

Efficacy and comparative effectiveness of telephone and smartphone remote continuing care interventions for alcohol use disorder: a randomized controlled trial

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Abstract

Background and Aims: Management of alcohol use disorder (AUD) could be enhanced by effective remote treatments. This study tested whether supplementing intensive outpatient programs (IOPs) with continuing care delivered via (1) telephone, (2) smartphone or (3) their combination improves outcomes relative to (4) IOP only. Continuing care conditions were also compared.

Design: Randomized controlled trial of four groups with 3-, 6-, 9-, 12- and 18-month follow-ups.

Setting: University research center in Philadelphia, PA, USA.

Participants: Participants ($n = 262$) met DSM-V criteria for AUD, were largely male (71%) and African American (82%).

Interventions and Comparator: Telephone monitoring and counseling (TMC; $n = 59$), addiction comprehensive health enhancement support system (ACHESS; $n = 68$) and TMC + ACHESS ($n = 70$) provided for 12 months. The control condition received IOP only (TAU; $n = 65$).

Measurement: The primary outcome was percentage of days heavy drinking (PDHD) in months 1–12. Secondary outcomes were any drinking, any drug use, drinking consequences and quality of life.

Findings: Mean PDHD in months 1–12 was 10.29 in TAU, 5.41 in TMC, 6.80 in ACHESS and 5.99 in TMC + ACHESS. PDHD was lower in TMC [Cohen's $d = 0.35$, $P = 0.018$, 95% confidence interval (CI) = (-1.42, -0.20)], ACHESS [$d = 0.31$, $P = 0.031$, 95% CI = (-1.27, -0.06)] and TMC + ACHESS [$d = 0.36$, $P = 0.009$, 95% CI = (-1.40, -0.20)] than in TAU. Differences between TMC + ACHESS, TMC and ACHESS were small ($d \leq 0.06$) and non-significant. Findings were inconclusive as to whether or not the treatment conditions differed on PDHD at 18 months. A significant effect was obtained on any drinking, which was higher in months 1–12 in TAU than in TMC [odds ratio (OR) = 3.02, standard error (SE) = 0.43, 95% CI = (1.30, 6.99), $P = 0.01$] and TMC + ACHESS [OR = 2.43, SE = 0.39, 95% CI = (1.12, 5.27), $P = 0.025$]. No other significant effects were obtained on other secondary outcomes during or after treatment.

Conclusions: A telephone-delivered intervention and a smartphone-delivered intervention, alone and in combination, provided effective remote continuing care for alcohol use disorder. The combination of both interventions was not superior to either alone and effects did not persist post-treatment.

KEYWORDS

Alcohol use disorder, continuing care, outcome, smartphone, telephone, treatment

INTRODUCTION

Individuals with alcohol use disorder (AUD) often require continuing care to achieve stable recoveries [1]. One challenge in providing continuing care is that many individuals cannot attend sessions at clinics due to living in rural areas, employment or family responsibilities, lack of transportation, illness or disabilities. Moreover, major events such as the COVID 19 pandemic can preclude clinic visits. Therefore, there is a need for remote interventions that provide effective follow-up care for individuals with AUD [2–5]. However, relatively little research has focused upon remote delivery of this phase of care, and no study has directly compared different remote interventions [6].

Two promising remote continuing care interventions for AUD are telephone monitoring and counseling (TMC) and the addiction comprehensive health enhancement support system (ACHESS), a smartphone program. TMC combines measurement-based care with elements of cognitive behavioral therapy (CBT) [7,8], whereas ACHES provides recovery support services with minimal monitoring by a care team [9]. The present study extends prior work by determining whether adding TMC, ACHES or an integrated combination of both interventions to intensive outpatient programs (IOPs) improves outcomes for AUD. Moreover, the study examines whether TMC and ACHES differ, and whether the combination intervention is superior to the individual interventions.

Telephone continuing care

In IOP completers, TMC produced better alcohol use outcomes than clinic-based group counseling and relapse prevention continuing care [7]. Adding TMC while patients were attending IOP produced significantly less alcohol use than IOP alone during the 18-month intervention, but not during a 6-month post-treatment follow-up [8]. TMC is more effective for poorer prognosis patients, such as those who fail to achieve abstinence early in treatment, have poor social support or have low motivation [10–12].

Smartphone-based recovery support

Computer- and smartphone-delivered interventions for AUD fall into two categories: digitized versions of existing interventions such as CBT and packages that include a variety of components and tools

thought to provide support and reduce risk of relapse [13]. ACHES, an example of this latter category, is a smartphone system that offers access to 12 components tailored to meet patients' recovery needs, with minimal monitoring by clinical staff [9].

In a controlled trial, patients with AUD who completed residential treatment were randomized to receive ACHES for 8 months or standard continuing care. Patients receiving ACHES reported 49% fewer risky drinking days at 4-, 8- and 12-month follow-ups. Rates of alcohol abstinence were higher in ACHES than in treatment as usual (TAU) at 8 and 12 months [9]. In another study, ACHES nearly doubled retention for women in treatment [14]. In a review that identified studies of six smartphone apps designed to reduce alcohol use, ACHES was one of only two interventions that demonstrated efficacy [15].

Integration of counselor-delivered and smartphone recovery supports

Smartphone technology can bridge periods between continuing care sessions. It provides recovery support during the evenings and at weekends when counselors are often unavailable [16–20]. In a review of studies where smartphones were added to psychotherapy for behavioral disorders [21], effects favoring the smartphone interventions were in the moderate-to-large range. Effective interventions featured better integration of telephone technology with psychotherapy, smartphone protocols that supported psychotherapy goals and face-to-face introductions to the program [21]. An important challenge for the alcohol treatment field is to determine how best to integrate smartphone application (app) recovery supports and counselor-delivered continuing care. The combination of two remote interventions with complementary features, such as TMC and ACHES, could be a particularly effective package.

