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Title: A smartphone application for alcoholism recovery: A randomized controlled trial

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Abstract

Importance: Patients leaving treatment for alcohol-use disorders (AUDs) are not typically offered evidence-based continuing care, although research suggests that continuing care is associated with better outcomes. A smartphone-based application could provide effective continuing care.

Objective: To determine whether a smartphone-based application can reduce heavy drinking days for patients leaving residential treatment for AUDs.

Design: An un-blinded randomized controlled trial. Patients were randomized to treatment as usual or treatment as usual plus a smartphone with A-CHESS, an application designed to improve continuing care for AUDs. "A-CHESS" stands for *Addiction – Comprehensive Health Enhancement Support System.*

Setting: Three residential programs operated by one treatment organization in the Midwest and 2 residential programs operated by one organization in the Northeastern US.

Participants: 349 patients who met the criteria for DSM-IV alcohol dependence when they entered residential treatment. 179 were randomized to the control group and 170 to the treatment group.

Intervention: Treatment as usual varied; none of the residential programs offered patients coordinated continuing care after discharge. A-CHESS provides monitoring, information, communication, and support services to patients, including ways for patients and counselors to stay in contact. The intervention lasted 8 months and the follow-up period lasted 4 months.

Main Outcome Measure: Heavy drinking days—the number of days during which a patient's drinking in a 2-hour period exceeded, for men, 4 standard drinks and for women,

3 standard drinks. Patients were asked to report their heavy drinking days in the previous 30 days on surveys taken 4, 8, and 12 months after discharge from residential treatment.

Results: For the 8 months of the intervention and 4 months of follow-up, patients in the A-CHESS group reported significantly fewer heavy drinking days than patients in the control group (M = 1.39 vs. 2.75, respectively; 95% CI [.46, 2.27]).

Conclusions and Relevance: The findings suggest that a multi-featured smartphone application may have a significant effect on patients in continuing care for AUDs. [316 words.]

Trial registration: clinicaltrials.gov Identifier: NCT01003119

Key words: *alcohol dependence, eHealth, mobile devices, continuing care, heavy drinking days*

Alcohol dependence is a stable, lifetime psychiatric diagnosis.[1,2] It is a chronic disorder characterized by frequent relapse,[3] and evidence shows that continuing care for alcohol and drug use disorders is associated with better outcomes.[4] Nonetheless, patients leaving treatment for alcohol use disorders (AUDs) are not typically offered aftercare with ongoing monitoring,[3,5] in part because of the overstressed infrastructure for delivering AUDs treatment.[6]

Technology offers one possible way of providing continuing care for AUDs. Compared to traditional face-to-face care, technology can give more readily available, personalized care while using less counselor time. This paper describes a randomized trial of a mobile technology application called A-CHESS (Alcohol – Comprehensive Health Enhancement Support System). A-CHESS, described below under "Description of the Interventions," was created to improve continuing care for AUDs by offering, at any time and almost anywhere, emotional and instrumental support and a monitoring service designed to increase the user's motivation.[7] This paper reports the primary outcome from the trial, which tested the hypothesis that a multi-featured smartphone-based application can reduce heavy drinking days over 12 months in patients leaving residential care for AUDs. We also report the effect of A-CHESS on 2 secondary outcomes: abstinence and negative consequences of drinking.

METHODS

Study Design and Participants

The A-CHESS study was an un-blinded randomized trial with 349 patients who met the criteria for DSM-IV alcohol dependence when they entered treatment at 3 residential programs operated by one nonprofit organization in the Midwestern U.S. and 2 programs

operated by one nonprofit organization in the Northeastern U.S. Patients had to be at least 18 years old and willing to be randomized. They also had to identify 2 backup contacts—people who could provide information about how to reach the patient for one year. Patients were excluded if they had a psychiatric or medical condition that precluded participating in the study (a history of suicidality, a significant developmental or cognitive impairment that would limit the ability to use A-CHESS, or vision problems).

