

Supplementary Online Content

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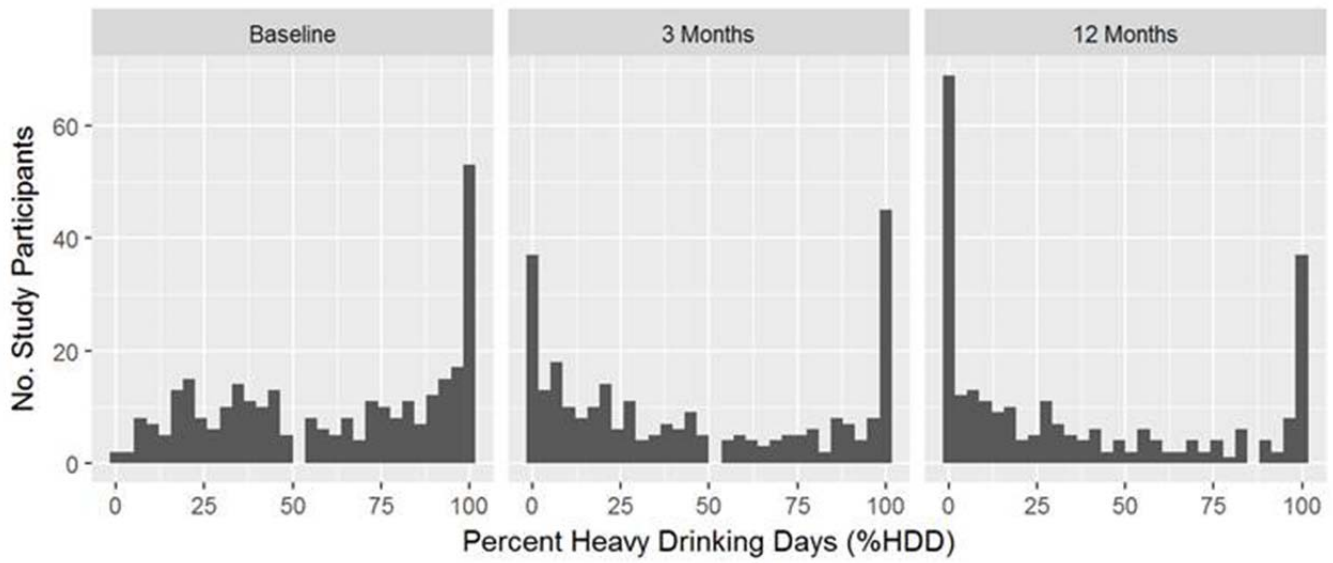
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This supplementary material has been provided by the authors to give readers additional information about their work.

eFigure: Distribution of Heavy Drinking Days in the Past 28 days Outcome at Baseline, 3 Months and 12 Months



eAppendix 1: Description of approach for handling missing data

General approach. We applied multiple imputation¹⁻⁴ using chained equations (MICE), also known as a fully conditional specification (FCS).⁵ This approach assumes that the data are missing at random (MAR), an untestable assumption, but one that is less restrictive than the missing completely at random (MCAR) assumption implicit in conducting a complete case analyses.⁶ eTable1 shows percent missing each outcome. Analyses investigating whether baseline demographics and risk factors differed based on the availability of 12-month follow-up of the primary outcomes found several significant differences (eTable2), indicating that MCAR is unlikely to be satisfied. In our MICE implementation, we imputed continuous and binary outcomes using predictive mean matching (PMM), and ordinal variables using proportional odds models. We imputed 30 datasets, where for each dataset we ran the Gibbs sampler for 25 iterations. Imputations were generated using the mice package⁷ version 2.25 of the R statistical program, Microsoft R Open version 3.3.1. Estimates from outcome regression models estimating treatment effects were combined across the imputed datasets by using Rubin's rules.⁶

Variables included in the imputation model. The following variables were included for each variable with missing values: all of the demographic variables included in Table 1 of the manuscript, as well as continuous age; the outcome value measured at other time points (e.g., to impute the number of heavy drinking days (HDD) at 12 months, we included the baseline value as well as the 3-month value; to impute HDD at 3 months, we included the baseline and 12-month values); each of the covariates used in the outcome model, namely age, treatment group, and the three stratification variables used for randomized treatment assignment (gender, site, and an indicator for alcohol dependence); and interaction terms between treatment group and the stratification variables (to allow for analyses of interactions in separate, follow-up papers).

