in the past 7 days they have done: vigorous physical activity, moderate physical activity, and walking. Participants then indicate how much time per day they usually spent on each activity in hours and minutes. Participants are also asked how many hours they usually spent sitting on weekdays over the past 7 days (Hagstromer et al., 2006).
Meals	Participants reported how many meals on average they have eaten per day during the past 3 months.
Self-esteem, Happiness, and Satisfaction with Life	Three single-item measures were used to assess self-esteem (Robins et al., 2001), happiness, and satisfaction with life (Diener et al., 1985). For self-esteem, participants indicated their agreement with the statement "I have high self-esteem" on a scale from 1 (*not very true of* me) to 10 *(very true of* me). For happiness, participants rated how happy they were with their life in general on a scale of 1 (*completely unhappy*) to 10 (*completely happy*). For satisfaction with life, participants indicated their agreement with the statement "I am satisfied with my life" on a scale of *strongly disagree* (1) to *strongly agree* (7).
Abstinence Self-Efficacy Single Item	Participants rated how confident they were that they could remain abstinent or drink/use drugs without problem in the next 3 months on a scale from *not at all confident* (1) to *very confident* (10).
Daily Spiritual Experiences Scale (DSES)	This questionnaire assesses spiritual and/or religious experiences. The questionnaire includes items with the word "God" used but includes instructions for participants that if "God" is not a comfortable word that they should substitute it for one that calls to mind the divine and holy for them. Participants read 15 items describing spiritual and/or religious experiences that a person may have and rate how often they have this experience from *many times a day* (1) to *never or almost never* (6). The last item asks participants how close they feel to God from *not close* (1) to *as close as possible* (4) (Underwood & Teresi, 2002)

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An Investigation of SMART Recovery: protocol for a longitudinal cohort study of individuals making a new recovery attempt from alcohol use disorder

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ABSTRACT

Introduction

Alcohol use disorder (AUD) remains one of the most pervasive of all psychiatric illnesses conferring a massive health and economic burden. In addition to professional treatments to address AUD, mutual-help organizations (MHOs) such as Alcoholics Anonymous (AA) and newer entities like Self-Management and Recovery Training (SMART Recovery) play increasingly important roles in many societies. While much is known about the positive effects of AA, very little is known about SMART. Hence, this study seeks to estimate real-world patterns of utilization and benefit from SMART Recovery as well as explore for whom (moderators) and how (mechanisms) SMART confers recovery benefits.

Methods and analysis

Naturalistic, longitudinal, cohort study (N=368) of individuals with AUD recruited between February 2019-February 2022, initiating a new recovery attempt who self-select into one of four groups at study entry: 1. SMART Recovery; 2. AA; 3. SMART+AA; 4. Neither SMART nor AA; (stratified by DSM 5 severity markers), with assessments conducted at intake, and 3-, 6-, 9-, 12-, 18-, and 24-months. Primary outcomes are: Frequency of SMART and AA meetings attendance; Percent Days Abstinent (PDA) and percent days heavy drinking (PDHD). Secondary outcomes include: psychiatric distress; quality of life and functioning. Moderator variables include sex/gender; race/ethnicity; spirituality. Mediational variables include: social networks; coping skills; self-efficacy; impulsivity. Multivariable regression with propensity score matching will test for patterns of attendance and effects of participation over time on outcomes and test for mechanisms and moderators.

Ethics and dissemination

This study is approved by the Mass General Brigham Institutional Review Board. Results will be published in peer-reviewed journals and presented conferences.

Registration and Funding

This is a non-randomized, naturalistic, longitudinal, cohort study, and thus was not registered in advance. Results, therefore, should be considered exploratory. The study was funded by the US National Institute of Alcohol Abuse and Alcoholism (NIAAA; 5R01AA026288; K24AA022136).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Individuals (N=368) with primary alcohol use disorder who self-select into either SMART Recovery, Alcoholics Anonymous (AA), both SMART and AA, or neither, will be compared over time on addiction recovery processes and outcomes.
- Participant characteristics, changes processes, and outcomes will be measured prospectively using validated measures at study intake, and again at 3-, 6-, 9-, 12-, 18-, and 24-months later.
- Primary outcomes will be: number of SMART and AA meetings attended per week at each follow-up; percent days abstinent (PDA); percent days heavy drinking (PDHD); alcohol use disorder remission status; alcohol/drug related consequences. Secondary outcomes include quality of life and functioning psychiatric distress, self-esteem, happiness.
- The study has a cohort based, naturalistic, non-randomised, design; research staff are not blinded to participants' self-selected recovery pathway and the use of self-report measures, despite psychometric validation, can yield social desirability and recall biases.
- Descriptive and longitudinal inferential modeling analyses will be conducted (accounting for missing data) to describe and estimate effects related to different pathway choices.
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INTRODUCTION

Alcohol and other drug use disorders confer a prodigious burden of disease, disability, and premature mortality in most middle- and high-income countries globally. To help alleviate this burden, most countries provide an array of professionally delivered addiction treatment services. Yet, despite these efforts, such services are often unable to meet both acute care and long-term relapse prevention needs of the millions or tens of millions affected annually. In response, most countries also possess an array of informal community-based peer recovery support services which can provide ongoing assistance for individuals suffering from these disorders [1]. The oldest and largest of these are the 12-step mutual-help organizations (MHOs), such as Alcoholics Anonymous (AA). Rigorous research evidence has now demonstrated that when AA is subjected to the same scientific standards as other addiction focused interventions it does as well on most outcomes measures, is better at sustaining abstinence and remission over time, and is highly cost effective [1].

A limitation of the current standard of care, however, borne out of a limitation in available empirical data, is the fact that referral oftentimes focuses solely on spiritually-oriented 12-step organizations, such as AA, which is the only empirically-supported MHO continuing care referral option. Not everyone chooses AA as a pathway to recovery for various reasons, and alternative MHO options - although much newer and smaller - are growing and may contain many of the same positive therapeutic elements and dynamics possessed by AA [2, 3]. These therapeutic pathways include adaptive social network changes, increases in social abstinence self-efficacy, and reducing negative affect. Indeed, some preliminary evidence suggests such organizations may confer similar benefits for those who self-select into them [4].

The largest and possibly most well-known of these newer alternative MHOs is Self-Management and Recovery Training (SMART) Recovery. There are approximately 1,200 SMART groups nationwide and another 1,000 internationally. SMART also has a strong online support presence including online meetings, forums, and chat rooms. Unlike AA, SMART is founded upon cognitive-behavioral principles and practices and is led by trained facilitators. It focuses on enhancing and maintaining motivation to abstain or (more recently) reduce use to non-problematic levels, coping with urges, problem solving, and lifestyle balance [5]. It also advocates for appropriate use of professional psychosocial and pharmacological treatments. A compelling aspect of SMART as an MHO is, because it is itself based on empirically-derived CBT principles, it provides a philosophically compatible recovery resource that is aligned with cognitive-behavioral treatment principles, which make up a large majority of national and international evidence-based treatments [6]. Consequently, SMART is appealing to many individuals with SUD [5], yet due to the lack of empirical evidence supporting its effectiveness, clinicians remain less likely to discuss or refer patients to SMART [7, 8]. This has hindered its growth and prevented many the opportunity to learn about and try SMART.

Compared to the dozens of high-quality studies examining 12-step MHOs [9-12], there have been just a handful of studies on SMART. We conducted a systematic review of this research [13] and found that only 12 studies exist (4 of which are unpublished dissertations) that have focused on SMART Recovery and used any kind of formal measurement. Most of these (8 out of the 12) are cross-sectional with mixed results and suffer from considerable biases as they possess substantial methodological limitations making it difficult to draw firm conclusions [14-16]. For instance, these studies have rarely assessed mental health status or its severity, despite the high rates of comorbidity between AUD and mental health. Two recent high-quality studies

examining SMART Recovery, however, have been conducted, one in a criminal justice context, the other examining its effect on heavy alcohol use in an RCT.

The criminal justice study was a large quasi-experimental study of criminal offenders in Australia [17]. It compared a group of individuals participating in SMART Recovery and/or a criminal justice intervention (called "Getting SMART") designed to link offenders with SMART meetings following prison release, to a group of control participants who did not interact with any SMART materials or attended meetings, but who were matched on various other relevant characteristics through the use of propensity scores. The study found that participation in Getting SMART by itself, and Getting SMART + SMART Recovery meeting attendance, was associated with a reduced overall rate of reconviction with rates of reconviction reduced by 19 and 22%, respectively. For violent reconvictions, rates were reduced by 30% for Getting SMART participation and 42% for Getting SMART + SMART Recovery. While an important and promising set of results in their own right, unfortunately, the authors did not examine or report any alcohol/drug use outcomes [17].

There has been only one small, randomized trial evaluating SMART Recovery, which randomized people to (a) "Overcoming Addictions" (OA) - a SMART Recovery web application, (b) SMART Recovery meeting attendance, or (c) OA + SMART Recovery meeting attendance combined. The study found participants from all groups benefitted equally with respect to alcohol outcomes [18]. This finding underlines the promise of SMART Recovery to provide recovery support. Unfortunately, however, this trial did not include a control group, who did not have any exposure to SMART materials. Given, however, that all groups participated in SMART, it is not clear if observed benefits were simply naturally occurring improvements in alcohol outcomes, or really a function of SMART participation. Another limitation is that it only enrolled subjects with heavy drinking problems and excluded participants with more severe forms of AUD, who more typically enroll in formal treatment and are thus in need of referral options for continuing care.

A more recent study examined participation among individuals with alcohol use disorder recruited from various online and community venues with varying lengths of sobriety who self-selected into one of four different types of MHOs: Alcoholics Anonymous, LifeRing Secular Organization, SMART Recovery, and Women for Sobriety[4]. This study found that SMART Recovery participants had as good alcohol outcomes at 6- and 12-month follow-ups as those attending other MHOs. Again, however, the study did not include a control group with no MHO involvement.

These results provide some preliminary information about real-world benefits related to SMART Recovery participation. There is very little, if any, information regarding how involved they become or the mechanisms of behavior change through which SMART may help individuals attain AUD remission and recovery (e.g., via social changes, coping skills, recovery motivation, abstinence self-efficacy; reduced impulsivity). SMART has the potential to be a secular MHO alternative to 12-step MHOs for those preferring the secular and cognitive-behavioral foundation of SMART, yet in order to increase clinical confidence and referrals, more systematic research is needed. This study will be one of the first rigorous, real-world, evaluations of SMART providing objective estimates of recovery benefit (e.g., abstinence, AUD remission, quality of life, psychosocial functioning), and will explore the mechanisms (e.g., social network changes, self-efficacy, decreased impulsivity) and moderators (e.g., sex, race/ethnicity, addiction severity, psychiatric co-morbidity) of behavior change to determine how SMART Recovery may help its affiliates achieve and maintain remission from addiction and who seems to benefit most.

To this end this study has the following specific aims: 1. Characterize and describe professional and non-professional recovery support service participation choices, migrations, and pathways using group trajectory analyses over a two-year period for individuals (N=368) starting a new AUD recovery attempt. More specifically in this regard, we will investigate the real-world effectiveness of SMART Recovery by comparing outcomes of AUD individuals making a new recovery attempt (N=368) pursuing either a SMART Recovery pathway (online or face-to-face; N=184) or a non-SMART recovery pathway (N=184). Because, according to SMART Recovery's annual survey data, roughly half of SMART participants also attend AA, we will use a stratified design to enroll persons with AUD making naturally occurring continuing care choices vis-à-vis participation in MHOs in a balanced fashion and follow them prospectively across a 24-month period. Of note, self-selection of treatment/recovery pathway options has been shown to potentially enhance outcomes. This will be explored in this study as well. This stratified design will allow us to compare the outcomes of persons choosing to participate in SMART Recovery vs. not (balanced by AUD severity), while accounting for simultaneous choices regarding AA or neither AA or SMART MHO participation. 2: Explore moderators and mechanisms of behavior change. Exploration of factors that may help uncover who (i.e., moderators) and why (i.e., mechanisms) SMART affiliates benefit from participation will be investigated. Moderators will include sex and gender, addiction severity, psychiatric distress; and mechanisms will include social network changes, recovery motivation, cognitive-behavioral coping, abstinence self-efficacy, and impulsivity.

METHODS AND ANALYSIS

Study overview

This study is a naturalistic, prospective, longitudinal cohort study of 368 individuals making a new recovery attempt from AUD with seven assessments over a 24-month follow-up period. Following the baseline assessment, research staff will conduct additional follow-up assessments at 3, 6, 9, 12, 18, and 24 months after study enrollment. Assessments include both self-reports by participants using online surveys, and staff-administered assessments, conducted via phone and/or Zoom. Baseline visits were conducted from February 2019 to February 2022. Follow-up visits are ongoing and will continue until approximately February 2024. The study was fully reviewed and approved by the Institutional Review Board at Mass General Brigham, Boston, MA USA.

Sample size determination

The primary outcome variables are percent days abstinence (PDA) and percent days heavy drinking (PDHD; NIAAA-defined). Secondary outcomes include quality of life and psychosocial functioning. To estimate a plausible effect size to be expected in PDA as a function of mutual help organization (MHO) utilization, we examined the PDA outcomes in Project MATCH [19] for persons utilizing AA vs. not. Effects were surprisingly consistent across time, with patients with any AA utilization reporting a higher average number of PDA than patients with no AA involvement (d=0.45, 0.39, 0.38, 0.42, and 0.39 at 3-, 6-, 9-, 12- and 15-month follow-up respectively). Thus, conservatively, we are powering this study to detect an effect size of d=0.35. Using SAS proc power we determined that n=130 per group are necessary to detect d=0.35, leading to a combined sample size of n=260 (equally balanced, due to stratification, in terms of AA utilization and addiction severity). With a conservatively estimated retention rate of

75%, we would need to enroll n=347 to retain n=260. Given our stratified design (i.e., 2 [SMART vs. not] x 2 [12-step vs. not] x 3 [mild vs. moderate vs. severe AUD] design = 12 stratification cells), we proposed to enroll a final sample size of n=348 (i.e., n=29 per cell). In addition, 20 further participants were enrolled to increase representation of individuals attending SMART Recovery and to account for participants who withdrew, were terminated from the study, were found ineligible, or were otherwise no longer participating (e.g., death unrelated to the study).

Using this design, we will be equally well powered to test the main effect of 12-step participation. In terms of conducting pair-wise comparisons between the four possible combinations of using SMART Recovery and/or 12-Step, this sample size would enable us to detect pairwise differences of medium effect size (d=0.50). Improvements over our conservatively estimated retention rate would increase power (e.g., could detect d=0.46 with 85% retention).

Recruitment

Participants were recruited through SMART Recovery meetings, inpatient and outpatient treatment programs, and a variety of commercial recruitment sources during the recruitment period (January 2019 to January 2022).

Flyers and postcards for the study were distributed around buildings of Massachusetts General Hospital, particular around inpatient and outpatient SUD clinics. SMART facilitators were asked to advertise the study at SMART meetings and were provided with recruitment postcards and flyers. The study was also advertised on the SMART San Diego website. Additional recruitment methods included ResearchMatch, PeRC, TrialFacts, Rally for Recruitment, the Metro Newspaper, radio advertisements, MBTA advertisement, Facebook, Craigslist, and Reddit. For radio, MBTA, Facebook, and Craigslist advertisements, this study was advertised along with another ongoing R01 study of individuals making a new recovery attempt from AUD with similar eligibility criteria. Monthly meetings were also held with regional SMART Recovery MHO group facilitators to provide them with updates and inquire if there was anything we could provide to help facilitate study recruitment from online SMART resources or SMART meetings.

Interested individuals called the study-specific phone line, emailed the study-specific email address, or filled out an online screening form. Individuals were then able to participate in a brief 10–15-minute phone screen, during which eligibility criteria were confirmed. If the individual was eligible to participate, the baseline visit was scheduled and contact information for two locator contacts who can assist research staff in locating participants was collected.

Consent Process: Participants completed the consent process with a trained study staff member and were encouraged to ask questions about any aspect of the study. Through this process, participants were informed about the nature and extent of the study duration and procedures including the types of assessments administered, the risks and benefits of participation, as well as the financial renumeration schedule and protocol, and given telephone and email contact information in order to contact study staff at any time during the course of the study (see Consent Form in Supplementary Materials section for more details).

Eligibility

Participants were required to be 18 years or older, living in the New England or San Diego metropolitan area, and willing to travel to Boston, Massachusetts, to complete study visits (for

New England residents) or to complete study visits remotely (due to COVID-19 and for the San Diego participants). The geographical catchment area eligibility criteria were expanded to include people from the San Diego area in December 2020 to increase the number of SMART participants in the study. Since all visits were conducted remotely beginning in March 2020 due to the COVID-19 pandemic, participants from the New England area would also be considered eligible even if they could not travel to the Boston office for assessments in the foreseeable future.

Participants could be using other drugs but had to report alcohol as their primary substance of concern; they were also required to have a self-perceived alcohol problem, to meet current criteria for DSM 5 alcohol use disorder (AUD) using semi-structured interview; to have consumed alcohol in the past 90 days and report currently engaged in a new recovery attempt defined as "a serious effort to abstain from drinking or to drink without problems in the past 90 days or planning to make one in the next 14 days."

Additionally, participants were required to provide locator contact information for two close friends/family members in case we were unable to contact the participant directly; provide their social security number for reimbursement or be willing to not receive reimbursement; provide a urine sample and breathalyzer (for in-person visits) or remote saliva test (for remote visits) for biochemical verification; and provide a stable home address and contact information. These initial bioassay requirements were not required following the start of COVID-19 lock-downs which began in March 2020.

Methods

All assessments were initially conducted (prior to COVID) with a study research coordinator in person at our downtown Boston offices at the MGH Recovery Research Institute. Each assessment consisted of staff-administered and self-administered surveys, which were completed via REDCap (a secure, web-based application designed to support data capture for research studies), a computerized task to assess impulsivity (Go/No-Go task), and biochemical verification tests of abstinence (breathalyzer, urine) for all participants at all time points. For in person visits, the baseline and follow-up assessments lasted for approximately 3 hours. At the end of the first visit and every follow-up visit, the next follow-up was scheduled.

Due to the COVID-19 pandemic, all assessments were transitioned to be conducted remotely beginning in March 2020. During remote visits, the computerized task and urine and breath biochemical verifications of abstinence were not completed. A web-based version of the computerized task was tested, but the effects of internet speed on results made data unreliable. In lieu of the urine and breathalyzer tests, saliva tests were implemented for remote visits from March 2021 to May 2021 but were discontinued due to documented inconsistent results. Relative to in-person assessments, remote assessments were shorter with assessments lasting approximately 1.5 hours (for baseline) or 45 minutes (for follow-ups) on the phone and approximately 1 hour for participants to complete surveys individually.