Study Procedures

An onsite project coordinator employed at each program identified eligible patients from the program's administrative database. About 2 weeks before an eligible patient left residential treatment, the coordinator discussed the study with the patient, including data to be collected and procedures, benefits, and risks of participating. Willing patients gave written informed consent and were enrolled. The coordinator then collected pretest data and contacted the project director to get a group assignment. Patients were randomized in a 1:1 ratio to control or A-CHESS. The project director used a computer-generated random allocation sequence implemented using sequentially numbered containers. The sequence was unknown to the onsite coordinators before they contacted the project director. Randomization was stratified by program and used blocks of 8. The study was approved by the Institutional Review Board at the University of Wisconsin – Madison and registered at clinicaltrials.gov (NCT01003119).

Patients were randomized to the groups for 8 months and a follow-up period of 4 months. The control group received treatment as usual; the A-CHESS group received treatment as usual plus a smartphone with A-CHESS for the 8-month intervention period. Recruitment took place from February 2010 through June 2011 and the intervention from

February 2010 through May 2012. The recruitment and intervention periods both ended 2 months early because recruitment was accomplished more quickly than planned.

Description of the Interventions

None of the 5 programs provided coordinated continuing care after residential treatment. At the 3 Midwestern programs, counselors encouraged patients to attend ongoing outpatient treatment. At one of the Northeastern programs, most patients leaving residential treatment went to a halfway house; length of stay at the halfway house varied greatly. The halfway houses forbid the use of alcohol and other drugs and required residents to seek fulltime work or equivalent volunteer activity and mandated attendance at treatment group sessions and AA meetings. At the other Northeastern program, patients moved after residential treatment to a variety of situations (e.g., back to their own homes; halfway houses; sober housing—usually single- or double-occupancy rooms in buildings that require proof of sobriety).

Patients in the A-CHESS group received a smartphone with the A-CHESS application, phone service, and a data plan. A-CHESS had common smartphone functions, such as digital voice services, text messaging, and Web access. The application had both static content (e.g., audio guided relaxation) and interactive features. For example, if a patient neared a high-risk location (a bar or liquor store she used to frequent), GPS initiated an alert asking the patient if she wanted to be in that location. **Table 1** shows A-CHESS services; screen shots of A-CHESS are available at http://chess.wisc.edu/achess-archive. Each patient using A-CHESS had a unique account that enabled researchers to automatically collect A-CHESS use data in server log files. The server tracked the date and time a patient entered A-CHESS, the service(s) selected, how long the patient used each service, pages viewed, and whether

the patient sent or received messages. With the patient's permission, the patient's counselor could access information about the patient's A-CHESS use through a secure website. Before leaving residential treatment, patients were required to demonstrate a minimal understanding of A-CHESS (i.e., the ability to set up their profile and use the discussion board and texting features) and to have entered at least 2 people (who could be the same as or different from the 2 backup contacts) to be contacted if they pressed the phone's panic button. Patients were free to use the phones for personal purposes throughout the intervention. Only the use of A-CHESS services was monitored. Use of smartphone services such as texting and emails was not monitored.

Implementation

During the 8-month intervention, counselors at the residential treatment programs stayed in contact with A-CHESS patients mainly in 3 ways. Each week, patients were asked to complete the Brief Alcohol Monitoring Index, which asked them about both protective and risky items, such as lifestyle balance, negative affect, and recent substance use. If the patient's score on the index exceeded a preset threshold or the patient did not complete the index, A-CHESS automatically contacted the counselor. Counselors could also send messages to patients through A-CHESS, and counselors were automatically notified—if permitted by the patient—whenever the patient pressed the phone's panic button.

Researchers called patients to administer the same survey at 3 points—4, 8, and 12 months after discharge from treatment. The survey included questions about heavy drinking days, quality of life, treatment services received, and coping behavior, and took 15 to 25 minutes to complete. If researchers' calls and messages went unanswered,

researchers contacted the backup contacts. On average, 20 contacts were required per patient to complete 3 phone surveys.