Additionally, to allow for a richer imputation model, we also considered for inclusion in the model a large number of additional variables, which comprised all of the outcomes variables from manuscript Tables 2 and 3 of the manuscript and eTable3 of the supplemental material, as well as a set of auxiliary variables (listed below). We applied the following procedure to select these additional variables into the imputation model. First, among those participants with complete data, we estimated the univariate association of each candidate predictor with both the outcome itself and with a missingness indicator for that variable. We then included all variables that were associated (defined as $P < 0.05$) with either the outcome or with missingness. To prevent too many variables from being included into the model which could lead to poor imputations, we allowed only 25 additional variables to be included in the model (prioritizing those with the largest associations with the outcome).⁷ Finally, we did not permit drinking outcomes from the same time period to be included in the model imputing a different outcome from that time period, since those variables tended to always be missing on the same person (e.g., for someone who did not complete the timeline follow-back (TLFB) at 12 months, all 12-month drinking outcomes would be missing).

Candidate auxiliary variables for inclusion in the imputation model.

Recruitment-based Measures

- Number of no-shows for enrollment visit
- Number of reschedules of enrollment visit
- Number of days between phone screen and enrollment visit

Patient Characteristics

- AUD severity at baseline (DSM-5 symptom count from Alcohol MINI)⁸
- GAD severity (GAD-7) at baseline, scaled
- Depression Severity (PHQ-9) at baseline, scaled
- PTSD from PCL at baseline, scaled

- Prior alcohol treatment at baseline
- Average drinks per day at baseline, 3 months, and 12 months

Utilization and Diagnoses from Medical Record (in year before randomization, randomization to 3 months, and 3-12 months after randomization)

- Number of hospitalizations
- Number of ED visits
- Number of VA inpatient addiction treatment days
- Number of VA outpatient addictions treatment visits
- Number of outpatient mental health visits
- Number of outpatient homeless services
- Use of AUD medications
- AUD medication possession ratio (#Days supply 0-365 days/365 days)
- Diagnosis of AUD
- Diagnosis of major depression
- Diagnosis of PTSD
- Diagnosis of DUD
- Diagnosis of serious mental illness (Diagnosis of Bipolar, Schizophrenia or schizoaffective)
- Physical health comorbidity (diabetes, heart failure, etc)

Follow-up Measures

- Number of call attempts at 3 months and 12 months
- Length of interview at 3 months (minutes)
- Confirmation of alternate contact info at 3 months
- Number of days between randomization and 3 month survey completion, 12 month survey completion, and 12 month lab completion

eAppendix 2. Methods for Comparing Follow-up EHR AUDIT-Cs in the “No Contact” and “Potentially Recruited” Groups of Men

Prior research has shown that AUDIT-C scores in VAs EHR are much lower than AUDIT-C scores from confidential surveys of the same patients.⁹ Nevertheless, AUDIT-Cs collected as part of routine medical care in the VA are strongly associated with a biomarker of average consumption and have strong predictive validity.¹⁰ Therefore they were used to assess whether the many steps in recruitment,¹¹ could have resulted in decreased drinking by “Potentially Recruited” men, compared to those who were randomized to the No Contact Group.

A total of 4476 men and 520 women were potentially eligible for recruitment based on an EHR screen (total 4,996), and 1110 of the men were randomized to No Contact Group, leaving 3,366 potentially recruited men (Figure 1). Of the 3,366 potentially recruited men, 2,779 (82.6%) had one or more follow-up AUDIT-Cs within 24 months after sampling (mean=1.56). Among the 1110 men in the no contact group, 927 (83.5%) had one or more AUDIT-C in their EHR in the following 24 months (mean=1.51). In terms of whether or not a follow-up AUDIT-C occurred, there was no difference between the two groups ($p=0.219$).