All participants (in-person and remote) agreed to provide their phone numbers and email information and that of two locator contacts so that they may be contacted for follow-up assessment reminders. Research staff contacted and confirmed the contact information of the locator contacts as needed if research staff loses touch with the participant. Participants indicated their preferred method of contact (phone call, email, or text message) for receiving automated reminders throughout the project period. In keeping with a validated research follow-up protocol for maximizing retention in clinical addiction research, after the baseline assessment, research

staff proactively reached out to participants for reminders and to check if there were any changes to their contact information. Check-ins occurred 1 month, 14 days, 7 days, and 24 hours before the next scheduled visit. These messages are automated and sent with Twilio, which is an approved REDCap module by Mass General Brigham.

Participants are compensated $45 for completing the baseline visit and $55, $60, $65, $70, $75, and $85 for completing the 3-, 6-, 9-, 12-, 18-, and 24-month follow-up visits, respectively. Payment for each timepoint is broken up into payment for the staff-administered surveys, self-administered surveys, and travel reimbursement. During remote visits due to COVID-19, all participants were still paid the travel reimbursement to maintain the same payment structure used for in-person assessments.

Measures

Staff-administered measures assess the following: substance use history including capture of primary outcomes (percent days of heavy drinking; percent days abstinent from alcohol/other drugs), AUD and SUD status and severity (including remission status), tobacco use, treatment utilization for physical health problems and alcohol/drug use problems, anti-craving and anti-relapse medications (alcohol and opioids), mental and emotional health diagnoses, hospitalizations, treatment history, and psychiatric medication use, social networks, 12-step/MHO attendance history, online resource utilization, SMART involvement, 12-step MHO involvement (MM-HAS), recovery/abstinence time, recovery support services and formal treatment program utilization, substance use change over the past year (YES), impulsivity (Go/No-go cognitive task), and biochemical verification of substance use (breathalyzer, urine drug screen).

Self-administered measures assess the following: demographics, criminal justice involvement, religiosity and spirituality (RBBS, religious and spiritual intensity, DSES), stress and psychiatric distress (PSS-4, K6), coping (CSS), self-efficacy (A-DSES-20, single item self-efficacy), alcohol/other drug craving (PADCS-5), commitment to sobriety (CSS-5), substance use consequences (SIP-2R), recovery status (questions about recovery, drinking goal), recovery capital (BARC-10), behavioral addictions, medical marijuana use, medication attitudes, impulsive behavior (SUPPS-S), quality of life and psychosocial functioning (TPS, Q-LES-Q, EQ5D3L, EUROHIS-QOL, self-esteem, happiness, and satisfaction with life), and physical health (PSQI, pain VAS, IPAQ, meals).

All measures were administered at each timepoint except for the Year End Summary (YES), SUD DART, and Questions about Recovery, which were administered at baseline, 12-months, and 24-months. Detailed descriptions of measures are available in Supplement 1.

COVID-19 impact

The COVID-19 pandemic significantly affected the conduct of study assessments as all assessments were transitioned to fully remote visits beginning in March 2020. As previously noted, this shift to remote assessments meant that we were unable to conduct the Go/No-go cognitive measure, breathalyzer, or urine screen. Due to these changes, all substance use outcomes are self-reported. Self-administered saliva tests were used briefly as a replacement, but inconsistent results (e.g., false negatives, partial results, no results) made data collected from these tests unreliable and this strategy was stopped.

Additionally, recruitment was halted as the study team transitioned to remote assessments and many previous recruitment methods were no longer viable (e.g., recruitment from outpatient

clinics, advertisements on Boston area trains). It was particularly challenging to recruit individuals attending SMART as meetings were halted, then moved to virtual-only. To address these challenges, we expanded the recruitment area to San Diego, where there is a large SMART Recovery MHO participation community. We also maintained contact with SMART facilitators throughout the recruitment period to encourage them to share the study with meeting attendees and solicit feedback on how to best improve recruitment of SMART participants.

To capture potential changes in recovery resource utilization due to the COVID-19 pandemic, we added a staff-administered measure related to use of online recovery resources and social network site use. In addition, a supplemental study focusing on the impact of COVID-19 was conducted, consisting of both quantitative measures and a qualitative interview with a sub-group (n=80) of study participants selected at random from the SMART, AA, SMART+AA, and neither cohorts (n=20 from each group).

Limitations

The study employs a cohort based, naturalistic, non-randomised, design and research staff are not blinded to participants' self-selected recovery pathways. The use of self-report measures, despite having good psychometric properties and adequate validation, can still yield social desirability and memory recall biases.

Patient and public involvement

No patient or public involvement.

Data analysis plan

Aim 1 Effectiveness. We will use multiple linear regression analyses to determine whether our primary stratification factor of interest (predictor: SMART vs. no SMART) is associated with alcohol outcomes (primary dependent variables: PDA; PDHD) at 24-month (primary end-point), and 3-, 6-, 9-, 12- and 18-month (secondary) follow-ups, while controlling for other confounding variables (e.g., baseline variation in levels of the outcome variables) and by using propensity score matching methods that we have used successfully in prior work. We will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity. We will also test longitudinal models to investigate the dynamic relationship of these various recovery pathways over time (e.g., using hierarchical linear modeling as we have done previously [20]) controlling for baseline variation in the outcome variables.

Aim 2a. Mechanisms and Moderators. We will use mediational modeling, using the product-of-coefficients approach [21, 22] to test how SMART Recovery confers benefit (or fails to do so). The independent variable will be stratification group (i.e., SMART vs. no SMART), and the outcome variables will be PDA (primary), PDHD, AUD remission, quality of life, and measures of psychosocial functioning. The mediators will be our theorized mechanisms of change (e.g., social network changes, recovery motivation, coping, self-efficacy, impulsivity), which we will quantify as change since baseline in these constructs as measured via REDCap administered scales prior to the outcome (e.g., change in craving observed from baseline to 3-month would be used to predict 6-month ultimate outcomes). We will use multiple mediation to determine the relative impact of each mechanism, and moderated multiple mediation to identify differences in

mechanisms across (moderator) subgroups (e.g., males vs. females, severe AUD addiction severity vs. moderate/mild), similar to our prior approach in delineating mechanisms of behavior change in AA [23-25].

Aim 2b. Dose-response relationship of SMART Recovery. Using only data from participants in the stratified SMART group, we will use linear regression (primary outcome: PDA) to test if the level of SMART involvement, as measured by the SMART Involvement Scale, is related to PDA at 24-month (primary endpoint) and other follow-up points over time. We will use basic model building practices to determine if such an effect persists after accounting for demographics, other important contextual variables, moderators, and baseline levels of the theorized mechanisms of change. In follow-up analyses, we will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity.

Multiple Testing. We will use the false recovery rate adjustment [26] to control for multiple testing.

Missing Data. Some data will inevitably be missing. We will explore patterns of missingness to determine if missingness is occurring at random (MAR) (i.e., unrelated to the value of the missing observation) or likely to be missing not at random (MNAR). For each analysis, we will use a variety of recommended strategies to address the issue of missing data (e.g., multiple imputation, maximum likelihood estimation)[27]. Consistency in findings across missing data methods will enhance our confidence in the findings. Note that study participation will be completely separate from SMART participation; thus, participants should feel comfortable remaining in the study regardless of whether they continue in SMART or not. Assuming some attrition, we plan to conduct analyses examining predictors of attrition and control for these.

ETHICS AND DISSEMINATION

All study procedures are approved by the Institutional Review Board of Mass General Brigham (approval number: 2017P002029). Written consent was received from all participants following an explanation of the study, including confidentiality and freedom of choice to participate. Results will be published in relevant peer-reviewed scientific journals and presented at conferences.

AUTHORS' CONTRIBUTIONS

JK developed the idea and conceptualized the study design and led the writing of the manuscript. SL contributed to conducting the study and writing the manuscript. BH contributed to study design and development and statistical analysis as well as reviewing and editing final versions of the manuscript.

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COMPETING INTERESTS STATEMENT

None declared.

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Supplement 1 – Measures

Table 1 (staff-administered measures)

Measure	Description
Substance Use History	Participants answered a series of questions about 15 substances/classes of substances (hereafter simply referred to as substances) from the Global Appraisal of Individual Needs (GAIN-I; (Dennis et al., 2002)): 1) Alcohol, 2) Marijuana, 3) Heroin, 4) Methadone, 5) Buprenorphine and its formulations (e.g., suboxone), 6) Other opioids (e.g., pharmaceutical opioids), 7) Cocaine, 8) Amphetamines (including MDMA), 9) Methamphetamine, 10) Benzodiazepines, 11) Barbiturates, 12) Hallucinogens, 13) Synthetic drugs (e.g., synthetic cannabinoid like "K2" and synthetic cathinones such as "bath salts"), 14) Inhalants, and 15) Steroids, as well as "Other" (specified by participant). At baseline, participants reported which of these substances they used 10 or more times in their life. Then for each substance endorsed, they provided information on the following from the Form-90 (Miller & Delboca, 1994): a) Age of first use; b) If they had ever used the substance regularly (i.e., at least once per week) (yes/no) and if so, the age of first regular use; c) Whether they had used the substance in the past three months (yes/no), and if so how many days out of the past 90 they used the substance and d) If they had not used the substance in the past 3 months, the date of their last use. For follow-ups, the questionnaire assessed if participants had used these substances in any capacity in the past 3 months, if they had used the substances regularly over the past 3 months, and out of how many of the past 90 days they used the substance. Participants then chose their primary substance ("drug of choice") and secondary substance from the substances they had used (lifetime use for baseline assessment, past 3 month use for follow-ups). Finally, participants were asked for how many of the past 90 days their use of alcohol/drugs interfered with their functioning, and how many out of the past 90 days they got drunk at all or high for most of the day.
Alcohol Use Disorder DART	Participants were asked this validated semi-structured interview to capture AUD status (AUD severity and withdrawal symptoms). Participants were first asked if they had consumed alcohol in the past 3 months. If the participant answered 'yes', the DART would pertain to the past 3 months. If the participant answered 'no', they would be asked if they consumed alcohol during the past 12 months, and the DART would pertain to the past 12 months. If the participant answered 'no' to both the questions, they would only be asked if they experienced strong urges or cravings to drink.
Substance Use Disorder DART	Participants were asked about the recreational drugs/medications they used in the past 12 months. They then ranked the substances in the order that they caused problems for them. The DART was administered for the top 3 substances that caused the most problems for participants.
NIH PhenX Toolkit	Participants reported on lifetime use of cigarettes, e-cigarettes, or another tobacco/nicotine product (specified by participant). For those who smoked cigarettes, they reported on the following: 1) Age of first regular use; 2) Of how many of the past 30 days they smoked cigarettes 3) Average number of cigarettes smoked per day in the past 30 days 4) Whether or not they had ever made a serious attempt to quit smoking. This was asked pertaining to 'lifetime' for the baseline visit and for the past 90 days in the follow-up visits. If participants had made a serious quit attempt either in their life (baseline) or in the past 90 days (follow-up), they reported how old they were when they most recently quit smoking, the number of quit attempts in the past 90 days, the longest length of time they had quit smoking for, as well as on psychosocial smoking cessation resources. If not currently still smoking, participants reported the age when they stopped smoking, as well as psychosocial smoking cessation resources used in their most recent quit attempt. Finally, regarding smoking cessation, all participants answered a single item with four multiple choice options to gauge attitudes toward inclusion of smoking cessation in AOD treatment (e.g., "Services that help people stop smoking…should be automatically included in addiction treatment.").

	(National Cancer Institute, 2009; National Institutes of Health & U.S. Food and Drug Administration, 2013; Prorok et al., 2000).
Treatment for Injuries or Physical Health Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for health problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Treatment for Alcohol and Drug Use Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for alcohol or drug use problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Anti-craving and Anti-relapse Medications (Alcohol and Opioids)	At baseline, participants reported whether they had ever been prescribed a medication to prevent them from drinking alcohol or using opioids. At follow-up visits, participants were asked if they had been newly prescribed any medication to prevent them from drinking alcohol or using opioids in the past 3 months. If participants responded yes to either item, participants reported lifetime (baseline), past 3 months (follow-up) and current (baseline and follow-up) use of specific medications from the Form-90, including both generic and brand names (Miller & Delboca, 1994). Participants were also asked to rate what proportion of the time they used each medication as medically indicated.
Mental and Emotional Health: Diagnoses, Hospitalizations, Treatment History	Participants reported whether they had ever been told that they had a mental health condition by a doctor, nurse, or counselor, including agoraphobia, anorexia nervosa, bipolar disorder, bulimia nervosa, delusional disorder, dysthymic disorder, generalized anxiety disorder, major depressive disorder, obsessive-compulsive disorder, panic disorder, personality disorder, post-traumatic stress disorder, schizoaffective disorder, schizophrenia, social anxiety disorder, specific phobia, substance use disorder, and other. For each diagnosis endorsed, participants indicated whether this had been a problem for them in the past 12 months. Participants reported treatment in an emergency room and admissions to a hospital for at least one night for mental, emotional, behavioral, or psychological problems. Participants reported for both lifetime and past 3 months. Participants also reported the number of times they had seen a mental health doctor in an office or outpatient clinic (including telehealth) in the past 3 months, on how many of the past 90 days they had been bothered by mental, emotional, behavioral, or psychological problems, and on how many of the past 90 days these problems had kept them from meeting their responsibilities or made them feel like they could not go on (Dennis et al., 2002; Miller & Delboca, 1994).
Mental and Emotional Health: Psychiatric Medication Use	Participants were asked if they had ever been prescribed medication by a physician or medical practitioner to help them with a mental health condition (lifetime use). If they said yes, they were asked which medication they had ever been prescribed with the options antidepressants, anti-anxiety medication, anti-psychotics, mood stabilizers, stimulants, painkillers, medications for sleep and other (to be specified). Participants were then asked if they were still taking the medicines they indicated. If participants were still taking the medicines, they were asked what proportion of the time they take the prescribed medication as medically indicated. At follow-up visits, participants were asked if they were still using any medication that they had been using at the prior study visit, whether they had been newly prescribed any medication to help with a mental health condition, and if yes, what type of medication. For each medication endorsed, participants reported what proportion of the time they used the medication as medically indicated (Dennis et al., 2002; Miller & Delboca, 1994).
Social Support Questionnaire (SSQ)	Participants were asked to list the initials of up to 5 family members, up to 5 friends, and up to 3 other important people in their life who they felt close to. For each person, they listed their initials, relationship, alcohol use pattern, drug use pattern, days per month they had

	contact with this person over the past 3 months (including contact via phone/text), how much they value their relationship on a scale of 1 (*not at all*) to 10 (*a great deal*) and how helpful they are in their recovery efforts on a scale of 1 (*not at all helpful*) to 10 (*a great deal*) (Zywiak et al., 2009).
12-step/MHO Attendance History	At baseline, participants were asked about lifetime attendance to help with their AOD problem at 12 different MHOs, with an "other" option specified by participant (Kelly et al., 2011): 1) Alcoholics Anonymous (AA); 2) Narcotics Anonymous (NA); 3) Marijuana Anonymous (MA); 4) Cocaine Anonymous (CA); 5) Crystal Methamphetamine Anonymous (CMA); 6) SMART Recovery; 7) LifeRing Secular Recovery; 8) Moderation Management; 9) Celebrate Recovery; 10) Women for Sobriety; and 11) Secular Organization for Sobriety (S.O.S.).; 12) Dual Diagnosis Anonymous (DDA); and 13) Other. Other options were examined for possible inclusion in existing categories, and recategorized as appropriate. At follow-ups, participants reported attendance for the past 3-months. For each MHO attended, participants reported a) Whether they attended regularly (at least once per week), b) Number of meetings in the past 3 months, and c) Whether they had ever attended a meeting online.
Online Resources and Social Network Sites	For each MHO that a participant had attended online (as noted in "12-step/MHO Attendance History"), participants reported how many meetings they had attended online in the past 3 months, how they accessed these meetings (video, audio only, telephone, etc.), and how helpful they felt the online meetings were on a scale of 1 to 10. Participants also reported whether they used any online or mobile technologies to support their AOD problem resolution or recovery in their lifetime (baseline) and in the past 3 months. Potential online and mobile technologies included recovery-focused social network sites (e.g., InTheRooms.com), general social network sites (e.g., Facebook), and mobile smartphone applications. For each online or mobile technology endorsed, participants indicated how many of the past 90 days they had used the technology for recovery and how helpful they found it on a scale of 1 to 10. Participants were also given the opportunity to provide any other information or comments on their use of online or mobile recovery resources.
SMART Involvement	Questions about SMART involvement were asked for participants who had attended SMART Recovery. Participants were asked how long they have been attending SMART Recovery, how they heard about SMART Recovery, whether they consider themselves to be a current member of SMART Recovery (*yes/no*), how many times they have attended SMART recovery in their lifetime (*numerical value*) and if another member of SMART Recovery served as a personal mentor or guide to them in the past 3 months (*yes/no*). The participants were asked questions about their participation in SMART meetings in the past 3 months to gauge the frequency of the use of SMART meetings, tools, website, and web-application 'Overcoming Addictions.' Participants were also asked four questions about their level of engagement in SMART meetings.
Recovery/Abstinence time	Participants were asked to report in years and months how long they had been either 1) Sober (not using any alcohol/drugs) or 2) Drinking/using drugs without problems.
Multidimensional Mutual-Help Activity Scale (MM-HAS)	Questions from the MM-HAS were asked for participants who had attended meetings of any of the following MHOs: Alcoholics Anonymous, Narcotics Anonymous, Marijuana Anonymous, Cocaine Anonymous, Crystal Methamphetamine Anonymous, and Dual Diagnosis Anonymous. For each organization, participants were asked if they currently considered themselves to be a part of the MHO, their activities as part of the MHO in the past 3 months (sponsor, contact with sponsor outside a meeting, contact with other members outside a meeting, read 12 step literature outside of a meeting, shared or talked during meetings, helped with setting up/running a meeting), and the number of steps out of the 12 step program that they completed while participating in the MHO in the past 3 months. Participants were then asked to rate the helpfulness, enjoyability, and safety of the