Study hypotheses

TMC, ACHES and TMC + ACHES were predicted to be superior to standard care (i.e. IOP plus clinic-based continuing care only) on the primary outcome, frequency of heavy drinking days during the 12-month treatment period. Comparative effectiveness analyses examined differences between TMC and ACHES and between TMC + ACHES and TMC and ACHES. Secondary outcomes examined were any drinking, any drug use, negative consequences of alcohol

use and quality of life. A biological measure of heavy drinking [disialo carbohydrate-deficient transferrin (%dCDT)] was obtained to validate self-reports of alcohol use. Outcomes at an 18-month follow-up were also examined in secondary analyses.

METHODS

Design

The study had a four-group design in which treatments were compared during the 12-month treatment phase and at post-treatment follow-up (18 months post-baseline). Follow-ups were at 3, 6, 9, 12 and 18 months. The trial protocol was registered at <https://clinicaltrials.gov/ct2/show/NCT02681406?id=NCT02681406&draw=2&rank=1>, and published elsewhere [22].

Participants were randomized to either TMC ($n = 59$), ACHES ($n = 68$), TMC + ACHES ($n = 70$) or TAU ($n = 65$). The allocation sequence was provided by SAS PROC PLAN, blocking on groups of 16. Randomization was stratified by site, gender and co-occurring drug use. The latter two factors were included because these factors have often predicted outcome and differential treatment response in our prior studies, as well as other studies of AUD treatment. K.G.L., the study statistician, provided the random sequences, and the allocations by other study staff. Although efforts were made to blind research personnel conducting follow-up assessments to treatment condition, it was ultimately not possible to do so. Most participants at some point during the lengthy treatment phase asked research staff questions during a follow-up about the intervention they were receiving or equipment provided (e.g. smartphone, data plan, telephone), and it was therefore not feasible to maintain complete blinding to condition.

Participants

Participants were 262 adults recruited from four publicly funded IOPs in Philadelphia. Criteria for participation were: DSM-V diagnosis of current, moderate to severe AUD; completed 3 weeks of IOP; aged 18–75 years; no current psychotic disorder or dementia; no acute medical problem requiring inpatient treatment; and not receiving other addiction treatment. Participants had to provide the name, verified telephone number and address of two or more contacts willing to provide participant locator information to aid in follow-up; and be functionally literate.

Of 634 patients screened, 269 were eligible and were enrolled (seven pilots who were not included in the analyses and 262 randomized participants) (see Figure 1). Primary reasons for failure to enter the study were: not reached after initial screening (132 of 365 not eligible, 36%); no show for scheduled baseline assessment and unable/unwilling to re-schedule (121, 33%); no current moderate or severe AUD (58, 16%); and in treatment longer than 6 weeks (36, 10%).

Participants were aged, on average, 46.9 [standard deviation (SD) = 7.4] years, with 11.6 (SD = 1.8) years of education. The majority were male (71%), African American (82%) and never married (67%). Current co-occurring disorders included cocaine (39%), anxiety (35.0%) and major depression (26%). Participants used alcohol on 45.0% (SD = 30.7) of the days in the 3 months prior to baseline (i.e. 39.6 days, SD = 25.8), which included 3–4 weeks of IOP (see Table 1).

Interested patients were referred to research technicians, who obtained informed consent to collect eligibility screening information. Patients were given appointments for the baseline assessment after 3 weeks of IOP. Patients who chose to not participate in the study continued to receive TAU. At the baseline assessment, patients signed a second informed consent after passing an informed consent quiz that demonstrated an understanding of the study. Patients then completed the remainder of the baseline assessments and were randomly assigned to one of the four treatment conditions [22].

Interventions

All participants received IOP, which provided 9 hours of group counseling per week for up to 3 months, plus up to 3 months of weekly continuing care. Treatment was based on 12-Step principles. In publicly funded SUD treatment programs in Philadelphia patients often start treatment at the IOP level, due to the chronic nature of their alcohol or drug problems, high rates of psychiatric comorbidity and lack of social support and structure in their lives.