Outcomes and Measures

It was hypothesized that, compared to the control group, A-CHESS would reduce patients' heavy drinking days (the primary outcome) as well as increase abstinence and decrease the negative consequences of drinking (secondary outcomes). Data for all 3 outcomes came from the telephone survey conducted 4, 8, and 12 months after discharge from residential treatment.

Heavy drinking days were defined as days on which a patient's drinking in a 2-hour period exceeded, for men, 4 standard drinks and for women, 3 standard drinks. Patients reported the number of heavy drinking days they had in the previous 30 days. For abstinence, patients reported whether they had had a drink in the previous 30 days. Negative consequences of drinking were derived from The Short Inventory of Problems – Revised (SIP-R).[8,9] This instrument has items with a 5-point Likert-type scale for responses from "hardly ever" to "very likely." We retained 4 of these items (eating improperly, hurting someone, having one's status damaged, and abusing money) and made 4 other items (involvement with the Department of Children and Family Services, lost job, being arrested, and having an accident) dichotomous. Because of this departure from the established instrument, the 8 items were examined individually rather than as a single scale.

Patients also provided on the surveys qualitative feedback about A-CHESS, such as services they liked or problems they were having.

Statistical Analysis

Sample size was based on results of a telephone-based intervention, which found the percent of days of heavy alcohol use 12 months after intervention to be 18% for the treatment-as-usual group and 7% for the intervention group.[10] Using these values, it was estimated that 142 people per group would provide sufficient power ($1-\beta \geq .80$) to detect the same effect size between groups ($h = .34$) using a 2-tailed test with $\alpha = .05$.

The primary outcome, heavy drinking days, was analyzed with mixed-effects models. These models allow for correlating repeated measurements within patients, using all available data (allowing for intention-to-treat rather than only complete-case analysis), and providing unbiased estimates when data are missing at random. Each model included a random effect for patient and fixed effects for the intervention arm (A-CHESS vs. control), month (4, 8, and 12), and arm-by-month interaction, with a first-order autoregressive covariance structure used for the repeated measure of month. Because patients were randomized within each treatment program, program was considered a design variable and included as an additional fixed effect in the model. Secondary outcomes consisted of Likert-type and dichotomous variables. Negative consequences of drinking with Likert-type responses were analyzed with the same mixed-effects approach used for the primary outcome. Abstinence and dichotomous negative consequences of drinking were analyzed using Fisher's exact test. All analyses were conducted using IBM SPSS (v.21). All tests were 2-sided with a $\alpha = .05$.

RESULTS

Baseline Characteristics and A-CHESS Use Data

The **Figure** shows the flow of patients from initial screening through the end of the follow-up period. Baseline characteristics of patients enrolled in the study were not

significantly different between groups (**Table 2)**. Most patients were white (80%), male (61%), and unemployed (79%); most used or abused drugs in addition to alcohol (63%). Mean patient age was 38 years (SD = 10; median = 39).

Although 179 patients were randomized to the A-CHESS group, 286 phones were given to patients during the study because 113 phones were replaced: 56 phones did not work properly, 19 were stolen, 20 were damaged by patients, and 22 were lost. No patients withdrew from the study, although 21 patients in the control group and 14 patients in the A-CHESS group did not provide data for any of the 3 surveys. The rate of survey completion was not significantly different between groups. Patients were included in the analysis if they completed at least one survey according to the intention-to-treat principle.

During the 8-month intervention period, patients randomized to the A-CHESS group used the system, on average, 40% of days (mean number of days of use: 97.36) and viewed 2,154 pages, excluding pages viewed when patients were trained to use A-CHESS. A-CHESS was used slightly less on weekends compared to weekdays. Peak use occurred about 8 A.M. (which corresponds to when users received a daily motivational message), tapering throughout the day to little or no use between midnight and 7 A.M.