	MHO from a scale of 1 (*not at all helpful, do not enjoy at all,* or *not at all safe*) to 10 (*extremely helpful, enjoy a great deal,* or *completely safe*) (Kelly et al., 2013; Kelly et al., 2011).
Recovery support services and formal treatment programs (RSSTX)	The questionnaire assessed history of participation in nine psychosocial treatment and recovery support services: 1) Sober living environment; 2) Recovery high school; 3) College recovery program/community 4) Recovery community center (RCC); 5) Faith-based recovery services (e.g., a recovery group provided by a church, synagogue, mosque, etc.); 6) State or local recovery community organization (RCO); 7) Outpatient addiction treatment; 8) Alcohol/drug detoxification services; 9) Inpatient or residential treatment. If they responded yes to any treatment service (7, 8 or 9), they reported the number of times they used the service (i.e., number of treatment episodes) in their lifetime (baseline) and the past 3 months (baseline and follow-up). (Dennis et al., 2002; Miller & Delboca, 1994).
Year End Summary (YES)	At baseline, 12-month follow-up, and 24-month follow up, participants were asked if they felt like they were better off now than they were 12 months ago in terms of their alcohol and drug problems (worse off, same, better off). Participants were then asked to elaborate on the reason for that answer. Participants were asked if their substance use had changed or stayed the same in the past 12 months (changed for the better, changed for the worse, stayed the same). If participants reported 'stayed the same', they were asked what factors they thought were most responsible for their substance use staying the same.
Timeline Follow Back (TLFB)	Participants provided specific dates for alcohol use, substance use, MHO attendance, inpatient and outpatient addiction treatment, inpatient and outpatient mental health treatment, and incarceration for the past 3 months (baseline, 3-, 6-, 9-, and 12-month follow-ups) or 6 months (18- and 24-month follow-ups) (Miller & Delboca, 1994). For alcohol use, participants were asked to report the number of standard drinks consumed on each drinking day. For MHO attendance and outpatient treatment for addiction and mental health, participants were asked to report whether services were in-person or online. During in-person study visits, a printed calendar was used to facilitate the TLFB. For remote visits, study staff prompted participants with potentially memorable dates within the timeframe (e.g., holidays).
Go/No-Go Cognitive Measure*	The Inquisit Go/No-Go Cognitive Measure is a computerized task used to assess impulsivity. The Inquisit script implemented the Go/No-Go Task as described in Fillmore et al. (2006). Participants were asked to press the spacebar when they see a green rectangle (*go*) but refrain from pressing the spacebar when they see a blue rectangle (*no-go*). The blue and green rectangles could be vertical or horizontal. The vertical rectangle had a high probability (4:1) of being green (*go*) and the horizontal rectangle had a high probability (4:1) of being blue (*no-go*). Participants were given information about the orientation of the rectangle shortly before the color of the rectangle was revealed. Participant response times and error rates were recorded. For remote visits, a web-based version of the Go/No-Go Task was tested, but due to the effect of internet speed on results, this measure was not included.
Breathalyzer*	Breathalyzer tests were used to establish a baseline level of substance use for participants at the first assessment and to ensure that data was not collected from participants who were impaired due to alcohol use. Breathalyzer tests were performed at baseline and all follow-up time points prior to starting each assessment. If a participant's BAC was above .02, study staff did not conduct the study visit; instead, study staff either waited with the participant until their BAC dropped to .02 or lower or attempted to re-schedule the participant's visit. If a participant's BAC was above the legal limit (.08), and the participant had driven to their assessment, study staff asked to hold the participant's car keys while waiting for their BAC to drop below the legal limit. If the participant insisted on holding their car keys and/or driving, or if the participant did not stay with study staff until their BAC dropped below .08, study staff called security as a safety precaution. Study staff also offered to arrange and pay for a cab to transport the participant home. If a participant had driven to the appointment

	and decided to take a cab home, the participant could return to pick up their car keys during business hours when their BAC was below .08. For remote visits, study staff were unable to perform breathalyzer tests and instead asked participants to verify that they had not used alcohol or other drugs prior to the assessment via self-report.
Urine Drug Screen*	Urine drug screens were used to establish baseline substance use at baseline and to verify self-reported estimates of alcohol and other drug use. For remote visits, study staff were unable to perform urine drug screens.
Saliva Test	Self-administered saliva tests were implemented in March 2021 as an alternative method of biochemical verification during remote visits. Participants were contacted prior to their assessment to confirm willingness to participate in the saliva test, what address the test would be mailed to, and whether the visit would be conducted over Zoom or on the phone. During the assessment, participants were able to self-administer the saliva test with study staff guidance. If participants completed the assessment over Zoom, participants showed the test results to the research coordinator who screenshotted the test and uploaded it to REDCap. If the participant completed the assessment over the phone, they uploaded images of the test to REDCap or, if unable to upload images, self-reported the results. Due to inconsistencies in saliva test results (no results, partial results, and false negatives), saliva test use was discontinued in May 2021.

* = not administered during remote visits

Table 2 (self-administered measures)

Measure	**Description**
Demographics Background	Participants reported the following: gender, race, ethnicity (whether participants were Hispanic/Latino), where they were living for the majority of the past 3 months (with family or other relatives, with group of friend(s) or non-family members, alone in own dwelling, homeless, hospital rehabilitation facility or nursing home, jail, prison or other correctional facility, other), current marital status (single, married, living with someone as if married, in a relationship, engaged to be married, legally separated, divorced, widowed), sexual orientation, left or right handed, highest level of schooling completed, highest level of schooling completed by either parent, whether they held a job in the past 3 months, (if yes) nature of employment (odd jobs, part time, full time), (if no) reason for unemployment, major source of financial support, total annual household income, type of health insurance, and financial well-being of their family. Numerical values were collected for the following in the past 3 months: unplanned absences from work/school, times disciplined on the job/at school, times your job/school has been in jeopardy, times you were suspended or fired from work/school (Dennis et al., 2002; Miller & Delboca, 1994).
Criminal Justice Involvement	The questionnaire used adapted items about criminal justice involvement from the Form-90 (Miller & Delboca, 1994). Participants reported on their current legal status (none, on probation only, on parole only, on probation and parole, awaiting charge, trial or sentence, outstanding warrant, case pending, other). At baseline, participants reported whether they had ever been arrested (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in their lifetime, and how many times for other reasons in their lifetime. At follow-up visits, participants reported whether they had been arrested in the past 3 months (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in the past 3 months, and how many times for other reasons in the past 3 months. At baseline, participants reported whether they had ever stayed in jail or prison overnight or longer (yes/no). If yes, they reported how many times in their lifetime and how many times in the past 3 months. At follow-up visits, participants only reported the number of times in the past 3 months.

Religious Background and Behaviors (RBBS)	At baseline, the questionnaire assessed if the participant considered themselves to be part of a religious group (No/none, Baptist, Buddhist, Catholic, Evangelical, Hindu, Jewish, Lutheran, Methodist, Mormon, Muslim, Presbyterian, Other Protestant, Shinto, Native American Church, Traditional Native American, Christian, Some other group). For all timepoints participants were asked which of the following describes them at this time: atheist, agnostic, unsure, spiritual, religious. Participants were asked how often they participated in religious activities in the past 3 months on a 7-point Likert scale (*never, rarely, once a month, twice a month, once a week, twice a week, almost daily, more than once a day*) and, at baseline, how often they participated in certain religious activities in their lifetime on a 3 point-Likert scale (*never, yes, in the past but not now, yes, and I still do*) (Connors et al., 1996).
Religious and Spiritual Intensity	The questionnaire included four items assessing participants' religiosity and spirituality. Participants reported the extent to which they considered themselves religious/spiritual on a Likert scale from *not religious/spiritual at all* (1) to *very religious/spiritual* (4). Participants reported the extent to which their religious/spiritual practices and beliefs help them with resolving an alcohol/drug problem on a scale from *do not help at all* (1) to *make all the difference* (5) (Idler et al., 2003).
Twelve Promises Scale (TPS)	This questionnaire assessed participants' current psychosocial state and attitudes towards drinking and using drugs. Participants rated how true each item was for them at the current time on a scale of *never true* (1) to *true most of the time* (5) (Kelly & Greene, 2013).
Perceived Stress Scale (PSS-4)	This questionnaire assessed participants' level of stress over the last month. Participants rated each item on a scale from *never* (1) to *very often* (5) (Warttig et al., 2013).
Kessler 6 (K6)	This six-item scale assessed psychiatric symptoms (also referred to as psychological distress). On a scale from *all of the time* (1) to *none of the time* (5), participants are asked how often they felt: nervous, hopeless, restless or fidgety, so depressed that nothing could cheer you up, that everything was an effort, and worthless (Kessler et al., 2003).
Coping Strategies Scale (CSS)	Participants were asked to select how often they used a variety of coping strategies or thoughts in the past 3 months to help them not use alcohol or drugs. Participants rated each item on a scale from *never* (1) to *frequently* (4) (Litt et al., 2003; Prochaska et al., 1988).
Alcohol and Drug Abstinence Self Efficacy (A-DSES-20)	Participants were asked about their feelings of confidence to not drink or use drugs in various situations in the past week. Participants rated their level of confidence for each scenario on a scale of *not at all confident* (1) to *extremely* (5) (Diclemente et al., 1994).
Penn Alcohol and Drug Craving (PADCS-5)	This questionnaire assessed the frequency and strength of cravings to use alcohol and other drugs during the past week. Participants reported how often they thought about drinking/using drugs, how strong the craving was at its most severe, how much time they have spent thinking about drinking/using drugs, how difficult it would have been to resist drinking/using drugs, and then rated their overall alcohol/drug craving with options ranging from *never thought about drinking/using drugs and never had the urge to drink/use drugs* to *thought about drinking/using drugs nearly all of the time and had the urge to drink/use drugs nearly all of the time* (Flannery et al., 1999).
Commitment to Sobriety Scale (CSS-5)	In this questionnaire, participants were asked 5 questions about their commitment to not using alcohol/drugs. Participants rated the extent to which they agreed with these statements on a scale from *strongly disagree* (1) to *strongly agree* (6) (Kelly & Greene, 2014).
Drinking Goal	In this questionnaire, participants chose one goal that was the most true to them currently from the 5 options: 1) Total abstinence; never use again; 2) Total abstinence; but realize a slip is possible; 3) Occasional use when urges strongly felt; 4) Temporary abstinence; or 5) Controlled use.

Short Inventory of Problems (SIP-2R)	This questionnaire assessed how often participants had experienced various problems during the past 3 months because of their drinking/drug. Participants indicated how often they had experienced each problem on a scale of *never* to *daily or almost daily*. Participants were also asked to indicate whether they had had an accident while drinking or intoxicated in the past 3 months (Miller et al., 1995).
Questions about Recovery	This questionnaire assessed recovery identity, definition, and what participants believe are the factors helping them resolve their problem with alcohol/drugs at baseline, 12-month follow-up, and 24-month follow-up. Participants selected a statement that best applied to them from whether they consider themselves to be *in recovery*, *seeking recovery* or *not in or seeking recovery*. If participants chose that they were 'in recovery', they were asked to provide the date they use to mark the beginning of their recovery. Participants were asked to provide their definition of recovery in one sentence (free response) and to select one of three statements that best fit their definition of recovery: 1) Abstinence from all drugs/alcohol; 2) Abstinence from only those drugs/alcohol with which they had a problem; or 3) Non-problematic/moderate use of drugs/alcohol, including those with which they had a problem. Participants were then asked to list the top 3 things that have helped or are helping them to resolve their problem with alcohol/drugs.
Brief Assessment of Recovery Capital (BARC-10)	The BARC-10 (Vilsaint et al., 2017) is a 10-item, abridged version of the Addiction Recovery Capital Scale (Groshkova et al., 2013). The BARC-10 measures personal (e.g., "I take full responsibility for my actions"), social (e.g., "I get lots of support from friends"), physical (e.g., "I have enough energy to complete the tasks I set for myself"), and environmental resources (e.g., "My living space has helped to drive my recovery journey") used to initiate and sustain recovery. Participants rated their agreement with each statement on a scale from *strongly disagree* (1) to *strongly agree* (6).
Behavioral Addictions	The questionnaire used items adapted from Laudet et al. (2015) to assess whether individuals ever had a problem with one or more other behaviors apart from AOD use in their lifetime (baseline) and currently, including 1) Eating disorder; 2) Sex/love addiction; 3) Gambling; 4) Video gaming addiction; 5) Compulsive shopping; 6) Internet addiction (for issues not assessed by other choices); 7) Compulsive exercise; 8) Internet pornography addiction; 9) Self-harm/injury and 10) Other (specified). "Other" options were examined for possible inclusion in existing categories, and recategorized as appropriate. Participants were asked if any reported behavioral addictions had been a problem for them in the past 3 month and if so, how many days out of 90. If reporting more than one, participants indicated which behavior had been the most problematic.
Medical Marijuana Use	Participants were asked if they had ever been recommended to use marijuana for medical reasons. If yes was indicated, participants were asked how many days out of the past 90 marijuana was used for medical reasons and to list up to three medical reasons for using marijuana.
Medication Attitudes	This questionnaire assessed participant attitudes toward medication for an alcohol problem, opioid problem, any kind of alcohol/drug problem, and emotional problem. Participants rated their agreement with the use of medication for these problems on a scale of *strongly disagree* (1) to *strongly agree* (6).
Impulsive behavior (SUPPS-S)	This questionnaire assessed impulsivity. Participants rated their agreement with 20 items describing situations or feelings related to impulsivity on a scale of *agree strongly* (1) to *disagree strongly* (4) (Coskunpinar et al., 2013).
Quality of Life (Q-LES-Q)	This measure of quality of life was used to assess satisfaction related to physical health, mood, relationships, activities, and economic status. Participants rated their satisfaction with

	each item during the past week on a scale of *very poor* (1) to *very good* (5) (Endicott et al., 1993).
Quality of Life (EQ5D3L)	This measure of quality of life was used to assess physical and mental health states. Participants rated their current mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Participants also rated their current overall physical and mental health states using a visual analogue scale with options between 0 (*worst*) and 100 (*best*) (Devlin & Brooks, 2017).
Quality of Life (EUROHIS-QOL)	This measure of quality of life is a widely used eight-item measure of quality of life, adapted from the World Health Organization Quality of Life – Brief Version (WHOQOL-BREF) (Schmidt et al., 2006). Participants rated each item on a 5-point Likert scale from 1 (*very poor, very dissatisfied,* or *not at all*) to 5 (*very good, very satisfied,* or *completely*) (da Rocha et al., 2012).
Pittsburgh Sleep Quality Index (PSQI)	This questionnaire assessed quality of sleep. Participants reported how many hours of sleep they got on average per night over the past month. Participants then rated their quality of sleep on a scale from *very good* (1) to *very bad* (4) (Buysse et al., 1989).
Pain Visual Analogue Scale (VAS)	This measure assessed physical pain. Participants rated the current severity of their pain using a visual analogue scale with options between 0 (*no pain*) to 100 (*very severe pain*) (Wewers & Lowe, 1990).
International Physical Activity Questionnaire (IPAQ)	This questionnaire asks participants about their level of physical activity over the past seven days. Participants indicate how many days in the past 7 days they have done: vigorous physical activity, moderate physical activity, and walking. Participants then indicate how much time per day they usually spent on each activity in hours and minutes. Participants are also asked how many hours they usually spent sitting on weekdays over the past 7 days (Hagstromer et al., 2006).
Meals	Participants reported how many meals on average they have eaten per day during the past 3 months.
Self-esteem, Happiness, and Satisfaction with Life	Three single-item measures were used to assess self-esteem (Robins et al., 2001), happiness, and satisfaction with life (Diener et al., 1985). For self-esteem, participants indicated their agreement with the statement "I have high self-esteem" on a scale from 1 (*not very true of* me) to 10 *(very true of* me). For happiness, participants rated how happy they were with their life in general on a scale of 1 (*completely unhappy*) to 10 (*completely happy*). For satisfaction with life, participants indicated their agreement with the statement "I am satisfied with my life" on a scale of *strongly disagree* (1) to *strongly agree* (7).
Abstinence Self-Efficacy Single Item	Participants rated how confident they were that they could remain abstinent or drink/use drugs without problem in the next 3 months on a scale from *not at all confident* (1) to *very confident* (10).
Daily Spiritual Experiences Scale (DSES)	This questionnaire assesses spiritual and/or religious experiences. The questionnaire includes items with the word "God" used but includes instructions for participants that if "God" is not a comfortable word that they should substitute it for one that calls to mind the divine and holy for them. Participants read 15 items describing spiritual and/or religious experiences that a person may have and rate how often they have this experience from *many times a day* (1) to *never or almost never* (6). The last item asks participants how close they feel to God from *not close* (1) to *as close as possible* (4) (Underwood & Teresi, 2002)

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Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Pathways to Change

Principal Investigator: John F. Kelly, Ph.D.

Site Principal Investigator:

Description of Subject Population: Adults with an alcohol use disorder making a new recovery attempt.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

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Why is this research study being done?

This research is being done to obtain greater knowledge about the pathways followed in new recovery attempts for individuals with an alcohol use disorder (AUD). We are asking you to take part in this research study because you identified yourself as someone with an AUD and is making a new attempt to change your alcohol use. About 348 people will take part in this research study. We expect to enroll all subjects within the greater Boston, Massachusetts area.

How long will you take part in this research study?

If you enroll today, it will take you a total of 24 months (two years) to complete this research study. During this time, you will complete a baseline assessment, along with follow-up surveys every 3-, 6-, 9-, 12-, 18-, and 24-months.

What will happen if you take part in this research study?

If you choose to enroll, you will be required to come to our downtown Boston office at the MGH Center for Addiction Medicine (within 3-minute walking distance of two major subway stops) to complete your assessments. You will complete your questionnaires via the Harvard Catalyst's Electronic Data Capture (REDCap; project-redcap.org) and with a research coordinator. You will be asked about basic demographic questions, substance use history, mutual-help organization attendance, psychiatric symptoms, psychosocial functioning, treatment service utilization, quality of life, and recovery motivation/support.

If you are a participant from the San Diego area, all of your study visits will take place remotely. The questionnaires will be asked over Zoom, Skype, or phone call and through an online link that is sent to your personal device.

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. The aim of this qualitative interview is to investigate the motivations, expectations, and experiences of individuals who do and do not participate in Mutual Help Organizations (MHOs) such as Alcoholics Anonymous and SMART Recovery. Additionally, we hope to assess how helpful individuals believe MHOs are in their recovery attempt and how MHOs and other recovery resources might be improved and adapted to better fit the needs of individuals currently seeking recovery from an Alcohol Use Disorder.

MHO attendance is not required to participate in this qualitative interview. We plan to include individuals following a variety of recovery pathways.

