RESEARCH REPORT





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Automated, tailored adaptive mobile messaging to reduce alcohol consumption in help-seeking adults: A randomized controlled trial

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Funding information

National Institute on Alcohol Abuse and Alcoholism, Grant/Award Number: R01AA025058

Abstract

Aims: To test differential outcomes between three 6-month text-messaging interventions to reduce at-risk drinking in help-seeking adults.

Design: A three-arm single-blind randomized controlled trial with 1-, 3-, 6- and 12-month follow-ups.

Setting: United States. A fully remote trial without human contact, with participants recruited primarily via social media outlets.

Participants: Seven hundred and twenty-three adults (mean = 39.9 years, standard deviation = 10.0; 62.5% female) seeking to reduce their drinking were allocated to 6 months of baseline 'tailored statically' messaging (TS; n = 240), 'tailored adaptive' messaging (TA; n = 239) or 'drink tracking' messaging (DT; n = 244).

Interventions: TS consisted of daily text messages to reduce harmful drinking that were tailored to demographics and alcohol use. TA consisted of daily, tailored text messages that were also adapted based on goal achievement and proactive prompts. DT consisted of a weekly assessment for self-reported drinking over the past 7 days.

Measurements: The primary outcome measure was weekly sum of standard drinks (SSD) at 6-month follow-up. Secondary outcome measures included drinks per drinking day (DDD), number of drinking days (NDD) per week and heavy drinking days (HDD) at 1-, 3-, 6- and 12-month follow-ups.

Findings: At 6 months, compared with DT, TA resulted in significant SSD reductions of 16.2 (from 28.7 to 12.5) drinks [adjusted risk ratio (aRR) = 0.80, 95% confidence interval (CI) = 0.71, 0.91] using intent-to-treat analysis. TA also resulted in significant improvements in DDD (aRR = 0.84; 95% CI = 0.77–0.92) and drinking days per week (b = -0.39; 95% CI = -0.67, -0.10), but not HDD compared with DT at 6 months. TA was not significantly different from TS at any time-point, except DDD at 6 months. All groups made improvements in SSD at 12-month follow-up compared with baseline with an average reduction of 12.9 drinks per week across groups.

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that can reduce weekly alcohol consumption in remote help-seeking drinkers over time.

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KEYWORDS

Adaptive, alcohol, clinical trial, digital, personalization, text messaging

INTRODUCTION

Excessive alcohol use is one of the world's most consequential personal and public health issues [1-5]. Individuals who consume alcohol have diverse patterns of use and treatment needs, but most interventions are tailored to a minority of individuals who drink severely and want to abstain [6]. Interventions to reduce alcohol consumption are primarily tailored to individuals with alcohol use disorder (AUD), omitting the majority of individuals who are drinking at risky levels without meeting AUD criteria [7, 8]. In 2019, approximately 5% of adults in the United States aged 21 years and older met criteria for an AUD, whereas more than 30% met criteria for at-risk drinking [8, 9]. Risky drinking cost the United States nearly \$250 billion in 2010 [10].

At-risk drinking refers to when individuals drink above the recommended guidelines for safe drinking [11], without meeting criteria for more severe AUD. Consequently, few at-risk drinkers seek formal care, with only 7% receiving traditional alcohol treatment in a given year [4]. Most individuals with at-risk drinking who pursue treatment seek self-guided moderation programs (e.g. websites and groups) [12]. Despite their short-term efficacy, alcohol reduction websites and mobile applications (apps) have limited long-term engagement [13-15]. Thus, those seeking tools to reduce drinking will need more proactive methods of engagement over time.

Text messaging is the most widely accessible communication medium in the world, with more than 90% of the global population owning a mobile phone and 97% of all mobile phones being equipped with text messaging [9]. There is no digital divide among race, age or other markers of systemic inequality [16] as seen with other communication media, such as mobile apps. There is a small but growing literature on text messaging for reducing excessive drinking [17-22]. A recent meta-analysis of 10 randomized controlled trials found small overall effect sizes in reduced binge drinking and drinks per week, a notable conclusion given that the interventions were brief, scalable and easily conducted [19, 22-30]. In these trials, gains were also largely maintained over time, suggesting potential messaging to produce longer-term successful outcomes.