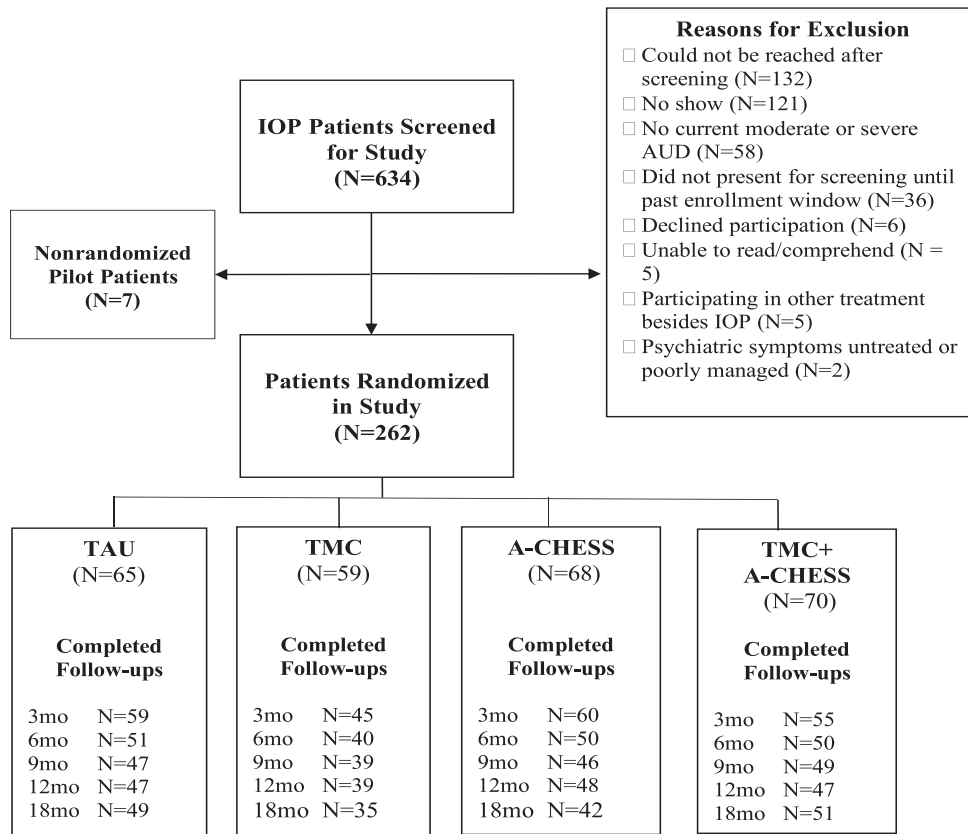
TMC

Participants had one face-to-face session to develop rapport with counselors. Telephone calls occurred weekly in month 1, twice monthly in months 2–4, monthly in months 5–7 and every other month in months 8–12 (i.e. 16 possible calls). Each call lasted 15–30 minutes. At the beginning of each call, participants completed a brief assessment of substance use and risk and protective factors. CBT-based counseling was linked to the results of that assessment and addressed anticipated risky situations. Potential coping strategies and behaviors were rehearsed, and reinforcement of positive behaviors and encouragement for involvement in pro-recovery activities were provided. Participants without reliable access to a telephone were given a mobile phone (i.e. not a smartphone) [22,23].

ACHES

Participants were provided with a smartphone, data plan and ACHES for 12 months. Technicians trained the participants to use ACHES. Protocols programmed into the smartphone defined what happened

FIGURE 1 Consort diagram



Note: Participants who died during the course of the study or asked to withdraw from the study: TAU=3, TMC=5, ACHES=4, TMC+ACHES=1

when participants entered high-risk situations or pressed the panic button to alert supports. Following 7 days of inactivity, ACHES sent a message to participants and alerted ACHES support staff, who encouraged use of ACHES via SMS. Technical support for ACHES operation was available via telephone.

ACHES collected information on confidence for maintaining abstinence (daily) and on 10 risk and protective factors (weekly). When data indicated that relapse risk was high, participants were encouraged via text messages to seek additional support. ACHES offered relaxation exercises, games for distraction, connections to on-line peer support, access to audio and written information on addiction, web links, global positioning system (GPS)-driven information on self-help meetings and inspirational messages [9,22].

TMC + ACHES

TMC and ACHES were provided as described above. In addition, when participants reported worrisome information on ACHES, alerts were sent directly to counselors. A graph with current and past assessment scores could be seen by counselors in the clinician dashboard [22]. These features were intended to facilitate faster outreach to patients when risk increased.

TAU

Participants who completed IOP were eligible to receive weekly clinic-based continuing care for 2–3 months.

Therapists

Eight therapists with 2–25 years of experience treating substance use disorders delivered TMC and TMC + ACHES. Six therapists were employed by three participating IOPs ($n = 56$ patients) and two therapists were Penn staff ($n = 73$ patients). Supervision was provided by the senior-level Penn therapist.

Measures

The structured clinical interview for DSM-IV (SCID) [24] and mini-international neuropsychiatric interview (M.I.N.I.) [25] determined DSM-IV substance use disorders and other psychiatric diagnoses, respectively. The addiction severity index (ASI) [26] obtained demographics, alcohol and drug use and treatment history at baseline. The time-line follow-back (TLFB) [27] assessed frequency of alcohol,

TABLE 1 Characteristics of participants at baseline

Variable	Total (n = 262)		TAU (n = 65)		TMC only (n = 59)		ACHESS only (n = 68)		TMC + ACHESS (n = 70)	
	Mean/%	SD	Mean/%	SD	Mean/%	SD	Mean/%	SD	Mean/%	SD
Age (years)	46.90	10.08	46.70	9.93	46.07	10.15	48.00	9.21	46.72	11.03
Male (%)	70.61	45.64	67.69	47.13	67.80	47.13	77.94	41.77	68.57	46.76
Never married (%)	66.79	47.19	70.77	45.84	64.41	48.29	66.18	47.66	65.71	47.81
African American (%)	82.44	38.12	81.54	39.10	83.05	37.84	86.76	34.14	78.57	41.33
High school education (%)	70.61	45.64	66.15	47.69	72.88	44.84	67.65	47.13	75.71	43.19
Cocaine use disorder (%)	42.25	49.49	38.46	49.03	37.29	48.77	53.85	50.24	39.13	49.16
Cannabis use disorder (%)	29.62	45.74	32.31	47.13	25.42	43.92	29.41	45.90	30.88	46.54
Current major dep dx (%)	26.34	44.13	29.23	45.84	32.20	47.13	19.12	39.62	25.71	44.02
Current anxiety dx (%)	35.50	47.94	33.85	47.69	35.59	48.29	33.82	47.66	38.57	49.03
PHQ-9 total score ^a	11.25	6.84	11.08	5.96	10.76	7.18	10.32	7.09	12.71	6.99
Years regular alcohol use	23.09	11.64	21.43	10.85	22.69	10.62	25.09	11.72	23.03	12.99
Number prior alcohol txs	3.57	4.01	3.85	4.38	2.67	2.46	3.75	3.91	3.90	4.70
TLFB % days drinking ^b	44.00	28.62	41.35	29.40	45.34	28.52	46.36	28.59	46.86	30.45
TLFB % days heavy drinking	38.14	29.00	34.46	29.65	37.84	28.83	42.09	27.97	40.08	30.44
TLFB % days cocaine	10.84	19.21	7.90	16.16	10.90	21.10	15.10	23.63	10.29	17.13
SIP-R total score ^c	11.81	3.75	11.35	3.88	11.47	3.69	11.96	4.00	12.36	3.43
SF-12 MH score ^d	62.93	33.65	57.69	34.21	70.69	31.81	62.50	34.69	61.79	33.17
SF-12 PH score ^d	52.54	22.47	50.58	23.43	53.88	22.73	55.33	19.35	50.54	24.21

Abbreviations: ACHESS, addiction comprehensive health enhancement support system; SD, standard deviation; TAU, treatment as usual; TMC, telephone monitoring and counseling.

^aPatient Health Questionnaire (PHQ). Higher scores indicated greater depression.