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Study staff will reach out directly to a pre-determined number of interested individuals via email or phone call to offer them the opportunity to participate in this qualitative interview and schedule an interview time. The interview will be approximately 30-60 minutes in length and will be conducted via Zoom or over the phone and will be recorded. This is done purely for data summarization purposes and once the data are transcribed, the recordings will be deleted. Participants will be compensated an additional $50 following completion of the interview.

You are not required to participate in the optional qualitative interview in order to participate in the Pathways to Change Study. You can still take part in the original research study whether or not you choose to participate in this additional qualitative interview. Signing this form does not guarantee that you will be able to participate in the qualitative interview.

Do you consent to participate in the qualitative interview if selected?

[ ] YES [ ] NO Initial _____

You will receive text/email reminders about upcoming appointments through REDCap's automated email feature and integrated Twilio SMS and voice call services. Both REDCap and Twilio are secure services for these appointment reminders.

Text messages by mobile/cell phones are a common form of communication. The Recovery Health research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not receive text messages with staff associated with this research study at any time. You can do this in person at your upcoming visit, by calling 617-643-5927, or by emailing recoveryhealth@mgh.harvard.edu.

- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

What are the risks and possible discomforts from being in this research study?

The risk of participating in this study is expected to be very small because your privacy is protected by law. We may report medical information if you need medical help, if we feel you might be in danger of harming yourself or others, or if there is any suspicion of child abuse or elder abuse.

It is possible that you may experience some discomfort during scheduled assessments from the questionnaires, as they ask for some sensitive personal information. However, you are free not to participate in any aspect of the study that makes you uncomfortable.

What are the possible benefits from being in this research study?

You will gain no direct benefit from participation in this study. However, this study has the potential to contribute valuable information about recovery pathways for individuals with alcohol use disorder, and may provide additional support for mutual-help organizations.

What other treatments or procedures are available for your condition?

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This study does not provide any treatment to you. Rather, we will ask you about your experiences with various treatments that you have been receiving or have received. You do not have to take part in this study to be able to obtain mental health services.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. John F. Kelly, Ph.D., is the person in charge of this research study. You can call him at 617-643-1980, Monday-Friday, 9am-5pm. You may leave a message at this number and he will return your call. You can also call research staff at 617-643-9850, Monday-Friday 9am-5pm with questions about this research study. If you have questions about the scheduling of appointments or study visits, call research staff at 617-643-9850.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

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Detailed Information

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding recovery from alcohol use disorder. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be compensated up to $455 for completing the questionnaires. That is $15, $25, $30, $35, $40, $45, and $55 for the baseline, 3-, 6-, 9-, 12-, 18-, and 24-month assessments, respectively. Additionally, you will be compensated $20 for each of the computer-based REDCap surveys you complete at each assessment. Finally, in order to help offset the cost of travel, you will be compensated $10 per assessment for coming to our offices. In order to receive payment for this study, we will need your Social Security Number (SSN). We need to collect this information in order to comply with tax reporting obligations. This information is confidential and protected, and will be stored securely and redacted when no longer required.

	Computer-based REDCap Surveys	In-Person Study Visits with Staff	Travel Reimbursement
Baseline	$20	$15	$10
3-Month Follow-Up	$20	$25	$10
6-Month Follow-Up	$20	$30	$10
9-Month Follow-Up	$20	$35	$10
12-Month Follow-Up	$20	$40	$10
18-Month Follow-Up	$20	$45	$10
24-Month Follow-Up	$20	$55	$10
Total:			Up to $455

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. Participants will be compensated an additional $50 following completion of the qualitative interview.

What will you have to pay for if you take part in this research study?

There are no costs to participate in this research. All questionnaires and surveys will be provided to you by study staff members.

Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

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The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Signature of Subject (choose one):

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject | Date | Time (optional)

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above. **I understand that I am eligible to be compensated for my participation but am choosing not to be.**

Subject | Date | Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent Form Version Date: 06/04/2021

Date: Research Staff conducting the screen:	
Thank you for your interest in our research study. My name is [RC NAME] and I am a research coordinator at the Recovery Research Institute within the Department of Psychiatry at the Massachusetts General Hospital. Is this a good time for you to talk about the study?	☐ Yes ☐ No
[IF NO] What time would be good for me to give you more information about the study and do a short phone screen to see if you are eligible? I appreciate your time. Have a great day.	Date: [MM/DD/YYYY]
[IF YES] I am going to ask you a series of questions to determine if you are eligible to participate in this study. Some of these questions may not apply to you, but please answer them to the best of your ability. At the end of the screen, I will tell you if you are eligible to participate or if you have been found ineligible. In order to protect the integrity of the study, if you are found ineligible, I will unfortunately not be able to tell you the specific reason why you were found ineligible to participate. Knowing this, do you agree to proceed to screen for the study?	☐ Yes ☐ No
[IF YES] Okay great! First, may I ask how you heard about the study?	☐ Twitter ☐ Facebook ☐ RRI Website ☐ Flyer ☐ RSVP for Health ☐ Word of Mouth ☐ SMART Meeting ☐ Craigslist ☐ Metro ☐ MBTA ☐ West End Clinic ☐ ARMS ☐ Did not specify ☐ Other
[IF OTHER] What was the other source from which you heard about this study?	_____
[IF FLYER] Where did you get the flyer from?	_____
Where are you located?	☐ New England (MA, NH, RI, etc.) ☐ California ☐ Other
[IF OTHER] If located outside of New England or California, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	

Great! Let me tell you a little bit about our study, so you can decide if this is something you'd like to participate in. The study is funded by the National Institutes of Health to learn more about the different pathways, resources, and services that individuals may use to overcome an alcohol problem. We hope this study will help advance treatment and recovery support service options. If you decide to take part in the study, your participation would include 7 visits to our Boston office over the course of 2 years. During each visit, you would complete a series of questionnaires, computerized tasks, and biochemical verification of abstinence, which includes a urine sample and breathalyzer test. In the event that your visits will take place remotely (e.g., over the phone or zoom), study procedures are similar; however, you would complete a self-administered saliva test that is mailed to you in advance. Each visit will take approximately 3 hours. How does that sound so far?	☐ Yes, remains interested ☐ No longer interested
[IF NO LONGER INTERESTED] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[IF REMAINS INTERESTED] Great. Before I can enroll you in this study, I need to ask you some questions to make sure you are eligible. These questions are about your health and medical history, including your alcohol use, and should take about 10 minutes of your time. Some of the questions may make you feel uncomfortable. You may stop at any time. Does that sound okay? I will record your answers in writing, but only collect detailed contact information if you qualify for the study and want to schedule an in-person visit. As a reminder, collected information is completely confidential and protected. There is always risk of loss of confidentiality but we will take appropriate responsible steps to ensure confidentiality. Okay to begin?	☐ Yes ☐ No
[IF NO] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[IF YES] [ps_name], could you please verify the spelling of your first name?	

How old are you?	_____
Research Staff Use: Is the participant older than 18?	☐ Yes ☐ No
STOP SCREEN. If under 18, NOT ELIGIBLE to participate. [IF INELIGIBLE] Thank you, [es_name]. Unfortunately, you are not eligible to participate in our study. You may be eligible to participate in future research studies. If you are interested in participating in future research studies, we can take your contact information and reach out to you with future study opportunities.	
[IF FROM NEW ENGLAND] Are you willing to travel to Boston to complete study visits?	☐ Yes ☐ No
[IF NO OR FROM CALIFORNIA] Are you willing to conduct all visits remotely (e.g. over phone or Zoom)?	☐ Yes ☐ No
[IF NO] If unwilling to travel to Boston for the research study and unwilling to conduct visits remotely, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Is there any reason that you would not be living in the Boston area within the next 2 years?	☐ Yes ☐ No
[IF YES] Would you be willing to conduct visits remotely if you were no longer in the Boston area?	☐ Yes ☐ No
[IF NO] If participant will not be in Boston for the next 2 years and is not willing to conduct visits remotely, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Are you willing to give us the contact information for two of your friends or family members, so that we can reach out to them, in case we lost contact with you? We ask for this information because obtaining complete data from you is very important to the study. The last study visit will take place 2 years from the time of your baseline visit. We want to make sure we can reach you to complete your final visit at that time.	☐ Yes ☐ No
[IF NO] If they aren't willing to provide collateral contacts NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Are you willing to provide your SSN in order to receive reimbursement? *(If asked for more information: If payments to you are $600 or greater in a calendar year, Partners will report this to the Internal Revenue Service (IRS) and you will receive a 1099-MISC income form and Partners will use your SSN for this tax-related purpose.* *If you do not provide your SSN, we cannot issue you a payment for participation. You may still choose to participate in this study and decline reimbursement).*	☐ Yes, I am willing to provide my SSN to receive the study payment. ☐ No, I am not willing to provide my SSN; however, I still wish to participate in this study. I understand that I will not receive payments for being in this study unless I provide my SSN. ☐ No, I am not willing to provide my SSN and decline to participate in this study.

[IF NO] If unwilling to provide SSN and decline to participate in the study, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
During assessments, are you willing to provide a urine sample and complete a breathalyzer test for biochemical verification? Or in the event that your visit takes place remotely, are you willing to provide a self-administered saliva test with study staff guidance? This test would be mailed to your current address before the study visit and can be disposed of after use. Although you do not need to abstinent to participate in this study, we ask that participants not drink or use drugs before coming in for their assessment or before completing their remote assessment. If the breathalyzer test or saliva test indicates that you are under the influence of alcohol when you come in for your assessment or begin your remote assessment, we will need to re-schedule the visit.	☐ Yes ☐ No
[IF NO] If unwilling to participate in biochemical verification, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Do you have a stable home address and contact information?	☐ Yes ☐ No
[IF NO] If participant does not have a stable home address and/or contact information, NOT ELIGIBLE to participate[Do not stop screen, complete screen in its entirety]	
Have you consumed alcohol in the past 3 months?	☐ Yes ☐ No
[IF NO] If participant has not consumed alcohol in past 3 months, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Do you think you have a problem with alcohol?	☐ Yes ☐ No
[IF NO] If participant does not think they have a problem with alcohol, NOT ELIGIBLE to participant [Do not stop screen, complete screen in its entirety]	
[IF YES] I'm going to ask you a series of questions about your alcohol use during the past 12 months.	In the past 12 months, have you: ☐ Had times when you ended up drinking more, or longer, than you intended? ☐ More than once wanted to cut down or stop drinking, or tried to, but couldn't? ☐ Spent a lot of time drinking? Or being sick or getting over other aftereffects? ☐ Experienced craving — a strong need, or urge, to drink?

	☐ Found that drinking – or being sick from drinking – often interfered with taking care of your home or family? Or caused job troubles? Or school problems? ☐ Continued to drink even though it was causing trouble with your family or friends? ☐ Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink? ☐ More than once gotten into situations while or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in a dangerous area, or having unsafe sex)? ☐ Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout? ☐ Had to drink much more than you once did to get the effect you want? Or found that your usual number of drinks had much less effect than before? ☐ Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there?
Number of AUD criteria met:	[Total number of boxes checked in previous question]
AUD Severity:	☐ Does not meet criteria for AUD (0-1 symptoms) ☐ Mild (2-3 symptoms) ☐ Moderate (4-5 symptoms) ☐ Severe (6+ symptoms)
[IF DO NOT MEET CRITERIA FOR AUD] Does not meet sufficient criteria for AUD diagnosis (0 or 1 AUD criterion), NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Meet sufficient criteria for AUD diagnosis (2+ AUD criteria = mild, moderate, or severe).	
Are you currently making a new recovery attempt, that is, a serious effort to abstain from drinking or to drink without problems?	☐ Yes ☐ No
(IF YES) When did you start this attempt?	Date: [MM/DD/YYYY] Days since new recovery attempt began:
Has the participant's new recovery attempt begun within the past 90 days?	☐ Yes ☐ No
[IF NO, > 90 DAYS] If recovery attempt started more than 90 days ago, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
(IF NO, NOT CURRENTLY MAKING A NEW RECOVERY ATTEMPT) Are you planning to make a new recovery attempt or serious effort to abstain from drinking or to drink without problems?	☐ Yes ☐ No

[IF NO] If not planning to make a new recovery attempt, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
(IF YES) When will you start?	Date: [MM/DD/YYYY] Days until new recovery attempt begins: _____ (Must be less than 14 days away)
Is the participant's new recovery attempt beginning in the next 14 days?	☐ Yes ☐ No
[IF NO] If not planning to make a new recovery attempt either at all OR within next 14 days, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Is alcohol the primary substance from which you are seeking recovery?	☐ Yes ☐ No
(IF NO) What is the primary substance from which you are seeking recovery?	☐ Marijuana ☐ Cocaine (coke, crack, freebase) ☐ Heroin ☐ Methadone ☐ Suboxone/Subutex/Buprenorphine ☐ Other opioids (e.g. prescription opioids) ☐ Hallucinogens ☐ Synthetic Marijuana / Synthetic Drugs ☐ Amphetamine (uppers) ☐ Methamphetamine (crank, meth, crystal) ☐ Benzodiazepines (sedatives/tranquilizers) ☐ Barbiturates (downers) ☐ Inhalants ☐ Steroids ☐ Other substance (not specified above) [please specify:]
[IF PRIMARY SUBSTANCE NOT ALCOHOL] Report their primary substance. If alcohol is not primary substance, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Have you participated in any of the following mutual-help organizations in the past 30 days?	☐ Alcoholics Anonymous ☐ Narcotics Anonymous ☐ Other 12-Step Fellowship ☐ SMART Recovery ☐ Other mutual-help organization ☐ None of the above ☐ If other, please specify: _____
Are you planning to participate in SMART Recovery during this recovery attempt or serious effort?	☐ Yes ☐ No

(IF YES) How will you participate in SMART Recovery?	☐ In-person meetings only ☐ In-person meetings and online ☐ Online only
Are you planning to participate in Alcoholics Anonymous during this recovery attempt or serious effort?	☐ Yes ☐ No
[IF NO PARTICIPATION IN SMART OR AA AND NO PLANNED PARTICIPATION] If participant has not participated in SMART and/or AA in the past 30 days and does not plan to participate in SMART and/or AA, NOT ELIGIBLE to participate	
RESEARCH STAFF USE: Does the participant meet the eligibility criteria?	☐ Yes ☐ No
[IF NO] Thank you, [es_name]. Unfortunately, you are not eligible to participate in our study. In order to protect the integrity of the study, as mentioned before, I will not be able to tell you the specific reason why you were found ineligible to participate. However, you may be eligible to participate in future research studies. If you are interested in participating in future research studies, we can take your contact information and reach out to you with future study opportunities.	
[Ask question to all callers, including those who have been found ineligible] Are you interested in participating in future research studies? If so, we can take your contact information and reach out to you with future study opportunities.	☐ Yes ☐ No
(IF YES) Collect contact information and note interest in screening log. Thank you so much for calling.	☐ Primary Contact Number: _____ ☐ Email Address: _____
ELIGIBLE Great! It sounds like you are eligible to participate in our study! So now let me tell you a little bit more about the study.	
If you decide take part in this study, the visits would include an initial assessment followed by 3-, 6-, 9-, 12-, 18-, and 24-month follow-up assessments. The questionnaires during visits will include questions regarding various topics such as your demographic information, substance use history, treatment service utilization and recovery support, among others. To compensate you for your time and effort, we would compensate you up to $455. That is $45,	☐ Yes ☐ No

$55, $60, $65, $70, $75, and $85 for the initial visit and 3-,- 6-,- 9-,- 12-,- 18-,- and 24-month follow-up visits, respectively. The reason I say "up to $455" is because we are unable to pay participants for the assessments they do not come in to complete. Reimbursement will be by check and it may take up to 10 business days to receive payment after you complete your initial assessment, per our MGH guidelines, but payment will likely be faster for subsequent payments. In order to receive payment for participating in this study, you will need to provide your Social Security Number (SSN). This is necessary in order for us to comply with tax reporting obligations. This information is confidential and protected, and will be stored securely and redacted when no longer required. Finally, please know that your honesty is the most important part of this study: research studies only work if participants tell us how they truly think and feel. There are no "right" and "wrong" answers; never consider what you think we might like to hear. Always simply tell us how it is. So, what do you think? Would you like to participate in this study?	
[If NO] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[If YES] In just a moment, I will collect your contact information as well as the contact information for two people in your life, so we can reach out to them if we lose contact with you. We will simply tell them that you are in a study tracking health behaviors; they must confirm with us that they are willing to serve in this role. Before I ask you for your email address, I need to ask you about how you prefer to get emails from us. There are two options: receiving them using the "SEND SECURE" option, or receiving them without it. Let me explain: Email sent over the internet is not secure unless both parties are using an encryption technology. This provides a secure connection both on the sender's and receiver's communications while in transit. Without encryption, it is possible for other individuals	☐ Use SEND SECURE ☐ Don't use SEND SECURE ☐ N/A (no email) ☐ Contact Number:_____ ☐ Email Address: _____

(beyond the intended recipient of the email) to access and read the email and this could result in the unauthorized use or disclosure of your information, for which Partners HealthCare will not be held responsible. If you prefer to receive communications by unencrypted email despite these risks, your preference will apply to all emails sent to you from research staff in this study. If you would like to receive your emails encrypted, we will use the SEND SECURE option. In order to read these emails, you will need to do two things: 1. The first time you get a 'send secure' message, you need to register with Cisco Registered Envelope Service (CRES). This is done once and takes only a few minutes. 2. To read future secure emails you need to enter the password you created. If you would like to receive your emails unencrypted, we will not use the SEND SECURE option. What do you prefer?	
Who are the two people we can reach out to in case we are unable to contact you directly? These can be family members, friends, or partners. NOTE: Information for at least one contact person is required.	☐ Contact 1 Name: _____ ☐ Contact 1 Email: _____ ☐ Contact 1 Phone: _____ ☐ Contact 1 Relation: [Friend, Family, Partner, Other] ☐ Contact 2 Name: _____ ☐ Contact 2 Email: _____ ☐ Contact 2 Phone: _____ ☐ Contact 2 Relation: [Friend, Family, Partner, Other]
(If eligible and interested in participating) Schedule assessment	Time: HH:MM Date: [MM/DD/YYYY] Scheduling Notes: _____

[IF ELIGIBLE AND SCHEDULED FOR AN ASSESSMENT]
[IF IN PERSON VISIT] Okay, we are all set then. Your assessment will take place in person at our office and is scheduled for [schedule1]. I will send you an appointment confirmation and directions to our office shortly.

[IF REMOTE VISIT] Okay, we are all set then. Your assessment will take place over the phone on [schedule1]. I will send you an appointment confirmation shortly. The first thing we'll be doing during your enrollment visit is going over our consent form, which will be emailed to you. You'll need to sign the form electronically, so we recommend having access to a computer at the time of your assessment.