Heavy Drinking Days

Patients in the A-CHESS group reported significantly fewer heavy drinking days **(Table 3)** than patients in the control group for the intervention and follow-up period (P = .003) and at months 4 (P = .020) and 12 (P =.032), but not at month 8 (P = .096). The effects of site, month, and the group-by-month interaction were not significant (Ps = .536, .649, and .865, respectively). The results were consistent when all 2- and 3-way interactions were included in the model, with significant effects of A-CHESS overall (main effect; P =

.003) and at months 4 and 12 (simple effects; *P*s = .002 and .044), but not at month 8 (*P* = .259) or for any other factor or interaction (all *P*s > .05). Examining only cases with complete heavy-drinking-day data produced similar results (**Table 3**). Fisher's exact texts showed no significant differences between groups on the proportion of patients with complete heavy-drinking-day data or the proportion of missing data on each survey (**eTable 1**). Pattern mixture modeling was used to assess whether the patterns of missing data affected the outcomes. They did not (**eTable 1**).

Abstinence

A greater percentage of A-CHESS than control-group patients reported abstinence in the previous 30 days **(Table 4),** with significant differences at months 8 and 12 (*Ps* = .038, .014, respectively) but not at month 4 (*P* = .132). A-CHESS patients were also more likely to report abstinence at all 3 time points, with 51.9% reporting abstinence on all 3 surveys compared to 39.6% of control-group patients (odds ratio, 1.65 [95% CI, 1.05-2.57]; *P* = .032).

Negative Consequences of Drinking

No significant differences were found between groups overall or by month for any of the 4 Likert-type negative consequences (eating improperly, hurting someone, having one's status damaged, and abusing money) or any of the 4 dichotomous negative consequences (involvement with the DCFS, lost job, being arrested, and having an accident).

Patients reported having so few of the dichotomous consequences that monthly comparisons between groups could not be made. Instead, Fisher's exact test was used to compare the proportion of patients in each group reporting the consequence at any time point. Patients who were in jail at the time of a survey were counted as having an arrest.

Relationship Between Use and Outcome

An exploratory analysis showed that greater A-CHESS use was associated with fewer heavy drinking days. A-CHESS patients were divided into high and low use groups by a median split on days of use during the 8-month intervention. The mixed-effect model from the primary analysis was re-run, replacing the intervention group with use group. Results showed a significant effect overall (t[118.672] = 2.73, P = .007; mean difference 1.26, [95% CI .35-2.17]; d = .21), with high users reporting fewer heavy drinking days on average (mean[SE], .72[.32]) than low users (1.98 [.36]).

COMMENT

This randomized trial found that a smartphone application providing continuing care for AUDs decreased heavy drinking days and increased abstinence but had no significant effect on negative consequences of drinking.

The literature supports the effectiveness of continuing care in improving outcomes for AUDs,[11] as well as for computer-based interventions for AUDs.[12-16] Although high-quality studies have been published about computer-based interventions for continuing care of other chronic illnesses, such as diabetes and heart disease, they are rare for continuing care of AUDs.[17] To our knowledge, no other large randomized trial has been reported about the effectiveness of mobile technology for the continuing care of AUDs.

Although continuing care for AUDs is strongly related to positive outcomes, rates of patient participation are low.[10,18] Two studies found participation in aftercare for substance use disorders to be 59%[19] and 55%[20] at the end of 3 months. A study of Hazelden's MORE program—consisting of 7 sequential, web-based modules, along with periodic contact with a personal recovery coach—showed that only 40% of patients

accessed any module after treatment.[17] In contrast, more than 90% of patients in the A-CHESS group used the system at least once during months 1-4, and by 8 months, more than 40% of patients were still using the application at least weekly.