We found no difference in mean AUDIT-C scores comparing the no contact group to the potentially recruited men ($p=0.40$) using all AUDIT-C scores in the months 1-24 following randomization and generalized estimating equations (GEE) linear regression to account for clustering of repeated measures from the same individual,¹² and adjusting for baseline AUDIT-C score, number of days between baseline and follow-up AUDIT-C, and age at baseline.

eTable 1: Summary of missing data

Table (main text)	Variable	Follow-up	Missingness, n (%)						P-value ^a
			Total (N=304) No., %		Control (N=154) No., %		Intervention (N=150) No., %		
2	12-step involvement	12 months	46	(15.1)	20	(13.0)	26	(17.3)	0.34
2	Sought help for drinking	12 months	47	(15.5)	20	(13.0)	27	(18.0)	0.27
3	Percentage of heavy drinking days	3 months	31	(10.2)	13	(8.4)	18	(12.0)	0.35
3	Percentage of heavy drinking days	12 months	48	(15.8)	21	(13.6)	27	(18.0)	0.35
3	Good drinking outcome	3 months	30	(9.9)	14	(9.1)	16	(10.7)	0.70
3	Good drinking outcome	12 months	46	(15.1)	20	(13.0)	26	(17.3)	0.34
3	Abstinent	3 months	31	(10.2)	13	(8.4)	18	(12.0)	0.35
3	Abstinent	12 months	48	(15.8)	21	(13.6)	27	(18.0)	0.35
3	No heavy drinking days	3 months	31	(10.2)	13	(8.4)	18	(12.0)	0.35
3	No heavy drinking days	12 months	48	(15.8)	21	(13.6)	27	(18.0)	0.35
3	Below weekly limits	3 months	31	(10.2)	13	(8.4)	18	(12.0)	0.35
3	Below weekly limits	12 months	48	(15.8)	21	(13.6)	27	(18.0)	0.35
3	AUDIT-C [0-12]	12 months	34	(11.2)	14	(9.1)	20	(13.3)	0.28
3	AUDIT [0-40]	12 months	34	(11.2)	14	(9.1)	20	(13.3)	0.28
3	Percentage of days abstinent	3 months	31	(10.2)	13	(8.4)	18	(12.0)	0.35
3	Percentage of days abstinent	12 months	48	(15.8)	21	(13.6)	27	(18.0)	0.35
3	SIP score [0-45]	3 months	30	(9.9)	14	(9.1)	16	(10.7)	0.70
3	SIP score [0-45]	12 months	46	(15.1)	20	(13.0)	26	(17.3)	0.34
3	Overall readiness [1-10]	3 months	31	(10.2)	14	(9.1)	17	(11.3)	0.57
3	Overall readiness [1-10]	12 months	47	(15.5)	21	(13.6)	26	(17.3)	0.43
3	Importance [1-10]	3 months	30	(9.9)	14	(9.1)	16	(10.7)	0.70
3	Importance [1-10]	12 months	47	(15.5)	21	(13.6)	26	(17.3)	0.43
3	Confidence [1-10]	3 months	30	(9.9)	14	(9.1)	16	(10.7)	0.70
3	Confidence [1-10]	12 months	48	(15.8)	22	(14.3)	26	(17.3)	0.53
3	SF-12 question 1, general health status	3 months	28	(9.2)	13	(8.4)	15	(10.0)	0.69
3	SF-12 question 1, general health status	12 months	46	(15.1)	20	(13.0)	26	(17.3)	0.34
S4	GGT marker (log-transformed)	12 months	58	(19.1)	26	(16.9)	32	(21.3)	0.38
S4	CDT marker (log-transformed)	baseline	8	(2.6)	3	(1.9)	5	(3.3)	0.50
S4	CDT marker (log-transformed)	12 months	68	(22.4)	31	(20.1)	37	(24.7)	0.41
S4	MCV marker	baseline	1	(0.3)	1	(0.6)	0	(0.0)	1.0
S4	MCV marker	12 months	48	(15.8)	23	(14.9)	25	(16.7)	0.75