Given the ease of hyper-personalization when using technologybased interventions, one largely understudied, notable area of examination concerns technology-based interventions that tailor content and timing to personalize care over long periods of time around a larger drink reduction narrative [31-37]. In-person and phone-based stepped-care interventions that adapt their intensity and content over time based on participant needs and outcomes have proven efficacious [38-40], but few studies in any medium have been conducted to understand the effects of tailoring interventions to baseline characteristics versus adaptive tailoring interventions that change based on goals over time. In the current investigation's pilot study, Muench and

colleagues [23] found that different types of daily alcohol reduction messaging over 3 months were significantly better than drink tracking (DT), with the tailored adaptive (TA) intervention resulting in the largest reductions in harmful drinking.

The present study sought to address some of the limitations of prior trials [17-22, 41] by (1) recruiting individuals proactively seeking support on-line, (2) adapting care over time to goal achievement, (3) eliminating human contact and (4) including active comparator intervention and participant blinding, as well as long-term follow-up beyond 3 months. Our primary hypothesis was that TA messaging would produce better drinking outcomes compared to DT at 6-month follow-up.

METHODS

Design

randomized controlled trial, individuals with alcohol misuse received 6 months of one of three mobile messaging interventions. Drinking outcomes were assessed at 1 month (1M), 3 months (3M), 6 months (6M) and 12 months (12M; 6 months post-intervention).

Participants

Individuals concerned about their drinking were recruited (March 2019-February 2021) through social media outlets (e.g. Facebook) and on-line alcohol screening/help-seeking sources (e.g. AlcoholScreening. org). Taglines for advertisements read: 'thinking about your drinking' and 'thinking about cutting down on your drinking?'. Prospective participants were directed to text MODERATE to 55 753 or visit the study website for a screening survey (described below). IP blocking ensured that participants could only complete the survey once from any device. Advertising costs were approximately \$70 000 over the course of the study. This budget was larger than expected to recruit a more demographically diverse sample than our previous study [28].

To be eligible for the study, individuals must have (1) reported consuming at least 13 and 15 standard drinks per week (for women and men, respectively), which was later modified to nine and 11 standard drinks to increase enrollment (67 participants enrolled based on original criteria); (2) intended to reduce their drinking to healthier levels; (3) been aged 21-75 years (as 21 is the legal drinking age in the United States and > 75 years of age represents a demographic of drinkers who may be at increased risk of alcohol-related health consequences); (4) had an active e-mail address; (5) owned a mobile phone, willing to receive/respond to texts; (6) been fluent in English; and

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(7) demonstrated reading comprehension at the 8th-grade level, as determined by the consent form quiz.

Participants were ineligible for the study if they reported: evidence of severe AUD based on withdrawal symptoms; regular use of substances other than nicotine or caffeine [more than one or two times weekly (depending on the substance) in the past month]; lifetime history of psychosis or bipolar disorder or recent suicidal behavior; receiving alcohol treatment or seeking additional treatment while in the study; being pregnant or a desire to become pregnant during the study, or a medical condition that precluded alcohol use; interest in abstinence; or demonstrated poor comprehension of the study protocol (i.e. a score < 7 out of 10 on the consent form quiz). Ineligible individuals received on-line drinking resources, the SAMHSA treatment finder and referrals. The ineligible group (n = 2249) did not differ in age or gender (Ps > 0.05), but reported consuming more drinks per day and week (Ps < 0.001) than the eligible group, as well as more drinking days within the 30 days before the screener (P < 0.001) and more acute withdrawal symptoms (P < 0.001), making alternative treatment more appropriate.

Randomization

Individuals who were eligible and provided informed consent completed a baseline and tailoring survey. Data from 731 individuals on gender, age, number of standard drinks per week (18+ or < 18) and perceived effort needed to reach drinking goals (separated by median score) were then entered into randomization software (Biostatistics Randomization Management System) to ensure equal distribution of important demographic and alcohol use characteristics.

After randomization, participants' messaging programs were activated, and information regarding their condition was delivered via e-mail. All participants received NIAAA guidelines for safe non-risky drinking and standard drink definitions, information about study assessments and were informed that they could text STOP to discontinue their messages at any time. Text messages began within 1 business day of randomization and stopped automatically 6 months later.