Whether smartphones will be practical as continuing care of AUDs depends in part on how much they cost and whether costs will be reimbursed. In this study, 12 weeks of A-CHESS cost about $287 per patient, based on 1 hour/month of counselor time at $90/hour divided by 50 patients, 1 hour/month for system administrator time at $50/hour divided by 170 patients, $60/month for the data plan, and $100 to buy the phone. This cost of such interventions as A-CHESS will decrease dramatically as more people have smartphones and data plans of their own, though low-income patients may be less likely to have them.

If other studies confirm our results, such applications could provide the type of care identified as most effective—that is, having long duration (i.e., at least 12 months) and involving proactive efforts to change patient behaviors.[19] The Affordable Care Act emphasizes (via accountable care organizations) a single payment for a defined population, with a reward for good outcomes. An A-CHESS-like system may make sense under these new rules, especially if the investment in phones and data plans pays for itself in reductions in other healthcare costs, lost productivity, and other expenses.

The study has limitations. It involved only 2 treatment organizations and 5 programs. A test involving more programs is needed to confirm our results, and a longer test than 8 months may be merited, given that patients have a chronic disease. We would also include more counselor and family involvement and more proactive outreach in a future test. Finally, the study involved only patient self-report, without urine testing, and each survey asked only about drinking in the past 30 days.

Thousands of healthcare apps for smartphones are on the market, with more becoming available every day, but very few have been rigorously tested. The under-treatment of AUDs and the severity of problems associated with AUDs make it critical to develop applications that work. The promising results of this trial in continuing care for AUDs point to the possible value of a smartphone intervention for treatment of AUDs and perhaps other chronic illnesses.

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Figure legend

Fig. 1. Participant flow.

Table 1: A-CHESS Services

A-CHESS Service	Description
Discussion Groups	Patients can anonymously exchange emotional support and information with other patients via online bulletin-board support groups.
Ask an Expert	Allows patients to receive personal responses to their questions from experts in addiction within 48 hours.
Open Expert	Responses to questions sent to Ask an Expert that are of general interest are rendered anonymous and made available for all users to view.
Personal Stories	Professionally produced text and video accounts of recovery experiences based on interviews of patients and family members. Stories focus on ways to manage addiction, make different choices, and cope with challenges.
Instant Library	Detailed summaries of articles, chapters, and manuals on addiction management.
Frequently Asked Questions	Brief answers to frequently asked questions about addiction, such as "Why do some people become addicted to drugs, while others don't?" and "How do I deal with cravings for alcohol?" Links to additional A-CHESS services offer more detailed information and support.
Web Links	Provide access for patients to approved addiction-related web sites (and specific pages within sites).
Easing Distress	A computerized cognitive-behavior therapy program designed to help people cope with harmful thoughts that can stymie efforts to prevent relapse. It helps assess logical errors, attributional style, and the tendency to exaggerate distress, and offers practical exercises to improve cognitive problem-solving skills.
Healthy Events	Alerts the patient about healthy drug- and alcohol-free events taking place in the city where they live.
High-Risk Locations	Global positioning system (GPS) technology tracks when patients approach an area where they traditionally obtained or consumed alcohol so they can receive "just-in-time" support for getting through the high-risk situation. To activate, individuals voluntarily register places where they regularly obtained or consumed alcohol in the past and now designate as high-risk locations for relapse.
Daily Thoughts	Motivational quotes (usually about sobriety) sent via text messaging each morning to A-CHESS patients.
Sobriety Counter	Appears on the home page of A-CHESS to remind patients of how many days they have been sober.
Panic Button	Provides immediate help to avoid an imminent relapse (e.g., if urges and cravings become severe and help is desired). Pressing the Panic Button starts an intervention (set up during training) that includes automated reminders to the patient (personal motivations for not drinking); computer-generated alerts to key people (e.g., counselor, sponsor, family), who may reach out to the patient via phone or in person; and specific tools for dealing with urges.
Weekly Check-In	Brief survey (Brief Alcohol Monitoring Index) to obtain patient data on negative affect, lifestyle balance, and recent substance use. *Check-in* information is used by A-CHESS for triage and feedback. Patients' counselors are automatically notified if a patient score exceeds a predetermined threshold. The counselor can view a summary report of check-in data.