^bTime-line follow-back (TLFB). Higher scores indicate more frequent alcohol or drug use.

^cShort Inventory of Problems (SIP). Higher scores indicate more negative consequences for drinking.

^dShort Form (SF) survey Mental Health (MH) and Physical Health (PH). Higher scores indicate better mental or physical health.

heavy alcohol and cocaine use. The reliability and validity of the TLFB has been repeatedly demonstrated [28–30]. The short inventory of problems (SIP) [31] assessed negative consequences of alcohol use. Quality of life was obtained with the Short Form survey (SF-12) [32]. Urine toxicology assessed other drug use (e.g. cocaine, amphetamines, opiates, barbiturates, benzodiazepines and THC). The TLFB, ASI, SIP, SF-12 and urine toxicology were obtained at baseline and 3-, 6-, 9-, 12- and 18-month follow-ups; %dCDT [33] provided a biological measure of heavy drinking during the past few months at baseline and 18 months.

The primary outcome measure was percentage of days of heavy drinking (PDHD; i.e. five or more drinks/day for men, four or more drinks/day for women) during the 12-month treatment phase. PDHD has been identified as the optimal measure of alcohol treatment outcome [34]. Secondary outcomes were: PDHD at 18 months; and any alcohol use within a given follow-up period (yes/no), any drug use within a given follow-up period (yes/no, as determined by self-report measures and urine drug screens), alcohol use related negative consequences (SIP) and quality of life (SF-12) during months 3, 6, 9, 12 and 18 months. These measures were selected to provide a fuller picture of overall substance use severity and health outcome.

Data analyses

TLFB data on PDHD were aggregated into a 3-month pre-treatment baseline period and five 3-month periods post-randomization (months 1–3, 4–6, 7–9, 11–12, 16–18). Urine toxicology and ASI drug use self-reports were obtained at baseline and 3, 6, 9, 12 and 18 months and were combined with TLFB to create a secondary outcome indicating absence or presence of drug use.

For the primary outcome of PDHD during the treatment phase, mixed-effects models were used to compare treatment conditions [35]. PDHD was square-root-transformed because of high levels of positive skewness. All models included the stratification variables (e.g. a four-level categorical variable for site, binary variables for gender and baseline drug use), a four-level categorical variable for treatment group and a centered version of the square-root-transformed baseline PDHD variable as a baseline covariate. Pairwise contrasts were used to compare the treatment conditions, with the primary comparisons of each intervention with TAU unadjusted for multiplicity (i.e. tested at the 5% level) and the other three comparisons tested at adjusted levels ($P < 0.017$).

Secondary outcomes for the treatment phase were analyzed in a similar manner, using linear mixed-effects models for the SIP and

SF12 mental health and physical functioning scales and mixed-effects logistic regression models for the binary responses of any drinking and any drug use. Baseline version of the outcome was included as a covariate, except for any drinking, for which baseline percentage of days drinking was used. Secondary analyses were not adjusted for multiplicity [36].

For the secondary analyses of the outcomes at the 18-month time-point, linear and logistic regression models were used, again with baseline versions of outcomes included as covariates using robust standard errors (SEs). In addition, %dCDT at baseline and 18 months was compared in participants reporting none versus any heavy drinking in the prior month to provide confirmation of self-reported TLFB drinking data.

Missing data in longitudinal studies are classified in three ways [37]: missing completely at random (MCAR), indicating that missing values are statistically independent of any other variables, observed or unobserved; missing at random (MAR), where the missing values may depend upon observed variables (baseline and available longitudinal variables); and not missing at random (NMAR), where missing values may depend on unobserved data. The mixed-effects models described above give valid estimates under MAR, while generalized estimating equation (GEE) models give valid estimates under MCAR. To examine sensitivity of the primary analyses to missing data, GEE models were also used to compare the groups. In addition, a pattern-mixture analysis [37,38] was performed, using time to drop-out as a categorical indicator of missing data pattern to provide results under one type of an NMAR assumption.

To evaluate the sensitivity of the results to random imbalances of the distributions of prognostic variables among the treatment groups, further analyses were performed for the treatment phase. For each outcome, the variables listed in Table 1 were evaluated as predictors and were included as covariates in the mixed-effects models described above if they were significant at the 5% level.

Hedeker *et al.*'s [39] methods were used to determine sample size. Based on previous studies in these populations [7,8,11], we assumed 25% loss to follow-up between baseline and month 18, with approximately equal rates of dropout across the treatment groups and a within-subject correlation of approximately $r = 0.35$. The baseline sample of 262 then provided 80% power at a 5% significance level for an effect size of Cohen's $d = 0.35$ for the primary pairwise comparisons on the three intervention groups to the TAU group.

RESULTS

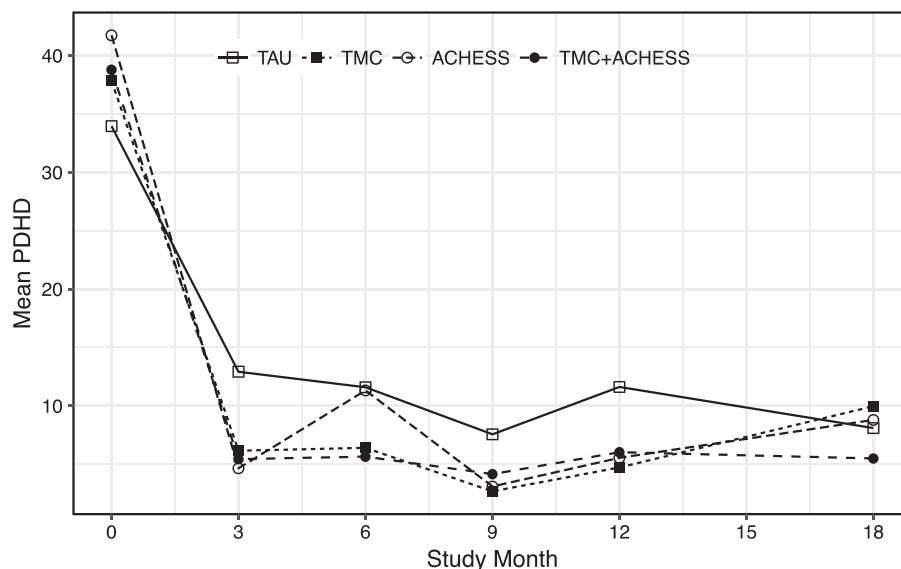
Participation in TMC and ACHES

The mean number of telephone sessions was 8.1 in TMC and 10.7 in TMC + ACHES. In participants who completed the orientation session, means were 10.2 in TMC ($n = 43$) and 11.00 in TMC + ACHES ($n = 60$). In ACHES, the system was used an average of 20 days per month in months 1 and 2 and declined thereafter to approximately 14 days per month. In TMC + ACHES, the system was used 16 days per month in months 1 and 2 and declined thereafter to approximately 10 days per month.