^a P-values from Fisher's exact test for a difference in the percentage missing comparing the intervention to the control arm

eTable 2: Association of baseline covariates with missingness of primary outcomes

Variable	Percentage of heavy drinking days (12 months)				Good drinking outcome (12 months)					
	Missing (n = 48) No., %		Not missing (n = 256) No., %		P- value ^a	Missing (n = 46) No., %		Not missing (n = 258) No., %		P- value ^a
Male	38	(79.2)	237	(92.6)	0.01	36	(78.3)	239	(92.6)	< 0.01
Age, years					0.01					0.02
21-34	11	(22.9)	43	(16.8)		11	(23.9)	43	(16.7)	
35-49	15	(31.2)	50	(19.5)		14	(30.4)	51	(19.8)	
50-64	20	(41.7)	111	(43.4)		19	(41.3)	112	(43.4)	
65+	2	(4.2)	52	(20.3)		2	(4.3)	52	(20.2)	
Patient-reported race					< 0.01					< 0.01
Native American	3	(6.2)	22	(8.6)		2	(4.3)	23	(8.9)	
Asian	1	(2.1)	1	(0.4)		1	(2.2)	1	(0.4)	
Native Hawaiian/PI	0	(0.0)	5	(2.0)		0	(0.0)	5	(1.9)	
Black	11	(22.9)	28	(10.9)		10	(21.7)	29	(11.2)	
White	24	(50.0)	182	(71.1)		24	(52.2)	182	(70.5)	
Bi/multi-racial	6	(12.5)	16	(6.2)		6	(13.0)	16	(6.2)	
Other	3	(6.2)	2	(0.8)		3	(6.5)	2	(0.8)	
Hispanic	7	(14.6)	14	(5.5)	0.03	6	(13.0)	15	(5.8)	0.11
Marital status					0.77					0.66
Divorced/Separated	18	(37.5)	86	(33.6)		17	(37.0)	87	(33.7)	
Refused/Unknown	0	(0.0)	1	(0.4)		0	(0.0)	1	(0.4)	
Never Married	7	(14.6)	49	(19.1)		6	(13.0)	50	(19.4)	
Married/Partnered	23	(47.9)	113	(44.1)		23	(50.0)	113	(43.8)	
Widowed	0	(0.0)	7	(2.7)		0	(0.0)	7	(2.7)	
Education					0.58					0.47
Less than or some high school	3	(6.2)	9	(3.5)		3	(6.5)	9	(3.5)	
High school grad or GED	8	(16.7)	45	(17.6)		7	(15.2)	46	(17.8)	
Some college/tech school	24	(50.0)	146	(57.0)		23	(50.0)	147	(57.0)	
College or post graduate	13	(27.1)	56	(21.9)		13	(28.3)	56	(21.7)	
Income					1.0					0.97
<\$15,000	7	(14.6)	42	(16.4)		6	(13.0)	43	(16.7)	
\$15,000-29,999	10	(20.8)	52	(20.3)		10	(21.7)	52	(20.2)	
\$30,000-59,999	16	(33.3)	80	(31.2)		15	(32.6)	81	(31.4)	
>=\$60,000	15	(31.2)	80	(31.2)		15	(32.6)	80	(31.0)	
Refuse/unknown	0	(0.0)	2	(0.8)		0	(0.0)	2	(0.8)	
Current Smoker	28	(58.3)	106	(41.4)	0.04	26	(56.5)	108	(41.9)	0.08
PHQ-9 >=10	25	(52.1)	113	(44.1)	0.35	23	(50.0)	115	(44.6)	0.52
PHQ-9 Question #9:					0.6					0.72
No	42	(87.5)	211	(82.4)		40	(87.0)	213	(82.6)	
Yes	6	(12.5)	44	(17.2)		6	(13.0)	44	(17.1)	
Refused	0	(0.0)	1	(0.4)		0	(0.0)	1	(0.4)	
GAD-7 >= 10	23	(47.9)	69	(27.0)	< 0.01	21	(45.7)	71	(27.5)	0.02
PCL-C DSM-IV past month PTSD					0.02					0.03
No	20	(41.7)	155	(60.5)		20	(43.5)	155	(60.1)	
Yes	28	(58.3)	97	(37.9)		26	(56.5)	99	(38.4)	
Missing	0	(0.0)	4	(1.6)		0	(0.0)	4	(1.6)	