Again, my name is [rcname], and if you have any additional questions or anything comes up, please don't hesitate to reach out by phone or email. (Confirm he/she has your contact information). Thank you again for your interest and participation in our study. It was great talking with you! CALL END.

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Pg
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7-8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10-11
		(*b*) Describe any methods used to examine subgroups and interactions	10-11
		(*c*) Explain how missing data were addressed	11
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	10-11
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted	N/A

		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	N/A
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

An Investigation of SMART Recovery: protocol for a longitudinal cohort study of individuals making a new recovery attempt from alcohol use disorder

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An Investigation of SMART Recovery: protocol for a longitudinal cohort study of individuals making a new recovery attempt from alcohol use disorder

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ABSTRACT

Introduction

Alcohol use disorder (AUD) remains one of the most pervasive of all psychiatric illnesses conferring a massive health and economic burden. In addition to professional treatments to address AUD, mutual-help organizations (MHOs) such as Alcoholics Anonymous (AA) and newer entities like Self-Management and Recovery Training (SMART Recovery) play increasingly important roles in many societies. While much is known about the positive effects of AA, very little is known about SMART. Hence, this study seeks to estimate real-world patterns of utilization and benefit from SMART Recovery as well as explore for whom (moderators) and how (mechanisms) SMART confers recovery benefits.

Methods and analysis

Naturalistic, longitudinal, cohort study (N=368) of individuals with AUD recruited between February 2019-February 2022, initiating a new recovery attempt who self-select into one of four groups at study entry: 1. SMART Recovery; 2. AA; 3. SMART+AA; 4. Neither SMART nor AA; (stratified by DSM 5 severity markers), with assessments conducted at intake, and 3-, 6-, 9-, 12-, 18-, and 24-months. Primary outcomes are: Frequency of SMART and AA meetings attendance; Percent Days Abstinent (PDA) and percent days heavy drinking (PDHD). Secondary outcomes include: psychiatric distress; quality of life and functioning. Moderator variables include sex/gender; race/ethnicity; spirituality. Mediational variables include: social networks; coping skills; self-efficacy; impulsivity. Multivariable regression with propensity score matching will test for patterns of attendance and effects of participation over time on outcomes and test for mechanisms and moderators.

Ethics and dissemination

This study is approved by the Mass General Brigham Institutional Review Board. Results will be published in peer-reviewed journals and presented conferences.

Registration and Funding

This is a non-randomized, naturalistic, longitudinal, cohort study, and thus was not registered in advance. Results, therefore, should be considered exploratory. The study was funded by the US National Institute of Alcohol Abuse and Alcoholism (NIAAA; 5R01AA026288; K24AA022136).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The prospective naturalistic "real-world" nature of following individuals (N=368) with primary alcohol use disorder who are self-selecting into either SMART Recovery, Alcoholics Anonymous (AA), both SMART and AA, or neither, and comparing their addiction recovery outcomes over time is considered a strength of this study.
- Frequent follow-up assessments using psychometrically validated measures across a two-year period will allow for examination of the dynamic topography of health-related behavior change and is considered a study strength.
- Multidimensional assessment of multiple clinical, public health, and public safety outcomes will be conducted capturing a broad bandwidth of variables with relevance to a wide array of treatment and policy stakeholders and is considered a strength.
- Some limitations of the study are that research staff are not blinded to participants' self-selected recovery pathway and the use of self-report measures, despite psychometric validation, can yield social desirability and recall biases.
- Assessment data and study results rely on self-report and the majority of study assessments are conducted remotely (due to COVID-19 restrictions) without objective validation using bioassay and is a limitation.

INTRODUCTION

Alcohol and other drug use disorders confer a prodigious burden of disease, disability, and premature mortality in most middle- and high-income countries globally. To help alleviate this burden, most countries provide an array of professionally delivered addiction treatment services. Yet, despite these efforts, such services are often unable to meet both acute care and long-term relapse prevention needs of the millions or tens of millions affected annually. In response, most countries also possess an array of informal community-based peer recovery support services which can provide ongoing assistance for individuals suffering from these disorders [1]. The oldest and largest of these are the 12-step mutual-help organizations (MHOs), such as Alcoholics Anonymous (AA). Rigorous research evidence has now demonstrated that when AA is subjected to the same scientific standards as other addiction focused interventions it does as well on most outcomes measures, is better at sustaining abstinence and remission over time, and is highly cost effective [1].

A limitation of the current standard of care, however, borne out of a limitation in available empirical data, is the fact that referral oftentimes focuses solely on spiritually-oriented 12-step organizations, such as AA, which is the only empirically-supported MHO continuing care referral option. Not everyone chooses AA as a pathway to recovery for various reasons, and alternative MHO options - although much newer and smaller - are growing and may contain many of the same positive therapeutic elements and dynamics possessed by AA [2, 3]. These therapeutic pathways include adaptive social network changes, increases in social abstinence self-efficacy, and reducing negative affect. Indeed, some preliminary evidence suggests such organizations may confer similar benefits for those who self-select into them [4].

The largest and possibly most well-known of these newer alternative MHOs is Self-Management and Recovery Training (SMART) Recovery. There are approximately 1,200 SMART groups nationwide and another 1,000 internationally. SMART also has a strong online support presence including online meetings, forums, and chat rooms. Unlike AA, SMART is founded upon cognitive-behavioral principles and practices and is led by trained facilitators. It focuses on enhancing and maintaining motivation to abstain or (more recently) reduce use to non-problematic levels, coping with urges, problem solving, and lifestyle balance [5]. It also advocates for appropriate use of professional psychosocial and pharmacological treatments. A compelling aspect of SMART as an MHO is, because it is itself based on empirically-derived CBT principles, it provides a philosophically compatible recovery resource that is aligned with cognitive-behavioral treatment principles, which make up a large majority of national and international evidence-based treatments [6]. Consequently, SMART is appealing to many individuals with SUD [5], yet due to the lack of empirical evidence supporting its effectiveness, clinicians remain less likely to discuss or refer patients to SMART [7, 8]. This has hindered its growth and prevented many the opportunity to learn about and try SMART.

Compared to the dozens of high-quality studies examining 12-step MHOs [9-12], there have been just a handful of studies on SMART. We conducted a systematic review of this research [13] and found that only 12 studies exist (4 of which are unpublished dissertations) that have focused on SMART Recovery and used any kind of formal measurement. Most of these (8 out of the 12) are cross-sectional with mixed results and suffer from considerable biases as they possess substantial methodological limitations making it difficult to draw firm conclusions [14-16]. For instance, these studies have rarely assessed mental health status or its severity, despite the high rates of comorbidity between AUD and mental health. Two recent high-quality studies

examining SMART Recovery, however, have been conducted, one in a criminal justice context, the other examining its effect on heavy alcohol use in an RCT.

The criminal justice study was a large quasi-experimental study of criminal offenders in Australia [17]. It compared a group of individuals participating in SMART Recovery and/or a criminal justice intervention (called "Getting SMART") designed to link offenders with SMART meetings following prison release, to a group of control participants who did not interact with any SMART materials or attended meetings, but who were matched on various other relevant characteristics through the use of propensity scores. The study found that participation in Getting SMART by itself, and Getting SMART + SMART Recovery meeting attendance, was associated with a reduced overall rate of reconviction with rates of reconviction reduced by 19 and 22%, respectively. For violent reconvictions, rates were reduced by 30% for Getting SMART participation and 42% for Getting SMART + SMART Recovery. While an important and promising set of results in their own right, unfortunately, the authors did not examine or report any alcohol/drug use outcomes [17].

There has been only one small, randomized trial evaluating SMART Recovery, which randomized people to (a) "Overcoming Addictions" (OA) - a SMART Recovery web application, (b) SMART Recovery meeting attendance, or (c) OA + SMART Recovery meeting attendance combined. The study found participants from all groups benefitted equally with respect to alcohol outcomes [18]. This finding underlines the promise of SMART Recovery to provide recovery support. Unfortunately, however, this trial did not include a control group, who did not have any exposure to SMART materials. Given, however, that all groups participated in SMART, it is not clear if observed benefits were simply naturally occurring improvements in alcohol outcomes, or really a function of SMART participation. Another limitation is that it only enrolled subjects with heavy drinking problems and excluded participants with more severe forms of AUD, who more typically enroll in formal treatment and are thus in need of referral options for continuing care.

A more recent study examined participation among individuals with alcohol use disorder recruited from various online and community venues with varying lengths of sobriety who self-selected into one of four different types of MHOs: Alcoholics Anonymous, LifeRing Secular Organization, SMART Recovery, and Women for Sobriety[4]. This study found that SMART Recovery participants had as good alcohol outcomes at 6- and 12-month follow-ups as those attending other MHOs. Again, however, the study did not include a control group with no MHO involvement.

These results provide some preliminary information about real-world benefits related to SMART Recovery participation. There is very little, if any, information regarding how involved they become or the mechanisms of behavior change through which SMART may help individuals attain AUD remission and recovery (e.g., via social changes, coping skills, recovery motivation, abstinence self-efficacy; reduced impulsivity). SMART has the potential to be a secular MHO alternative to 12-step MHOs for those preferring the secular and cognitive-behavioral foundation of SMART, yet in order to increase clinical confidence and referrals, more systematic research is needed. This study will be one of the first rigorous, real-world, evaluations of SMART providing objective estimates of recovery benefit (e.g., abstinence, AUD remission, quality of life, psychosocial functioning), and will explore the mechanisms (e.g., social network changes, self-efficacy, decreased impulsivity) and moderators (e.g., sex, race/ethnicity, addiction severity, psychiatric co-morbidity) of behavior change to determine how SMART Recovery may help its affiliates achieve and maintain remission from addiction and who seems to benefit most.

To this end this study has the following specific aims: 1. Characterize and describe professional and non-professional recovery support service participation choices, migrations, and pathways using group trajectory analyses over a two-year period for individuals (N=368) starting a new AUD recovery attempt. More specifically in this regard, we will investigate the real-world effectiveness of SMART Recovery by comparing outcomes of AUD individuals making a new recovery attempt (N=368) pursuing either a SMART Recovery pathway (online or face-to-face; N=184) or a non-SMART recovery pathway (N=184). Because, according to SMART Recovery's annual survey data, roughly half of SMART participants also attend AA, we will use a stratified design to enroll persons with AUD making naturally occurring continuing care choices vis-à-vis participation in MHOs in a balanced fashion and follow them prospectively across a 24-month period. Of note, self-selection of treatment/recovery pathway options has been shown to potentially enhance outcomes. This will be explored in this study as well. This stratified design will allow us to compare the outcomes of persons choosing to participate in SMART Recovery vs. not (balanced by AUD severity), while accounting for simultaneous choices regarding AA or neither AA or SMART MHO participation. 2: Explore moderators and mechanisms of behavior change. Exploration of factors that may help uncover who (i.e., moderators) and why (i.e., mechanisms) SMART affiliates benefit from participation will be investigated. Moderators will include sex and gender, addiction severity, psychiatric distress; and mechanisms will include social network changes, recovery motivation, cognitive-behavioral coping, abstinence self-efficacy, and impulsivity.

METHODS AND ANALYSIS

Study overview

This study is a naturalistic, prospective, longitudinal cohort study of 368 individuals making a new recovery attempt from AUD with seven assessments over a 24-month follow-up period. Following the baseline assessment, research staff will conduct additional follow-up assessments at 3, 6, 9, 12, 18, and 24 months after study enrollment. Assessments include both self-reports by participants using online surveys, and staff-administered assessments, conducted via phone and/or Zoom. Baseline visits were conducted from February 2019 to February 2022. Follow-up visits are ongoing and will continue until approximately February 2024. All study procedures are approved by the Institutional Review Board of Mass General Brigham (approval number: 2017P002029). Written consent was received from all participants following an explanation of the study, including confidentiality and freedom of choice to participate.

Sample size determination

The primary outcome variables are percent days abstinence (PDA) and percent days heavy drinking (PDHD; NIAAA-defined). Secondary outcomes include quality of life and psychosocial functioning. To estimate a plausible effect size to be expected in PDA as a function of mutual help organization (MHO) utilization, we examined the PDA outcomes in Project MATCH [19] for persons utilizing AA vs. not. Effects were surprisingly consistent across time, with patients with any AA utilization reporting a higher average number of PDA than patients with no AA involvement (d=0.45, 0.39, 0.38, 0.42, and 0.39 at 3-, 6-, 9-, 12- and 15-month follow-up respectively). Thus, conservatively, we are powering this study to detect an effect size of d=0.35. Using SAS proc power we determined that n=130 per group are necessary to detect d=0.35, leading to a combined sample size of n=260 (equally balanced, due to stratification, in

terms of AA utilization and addiction severity). With a conservatively estimated retention rate of 75%, we would need to enroll n=347 to retain n=260. Given our stratified design (i.e., 2 [SMART vs. not] x 2 [12-step vs. not] x 3 [mild vs. moderate vs. severe AUD] design = 12 stratification cells), we proposed to enroll a final sample size of n=348 (i.e., n=29 per cell). In addition, 20 further participants were enrolled to increase representation of individuals attending SMART Recovery and to account for participants who withdrew, were terminated from the study, were found ineligible, or were otherwise no longer participating (e.g., death unrelated to the study).

Using this design, we will be equally well powered to test the main effect of 12-step participation. In terms of conducting pair-wise comparisons between the four possible combinations of using SMART Recovery and/or 12-Step, this sample size would enable us to detect pairwise differences of medium effect size (d=0.50). Improvements over our conservatively estimated retention rate would increase power (e.g., could detect d=0.46 with 85% retention).

Recruitment

Participants were recruited through SMART Recovery meetings, inpatient and outpatient treatment programs, and a variety of commercial recruitment sources during the recruitment period (January 2019 to January 2022).

Flyers and postcards for the study were distributed around buildings of Massachusetts General Hospital, particular around inpatient and outpatient SUD clinics. SMART facilitators were asked to advertise the study at SMART meetings and were provided with recruitment postcards and flyers. The study was also advertised on the SMART San Diego website. Additional recruitment methods included ResearchMatch, PeRC, TrialFacts, Rally for Recruitment, the Metro Newspaper, radio advertisements, MBTA advertisement, Facebook, Craigslist, and Reddit. For radio, MBTA, Facebook, and Craigslist advertisements, this study was advertised along with another ongoing R01 study of individuals making a new recovery attempt from AUD with similar eligibility criteria. Monthly meetings were also held with regional SMART Recovery MHO group facilitators to provide them with updates and inquire if there was anything we could provide to help facilitate study recruitment from online SMART resources or SMART meetings.

Interested individuals called the study-specific phone line, emailed the study-specific email address, or filled out an online screening form. Individuals were then able to participate in a brief 10–15-minute phone screen, during which eligibility criteria were confirmed (see Supplementary materials for a copy of Eligibility Screen). If the individual was eligible to participate, the baseline visit was scheduled and contact information for two locator contacts who can assist research staff in locating participants was collected.

Consent Process: Participants completed the consent process with a trained study staff member and were encouraged to ask questions about any aspect of the study. Through this process, participants were informed about the nature and extent of the study duration and procedures including the types of assessments administered, the risks and benefits of participation, as well as the financial renumeration schedule and protocol, and given telephone and email contact information in order to contact study staff at any time during the course of the study (see Consent Form in Supplementary Materials section for more details).

Eligibility

Participants were required to be 18 years or older, living in the New England or San Diego metropolitan area, and willing to travel to Boston, Massachusetts, to complete study visits (for New England residents) or to complete study visits remotely (due to COVID-19 and for the San Diego participants). The geographical catchment area eligibility criteria were expanded to include people from the San Diego area in December 2020 to increase the number of SMART participants in the study. Since all visits were conducted remotely beginning in March 2020 due to the COVID-19 pandemic, participants from the New England area would also be considered eligible even if they could not travel to the Boston office for assessments in the foreseeable future.

Participants could be using other drugs but had to report alcohol as their primary substance of concern; they were also required to have a self-perceived alcohol problem, to meet current criteria for DSM 5 alcohol use disorder (AUD) using semi-structured interview; to have consumed alcohol in the past 90 days and report currently engaged in a new recovery attempt defined as "a serious effort to abstain from drinking or to drink without problems in the past 90 days or planning to make one in the next 14 days."

Additionally, participants were required to provide locator contact information for two close friends/family members in case we were unable to contact the participant directly; provide their social security number for reimbursement or be willing to not receive reimbursement; provide a urine sample and breathalyzer (for in-person visits) or remote saliva test (for remote visits) for biochemical verification; and provide a stable home address and contact information. These initial bioassay requirements were not required following the start of COVID-19 lock-downs which began in March 2020.

Methods

All assessments were initially conducted (prior to COVID) with a study research coordinator in person at our downtown Boston offices at the MGH Recovery Research Institute. Each assessment consisted of staff-administered and self-administered surveys, which were completed via REDCap (a secure, web-based application designed to support data capture for research studies), a computerized task to assess impulsivity (Go/No-Go task), and biochemical verification tests of abstinence (breathalyzer, urine) for all participants at all time points. For in person visits, the baseline and follow-up assessments lasted for approximately 3 hours. At the end of the first visit and every follow-up visit, the next follow-up was scheduled.

Due to the COVID-19 pandemic, all assessments were transitioned to be conducted remotely beginning in March 2020. During remote visits, the computerized task and urine and breath biochemical verifications of abstinence were not completed. A web-based version of the computerized task was tested, but the effects of internet speed on results made data unreliable. In lieu of the urine and breathalyzer tests, saliva tests were implemented for remote visits from March 2021 to May 2021 but were discontinued due to documented inconsistent results. Relative to in-person assessments, remote assessments were shorter with assessments lasting approximately 1.5 hours (for baseline) or 45 minutes (for follow-ups) on the phone and approximately 1 hour for participants to complete surveys individually.

All participants (in-person and remote) agreed to provide their phone numbers and email information and that of two locator contacts so that they may be contacted for follow-up assessment reminders. Research staff contacted and confirmed the contact information of the locator contacts as needed if research staff loses touch with the participant. Participants indicated their preferred method of contact (phone call, email, or text message) for receiving automated

reminders throughout the project period. In keeping with a validated research follow-up protocol for maximizing retention in clinical addiction research, after the baseline assessment, research staff proactively reached out to participants for reminders and to check if there were any changes to their contact information. Check-ins occurred 1 month, 14 days, 7 days, and 24 hours before the next scheduled visit. These messages are automated and sent with Twilio, which is an approved REDCap module by Mass General Brigham.