During treatment outcomes

Primary outcome

A total of 771 follow-ups were made at months 3, 6, 9 and 12 (73.57% of the planned 1048 follow-ups). For the four treatment conditions, the average number of follow-ups (out of four) was 3.12 (SD = 1.31) for TAU, 2.76 (SD = 1.61) for TMC, 2.99 (SD = 1.42) for ACHES and 2.98 (SD = 1.44) for TMC + ACHES. An overdispersed



NOTE: SEs at Month 0 range from 3.32 to 3.75, and from 1.32 to 3.76 for the other months

FIGURE 2 Percentage of days heavy drinking (PDHD) in each treatment condition at baseline and 3-, 6-, 9-, 12- and 18-month follow-ups

Poisson regression model showed no significant effect of treatment condition on the number of follow-ups made ($\chi^2_{(3)} = 2.11, P = 0.55$) or significant pairwise differences between the conditions (P -values > 0.18).

Mean PDHD in months 1–12 was 10.29 (SE = 1.79) in TAU, 5.41 (SE = 1.68) in TMC, 6.80 (SE = 1.95) in ACHESS and 5.99 (SE = 1.35) in TMC + ACHESS (see Figure 2, Table 2). Table 3 shows the model-based estimates for pairwise contrasts between the interventions during the 12-month treatment period, together with effect size estimates, under the three sets of missing data assumptions. For the MAR analyses, the group × time interaction was not significant ($F_{(534)} = 0.80,$

$P = 0.50$), so the effects are for treatment pooled over time. There was a significant overall effect of treatment condition on levels of PDHD during the treatment phase ($F_{(3537)} = 2.95, P = 0.03$). PDHD was lower in TMC [$d = 0.35, P = 0.018, 95\%$ confidence interval (CI) = (-1.42, -0.20)], ACHESS [$d = 0.31, P = 0.031, 95\%$ CI = (-1.27, -0.06)] and TMC + ACHESS [$d = 0.36, P = 0.009, 95\%$ CI = (-1.40, -0.20)] than in TAU. There were no significant differences between the three intervention groups during treatment, with effect sizes of $d \leq 0.06$.

In the pattern-mixture mixed-effects model, the interaction between the group and pattern variables was not significant ($F_{(6538)} = 1.18, P = 0.31$), while there was a significant overall effect

TABLE 2 Primary and secondary outcomes at all follow-ups

Response	Group	Month					
		Months 1–12 (mean/SE)	3 (mean/SE)	6 (mean/SE)	9 (mean/SE)	12 (mean/SE)	18 (mean/SE)
Primary							
PDHD ^a	TAU	10.29 (1.79)	12.92 (3.08)	11.59 (2.63)	7.56 (2.47)	11.62 (3.48)	8.10 (2.74)
	TMC	5.41 (1.68)	6.15 (2.16)	6.40 (2.35)	2.68 (1.58)	4.72 (1.74)	9.97 (3.33)
	ACH	6.80 (1.95)	4.65 (1.85)	11.32 (3.31)	3.09 (1.32)	5.55 (1.90)	8.79 (3.76)
	TMC + ACH	5.99 (1.35)	5.43 (1.92)	5.65 (2.22)	4.15 (1.42)	6.03 (2.20)	5.49 (1.79)
Secondary							
Any alcohol ^b	TAU		59.32 (6.45)	56.86 (7.00)	59.35 (7.43)	63.83 (7.08)	51.02 (7.22)
	TMC		37.78 (7.31)	42.50 (7.92)	35.90 (7.78)	46.15 (8.09)	50.00 (8.70)
	ACH		54.24 (6.54)	50.00 (7.14)	43.48 (7.39)	47.92 (7.29)	44.19 (7.66)
	TMC + ACH		43.64 (6.75)	44.00 (7.09)	42.00 (7.05)	53.19 (7.36)	43.14 (7.00)
Drug use ^a	TAU		57.63 (6.49)	58.82 (6.96)	52.17 (7.45)	68.09 (6.87)	65.31 (6.87)
	TMC		51.11 (7.54)	60.00 (7.84)	53.85 (8.09)	61.54 (7.89)	61.76 (8.46)
	ACH		52.54 (6.56)	58.00 (7.05)	60.87 (7.28)	54.17 (7.27)	55.81 (7.56)
	TMC + ACH		45.45 (6.78)	52.00 (7.34)	56.00 (7.09)	44.68 (7.33)	49.02 (7.07)
SIP total ^d	TAU		16.12 (1.95)	13.63 (2.00)	9.91 (1.72)	12.55 (2.01)	12.58 (1.98)
	TMC		13.24 (2.01)	12.45 (2.57)	6.38 (1.83)	10.46 (2.37)	13.00 (2.70)
	ACH		11.95 (1.85)	11.78 (1.95)	11.17 (1.82)	10.04 (1.91)	12.30 (2.27)
	TMC + ACH		11.98 (1.90)	13.04 (2.14)	10.28 (1.89)	12.15 (2.24)	12.69 (2.09)
SF-12 MH ^e	TAU		64.83 (2.73)	62.50 (3.34)	63.59 (3.58)	65.96 (3.26)	67.75 (3.16)
	TMC		59.17 (3.47)	64.38 (3.81)	60.58 (3.66)	61.22 (3.78)	61.43 (4.39)
	ACH		58.69 (2.85)	64.75 (2.74)	62.50 (3.25)	63.80 (3.19)	64.49 (3.33)
	TMC + ACH		60.45 (2.84)	58.00 (3.00)	61.50 (3.59)	60.11 (4.03)	61.76 (3.44)
SF-12 PH ^e	TAU		60.17 (4.65)	58.33 (5.32)	65.22 (4.94)	63.83 (5.26)	65.50 (4.51)
	TMC		67.78 (4.54)	62.50 (6.00)	66.67 (4.80)	64.10 (4.64)	73.57 (4.69)
	ACH		61.44 (4.50)	61.00 (4.75)	62.50 (4.71)	64.58 (4.76)	63.64 (5.17)
	TMC + ACH		56.82 (5.00)	59.50 (5.24)	59.00 (5.48)	57.98 (5.38)	67.65 (4.71)