Panic disorder, current	9	(18.8)	20	(7.8)	0.03	8	(17.4)	21	(8.1)	0.06
Alcohol Use Disorder, past year	41	(85.4)	182	(71.1)	0.05	39	(84.8)	184	(71.3)	0.07
Drug Use Disorder (Any), past year	8	(16.7)	49	(19.1)	0.84	7	(15.2)	50	(19.4)	0.68
Alcohol Dependent	36	(75.0)	144	(56.2)	0.02	34	(73.9)	146	(56.6)	0.03

^a P-values test for a difference in distribution across missingness status, based on either Fisher's exact test (variables with 2-3 categories) or analysis of variance (variables with ≥ 4 categories)

^b SI or thoughts of hurting self (Any in the past two weeks)

eTable 3: Comparison of treatment effect estimates from multiple imputation to those from complete case analysis

Outcome	Multiple imputation		Complete case analysis			
	Estimate (95% CI)	P value	Estimate (95% CI)	P value		
12 months						
Percentage of heavy drinking days, N, OR	1.2	(0.78, 1.8)	0.44	1.2	(0.79, 1.7)	0.43
Good drinking outcome, N, OR	0.72	(0.38, 1.4)	0.32	0.68	(0.35, 1.3)	0.27
Abstinent, N, OR	0.64	(0.29, 1.4)	0.26	0.75	(0.31, 1.8)	0.51
No heavy drinking days, N, OR	0.98	(0.55, 1.7)	0.95	0.99	(0.55, 1.8)	0.98
Below weekly limits, N, OR	0.65	(0.35, 1.2)	0.16	0.65	(0.35, 1.2)	0.18
AUDIT-C [0-12], N, Δ	-0.49	(-1.1, 0.1)	0.1	-0.45	(-1.1, 0.16)	0.15
AUDIT [0-40], N, Δ	-0.82	(-2.2, 0.54)	0.24	-0.85	(-2.2, 0.51)	0.22
Percentage of days abstinent, N, OR	0.65	(0.45, 0.96)	0.03	0.69	(0.47, 1)	0.05
SIP score [0-45], N, Δ	-0.3	(-1.9, 1.3)	0.71	-0.33	(-1.7, 1.0)	0.63
Overall readiness [1-10], N, Δ	-0.07	(-0.81, 0.66)	0.84	0.03	(-0.65, 0.71)	0.93
Importance [1-10], N, Δ	0	(-0.71, 0.71)	1	0.11	(-0.61, 0.82)	0.77
Confidence [1-10], N, Δ	-0.34	(-1, 0.32)	0.31	-0.32	(-0.97, 0.34)	0.34
GGT marker (log-transformed), N, Δ	0.05	(-0.11, 0.21)	0.51	0.06	(-0.11, 0.22)	0.51
CDT marker (log-transformed), N, Δ	-0.02	(-0.14, 0.09)	0.69	0.02	(-0.09, 0.12)	0.78
MCV marker, N, Δ	0.39	(-0.38, 1.2)	0.32	0.4	(-0.24, 1.1)	0.22
SF-12 question 1, general health status , N, OR	1.8	(1.1, 2.9)	0.02	1.8	(1.1, 2.8)	0.02
Any hospitalizations, N, OR	0.65	(0.23, 1.8)	0.41	0.65	(0.23, 1.8)	0.41
Days hospitalized, N, RR	0.35	(0.12, 1)	0.06	0.35	(0.12, 1.0)	0.06
Any medication use, N, OR	6.3	(3.4, 11.8)	< 0.0001	6.3	(3.4, 11.8)	< 0.0001
Any medication refill, N, OR	4.9	(2.6, 9.2)	< 0.0001	4.9	(2.6, 9.2)	< 0.0001
VA additions treatment, N, OR	0.85	(0.45, 1.6)	0.6	0.85	(0.45, 1.6)	0.6
12-step involvement, N, OR	0.73	(0.34, 1.6)	0.41	0.73	(0.34, 1.6)	0.42
Any alcohol-related care aside from CHOICE care, N, OR	2.4	(1.3, 4.3)	0.01	2.4	(1.3, 4.3)	0.01
Lab monitoring, N, OR	6.8	(1.8, 25.9)	0.01	6.8	(1.8, 25.9)	0.01
Primary care, N, RR	1.1	(0.88, 1.3)	0.44	1.1	(0.88, 1.3)	0.44
Mental health, N, RR	0.56	(0.36, 0.88)	0.01	0.56	(0.36, 0.88)	0.01
Integrated mental health in primary care, N, RR	0.9	(0.49, 1.7)	0.73	0.9	(0.49, 1.7)	0.73
Total outpatient visits, N, RR	0.89	(0.74, 1.1)	0.19	0.89	(0.74, 1.1)	0.19
Average number of drinks per day, N, Δ	0.33	(-0.63, 1.3)	0.5	0.38	(-0.59, 1.4)	0.44
3 months						
Percentage of heavy drinking days, N, OR	1.0	(0.75, 1.4)	0.86	1	(0.78, 1.4)	0.78
Good drinking outcome, N, OR	0.63	(0.2, 2)	0.42	0.48	(0.16, 1.5)	0.21
Abstinent, N, OR	0.31	(0.06, 1.5)	0.15	0.24	(0.05, 1.2)	0.08
No heavy drinking days, N, OR	0.9	(0.43, 1.9)	0.79	0.94	(0.46, 1.9)	0.86
Below weekly limits, N, OR	0.51	(0.23, 1.2)	0.11	0.48	(0.21, 1.1)	0.08
Percentage of days abstinent, N, OR	0.72	(0.54, 0.96)	0.02	0.72	(0.55, 0.96)	0.02
SIP score [0-45], N, Δ	0.65	(-0.77, 2.1)	0.37	0.42	(-0.95, 1.8)	0.55