Participants are compensated $45 for completing the baseline visit and $55, $60, $65, $70, $75, and $85 for completing the 3-, 6-, 9-, 12-, 18-, and 24-month follow-up visits, respectively. Payment for each timepoint is broken up into payment for the staff-administered surveys, self-administered surveys, and travel reimbursement. During remote visits due to COVID-19, all participants were still paid the travel reimbursement to maintain the same payment structure used for in-person assessments.

Measures

Staff-administered measures assess the following: substance use history including capture of primary outcomes (percent days of heavy drinking; percent days abstinent from alcohol/other drugs), AUD and SUD status and severity (including remission status), tobacco use, treatment utilization for physical health problems and alcohol/drug use problems, anti-craving and anti-relapse medications (alcohol and opioids), mental and emotional health diagnoses, hospitalizations, treatment history, and psychiatric medication use, social networks, 12-step/MHO attendance history, online resource utilization, SMART involvement, 12-step MHO involvement (MM-HAS), recovery/abstinence time, recovery support services and formal treatment program utilization, substance use change over the past year (YES), impulsivity (Go/No-go cognitive task), and biochemical verification of substance use (breathalyzer, urine drug screen).

Self-administered measures assess the following: demographics, criminal justice involvement, religiosity and spirituality (RBBS, religious and spiritual intensity, DSES), stress and psychiatric distress (PSS-4, K6), coping (CSS), self-efficacy (A-DSES-20, single item self-efficacy), alcohol/other drug craving (PADCS-5), commitment to sobriety (CSS-5), substance use consequences (SIP-2R), recovery status (questions about recovery, drinking goal), recovery capital (BARC-10), behavioral addictions, medical marijuana use, medication attitudes, impulsive behavior (SUPPS-S), quality of life and psychosocial functioning (TPS, Q-LES-Q, EQ5D3L, EUROHIS-QOL, self-esteem, happiness, and satisfaction with life), and physical health (PSQI, pain VAS, IPAQ, meals).

All measures were administered at each timepoint except for the Year End Summary (YES), SUD DART, and Questions about Recovery, which were administered at baseline, 12-months, and 24-months. Detailed descriptions of measures are available in Supplement 1.

COVID-19 impact

The COVID-19 pandemic significantly affected the conduct of study assessments as all assessments were transitioned to fully remote visits beginning in March 2020. As previously noted, this shift to remote assessments meant that we were unable to conduct the Go/No-go cognitive measure, breathalyzer, or urine screen. Due to these changes, all substance use outcomes are self-reported. Self-administered saliva tests were used briefly as a replacement, but inconsistent results (e.g., false negatives, partial results, no results) made data collected from these tests unreliable and this strategy was stopped.

Additionally, recruitment was halted as the study team transitioned to remote assessments and many previous recruitment methods were no longer viable (e.g., recruitment from outpatient clinics, advertisements on Boston area trains). It was particularly challenging to recruit individuals attending SMART as meetings were halted, then moved to virtual-only. To address these challenges, we expanded the recruitment area to San Diego, where there is a large SMART Recovery MHO participation community. We also maintained contact with SMART facilitators throughout the recruitment period to encourage them to share the study with meeting attendees and solicit feedback on how to best improve recruitment of SMART participants.

To capture potential changes in recovery resource utilization due to the COVID-19 pandemic, we added a staff-administered measure related to use of online recovery resources and social network site use. In addition, a supplemental study focusing on the impact of COVID-19 was conducted, consisting of both quantitative measures and a qualitative interview with a sub-group (n=80) of study participants selected at random from the SMART, AA, SMART+AA, and neither cohorts (n=20 from each group).

Limitations

The study employs a cohort based, naturalistic, non-randomised, design and research staff are not blinded to participants' self-selected recovery pathways. The use of self-report measures, despite having good psychometric properties and adequate validation, can still yield social desirability and memory recall biases.

Patient and public involvement

No patient or public involvement.

Data analysis plan

Aim 1 Effectiveness. We will use multiple linear regression analyses to determine whether our primary stratification factor of interest (predictor: SMART vs. no SMART) is associated with alcohol outcomes (primary dependent variables: PDA; PDHD) at 24-month (primary end-point), and 3-, 6-, 9-, 12- and 18-month (secondary) follow-ups, while controlling for other confounding variables (e.g., baseline variation in levels of the outcome variables) and by using propensity score matching methods that we have used successfully in prior work. We will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity. We will also test longitudinal models to investigate the dynamic relationship of these various recovery pathways over time (e.g., using hierarchical linear modeling as we have done previously [20]) controlling for baseline variation in the outcome variables.

Aim 2a. Mechanisms and Moderators. We will use mediational modeling, using the product-of-coefficients approach [21, 22] to test how SMART Recovery confers benefit (or fails to do so). The independent variable will be stratification group (i.e., SMART vs. no SMART), and the outcome variables will be PDA (primary), PDHD, AUD remission, quality of life, and measures of psychosocial functioning. The mediators will be our theorized mechanisms of change (e.g., social network changes, recovery motivation, coping, self-efficacy, impulsivity), which we will quantify as change since baseline in these constructs as measured via REDCap administered scales prior to the outcome (e.g., change in craving observed from baseline to 3-month would be

used to predict 6-month ultimate outcomes). We will use multiple mediation to determine the relative impact of each mechanism, and moderated multiple mediation to identify differences in mechanisms across (moderator) subgroups (e.g., males vs. females, severe AUD addiction severity vs. moderate/mild), similar to our prior approach in delineating mechanisms of behavior change in AA [23-25].

Aim 2b. Dose-response relationship of SMART Recovery. Using only data from participants in the stratified SMART group, we will use linear regression (primary outcome: PDA) to test if the level of SMART involvement, as measured by the SMART Involvement Scale, is related to PDA at 24-month (primary endpoint) and other follow-up points over time. We will use basic model building practices to determine if such an effect persists after accounting for demographics, other important contextual variables, moderators, and baseline levels of the theorized mechanisms of change. In follow-up analyses, we will conduct this analysis separately for participants in the stratified AA vs. no AA groups, so as to test specifically if the effect exists both within and outside of the context of simultaneously seeking help via AA. Similarly, we will repeat analyses within strata of AUD severity.

Multiple Testing. We will use the false recovery rate adjustment [26] to control for multiple testing.

Missing Data. Some data will inevitably be missing. We will explore patterns of missingness to determine if missingness is occurring at random (MAR) (i.e., unrelated to the value of the missing observation) or likely to be missing not at random (MNAR). For each analysis, we will use a variety of recommended strategies to address the issue of missing data (e.g., multiple imputation, maximum likelihood estimation)[27]. Consistency in findings across missing data methods will enhance our confidence in the findings. Note that study participation will be completely separate from SMART participation; thus, participants should feel comfortable remaining in the study regardless of whether they continue in SMART or not. Assuming some attrition, we plan to conduct analyses examining predictors of attrition and control for these.

ETHICS AND DISSEMINATION

All study procedures are approved by the Institutional Review Board of Mass General Brigham (approval number: 2017P002029). Written consent was received from all participants following an explanation of the study, including confidentiality and freedom of choice to participate. Results will be published in relevant peer-reviewed scientific journals and presented at conferences.

AUTHORS' CONTRIBUTIONS

JK developed the idea and conceptualized the study design and led the writing of the manuscript. SL contributed to conducting the study and writing the manuscript. BH contributed to study design and development and statistical analysis as well as reviewing and editing final versions of the manuscript.

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COMPETING INTERESTS STATEMENT

None declared.

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Date: Research Staff conducting the screen:	
Thank you for your interest in our research study. My name is [RC NAME] and I am a research coordinator at the Recovery Research Institute within the Department of Psychiatry at the Massachusetts General Hospital. Is this a good time for you to talk about the study?	☐ Yes ☐ No
[IF NO] What time would be good for me to give you more information about the study and do a short phone screen to see if you are eligible? I appreciate your time. Have a great day.	Date: [MM/DD/YYYY]
[IF YES] I am going to ask you a series of questions to determine if you are eligible to participate in this study. Some of these questions may not apply to you, but please answer them to the best of your ability. At the end of the screen, I will tell you if you are eligible to participate or if you have been found ineligible. In order to protect the integrity of the study, if you are found ineligible, I will unfortunately not be able to tell you the specific reason why you were found ineligible to participate. Knowing this, do you agree to proceed to screen for the study?	☐ Yes ☐ No
[IF YES] Okay great! First, may I ask how you heard about the study?	☐ Twitter ☐ Facebook ☐ RRI Website ☐ Flyer ☐ RSVP for Health ☐ Word of Mouth ☐ SMART Meeting ☐ Craigslist ☐ Metro ☐ MBTA ☐ West End Clinic ☐ ARMS ☐ Did not specify ☐ Other
[IF OTHER] What was the other source from which you heard about this study?	_____
[IF FLYER] Where did you get the flyer from?	_____
Where are you located?	☐ New England (MA, NH, RI, etc.) ☐ California ☐ Other
[IF OTHER] If located outside of New England or California, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	

Great! Let me tell you a little bit about our study, so you can decide if this is something you'd like to participate in. The study is funded by the National Institutes of Health to learn more about the different pathways, resources, and services that individuals may use to overcome an alcohol problem. We hope this study will help advance treatment and recovery support service options. If you decide to take part in the study, your participation would include 7 visits to our Boston office over the course of 2 years. During each visit, you would complete a series of questionnaires, computerized tasks, and biochemical verification of abstinence, which includes a urine sample and breathalyzer test. In the event that your visits will take place remotely (e.g., over the phone or zoom), study procedures are similar; however, you would complete a self-administered saliva test that is mailed to you in advance. Each visit will take approximately 3 hours. How does that sound so far?	☐ Yes, remains interested ☐ No longer interested
[IF NO LONGER INTERESTED] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[IF REMAINS INTERESTED] Great. Before I can enroll you in this study, I need to ask you some questions to make sure you are eligible. These questions are about your health and medical history, including your alcohol use, and should take about 10 minutes of your time. Some of the questions may make you feel uncomfortable. You may stop at any time. Does that sound okay? I will record your answers in writing, but only collect detailed contact information if you qualify for the study and want to schedule an in-person visit. As a reminder, collected information is completely confidential and protected. There is always risk of loss of confidentiality but we will take appropriate responsible steps to ensure confidentiality. Okay to begin?	☐ Yes ☐ No
[IF NO] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[IF YES] [ps_name], could you please verify the spelling of your first name?	

How old are you?	_____
Research Staff Use: Is the participant older than 18?	☐ Yes ☐ No
STOP SCREEN. If under 18, NOT ELIGIBLE to participate. [IF INELIGIBLE] Thank you, [es_name]. Unfortunately, you are not eligible to participate in our study. You may be eligible to participate in future research studies. If you are interested in participating in future research studies, we can take your contact information and reach out to you with future study opportunities.	
[IF FROM NEW ENGLAND] Are you willing to travel to Boston to complete study visits?	☐ Yes ☐ No
[IF NO OR FROM CALIFORNIA] Are you willing to conduct all visits remotely (e.g. over phone or Zoom)?	☐ Yes ☐ No
[IF NO] If unwilling to travel to Boston for the research study and unwilling to conduct visits remotely, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Is there any reason that you would not be living in the Boston area within the next 2 years?	☐ Yes ☐ No
[IF YES] Would you be willing to conduct visits remotely if you were no longer in the Boston area?	☐ Yes ☐ No
[IF NO] If participant will not be in Boston for the next 2 years and is not willing to conduct visits remotely, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Are you willing to give us the contact information for two of your friends or family members, so that we can reach out to them, in case we lost contact with you? We ask for this information because obtaining complete data from you is very important to the study. The last study visit will take place 2 years from the time of your baseline visit. We want to make sure we can reach you to complete your final visit at that time.	☐ Yes ☐ No
[IF NO] If they aren't willing to provide collateral contacts NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Are you willing to provide your SSN in order to receive reimbursement? *(If asked for more information: If payments to you are $600 or greater in a calendar year, Partners will report this to the Internal Revenue Service (IRS) and you will receive a 1099-MISC income form and Partners will use your SSN for this tax-related purpose.* *If you do not provide your SSN, we cannot issue you a payment for participation. You may still choose to participate in this study and decline reimbursement).*	☐ Yes, I am willing to provide my SSN to receive the study payment. ☐ No, I am not willing to provide my SSN; however, I still wish to participate in this study. I understand that I will not receive payments for being in this study unless I provide my SSN. ☐ No, I am not willing to provide my SSN and decline to participate in this study.

[IF NO] If unwilling to provide SSN and decline to participate in the study, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
During assessments, are you willing to provide a urine sample and complete a breathalyzer test for biochemical verification? Or in the event that your visit takes place remotely, are you willing to provide a self-administered saliva test with study staff guidance? This test would be mailed to your current address before the study visit and can be disposed of after use. Although you do not need to abstinent to participate in this study, we ask that participants not drink or use drugs before coming in for their assessment or before completing their remote assessment. If the breathalyzer test or saliva test indicates that you are under the influence of alcohol when you come in for your assessment or begin your remote assessment, we will need to re-schedule the visit.	☐ Yes ☐ No
[IF NO] If unwilling to participate in biochemical verification, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Do you have a stable home address and contact information?	☐ Yes ☐ No
[IF NO] If participant does not have a stable home address and/or contact information, NOT ELIGIBLE to participate[Do not stop screen, complete screen in its entirety]	
Have you consumed alcohol in the past 3 months?	☐ Yes ☐ No
[IF NO] If participant has not consumed alcohol in past 3 months, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Do you think you have a problem with alcohol?	☐ Yes ☐ No
[IF NO] If participant does not think they have a problem with alcohol, NOT ELIGIBLE to participant [Do not stop screen, complete screen in its entirety]	
[IF YES] I'm going to ask you a series of questions about your alcohol use during the past 12 months.	In the past 12 months, have you: ☐ Had times when you ended up drinking more, or longer, than you intended? ☐ More than once wanted to cut down or stop drinking, or tried to, but couldn't? ☐ Spent a lot of time drinking? Or being sick or getting over other aftereffects? ☐ Experienced craving — a strong need, or urge, to drink?

	☐ Found that drinking – or being sick from drinking – often interfered with taking care of your home or family? Or caused job troubles? Or school problems? ☐ Continued to drink even though it was causing trouble with your family or friends? ☐ Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink? ☐ More than once gotten into situations while or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in a dangerous area, or having unsafe sex)? ☐ Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout? ☐ Had to drink much more than you once did to get the effect you want? Or found that your usual number of drinks had much less effect than before? ☐ Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there?
Number of AUD criteria met:	[Total number of boxes checked in previous question]
AUD Severity:	☐ Does not meet criteria for AUD (0-1 symptoms) ☐ Mild (2-3 symptoms) ☐ Moderate (4-5 symptoms) ☐ Severe (6+ symptoms)
[IF DO NOT MEET CRITERIA FOR AUD] Does not meet sufficient criteria for AUD diagnosis (0 or 1 AUD criterion), NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
Meet sufficient criteria for AUD diagnosis (2+ AUD criteria = mild, moderate, or severe).	
Are you currently making a new recovery attempt, that is, a serious effort to abstain from drinking or to drink without problems?	☐ Yes ☐ No
(IF YES) When did you start this attempt?	Date: [MM/DD/YYYY] Days since new recovery attempt began:
Has the participant's new recovery attempt begun within the past 90 days?	☐ Yes ☐ No
[IF NO, > 90 DAYS] If recovery attempt started more than 90 days ago, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
(IF NO, NOT CURRENTLY MAKING A NEW RECOVERY ATTEMPT) Are you planning to make a new recovery attempt or serious effort to abstain from drinking or to drink without problems?	☐ Yes ☐ No

[IF NO] If not planning to make a new recovery attempt, NOT ELIGIBLE to participate. [Do not stop screen, complete screen in its entirety]	
(IF YES) When will you start?	Date: [MM/DD/YYYY] Days until new recovery attempt begins: _____ (Must be less than 14 days away)
Is the participant's new recovery attempt beginning in the next 14 days?	☐ Yes ☐ No
[IF NO] If not planning to make a new recovery attempt either at all OR within next 14 days, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Is alcohol the primary substance from which you are seeking recovery?	☐ Yes ☐ No
(IF NO) What is the primary substance from which you are seeking recovery?	☐ Marijuana ☐ Cocaine (coke, crack, freebase) ☐ Heroin ☐ Methadone ☐ Suboxone/Subutex/Buprenorphine ☐ Other opioids (e.g. prescription opioids) ☐ Hallucinogens ☐ Synthetic Marijuana / Synthetic Drugs ☐ Amphetamine (uppers) ☐ Methamphetamine (crank, meth, crystal) ☐ Benzodiazepines (sedatives/tranquilizers) ☐ Barbiturates (downers) ☐ Inhalants ☐ Steroids ☐ Other substance (not specified above) [please specify:]
[IF PRIMARY SUBSTANCE NOT ALCOHOL] Report their primary substance. If alcohol is not primary substance, NOT ELIGIBLE to participate [Do not stop screen, complete screen in its entirety]	
Have you participated in any of the following mutual-help organizations in the past 30 days?	☐ Alcoholics Anonymous ☐ Narcotics Anonymous ☐ Other 12-Step Fellowship ☐ SMART Recovery ☐ Other mutual-help organization ☐ None of the above ☐ If other, please specify: _____
Are you planning to participate in SMART Recovery during this recovery attempt or serious effort?	☐ Yes ☐ No

(IF YES) How will you participate in SMART Recovery?	☐ In-person meetings only ☐ In-person meetings and online ☐ Online only
Are you planning to participate in Alcoholics Anonymous during this recovery attempt or serious effort?	☐ Yes ☐ No
[IF NO PARTICIPATION IN SMART OR AA AND NO PLANNED PARTICIPATION] If participant has not participated in SMART and/or AA in the past 30 days and does not plan to participate in SMART and/or AA, NOT ELIGIBLE to participate	
RESEARCH STAFF USE: Does the participant meet the eligibility criteria?	☐ Yes ☐ No
[IF NO] Thank you, [es_name]. Unfortunately, you are not eligible to participate in our study. In order to protect the integrity of the study, as mentioned before, I will not be able to tell you the specific reason why you were found ineligible to participate. However, you may be eligible to participate in future research studies. If you are interested in participating in future research studies, we can take your contact information and reach out to you with future study opportunities.	
[Ask question to all callers, including those who have been found ineligible] Are you interested in participating in future research studies? If so, we can take your contact information and reach out to you with future study opportunities.	☐ Yes ☐ No
(IF YES) Collect contact information and note interest in screening log. Thank you so much for calling.	☐ Primary Contact Number: _____ ☐ Email Address: _____
ELIGIBLE Great! It sounds like you are eligible to participate in our study! So now let me tell you a little bit more about the study.	
If you decide take part in this study, the visits would include an initial assessment followed by 3-, 6-, 9-, 12-, 18-, and 24-month follow-up assessments. The questionnaires during visits will include questions regarding various topics such as your demographic information, substance use history, treatment service utilization and recovery support, among others. To compensate you for your time and effort, we would compensate you up to $455. That is $45,	☐ Yes ☐ No