Abbreviations: ACHESS, addiction comprehensive health enhancement support system; SE, standard error; TAU, treatment as usual; TMC, telephone monitoring and counseling.

^aPercentage of days heavy drinking (≥ 5 drinks/day for men, ≥ 4 drinks/day for women). Primary outcome months 1–12; secondary outcome month 18.

^bPercentage of participants with any alcohol use.

^cPercentage of participants with any indication of use of cocaine, amphetamines, opiates, barbiturates, benzodiazepines or tetrahydrocannabinol (THC) from urine toxicology or self-report (1 = positive, 0 = negative).

^dShort Inventory of Problems (SIP). Higher scores indicate more negative consequences for drinking.

^eShort Form (SF) survey. Higher scores indicate better mental health (MH) or physical health (PH).

TABLE 3 Treatment contrasts on primary outcome: PDHD months 1–12

Contrast	Mixed effects MAR analysis			Pattern mixture NMAR analysis		GEE MCAR analysis	
	Estimate (95% CI)	P-value	Cohen's <i>d</i>	Estimate (95% CI)	P-value	Estimate (CI 95%)	P-value
TAU – TMC	0.78 (0.13, 1.43)	0.018	0.35	0.82 (0.17 1.47)	0.013	0.78 (0.13 1.43)	0.017
TAU – ACHES	0.67 (0.06, 1.28)	0.031	0.31	0.69 (0.08 1.30)	0.027	0.67 (0.04 1.30)	0.038
TAU – TMC + ACH	0.80 (0.19, 1.41)	0.009	0.36	0.83 (0.22 1.44)	0.007	0.80 (0.19 1.41)	0.009
TMC – ACHES	–0.11 (–0.76, 0.54)	0.732	–0.04	–0.14 (–0.79 0.51)	0.676	–0.11 (–0.72 0.50)	0.717
TMC – TMC + ACH	0.02 (–0.63, 0.67)	0.947	0.02	0.01 (–0.64 0.66)	0.977	0.02 (–0.55 0.59)	0.939
ACHES – TMC + ACH	0.13 (–0.48, 0.74)	0.661	0.06	0.15 (–0.46 0.76)	0.631	0.13 (–0.44 0.70)	0.645

Treatment contrast analyses controlled for recruitment site, gender, any drug use at baseline and baseline PDHD.

Abbreviations: ACHES, addiction comprehensive health enhancement support system; CI, confidence interval; GEE, generalized estimating equation; MAR, missing at random; MCAR, missing completely at random; NMAR, not missing at random; PDHD, percentage of days heavy drinking; TAU, treatment as usual; TMC, telephone monitoring and counseling.

for treatment ($F_{(3538)} = 3.14$, $P = 0.02$) and a similar pattern of pairwise contrasts. For the GEE model under an MCAR assumption, the overall treatment effect was not significant ($\chi^2_{(3)} = 7.45$, $P = 0.059$), while the pairwise comparisons again showed the same pattern of significant results observed for the MAR and NMAR analyses. As the results under the three assumptions were very similar, it appears that missing data did not greatly influence the primary treatment comparisons.

Supporting information, Table S5 shows the pairwise comparisons when predictive baseline variables (e.g. years of alcohol use and percentage of days abstinence from alcohol and cocaine use) were included in these analyses. The pattern is similar to that of the main analyses, the only difference being that the ACHES versus TAU comparison is no longer significant ($P = 0.057$ – 0.067 among models).

Secondary outcomes

There was a significant treatment effect on any drinking ($F_{(3538)} = 2.65$, $P = 0.048$), which was higher in TAU than in TMC [odds ratio (OR) = 3.02, SE = 0.43, 95% confidence interval (CI) = (1.30, 6.99), $P = 0.01$] and TMC + ACHES [OR = 2.43, SE = 0.39, 95% CI = (1.12, 5.27), $P = 0.025$], with non-significant results in the same direction for ACHES [OR = 1.90, SE = 0.40, 95% CI = (0.87, 4.14), $P = 0.38$]. There were no significant treatment effects for the overall drug use ($F_{(3538)} = 0.45$, $P = 0.72$), SIP total ($F_{(3537)} = 0.35$, $P = 0.79$), SF-12MH ($F_{(3535)} = 0.79$, $P = 0.50$) or SF-12PH ($F_{(3535)} = 0.88$, $P = 0.45$) measures, and no pairwise differences among treatment levels (see Tables 2 and 4).

Post-treatment secondary outcomes

There were no significant differences between the treatment conditions on PDHD (GEE $\chi^2_{(3)} = 1.86$, $P = 0.60$), any drinking ($\chi^2_{(3)} = 1.72$, $P = 0.63$), any drug use ($\chi^2_{(3)} = 3.00$, $P = 0.39$), SIP ($\chi^2_{(3)} = 0.58$,

$P = 0.90$), SF-12MH ($\chi^2_{(3)} = 3.14$, $P = 0.37$) or SF-12PH ($\chi^2_{(3)} = 0.75$, $P = 0.86$) at 18 months (see Table 2 and pairwise comparisons in Table 4).