Overall readiness [1-10], N, Δ	-0.01	(-0.62, 0.59)	0.96	0	(-0.58, 0.57)	0.99
Importance [1-10], N, Δ	0.42	(-0.05, 0.9)	0.08	0.51	(0.06, 0.97)	0.03
Confidence [1-10], N, Δ	-0.21	(-0.79, 0.37)	0.47	-0.23	(-0.78, 0.32)	0.41
SF-12 question 1, general health status , N, OR	1.4	(0.85, 2.2)	0.2	1.38	(0.84, 2.3)	0.21
Any hospitalizations, N, OR	0.44	(0.08, 2.5)	0.35	0.44	(0.08, 2.5)	0.35
Days hospitalized, N, RR	0.25	(0.04, 1.4)	0.11	0.25	(0.04, 1.4)	0.11
Any medication use, N, OR	3.6	(1.5, 8.3)	0.01	3.6	(1.5, 8.3)	0.01
Any medication refill, N, OR	3.9	(1.3, 11.4)	0.01	3.9	(1.3, 11.4)	0.01
VA additions treatment, N, OR	0.84	(0.28, 2.5)	0.75	0.84	(0.28, 2.5)	0.75
Any alcohol-related care aside from CHOICE care, N, OR	2.7	(1.3, 5.3)	0.01	2.7	(1.3, 5.3)	0.01
Primary care visits, N, RR	1.1	(0.81, 1.5)	0.51	1.1	(0.8, 1.5)	0.51
Mental health visits, N, RR	0.81	(0.49, 1.3)	0.4	0.81	(0.49, 1.3)	0.4
Integrated mental health in primary care visits, N, RR	1.2	(0.63, 2.1)	0.63	1.2	(0.63, 2.1)	0.63
Total outpatient visits, N, RR	0.96	(0.79, 1.2)	0.72	0.96	(0.79, 1.2)	0.72
Average number of drinks per day, N, Δ	0.32	(-0.43, 1.1)	0.4	0.43	(-0.25, 1.1)	0.21

Legend.