Interventions

DT only

DT (active comparator condition) received a DT assessment (described below) via text each Sunday to track past-week drinking. Participants in all conditions received weekly DT, but only DT received a document detailing the benefits of weekly DT [23, 42], which was delivered via email.

Tailored statically (TS)

TS received daily tailored text messages, 50% of which were based on responses from the tailoring assessment (e.g. participant name,

gender, age and self-efficacy). For example, participants would receive different messages if they scored below versus above the median on the self-efficacy ruler, based on previous studies of excessive drinkers [23]. Such a message would read: 'Be compassionate with yourself. If your confidence to reduce your drinking is still low, don't test yourself unnecessarily by putting yourself in a highly tempting situation for heavy drinking'.

TA

TA received all TS features plus adaptive messaging. Text messages varied based on weekly self-reported goal achievement (see 'Weekly DT assessment'). For example, if a participant reported that they did not reach their goal, they could receive a message that read: 'It's been a month and you are still trying, which is the most important thing you can do. Treat the coming week as a fresh start'. In addition, TA participants were provided with a list of keywords at the beginning of the study, via text, and could proactively text a keyword for specific just-in-time messaging (i.e. immediate automated text messaging support). Keywords included 'Drinking' for support when the participant started drinking, 'Heavy' for support when the participant had more than two drinks and 'Win' when the participant succeeded at either managing a craving or drinking no more than their moderate drinking goal for the situation. Participants could also text COVID to receive 30 days of supplemental messages to help cope with the COVID-19 pandemic. TA participants were invited 30 days after enrollment to engage in a 30-day abstinence trial (regardless of their success in the study) and, following the trial, had the option to change from moderationto abstinence-focused messages. A description of the features of each program in table format can be found in the supporting information supplement.

At the conclusion of the study (6 months), participants in all conditions had the option to continue receiving weekly DT for 6 months, with each participant therefore receiving the same intervention between months 6 and 12 if they wished to continue.

Measures

All assessments were conducted using the REDCap survey system.

Screener

The screener included a 30-day shortened version of the Form-90 quantity–frequency measure of alcohol consumption (QFV-30) [43], the Short Alcohol Withdrawal Scale (SAWS) [44] and the Patient Health Questionnaire (PHQ-2) [45], in addition to questions regarding messaging plans and willingness to receive text messages. The QFV-30 has been validated against the time-line follow-back [46] method, alcohol withdrawal and severity via SAWS, and drug use via the Addiction Severity Index's 30-day frequency scale [47].

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Baseline assessment

The baseline survey assessed participant demographics and drinking behavior. Drinking quantity/frequency was assessed with a modified version of the QFV-30. This version assessed the (1) average number of days per week that one consumed at least one standard drink; (2) average number of drinks per drinking day (DDD); (3) total number of heavy drinking days (HDD) (i.e. four or more drinks versus five or more drinks); and (4) largest number of drinks consumed in one sitting (an additional question: 'What is the largest number of drinks you had in one sitting?'). This question was developed to understand change in the severity of a participant's heaviest drinking day, rather than only the number of days meeting the criteria for heavy drinking. Drinking consequences (e.g. perceived harm) were assessed with the Short Inventory of Problems (SIP) [48] and self-efficacy with the Brief Situational Confidence Questionnaire (BSCQ) [49].

Weekly DT assessment

The weekly DT assessment (sent every Sunday for 12 months) assessed number of drinking days (NDD) (at least one drink), DDD and HDD (four or more drinks for both males and females), during the previous 7 days. The TA group was additionally asked if they met their week's goal, to which they replied: 'N' not really, 'S' somewhat or 'M' mostly, which adjusted their messages accordingly.

Primary outcome

The primary outcome variable was weekly sum of standard drinks (SSD) at 6M. SSD is the product of the average number of days per week that one reported consuming at least one alcoholic drink and the average number of DDD. This information was assessed with a modified version of the QFV-90 (i.e. past 90 days). 6M was chosen as the primary time-point to understand between-group intervention effects, as it was the time-point before all participants were shifted to weekly DT.

Secondary outcomes

Secondary outcomes were number of HDD, NDD, DDD, largest drinks in one sitting (LD), non-risky drinking (i.e. meeting NIAAA nonrisky drinking guidelines: no more than seven drinks per week for women or 14 drinks per week for men [11]) and drinking-related selfefficacy and consequences.