Table 2. Baseline Demographics Characteristics by Treatment Group[a]

Characteristic	Control (n=179) No., %	A-CHESS (n=170) No., %
Age, mean (SD), y	38.4 (11.2)	38.3 (9.5)
Male	109 (60.9)	103 (60.6)
Started drinking before age 15	121 (67.6)	115 (67.6)
Race		
Caucasian	142 (79.3)	138 (81.2)
African American	24 (13.4)	21 (12.4)
Other	13 (7.3)	11 (6.5)
Highest level of education		
< HS	28 (15.6)	42 (24.7)
HS diploma or GED	136 (76)	115 (67.6)
4-year degree or above	15 (8.4)	13 (7.6)
Reasons for beginning treatment: Own initiative[b]	91 (50.8)	83 (48.8)
Post-treatment living arrangement		
Alone	22 (12.3)	21 (12.4)
With family	83 (46.4)	77 (45.3)
With roommates	7 (3.9)	11 (6.5)
Shelter	3 (1.7)	3 (1.8)
Halfway house	59 (33)	55 (32.4)
Unknown	5 (2.8)	3 (1.8)
Use/abuse drugs besides alcohol	113 (63.1)	105 (61.8)
Other drugs used/abused[cd]		
Cocaine	43 (38.4)	50 (47.6)
Stimulants (not including cocaine)	22 (19.6)	25 (23.8)
Opiates	51 (45.5)	45 (42.9)
Have other mental health problems/issues	81 (45.3)	83 (48.8)
Drinking or other drug use has led to:[c]		
Loss of job or legal issues	165 (92.2)	159 (93.5)
Loss of significant relationship	160 (89.4)	147 (86.5)
Continues to be affected by history of emotional or physical trauma	100 (55.9)	86 (50.6)
Not currently employed or self-employed	138 (77.1)	136 (80)

Abbreviations: SD, standard deviation; HS, high school; GED, General Educational Development

[a] Data presented as percentage of patients unless otherwise indicated

[b] Patients who indicated they began treatment on their own initiative, without also endorsing any other options (i.e., family pressure, employer pressure, court referral, state agency)

[c] Percentages do not sum to 100 because patients could endorse multiple items

[d] One control-group patient did not respond to this item.

Table 3. Group Differences[a] on Heavy Drinking Days Overall and by Month

Effect	Control M (SE)	A-CHESS M (SE)	Mean difference (95% CI)	*t* (df)	*P*	*d*[b]	*h*[c]
Analysis of All Available Data[d]							
Overall	2.75 (.34)	1.39 (.34)	1.37 (.46, 2.27)	2.98 (287.69)	.003	.23	.18
By month:							
4 months	3.01 (0.48)	1.50 (0.47)	1.52 (0.24, 2.80)	2.32 (802.26)	.020	.25	.19
8 months	2.65 (0.48)	1.54 (0.49)	1.11 (-0.20, 2.42)	1.67 (809.01)	.096	.18	.15
12 months	2.60 (0.49)	1.13 (0.50)	1.47 (0.13, 2.81)	2.15 (819.05)	.032	.24	.21
Analysis of Complete Cases Only[e]							
Overall	2.75 (0.35)	1.23 (0.35)	1.53 (.61, 2.44)	3.28 (275.79)	.001	.25	.16
By month:							
4 months	3.22 (0.49)	1.02 (0.49)	2.20 (0.88, 3.52)	3.27 (757.44)	0.001	.36	.12
8 months	2.43 (0.49)	1.59 (0.49)	0.84 (-0.48, 2.16)	1.25 (757.44)	0.210	.14	.24
12 months	2.61 (0.49)	1.07 (0.49)	1.53 (0.21, 2.85)	2.28 (757.44)	0.023	.25	.14

[a] The data were extremely skewed because most patients reported no heavy drinking days at each time point. To account for this nonnormality, the analysis was re-run after separately applying various transformations ($\sqrt{x}$, $\sqrt[3]{x}$, $\log(x+1)$, $\log(x/\bar{x}+.2)$, and $\sqrt{x+.5}$) to the outcome variable. Because the pattern of results across the transformations was consistent with the untransformed data, only results using the untransformed values are reported.