$55, $60, $65, $70, $75, and $85 for the initial visit and 3-,- 6-,- 9-,- 12-,- 18-,- and 24-month follow-up visits, respectively. The reason I say "up to $455" is because we are unable to pay participants for the assessments they do not come in to complete. Reimbursement will be by check and it may take up to 10 business days to receive payment after you complete your initial assessment, per our MGH guidelines, but payment will likely be faster for subsequent payments. In order to receive payment for participating in this study, you will need to provide your Social Security Number (SSN). This is necessary in order for us to comply with tax reporting obligations. This information is confidential and protected, and will be stored securely and redacted when no longer required. Finally, please know that your honesty is the most important part of this study: research studies only work if participants tell us how they truly think and feel. There are no "right" and "wrong" answers; never consider what you think we might like to hear. Always simply tell us how it is. So, what do you think? Would you like to participate in this study?	
[If NO] Thank you very much for your time, we understand that this study is not for everyone and we appreciate your interest. STOP SCREEN	
[If YES] In just a moment, I will collect your contact information as well as the contact information for two people in your life, so we can reach out to them if we lose contact with you. We will simply tell them that you are in a study tracking health behaviors; they must confirm with us that they are willing to serve in this role. Before I ask you for your email address, I need to ask you about how you prefer to get emails from us. There are two options: receiving them using the "SEND SECURE" option, or receiving them without it. Let me explain: Email sent over the internet is not secure unless both parties are using an encryption technology. This provides a secure connection both on the sender's and receiver's communications while in transit. Without encryption, it is possible for other individuals	☐ Use SEND SECURE ☐ Don't use SEND SECURE ☐ N/A (no email) ☐ Contact Number:_____ ☐ Email Address: _____

(beyond the intended recipient of the email) to access and read the email and this could result in the unauthorized use or disclosure of your information, for which Partners HealthCare will not be held responsible. If you prefer to receive communications by unencrypted email despite these risks, your preference will apply to all emails sent to you from research staff in this study. If you would like to receive your emails encrypted, we will use the SEND SECURE option. In order to read these emails, you will need to do two things: 1. The first time you get a 'send secure' message, you need to register with Cisco Registered Envelope Service (CRES). This is done once and takes only a few minutes. 2. To read future secure emails you need to enter the password you created. If you would like to receive your emails unencrypted, we will not use the SEND SECURE option. What do you prefer?	
Who are the two people we can reach out to in case we are unable to contact you directly? These can be family members, friends, or partners. NOTE: Information for at least one contact person is required.	☐ Contact 1 Name: _____ ☐ Contact 1 Email: _____ ☐ Contact 1 Phone: _____ ☐ Contact 1 Relation: [Friend, Family, Partner, Other] ☐ Contact 2 Name: _____ ☐ Contact 2 Email: _____ ☐ Contact 2 Phone: _____ ☐ Contact 2 Relation: [Friend, Family, Partner, Other]
(If eligible and interested in participating) Schedule assessment	Time: HH:MM Date: [MM/DD/YYYY] Scheduling Notes: _____

[IF ELIGIBLE AND SCHEDULED FOR AN ASSESSMENT]
[IF IN PERSON VISIT] Okay, we are all set then. Your assessment will take place in person at our office and is scheduled for [schedule1]. I will send you an appointment confirmation and directions to our office shortly.

[IF REMOTE VISIT] Okay, we are all set then. Your assessment will take place over the phone on [schedule1]. I will send you an appointment confirmation shortly. The first thing we'll be doing during your enrollment visit is going over our consent form, which will be emailed to you. You'll need to sign the form electronically, so we recommend having access to a computer at the time of your assessment.

Again, my name is [rcname], and if you have any additional questions or anything comes up, please don't hesitate to reach out by phone or email. (Confirm he/she has your contact information). Thank you again for your interest and participation in our study. It was great talking with you! CALL END.

Supplement 1 – Measures

Table 1 (staff-administered measures)

Measure	Description
Substance Use History	Participants answered a series of questions about 15 substances/classes of substances (hereafter simply referred to as substances) from the Global Appraisal of Individual Needs (GAIN-I; (Dennis et al., 2002)): 1) Alcohol, 2) Marijuana, 3) Heroin, 4) Methadone, 5) Buprenorphine and its formulations (e.g., suboxone), 6) Other opioids (e.g., pharmaceutical opioids), 7) Cocaine, 8) Amphetamines (including MDMA), 9) Methamphetamine, 10) Benzodiazepines, 11) Barbiturates, 12) Hallucinogens, 13) Synthetic drugs (e.g., synthetic cannabinoid like "K2" and synthetic cathinones such as "bath salts"), 14) Inhalants, and 15) Steroids, as well as "Other" (specified by participant). At baseline, participants reported which of these substances they used 10 or more times in their life. Then for each substance endorsed, they provided information on the following from the Form-90 (Miller & Delboca, 1994): a) Age of first use; b) If they had ever used the substance regularly (i.e., at least once per week) (yes/no) and if so, the age of first regular use; c) Whether they had used the substance in the past three months (yes/no), and if so how many days out of the past 90 they used the substance and d) If they had not used the substance in the past 3 months, the date of their last use. For follow-ups, the questionnaire assessed if participants had used these substances in any capacity in the past 3 months, if they had used the substances regularly over the past 3 months, and out of how many of the past 90 days they used the substance. Participants then chose their primary substance ("drug of choice") and secondary substance from the substances they had used (lifetime use for baseline assessment, past 3 month use for follow-ups). Finally, participants were asked for how many of the past 90 days their use of alcohol/drugs interfered with their functioning, and how many out of the past 90 days they got drunk at all or high for most of the day.
Alcohol Use Disorder DART	Participants were asked this validated semi-structured interview to capture AUD status (AUD severity and withdrawal symptoms). Participants were first asked if they had consumed alcohol in the past 3 months. If the participant answered 'yes', the DART would pertain to the past 3 months. If the participant answered 'no', they would be asked if they consumed alcohol during the past 12 months, and the DART would pertain to the past 12 months. If the participant answered 'no' to both the questions, they would only be asked if they experienced strong urges or cravings to drink.
Substance Use Disorder DART	Participants were asked about the recreational drugs/medications they used in the past 12 months. They then ranked the substances in the order that they caused problems for them. The DART was administered for the top 3 substances that caused the most problems for participants.
NIH PhenX Toolkit	Participants reported on lifetime use of cigarettes, e-cigarettes, or another tobacco/nicotine product (specified by participant). For those who smoked cigarettes, they reported on the following: 1) Age of first regular use; 2) Of how many of the past 30 days they smoked cigarettes 3) Average number of cigarettes smoked per day in the past 30 days 4) Whether or not they had ever made a serious attempt to quit smoking. This was asked pertaining to 'lifetime' for the baseline visit and for the past 90 days in the follow-up visits. If participants had made a serious quit attempt either in their life (baseline) or in the past 90 days (follow-up), they reported how old they were when they most recently quit smoking, the number of quit attempts in the past 90 days, the longest length of time they had quit smoking for, as well as on psychosocial smoking cessation resources. If not currently still smoking, participants reported the age when they stopped smoking, as well as psychosocial smoking cessation resources used in their most recent quit attempt. Finally, regarding smoking cessation, all participants answered a single item with four multiple choice options to gauge attitudes toward inclusion of smoking cessation in AOD treatment (e.g., "Services that help people stop smoking…should be automatically included in addiction treatment.").

	(National Cancer Institute, 2009; National Institutes of Health & U.S. Food and Drug Administration, 2013; Prorok et al., 2000).
Treatment for Injuries or Physical Health Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for health problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Treatment for Alcohol and Drug Use Problems	Participants reported treatment in an emergency room and admissions to a hospital for at least one night for alcohol or drug use problems. At baseline, participants reported for both lifetime and past 3 months. At follow-up visits, participants were asked to report only on treatments in the past 3 months (Dennis et al., 2002; Miller & Delboca, 1994).
Anti-craving and Anti-relapse Medications (Alcohol and Opioids)	At baseline, participants reported whether they had ever been prescribed a medication to prevent them from drinking alcohol or using opioids. At follow-up visits, participants were asked if they had been newly prescribed any medication to prevent them from drinking alcohol or using opioids in the past 3 months. If participants responded yes to either item, participants reported lifetime (baseline), past 3 months (follow-up) and current (baseline and follow-up) use of specific medications from the Form-90, including both generic and brand names (Miller & Delboca, 1994). Participants were also asked to rate what proportion of the time they used each medication as medically indicated.
Mental and Emotional Health: Diagnoses, Hospitalizations, Treatment History	Participants reported whether they had ever been told that they had a mental health condition by a doctor, nurse, or counselor, including agoraphobia, anorexia nervosa, bipolar disorder, bulimia nervosa, delusional disorder, dysthymic disorder, generalized anxiety disorder, major depressive disorder, obsessive-compulsive disorder, panic disorder, personality disorder, post-traumatic stress disorder, schizoaffective disorder, schizophrenia, social anxiety disorder, specific phobia, substance use disorder, and other. For each diagnosis endorsed, participants indicated whether this had been a problem for them in the past 12 months. Participants reported treatment in an emergency room and admissions to a hospital for at least one night for mental, emotional, behavioral, or psychological problems. Participants reported for both lifetime and past 3 months. Participants also reported the number of times they had seen a mental health doctor in an office or outpatient clinic (including telehealth) in the past 3 months, on how many of the past 90 days they had been bothered by mental, emotional, behavioral, or psychological problems, and on how many of the past 90 days these problems had kept them from meeting their responsibilities or made them feel like they could not go on (Dennis et al., 2002; Miller & Delboca, 1994).
Mental and Emotional Health: Psychiatric Medication Use	Participants were asked if they had ever been prescribed medication by a physician or medical practitioner to help them with a mental health condition (lifetime use). If they said yes, they were asked which medication they had ever been prescribed with the options antidepressants, anti-anxiety medication, anti-psychotics, mood stabilizers, stimulants, painkillers, medications for sleep and other (to be specified). Participants were then asked if they were still taking the medicines they indicated. If participants were still taking the medicines, they were asked what proportion of the time they take the prescribed medication as medically indicated. At follow-up visits, participants were asked if they were still using any medication that they had been using at the prior study visit, whether they had been newly prescribed any medication to help with a mental health condition, and if yes, what type of medication. For each medication endorsed, participants reported what proportion of the time they used the medication as medically indicated (Dennis et al., 2002; Miller & Delboca, 1994).
Social Support Questionnaire (SSQ)	Participants were asked to list the initials of up to 5 family members, up to 5 friends, and up to 3 other important people in their life who they felt close to. For each person, they listed their initials, relationship, alcohol use pattern, drug use pattern, days per month they had

	contact with this person over the past 3 months (including contact via phone/text), how much they value their relationship on a scale of 1 (*not at all*) to 10 (*a great deal*) and how helpful they are in their recovery efforts on a scale of 1 (*not at all helpful*) to 10 (*a great deal*) (Zywiak et al., 2009).
12-step/MHO Attendance History	At baseline, participants were asked about lifetime attendance to help with their AOD problem at 12 different MHOs, with an "other" option specified by participant (Kelly et al., 2011): 1) Alcoholics Anonymous (AA); 2) Narcotics Anonymous (NA); 3) Marijuana Anonymous (MA); 4) Cocaine Anonymous (CA); 5) Crystal Methamphetamine Anonymous (CMA); 6) SMART Recovery; 7) LifeRing Secular Recovery; 8) Moderation Management; 9) Celebrate Recovery; 10) Women for Sobriety; and 11) Secular Organization for Sobriety (S.O.S.).; 12) Dual Diagnosis Anonymous (DDA); and 13) Other. Other options were examined for possible inclusion in existing categories, and recategorized as appropriate. At follow-ups, participants reported attendance for the past 3-months. For each MHO attended, participants reported a) Whether they attended regularly (at least once per week), b) Number of meetings in the past 3 months, and c) Whether they had ever attended a meeting online.
Online Resources and Social Network Sites	For each MHO that a participant had attended online (as noted in "12-step/MHO Attendance History"), participants reported how many meetings they had attended online in the past 3 months, how they accessed these meetings (video, audio only, telephone, etc.), and how helpful they felt the online meetings were on a scale of 1 to 10. Participants also reported whether they used any online or mobile technologies to support their AOD problem resolution or recovery in their lifetime (baseline) and in the past 3 months. Potential online and mobile technologies included recovery-focused social network sites (e.g., InTheRooms.com), general social network sites (e.g., Facebook), and mobile smartphone applications. For each online or mobile technology endorsed, participants indicated how many of the past 90 days they had used the technology for recovery and how helpful they found it on a scale of 1 to 10. Participants were also given the opportunity to provide any other information or comments on their use of online or mobile recovery resources.
SMART Involvement	Questions about SMART involvement were asked for participants who had attended SMART Recovery. Participants were asked how long they have been attending SMART Recovery, how they heard about SMART Recovery, whether they consider themselves to be a current member of SMART Recovery (*yes/no*), how many times they have attended SMART recovery in their lifetime (*numerical value*) and if another member of SMART Recovery served as a personal mentor or guide to them in the past 3 months (*yes/no*). The participants were asked questions about their participation in SMART meetings in the past 3 months to gauge the frequency of the use of SMART meetings, tools, website, and web-application 'Overcoming Addictions.' Participants were also asked four questions about their level of engagement in SMART meetings.
Recovery/Abstinence time	Participants were asked to report in years and months how long they had been either 1) Sober (not using any alcohol/drugs) or 2) Drinking/using drugs without problems.
Multidimensional Mutual-Help Activity Scale (MM-HAS)	Questions from the MM-HAS were asked for participants who had attended meetings of any of the following MHOs: Alcoholics Anonymous, Narcotics Anonymous, Marijuana Anonymous, Cocaine Anonymous, Crystal Methamphetamine Anonymous, and Dual Diagnosis Anonymous. For each organization, participants were asked if they currently considered themselves to be a part of the MHO, their activities as part of the MHO in the past 3 months (sponsor, contact with sponsor outside a meeting, contact with other members outside a meeting, read 12 step literature outside of a meeting, shared or talked during meetings, helped with setting up/running a meeting), and the number of steps out of the 12 step program that they completed while participating in the MHO in the past 3 months. Participants were then asked to rate the helpfulness, enjoyability, and safety of the

	MHO from a scale of 1 (*not at all helpful, do not enjoy at all,* or *not at all safe*) to 10 (*extremely helpful, enjoy a great deal,* or *completely safe*) (Kelly et al., 2013; Kelly et al., 2011).
Recovery support services and formal treatment programs (RSSTX)	The questionnaire assessed history of participation in nine psychosocial treatment and recovery support services: 1) Sober living environment; 2) Recovery high school; 3) College recovery program/community 4) Recovery community center (RCC); 5) Faith-based recovery services (e.g., a recovery group provided by a church, synagogue, mosque, etc.); 6) State or local recovery community organization (RCO); 7) Outpatient addiction treatment; 8) Alcohol/drug detoxification services; 9) Inpatient or residential treatment. If they responded yes to any treatment service (7, 8 or 9), they reported the number of times they used the service (i.e., number of treatment episodes) in their lifetime (baseline) and the past 3 months (baseline and follow-up). (Dennis et al., 2002; Miller & Delboca, 1994).
Year End Summary (YES)	At baseline, 12-month follow-up, and 24-month follow up, participants were asked if they felt like they were better off now than they were 12 months ago in terms of their alcohol and drug problems (worse off, same, better off). Participants were then asked to elaborate on the reason for that answer. Participants were asked if their substance use had changed or stayed the same in the past 12 months (changed for the better, changed for the worse, stayed the same). If participants reported 'stayed the same', they were asked what factors they thought were most responsible for their substance use staying the same.
Timeline Follow Back (TLFB)	Participants provided specific dates for alcohol use, substance use, MHO attendance, inpatient and outpatient addiction treatment, inpatient and outpatient mental health treatment, and incarceration for the past 3 months (baseline, 3-, 6-, 9-, and 12-month follow-ups) or 6 months (18- and 24-month follow-ups) (Miller & Delboca, 1994). For alcohol use, participants were asked to report the number of standard drinks consumed on each drinking day. For MHO attendance and outpatient treatment for addiction and mental health, participants were asked to report whether services were in-person or online. During in-person study visits, a printed calendar was used to facilitate the TLFB. For remote visits, study staff prompted participants with potentially memorable dates within the timeframe (e.g., holidays).
Go/No-Go Cognitive Measure*	The Inquisit Go/No-Go Cognitive Measure is a computerized task used to assess impulsivity. The Inquisit script implemented the Go/No-Go Task as described in Fillmore et al. (2006). Participants were asked to press the spacebar when they see a green rectangle (*go*) but refrain from pressing the spacebar when they see a blue rectangle (*no-go*). The blue and green rectangles could be vertical or horizontal. The vertical rectangle had a high probability (4:1) of being green (*go*) and the horizontal rectangle had a high probability (4:1) of being blue (*no-go*). Participants were given information about the orientation of the rectangle shortly before the color of the rectangle was revealed. Participant response times and error rates were recorded. For remote visits, a web-based version of the Go/No-Go Task was tested, but due to the effect of internet speed on results, this measure was not included.
Breathalyzer*	Breathalyzer tests were used to establish a baseline level of substance use for participants at the first assessment and to ensure that data was not collected from participants who were impaired due to alcohol use. Breathalyzer tests were performed at baseline and all follow-up time points prior to starting each assessment. If a participant's BAC was above .02, study staff did not conduct the study visit; instead, study staff either waited with the participant until their BAC dropped to .02 or lower or attempted to re-schedule the participant's visit. If a participant's BAC was above the legal limit (.08), and the participant had driven to their assessment, study staff asked to hold the participant's car keys while waiting for their BAC to drop below the legal limit. If the participant insisted on holding their car keys and/or driving, or if the participant did not stay with study staff until their BAC dropped below .08, study staff called security as a safety precaution. Study staff also offered to arrange and pay for a cab to transport the participant home. If a participant had driven to the appointment

	and decided to take a cab home, the participant could return to pick up their car keys during business hours when their BAC was below .08. For remote visits, study staff were unable to perform breathalyzer tests and instead asked participants to verify that they had not used alcohol or other drugs prior to the assessment via self-report.
Urine Drug Screen*	Urine drug screens were used to establish baseline substance use at baseline and to verify self-reported estimates of alcohol and other drug use. For remote visits, study staff were unable to perform urine drug screens.
Saliva Test	Self-administered saliva tests were implemented in March 2021 as an alternative method of biochemical verification during remote visits. Participants were contacted prior to their assessment to confirm willingness to participate in the saliva test, what address the test would be mailed to, and whether the visit would be conducted over Zoom or on the phone. During the assessment, participants were able to self-administer the saliva test with study staff guidance. If participants completed the assessment over Zoom, participants showed the test results to the research coordinator who screenshotted the test and uploaded it to REDCap. If the participant completed the assessment over the phone, they uploaded images of the test to REDCap or, if unable to upload images, self-reported the results. Due to inconsistencies in saliva test results (no results, partial results, and false negatives), saliva test use was discontinued in May 2021.