SSD, HDD, NDD, DDD and LD were assessed with the QFV-30 at 1M, the QFV-90 at 3M and 6M and the QFV-180 (i.e. past 180 days) at 12M. Non-risky drinking was calculated from SSD. Drinking-related self-efficacy was assessed with the BSCQ at all timepoints and drinking-related consequences with the SIP at baseline (BL) and 6M.

Other outcomes

The number of TA participants who texted a keyword during the study was assessed (via messaging data) at 6M. Number of TA participants who opted to enroll in abstinence- versus moderation-related messages, and number of participants across interventions who opted to enroll in 6 months of additional messages, was assessed at 12M. Assessment adherence (e.g. average number of completed weekly assessments) was assessed at 12M. Other substance use was assessed at 6M via the frequent drug use scale (past 90 days). Use of other treatment resources during the study was assessed at 6M via the question: 'Over the last 90 days, which of the following resources, if any, have you used outside of the research study? (check all that apply)' (e.g. moderation management, 12-Step groups and individual treatment).

Reimbursement

Compensation (provided as e-gift cards) was provided via e-mail following completion of the baseline assessment and each follow-up assessment. Depending on the length of the assessment, it ranged from \$20 to \$50. Upon receipt of each follow-up assessment, participants received an additional \$5 or \$10 if they completed at least 75% of the total weekly assessments between the previous and current assessment. For example, if at least three of the four weekly assessments were completed by the time one received their 1-month assessment, they would be eligible for an additional \$5. For the other time-points (i.e. between 1 and 3 months, between 3 and 6 months and between 6 and 12 months), they would be eligible for an additional \$10 for completing 75% of the total assessments delivered within that time-frame.

Data analysis

The study was powered based on our R34 pilot data [23]. Analyses of SSD data at 12 weeks yielded large effect sizes for the TA-DT group comparison [d = 1.11, 95% confidence interval (CI) = 0.59-1.63] and the TS-DT group comparison (d = 0.79, 95% CI = 0.27-1.32) and small-to-medium effect size for the TS-TA group comparison (d = 0.36, 95% CI = 0.15-0.87), adjusting for baseline drinking severity. Thus, a total sample size of 155 participants in each group after attrition was needed to detect an effect for the primary and secondary outcome variables at a power of 0.80 and significance level of a = 0.05 when comparing differences between active treatments and the control.

SSD, DDD and HDD were modeled using negative binomial regressions; meeting NIAAA non-risky drinking guidelines was modeled using logistic regression; and NDD, SIP and BSCQ were modeled using linear regressions. We conducted regressions for all outcomes by group, with two dummy-coded indicators comparing TS and TA to DT (1 = TS or TA, 0 = DT), adjusting for baseline outcomes, gender (M/F), race (non-White/White), age and total weekly

assessments completed, given the established effects that these variables have on drinking behavior and outcomes [50-53]. We also examined the moderating effects of gender at birth and race. We only compared Black/African American-identified participants to White-identified participants, due to sample size limitations of other groups. Both intent-to-treat and completer analyses were performed for primary outcome drinking variables. The intentto-treat analysis was conducted for all secondary analyses. It included all participants who enrolled into the study, with missing data imputed using a baseline carried forward (BLCF) model. The BLCF model was chosen as it uses the most conservative assumptions in alcohol trials-that dropping out of the study was not predicted by any measured variables (that is, missing not at random); and that drinking for dropouts returned to baseline levels. The completer analysis only included participants who completed the follow-up assessment interview at that time-point. Analyses were conducted using SAS® software, version 9.4 (Carv. NC. USA) and Stata/MP version 15 software (College Station, TX, USA), with significance level set to 0.05.

Ethics

This study was approved by both the Feinstein Institutes for Medical Research and Solutions IRB and clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki. All participants provided electronic informed consent.

RESULTS

Participant flow

Study flow, reasons for exclusion, study assignment and retention are presented in the consort flow diagram (Figure 1). Between May 2019 and February 2021, 3944 individuals completed the screener, of whom 1695 (43%) met eligibility criteria. Of those, 1194 (70%) completed the baseline assessment. Questionable data (e.g. IDs associated with the same e-mail address) and responses submitted in < 10 min were discarded, together with unidentifiable data (n = 332; 27.8% of completed baseline assessments).