Confirmation of self-reported alcohol use data

Participants who reported any heavy drinking in month 18 had higher %dCDT scores than those who reported no heavy drinking in that month [heavy drinking: $n = 34$, mean = 1.97, SD = 1.30 versus no heavy drinking: $n = 79$, mean = 1.40, SD = 0.53, 95% CI = (–0.91, –0.23), $P = 0.001$]. The same pattern was observed at baseline [heavy drinking: $n = 118$, mean = 1.75, SD = 1.28 versus no heavy drinking: $n = 84$, mean = 1.42, SD = 0.81, 95% CI = (–0.64, –0.02), $P = 0.027$]. Therefore, the pattern of results with the %dCDT data support the validity of the TLFB data.

Other analyses

Analyses comparing the two Penn and six IOP counselors found no difference on PDHD ($\chi^2_{(3)} = 0.12$, $P = 0.72$). The treatment conditions did not differ at any follow-up on participation in 12-Step programs (all $P > 0.42$).

DISCUSSION

In the management of AUD it is crucial that effective recovery support services are available that can be provided remotely to individuals who are unable to attend clinic-based care. Effective remote services are even more essential during crises such as the COVID-19 pandemic [2–5]. This study confirmed prior research [7–9] which found that TMC and ACHES improved alcohol use outcomes when added to TAU. In addition, this study was the first to compare these two approaches, and the first to determine whether an integrated

TABLE 4 Treatment contrasts for all secondary outcomes

Outcome	Contrast	Treatment outcomes (months 1–12)			Follow-up outcomes (month 18)		
		Estimate	95% CI	P-value	Estimate	95% CI	P-value
Square-root PDHD ^a	TAU – TMC	-	-	-	-0.32	(-1.46, 0.82)	0.576
	TAU – ACHES	-	-	-	0.16	(-0.86, 1.18)	0.764
	TAU – TMC + ACH	-	-	-	0.37	(-0.55, 1.29)	0.434
	TMC – ACHES	-	-	-	0.48	(-0.66, 1.62)	0.405
	TMC – TMC + ACH	-	-	-	0.69	(-0.33, 1.71)	0.187
	ACHES – TMC + ACH	-	-	-	0.21	(-0.73, 1.15)	0.663
Any drinking ^b	TAU – TMC	1.10	(0.26, 1.94)	0.010	-0.17	(-1.09, 0.75)	0.715
	TAU – ACHES	0.64	(-0.14, 1.42)	0.108	-0.48	(-1.36, 0.40)	0.291
	TAU – TMC + ACH	0.89	(0.13, 1.65)	0.025	-0.48	(-1.34, 0.38)	0.275
	TMC – ACHES	-0.46	(-1.30, 0.38)	0.276	-0.31	(-1.25, 0.63)	0.520
	TMC – TMC + ACH	-0.22	(-1.04, 0.60)	0.607	-0.31	(-1.21, 0.59)	0.500
	ACHES – TMC + ACH	0.25	(-0.51, 1.01)	0.526	-0.00	(-0.88, 0.88)	0.996
Drug use ^c	TAU – TMC	-0.03	(-0.87, 0.81)	0.938	0.23	(-0.75, 1.21)	0.653
	TAU – ACHES	0.20	(-0.58, 0.98)	0.610	-0.44	(-1.36, 0.48)	0.347
	TAU – TMC + ACH	0.38	(-0.40, 1.16)	0.340	-0.48	(-1.34, 0.38)	0.281
	TMC – ACHES	0.24	(-0.58, 1.06)	0.573	-0.67	(-1.69, 0.35)	0.200
	TMC – TMC + ACH	0.42	(-0.40, 1.24)	0.321	-0.70	(-1.66, 0.26)	0.152
	ACHES – TMC + ACH	0.18	(-0.60, 0.96)	0.651	-0.03	(-0.95, 0.89)	0.945
SIP-R total ^d	TAU – TMC	1.82	(-2.16, 5.80)	0.370	-1.37	(-7.49, 4.75)	0.661
	TAU – ACHES	1.59	(-2.13, 5.31)	0.403	1.24	(-4.66, 7.14)	0.681
	TAU – TMC + ACH	1.35	(-2.37, 5.07)	0.478	0.42	(-5.17, 6.01)	0.882
	TMC – ACHES	-0.23	(-4.21, 3.75)	0.910	2.61	(-4.23, 9.45)	0.454
	TMC – TMC + ACH	-0.47	(-4.41, 3.47)	0.816	1.79	(-4.56, 8.14)	0.581
	ACHES – TMC + ACH	-0.24	(-3.96, 3.48)	0.900	-0.82	(-6.94, 5.30)	0.793
SF12 MH ^e	TAU – TMC	4.31	(-1.84, 10.46)	0.170	8.62	(-1.30, 18.54)	0.088
	TAU – ACHES	2.95	(-2.75, 8.65)	0.313	3.84	(-4.90, 12.58)	0.389
	TAU – TMC + ACH	3.58	(-2.10, 9.26)	0.217	5.95	(-3.03, 14.93)	0.194
	TMC – ACHES	-1.36	(-7.48, 4.76)	0.663	-4.78	(-14.72, 5.16)	0.347
	TMC – TMC + ACH	-0.73	(-6.83, 5.37)	0.816	-2.67	(-12.63, 7.29)	0.598
	ACHES – TMC + ACH	0.64	(-5.08, 6.36)	0.827	2.10	(-7.13, 11.33)	0.656
SF12 PH ^e	TAU – TMC	2.93	(-5.95, 11.81)	0.518	-4.04	(-16.68, 8.60)	0.531
	TAU – ACHES	-0.61	(-8.82, 7.60)	0.885	1.62	(-10.10, 13.34)	0.786
	TAU – TMC + ACH	5.45	(-2.74, 13.64)	0.193	-1.72	(-12.52, 9.08)	0.755
	TMC – ACHES	-3.54	(-12.40, 5.32)	0.434	5.67	(-7.72, 19.06)	0.407
	TMC – TMC + ACH	2.51	(-6.25, 11.27)	0.574	2.32	(-9.93, 14.57)	0.710
	ACHES – TMC + ACH	6.05	(-2.14, 14.24)	0.148	-3.35	(-15.09, 8.39)	0.576

Analyses controlled for recruitment site, gender, any drug use at baseline and the baseline version of the outcome variable (except that PDHD was used for any drinking). The two binary outcomes, any drinking and any drug use, have log-odds ratios (LOR) in the estimates column. Abbreviations: ACHES, addiction comprehensive health enhancement support system; CI, confidence interval; PDHD, percentage of days heavy drinking; TAU, treatment as usual; TMC, telephone monitoring and counseling.