[b] Cohen's *d* is calculated as the mean difference divided by the pooled standard deviation (in all cases, s_{pooled}=6.05, the pooled standard deviation at 4 months).

[c] Cohen's *h* is calculated as $\left|2arcsin\sqrt{P_1} - 2arcsin\sqrt{P_2}\right|$, where P_1 and P_2 are the proportion of days with heavy drinking (mean RDD days divided by 30) for the control group and A-CHESS, respectively.

[d] Model estimated means based on 314 patients (158 Control; 156 A-CHESS) because 35 patients provided no survey data (21 Control; 14 A-CHESS)

[e] Model estimated means based on 279 patients (143 Control; 136 A-CHESS) because 70 patients (36 Control; 34 A-CHESS) had missing heavy drinking day data on at least one survey (see eTable 1 for more detailed information on missingness).

Table 4. Prevalence and Odds of Abstinence[a] by Month

	Prevalence of Abstinence[b], n (%)		Odds of Abstinence[c]			
	Control	A-CHESS	Control	A-CHESS	OR (95% CI)	*P*[d]
Month 4	105 (68%)	118 (76%)	2.10	3.11	1.48 (.90-2.43)	.132
Month 8	101 (67%)	114 (78%)	2.02	3.56	1.76 (1.05-2.96)	.038
Month 12	95 (66%)	107 (79%)	1.90	3.69	1.94 (1.14-3.31)	.017

Abbreviations: OR, Odds ratio; CI, Confidence interval.

[a] Abstinence is defined as a patient reporting no drinking in the past 30 days.

[b] % reporting abstinence of relapse = n reporting abstinence ÷ total reports; % reporting relapse = 100 - % reporting abstinence

[c] Odds of abstinence = n reporting abstinence ÷ n reporting relapse; OR = $\text{odds}_{\text{A-CHESS}} \div \text{odds}_{\text{Control}}$

[d] *P* values calculated using Fisher's exact test

eTable 1. Prevalence of Missing Data Patterns for Heavy Drinking Days by Group[a, b]

	Frequency of Missing Data Patterns, n (%)		*P* values	
Months Data are Missing[c]	Control	A-CHESS	Fisher's Exact Test	Pattern Mixture Model
None	143 (79.9)	136 (80.0)	1.00	.367
4	2 (1.1)	0	.50	NA[e]
12	4 (2.2)	10 (5.9)	.10	.986
4 and 12	2 (1.1)	0	.50	NA[e]
8 and 12	7 (3.9)	10 (5.9)	.46	.336
4, 8, and 12[d]	21 (11.7)	14 (8.2)	.29	NA[f]
Total	179 (100.0)	170 (100.0)		

[a] Data are presented as number (percentage) of randomized patients.
[b] Looking at missing data for all patients rather than by group, 279 (79.9%) of 349 had complete data on heavy drinking days, 16 (4.6%) were missing data for one survey, 19 (5.4%) for 2 surveys, and 35 (10.0%) for all 3 surveys. The percent of missing data on heavy drinking days increased slightly over time, from 39 (11.2%) at month 4 to 52 (14.9%) at month 8 to 68 (19.5%) at month 12.
[c] There were no cases with missing data at month 8 only, or at months 4 and 8 only.
[d] Although some patients provided no survey data, the study had no formal dropouts.
[e] Comparisons between those with and without these missing data patterns would not be meaningful because the pattern was observed in only 2 patients who were in the same treatment group.
[f] A comparison between patients with and without this missing data pattern would not be meaningful because those with this pattern provided no outcome data.

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