Of 971 individuals with valid screening data who reported their recruitment source, 62.7% (n = 609) were recruited from Facebook, 22.7% (n = 221) from other sources [e.g. alcoholscreening.org (i.e. individuals followed a link to the study on the website)] and 14.5% (n = 141) heard about the study through someone else, such as a friend.

A total of 731 individuals completed the tailoring survey and were randomized: 246 to DT, 245 to TS and 240 to TA. At 12 months, eight participants (1%) disclosed that they did not have a drinking problem and took part in the study for the money. These participants were removed from analysis so that the final baseline sample was 244 in DT, 240 in TS and 239 in TA (723 total). During the intervention,

34 (4.7%) texted STOP within 6 months and one was withdrawn following a reported pregnancy.

Sample characteristics at baseline

At baseline, participants reported consuming an average of 26.9 standard drinks per week, 5.3 (1.5) days per week, 5.1 (2.6) DDD, 8.3 (3.7) drinks on their heaviest days and 13.7 (9.2) HDD per month. Only HDD differed significantly between groups, with the TA group showing a higher value than the TS and DT groups. See descriptive data in Table 1.

Primary outcomes

6M weekly SSD

All groups significantly reduced their SSD at 6M (Table 2). Reductions were greatest for TS (12.9 reduction in SSD) and TA (16.2 reduction in SSD), although only TA differed significantly from DT [adjusted risk ratio (aRR) = 0.80, 95% CI = 0.71, 0.91] (Table 2). No significant differences existed between TA and TS (P > 0.05).

Secondary outcome analysis

Weekly SSD

All groups reduced their SSD at 1M, 3M and 12M (Table 3). Both TA and TS reduced SSD significantly more than DT at 1M and 3M. No group differences existed at 12M (Figure 2; Table 3). No significant differences existed between TA and TS (P > 0.05).

HDD

All groups reduced their HDD at 1M, 3M and 12M (Table 3). There were no group differences with DT at any follow-up period (Table 3). No significant differences existed between TA and TS (P > 0.05).

DDD

All groups reduced their DDD at 1M, 3M and 12M (Table 3), except for DT at 1M, over the course of the study (Table 3). At the end of the intervention period (6M), the TA group reported significantly reduced drinking (6M mean reduction = 2.2 DDD; aRR = 0.84, 95% CI = 0.77, 0.92) compared to DT, while reductions for TS were not significantly different than DT (Table 2). Only TA was significantly different from DT at 1M, 3M and 12M (Table 3). TA was also significantly different from TS at 6M (P < 0.05).

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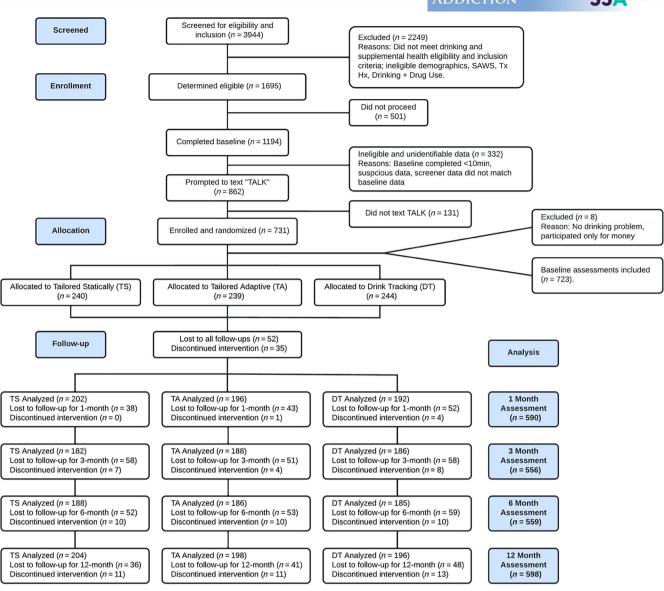


FIGURE 1 Consort flow-chart of participant recruitment, eligibility and monthly assessment follow-up. DT = drink tracking; TA = tailored adaptive; TS = tailored statically.