Abbreviations. PC, primary care; mh , mental health; PCMH, integrated primary care, mental health; total outpatient, total outpatient visits; M, mean; SD, standard deviation; AUDIT-C, Alcohol Use Disorders Identification Test, consumption questionnaire (0-12 points); AUDIT, Alcohol Use Disorders Identification Test (0-40 points); RR, relative risk; Δ, change from baseline; GGT, Gamma glutamyl transferase; CDT, carbohydrate deficient transferase; MCV, mean cell volume

eTable4: Secondary Outcomes at Three and Twelve Months

Secondary Outcomes	Baseline ^a				3 Months ^b				12 Months ^c				Comparison of Usual Care and NCM Groups ^d					
	UC		NCM		UC		NCM		UC		NCM		3 Months		12 Months			
													Estimate (95% CI)	P value	Estimate (95% CI)	P value		
PC visits, m (SD)	3.3	(3.1)	3.5	(3.0)	0.8	(1.2)	0.9	(1.4)	3.4	(4.0)	3.6	(4.1)	1.1	(0.8, 1.5)	0.51	1.1	(0.9, 1.3)	0.44
MH visits, m (SD)	2.3	(7.5)	2.7	(10.0)	0.7	(2.3)	0.8	(2.6)	2.9	(9.3)	2.3	(7.3)	0.8	(0.5, 1.3)	0.40	0.6	(0.4, 0.9)	0.01
PCMH visits, m (SD)	1.0	(2.6)	0.6	(1.6)	0.3	(1.1)	0.3	(0.7)	1.0	(3.7)	0.7	(2.0)	1.2	(0.6, 2.1)	0.63	0.9	(0.5, 1.6)	0.73
Total outpatient, m (SD)	13.1	(15.9)	14.5	(18.2)	4.6	(5.2)	4.6	(5.2)	17.2	(19.9)	16.2	(18.8)	1.0	(0.8, 1.2)	0.72	0.9	(0.7, 1.1)	0.19
AUDIT-C, ^e m (SD), Δ	9.2	(1.6)	9.2	(1.6)					7.7	(2.6)	7.3	(2.9)				- 0.49	(-1.09, 0.1)	0.10
AUDIT, ^e m (SD), Δ	19	(6.8)	19	(6.4)					15	(7.5)	13	(7.6)				- 0.82	(-2.18, 0.54)	0.24
GGT, ^f median (IQR), ^f Δ	3.7	(3.3, 4.4)	3.7	(3.4, 4.6)					3.7	(3.2, 4.3)	3.7	(3.2, 4.9)				0.05	(-0.11, 0.21)	0.51
CDT, ^f median (IQR), ^f Δ	0.53	(0.26, 0.88)	0.59	(0.26, 1.1)					0.47	(0.26, 0.88)	0.53	(0.26, 1.0)				- 0.02	(-0.14, 0.09)	0.69
MCV ^f median (IQR), Δ	92	(90, 98)	95	(92, 99)					92	(89, 96)	93	(90, 97)				0.39	(-0.38, 1.15)	0.32

Legend.

Abbreviations. PC, primary care; mh , mental health; PCMH, integrated primary care, mental health; total outpatient, total outpatient visits; M, mean; SD, standard deviation; AUDIT-C, Alcohol Use Disorders Identification Test, consumption questionnaire (0-12 points); AUDIT, Alcohol Use Disorders Identification Test (0-40 points); RR, relative risk; Δ, change from baseline; GGT. Gamma glutamyl transferase; CDT, carbohydrate deficient transferase; MCV, mean cell volume

^a Baseline measures assessed past year

^b Three month assessments evaluated past 3 months

^c 12 month assessments evaluated past year

^d All models were adjusted for the stratification variables (sex, alcohol dependence, site), baseline age, and baseline value of the outcome.

- e. AUDIT-C has a past year timeframe so was only collected at 12 months.
- f. Laboratory biomarkers were also only collected on all patients at baseline and 12 months.

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