* = not administered during remote visits

Table 2 (self-administered measures)

Measure	**Description**
Demographics Background	Participants reported the following: gender, race, ethnicity (whether participants were Hispanic/Latino), where they were living for the majority of the past 3 months (with family or other relatives, with group of friend(s) or non-family members, alone in own dwelling, homeless, hospital rehabilitation facility or nursing home, jail, prison or other correctional facility, other), current marital status (single, married, living with someone as if married, in a relationship, engaged to be married, legally separated, divorced, widowed), sexual orientation, left or right handed, highest level of schooling completed, highest level of schooling completed by either parent, whether they held a job in the past 3 months, (if yes) nature of employment (odd jobs, part time, full time), (if no) reason for unemployment, major source of financial support, total annual household income, type of health insurance, and financial well-being of their family. Numerical values were collected for the following in the past 3 months: unplanned absences from work/school, times disciplined on the job/at school, times your job/school has been in jeopardy, times you were suspended or fired from work/school (Dennis et al., 2002; Miller & Delboca, 1994).
Criminal Justice Involvement	The questionnaire used adapted items about criminal justice involvement from the Form-90 (Miller & Delboca, 1994). Participants reported on their current legal status (none, on probation only, on parole only, on probation and parole, awaiting charge, trial or sentence, outstanding warrant, case pending, other). At baseline, participants reported whether they had ever been arrested (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in their lifetime, and how many times for other reasons in their lifetime. At follow-up visits, participants reported whether they had been arrested in the past 3 months (yes/no). If yes, they reported how many times overall, how many times for DUI/DWI in the past 3 months, and how many times for other reasons in the past 3 months. At baseline, participants reported whether they had ever stayed in jail or prison overnight or longer (yes/no). If yes, they reported how many times in their lifetime and how many times in the past 3 months. At follow-up visits, participants only reported the number of times in the past 3 months.

Religious Background and Behaviors (RBBS)	At baseline, the questionnaire assessed if the participant considered themselves to be part of a religious group (No/none, Baptist, Buddhist, Catholic, Evangelical, Hindu, Jewish, Lutheran, Methodist, Mormon, Muslim, Presbyterian, Other Protestant, Shinto, Native American Church, Traditional Native American, Christian, Some other group). For all timepoints participants were asked which of the following describes them at this time: atheist, agnostic, unsure, spiritual, religious. Participants were asked how often they participated in religious activities in the past 3 months on a 7-point Likert scale (*never, rarely, once a month, twice a month, once a week, twice a week, almost daily, more than once a day*) and, at baseline, how often they participated in certain religious activities in their lifetime on a 3 point-Likert scale (*never, yes, in the past but not now, yes, and I still do*) (Connors et al., 1996).
Religious and Spiritual Intensity	The questionnaire included four items assessing participants' religiosity and spirituality. Participants reported the extent to which they considered themselves religious/spiritual on a Likert scale from *not religious/spiritual at all* (1) to *very religious/spiritual* (4). Participants reported the extent to which their religious/spiritual practices and beliefs help them with resolving an alcohol/drug problem on a scale from *do not help at all* (1) to *make all the difference* (5) (Idler et al., 2003).
Twelve Promises Scale (TPS)	This questionnaire assessed participants' current psychosocial state and attitudes towards drinking and using drugs. Participants rated how true each item was for them at the current time on a scale of *never true* (1) to *true most of the time* (5) (Kelly & Greene, 2013).
Perceived Stress Scale (PSS-4)	This questionnaire assessed participants' level of stress over the last month. Participants rated each item on a scale from *never* (1) to *very often* (5) (Warttig et al., 2013).
Kessler 6 (K6)	This six-item scale assessed psychiatric symptoms (also referred to as psychological distress). On a scale from *all of the time* (1) to *none of the time* (5), participants are asked how often they felt: nervous, hopeless, restless or fidgety, so depressed that nothing could cheer you up, that everything was an effort, and worthless (Kessler et al., 2003).
Coping Strategies Scale (CSS)	Participants were asked to select how often they used a variety of coping strategies or thoughts in the past 3 months to help them not use alcohol or drugs. Participants rated each item on a scale from *never* (1) to *frequently* (4) (Litt et al., 2003; Prochaska et al., 1988).
Alcohol and Drug Abstinence Self Efficacy (A-DSES-20)	Participants were asked about their feelings of confidence to not drink or use drugs in various situations in the past week. Participants rated their level of confidence for each scenario on a scale of *not at all confident* (1) to *extremely* (5) (Diclemente et al., 1994).
Penn Alcohol and Drug Craving (PADCS-5)	This questionnaire assessed the frequency and strength of cravings to use alcohol and other drugs during the past week. Participants reported how often they thought about drinking/using drugs, how strong the craving was at its most severe, how much time they have spent thinking about drinking/using drugs, how difficult it would have been to resist drinking/using drugs, and then rated their overall alcohol/drug craving with options ranging from *never thought about drinking/using drugs and never had the urge to drink/use drugs* to *thought about drinking/using drugs nearly all of the time and had the urge to drink/use drugs nearly all of the time* (Flannery et al., 1999).
Commitment to Sobriety Scale (CSS-5)	In this questionnaire, participants were asked 5 questions about their commitment to not using alcohol/drugs. Participants rated the extent to which they agreed with these statements on a scale from *strongly disagree* (1) to *strongly agree* (6) (Kelly & Greene, 2014).
Drinking Goal	In this questionnaire, participants chose one goal that was the most true to them currently from the 5 options: 1) Total abstinence; never use again; 2) Total abstinence; but realize a slip is possible; 3) Occasional use when urges strongly felt; 4) Temporary abstinence; or 5) Controlled use.

Short Inventory of Problems (SIP-2R)	This questionnaire assessed how often participants had experienced various problems during the past 3 months because of their drinking/drug. Participants indicated how often they had experienced each problem on a scale of *never* to *daily or almost daily*. Participants were also asked to indicate whether they had had an accident while drinking or intoxicated in the past 3 months (Miller et al., 1995).
Questions about Recovery	This questionnaire assessed recovery identity, definition, and what participants believe are the factors helping them resolve their problem with alcohol/drugs at baseline, 12-month follow-up, and 24-month follow-up. Participants selected a statement that best applied to them from whether they consider themselves to be *in recovery*, *seeking recovery* or *not in or seeking recovery*. If participants chose that they were 'in recovery', they were asked to provide the date they use to mark the beginning of their recovery. Participants were asked to provide their definition of recovery in one sentence (free response) and to select one of three statements that best fit their definition of recovery: 1) Abstinence from all drugs/alcohol; 2) Abstinence from only those drugs/alcohol with which they had a problem; or 3) Non-problematic/moderate use of drugs/alcohol, including those with which they had a problem. Participants were then asked to list the top 3 things that have helped or are helping them to resolve their problem with alcohol/drugs.
Brief Assessment of Recovery Capital (BARC-10)	The BARC-10 (Vilsaint et al., 2017) is a 10-item, abridged version of the Addiction Recovery Capital Scale (Groshkova et al., 2013). The BARC-10 measures personal (e.g., "I take full responsibility for my actions"), social (e.g., "I get lots of support from friends"), physical (e.g., "I have enough energy to complete the tasks I set for myself"), and environmental resources (e.g., "My living space has helped to drive my recovery journey") used to initiate and sustain recovery. Participants rated their agreement with each statement on a scale from *strongly disagree* (1) to *strongly agree* (6).
Behavioral Addictions	The questionnaire used items adapted from Laudet et al. (2015) to assess whether individuals ever had a problem with one or more other behaviors apart from AOD use in their lifetime (baseline) and currently, including 1) Eating disorder; 2) Sex/love addiction; 3) Gambling; 4) Video gaming addiction; 5) Compulsive shopping; 6) Internet addiction (for issues not assessed by other choices); 7) Compulsive exercise; 8) Internet pornography addiction; 9) Self-harm/injury and 10) Other (specified). "Other" options were examined for possible inclusion in existing categories, and recategorized as appropriate. Participants were asked if any reported behavioral addictions had been a problem for them in the past 3 month and if so, how many days out of 90. If reporting more than one, participants indicated which behavior had been the most problematic.
Medical Marijuana Use	Participants were asked if they had ever been recommended to use marijuana for medical reasons. If yes was indicated, participants were asked how many days out of the past 90 marijuana was used for medical reasons and to list up to three medical reasons for using marijuana.
Medication Attitudes	This questionnaire assessed participant attitudes toward medication for an alcohol problem, opioid problem, any kind of alcohol/drug problem, and emotional problem. Participants rated their agreement with the use of medication for these problems on a scale of *strongly disagree* (1) to *strongly agree* (6).
Impulsive behavior (SUPPS-S)	This questionnaire assessed impulsivity. Participants rated their agreement with 20 items describing situations or feelings related to impulsivity on a scale of *agree strongly* (1) to *disagree strongly* (4) (Coskunpinar et al., 2013).
Quality of Life (Q-LES-Q)	This measure of quality of life was used to assess satisfaction related to physical health, mood, relationships, activities, and economic status. Participants rated their satisfaction with

	each item during the past week on a scale of *very poor* (1) to *very good* (5) (Endicott et al., 1993).
Quality of Life (EQ5D3L)	This measure of quality of life was used to assess physical and mental health states. Participants rated their current mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Participants also rated their current overall physical and mental health states using a visual analogue scale with options between 0 (*worst*) and 100 (*best*) (Devlin & Brooks, 2017).
Quality of Life (EUROHIS-QOL)	This measure of quality of life is a widely used eight-item measure of quality of life, adapted from the World Health Organization Quality of Life – Brief Version (WHOQOL-BREF) (Schmidt et al., 2006). Participants rated each item on a 5-point Likert scale from 1 (*very poor, very dissatisfied,* or *not at all*) to 5 (*very good, very satisfied,* or *completely*) (da Rocha et al., 2012).
Pittsburgh Sleep Quality Index (PSQI)	This questionnaire assessed quality of sleep. Participants reported how many hours of sleep they got on average per night over the past month. Participants then rated their quality of sleep on a scale from *very good* (1) to *very bad* (4) (Buysse et al., 1989).
Pain Visual Analogue Scale (VAS)	This measure assessed physical pain. Participants rated the current severity of their pain using a visual analogue scale with options between 0 (*no pain*) to 100 (*very severe pain*) (Wewers & Lowe, 1990).
International Physical Activity Questionnaire (IPAQ)	This questionnaire asks participants about their level of physical activity over the past seven days. Participants indicate how many days in the past 7 days they have done: vigorous physical activity, moderate physical activity, and walking. Participants then indicate how much time per day they usually spent on each activity in hours and minutes. Participants are also asked how many hours they usually spent sitting on weekdays over the past 7 days (Hagstromer et al., 2006).
Meals	Participants reported how many meals on average they have eaten per day during the past 3 months.
Self-esteem, Happiness, and Satisfaction with Life	Three single-item measures were used to assess self-esteem (Robins et al., 2001), happiness, and satisfaction with life (Diener et al., 1985). For self-esteem, participants indicated their agreement with the statement "I have high self-esteem" on a scale from 1 (*not very true of* me) to 10 *(very true of* me). For happiness, participants rated how happy they were with their life in general on a scale of 1 (*completely unhappy*) to 10 (*completely happy*). For satisfaction with life, participants indicated their agreement with the statement "I am satisfied with my life" on a scale of *strongly disagree* (1) to *strongly agree* (7).
Abstinence Self-Efficacy Single Item	Participants rated how confident they were that they could remain abstinent or drink/use drugs without problem in the next 3 months on a scale from *not at all confident* (1) to *very confident* (10).
Daily Spiritual Experiences Scale (DSES)	This questionnaire assesses spiritual and/or religious experiences. The questionnaire includes items with the word "God" used but includes instructions for participants that if "God" is not a comfortable word that they should substitute it for one that calls to mind the divine and holy for them. Participants read 15 items describing spiritual and/or religious experiences that a person may have and rate how often they have this experience from *many times a day* (1) to *never or almost never* (6). The last item asks participants how close they feel to God from *not close* (1) to *as close as possible* (4) (Underwood & Teresi, 2002)

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Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Pathways to Change

Principal Investigator: John F. Kelly, Ph.D.

Site Principal Investigator:

Description of Subject Population: Adults with an alcohol use disorder making a new recovery attempt.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Why is this research study being done?

This research is being done to obtain greater knowledge about the pathways followed in new recovery attempts for individuals with an alcohol use disorder (AUD). We are asking you to take part in this research study because you identified yourself as someone with an AUD and is making a new attempt to change your alcohol use. About 348 people will take part in this research study. We expect to enroll all subjects within the greater Boston, Massachusetts area.

How long will you take part in this research study?

If you enroll today, it will take you a total of 24 months (two years) to complete this research study. During this time, you will complete a baseline assessment, along with follow-up surveys every 3-, 6-, 9-, 12-, 18-, and 24-months.

What will happen if you take part in this research study?

If you choose to enroll, you will be required to come to our downtown Boston office at the MGH Center for Addiction Medicine (within 3-minute walking distance of two major subway stops) to complete your assessments. You will complete your questionnaires via the Harvard Catalyst's Electronic Data Capture (REDCap; project-redcap.org) and with a research coordinator. You will be asked about basic demographic questions, substance use history, mutual-help organization attendance, psychiatric symptoms, psychosocial functioning, treatment service utilization, quality of life, and recovery motivation/support.

If you are a participant from the San Diego area, all of your study visits will take place remotely. The questionnaires will be asked over Zoom, Skype, or phone call and through an online link that is sent to your personal device.

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. The aim of this qualitative interview is to investigate the motivations, expectations, and experiences of individuals who do and do not participate in Mutual Help Organizations (MHOs) such as Alcoholics Anonymous and SMART Recovery. Additionally, we hope to assess how helpful individuals believe MHOs are in their recovery attempt and how MHOs and other recovery resources might be improved and adapted to better fit the needs of individuals currently seeking recovery from an Alcohol Use Disorder.

MHO attendance is not required to participate in this qualitative interview. We plan to include individuals following a variety of recovery pathways.

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Study staff will reach out directly to a pre-determined number of interested individuals via email or phone call to offer them the opportunity to participate in this qualitative interview and schedule an interview time. The interview will be approximately 30-60 minutes in length and will be conducted via Zoom or over the phone and will be recorded. This is done purely for data summarization purposes and once the data are transcribed, the recordings will be deleted. Participants will be compensated an additional $50 following completion of the interview.

You are not required to participate in the optional qualitative interview in order to participate in the Pathways to Change Study. You can still take part in the original research study whether or not you choose to participate in this additional qualitative interview. Signing this form does not guarantee that you will be able to participate in the qualitative interview.

Do you consent to participate in the qualitative interview if selected?

[ ] YES [ ] NO Initial _____

You will receive text/email reminders about upcoming appointments through REDCap's automated email feature and integrated Twilio SMS and voice call services. Both REDCap and Twilio are secure services for these appointment reminders.

Text messages by mobile/cell phones are a common form of communication. The Recovery Health research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not receive text messages with staff associated with this research study at any time. You can do this in person at your upcoming visit, by calling 617-643-5927, or by emailing recoveryhealth@mgh.harvard.edu.

- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

What are the risks and possible discomforts from being in this research study?

The risk of participating in this study is expected to be very small because your privacy is protected by law. We may report medical information if you need medical help, if we feel you might be in danger of harming yourself or others, or if there is any suspicion of child abuse or elder abuse.

It is possible that you may experience some discomfort during scheduled assessments from the questionnaires, as they ask for some sensitive personal information. However, you are free not to participate in any aspect of the study that makes you uncomfortable.

What are the possible benefits from being in this research study?

You will gain no direct benefit from participation in this study. However, this study has the potential to contribute valuable information about recovery pathways for individuals with alcohol use disorder, and may provide additional support for mutual-help organizations.

What other treatments or procedures are available for your condition?

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This study does not provide any treatment to you. Rather, we will ask you about your experiences with various treatments that you have been receiving or have received. You do not have to take part in this study to be able to obtain mental health services.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. John F. Kelly, Ph.D., is the person in charge of this research study. You can call him at 617-643-1980, Monday-Friday, 9am-5pm. You may leave a message at this number and he will return your call. You can also call research staff at 617-643-9850, Monday-Friday 9am-5pm with questions about this research study. If you have questions about the scheduling of appointments or study visits, call research staff at 617-643-9850.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

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Detailed Information

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding recovery from alcohol use disorder. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

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Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be compensated up to $455 for completing the questionnaires. That is $15, $25, $30, $35, $40, $45, and $55 for the baseline, 3-, 6-, 9-, 12-, 18-, and 24-month assessments, respectively. Additionally, you will be compensated $20 for each of the computer-based REDCap surveys you complete at each assessment. Finally, in order to help offset the cost of travel, you will be compensated $10 per assessment for coming to our offices. In order to receive payment for this study, we will need your Social Security Number (SSN). We need to collect this information in order to comply with tax reporting obligations. This information is confidential and protected, and will be stored securely and redacted when no longer required.

	Computer-based REDCap Surveys	In-Person Study Visits with Staff	Travel Reimbursement
Baseline	$20	$15	$10
3-Month Follow-Up	$20	$25	$10
6-Month Follow-Up	$20	$30	$10
9-Month Follow-Up	$20	$35	$10
12-Month Follow-Up	$20	$40	$10
18-Month Follow-Up	$20	$45	$10
24-Month Follow-Up	$20	$55	$10
Total:			Up to $455

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. Participants will be compensated an additional $50 following completion of the qualitative interview.

What will you have to pay for if you take part in this research study?

There are no costs to participate in this research. All questionnaires and surveys will be provided to you by study staff members.

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What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

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- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

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The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

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Signature of Subject (choose one):

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject	Date	Time (optional)

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above. **I understand that I am eligible to be compensated for my participation but am choosing not to be.**

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 06/04/2021