^aPercentage of days heavy drinking (≥ 5 drinks/day for men, ≥ 4 drinks/day for women). Primary outcome months 1–12; secondary outcome month 18.

^bPercentage of participants with any alcohol use.

^cPercentage of participants with any indication of use of cocaine, amphetamines, opiates, barbiturates, benzodiazepines or tetrahydrocannabinol (THC) from urine toxicology or self-report (1 = positive, 0 = negative).

^dShort Inventory of Problems (SIP). Higher scores indicate more negative consequences for drinking.

^eShort Form (SF) survey. Higher scores indicate better mental health (MH) or physical health (PH).

package that combined both interventions improved outcomes over either intervention alone. Therefore, the study focused upon both efficacy and comparative effectiveness.

With regard to efficacy, TMC, ACHES and TMC + ACHES produced lower scores on the primary outcome, frequency of heavy drinking days (PDHD) than TAU. An examination of the data from Figure 2 indicates that PDHD increased in TMC and ACHES after the 12-month treatment period. This erosion of treatment effects after TMC ended has been observed in one prior trial [8], but not in others [7,11]. TMC and TMC + ACHES were also superior to TAU on one of the secondary outcomes, any alcohol use, during the treatment phase. However, there were no effects on the other secondary outcome measures either during treatment or at 18 months. With regard to comparative effectiveness, the differences between the three continuing care interventions were small in magnitude ($d \leq 0.06$), and did not approach significance, either during or after treatment. Given these very small effect sizes, the lack of significant differences between the three experimental conditions is probably not due to insufficient power to find clinically meaningful differences.

These findings raise the intriguing possibility that extended continuing care for AUD provided via a smartphone program may be as efficacious as continuing care delivered by counselors via telephone sessions. However, it should be noted that in this and other studies [9] the provision of ACHES has included monitoring by trained personnel of substance use and other data produced by the system, with short messaging system (SMS)-based outreach to users when warranted. Therefore, ACHES is not entirely without a human component. In addition, TMC produced lower rates of any drinking compared to TAU, whereas ACHES did not. The results also raise the question of whether providing TMC or ACHES over longer periods might sustain positive effects.

There are several possible explanations for why TMC + ACHES was not more effective than either intervention alone. Given the efficacy of each intervention, ceiling effects may have been present. Counselors may not have utilized the information provided in the dashboard to speed up responses to participants who were struggling. The information generated by ACHES may not have captured relapse vulnerability, due to missing data or inaccurate reports. Although the interventions presumably have different mechanisms of action, combining them may not have the additive or synergistic effect that was anticipated.

This study had important strengths, including interventions shown to be efficacious in prior research, a strong active control condition, appropriate sample size, well-validated outcome measures, multiple follow-ups over 18 months, biological corroboration of self-reports of alcohol use and analyses demonstrating minimal if any impact of missing data. At the same time, the study had limitations. More than 80% of participants were African American, which is representative of clients in treatment for substance use disorders in publicly funded programs in Philadelphia, USA, but not outside major urban areas. While there is no reason to believe that these effects would not generalize to other IOP patients, different findings might

be obtained in patients who had not attended IOP for several weeks. Significant effects were found only on the heavy drinking primary outcome and one secondary, any drinking, and were moderate in size. However, reductions in heavy drinking days are seen as a key goal of treatment for alcohol use disorder [34,40], and the control condition was strong—a full course of IOP plus standard clinic-based continuing care. Biological measures of drinking outcome were obtained only at the 18-month follow-up. Finally, it was not possible to fully blind the study personnel conducting follow-ups to treatment condition.

CONCLUSION

Adding TMC, ACHES and the combination of TMC and ACHES to intensive outpatient treatment reduced heavy drinking by approximately 50% over 12 months while the interventions were provided, with positive effects deteriorating during the following 6 months in TMC and ACHES but not TMC + ACHES. However, the combined intervention was not more effective than either TMC or ACHES alone.

CLINICAL TRIAL REGISTRATION

Clinicaltrials.gov NCT02681406.

<https://clinicaltrials.gov/ct2/show/NCT02681406?id=NCT02681406&draw=2&rank=1>

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DECLARATION OF INTERESTS

D.H.G. and A.Q. have shareholder interest in CHES Health, a public benefit corporation that disseminates technology-based health-care interventions for patients and family members struggling with addiction. This relationship is extensively managed by the author and the University of Wisconsin–Madison's Conflict of Interest Committee. No other disclosures were reported.

AUTHOR CONTRIBUTIONS

James McKay: Conceptualization; formal analysis; funding acquisition; investigation; methodology; project administration; supervision. **David Gustafson:** Conceptualization; formal analysis; funding acquisition; investigation; methodology; project administration; software; supervision. **Megan Ivey:** Conceptualization; data curation; formal analysis; project administration; supervision. **Klaren Pe-Romashko:** Formal analysis; methodology; project administration; software. **Brenda Curtis:**

Conceptualization; investigation; methodology; project administration; software; supervision. **Tyrone Thomas:** Conceptualization; investigation; methodology; project administration; supervision. **David Oslin:** Conceptualization; investigation; methodology; software. **Daniel Polsky:** Conceptualization; formal analysis; funding acquisition; investigation; methodology; supervision. **Andrew Quanbeck:** Conceptualization; data curation; formal analysis; methodology; project administration; supervision. **Kevin Lynch:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; software.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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