NDD

All groups reduced their NDD at 1M, 3M and 12M (Table 3). At the end of the intervention period (6M), the TA group reported significantly reduced NDD compared to DT (b = -0.39, 95% CI = -0.67, -0.10) (Table 2). Both TA and TS were significantly different from DT at 1M follow-up, while only TA remained significant at 3M. No group differences existed at 12M (Table 3). No significant differences existed between TA and TS (P > 0.05).

LD

All groups reduced their LD at 1M, 3M and 12M (Table 3). At the end of the intervention period (6M), TA reported significantly reduced drinking compared to DT (mean reduction = 2.2 drinks; aRR = 0.91, 95% CI = 0.85, 0.97) (Table 2). Both TA and TS resulted in significantly

reduced LD at 1M and 3M compared to DT. Only TA remained significant at 12M due to BL differences (Table 3). No significant differences existed between TA and TS (P > 0.05).

Self-efficacy

All groups resulted in increases in self-efficacy, although there were no significant differences between groups at 6M (Table 3). Both TA and TS resulted in significantly higher self-efficacy at 1M.

Drinking consequences

Participants in all groups experienced substantial decreases in drinking consequences, although there were no significant condition differences at 6M (Table 3).

TABLE 1 Baseline characteristics of study participants, by intervention arm (n = 723).

Characteristic	DT (n = 244) n (%)	TS (n = 240) n (%)	TA (n = 239) n (%)
Gender: female	152 (62.3)	146 (60.8)	154 (64.4)
Race			
Asian/Pacific Islander	5 (2.0)	3 (1.3)	6 (2.5)
Black/African American	31 (12.7)	31 (12.9)	29 (12.1)
More than one race	8 (3.3)	6 (2.5)	13 (5.4)
Native American	1 (0.4)	3 (1.3)	2 (0.8)
White/Caucasian	193 (79.1)	193 (80.4)	188 (78.7)
Other	4 (1.7)	4 (1.7)	1 (0.4)
Ethnicity: Hispanic/Latinx	18 (7.4)	19 (7.9)	16 (6.7)
Marital status			
Single (never married)	63 (25.8)	59 (24.6)	67 (28.0)
Married	109 (44.7)	125 (52.1)	119 (49.8)
Separated	9 (3.7)	6 (2.5)	2 (0.8)
Divorced	46 (18.9)	38 (15.8)	35 (14.6)
Widowed	3 (1.2)	0 (0.0)	4 (1.7)
Education: bachelor's or more	174 (71.3)	172 (71.7)	155 (64.9)
Employment status			
Employed full-time	170 (69.7)	163 (67.9)	148 (61.9)
Employed part-time	36 (14.8)	43 (17.9)	48 (20.1)
Not employed	38 (15.6)	34 (14.2)	43 (18.0)
Met NIAAA guidelines for non-risky drinking ^a	17 (7.0)	15 (6.3)	8 (3.3)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years, <i>n</i> = 688)	39.1 (9.5)	40.5 (10.5)	40.2 (10.0)
Weekly sum of standard drinks	25.8 (14.1)	26.1 (13.3)	28.7 (19.0)
Heavy drinking days (≥ 4 drinks) over month	13.4 (8.9)	12.5 (9.3)	15.2 (9.3)
Drinks per drinking day	5.0 (2.5)	5.1 (2.3)	5.3 (2.9)
Drinking days per week	5.3 (1.5)	5.3 (1.6)	5.5 (1.4)
Largest drinks in one sitting	8.2 (3.8)	8.0 (3.6)	8.6 (3.7)

Abbreviations: DT = drink tracking mobile assessment; NIAAA = National Institute on Alcohol Abuse and Alcoholism; TA = tailored adaptive; TS = tailored statically; SD = standard deviation.

Non-risky drinking

The proportion of participants meeting NIAAA guidelines for non-risky drinking increased across groups during the study period, with only TS being significantly different from DT at 6M. The TA group was significantly different from DT at 1M and 3M (Table 3).

Other outcome analysis

Just-in-time messages

Twenty-five TA participants (10.5%) texted at least one keyword during the study (excluding the first week). The average number of texted keywords was 12.8 (SD = 39.8) words, between the second week and

6 months. The most commonly texted keywords were 'Drinking' [mean = 5.0, standard deviation (SD) = 20.5], 'Win' (mean = 4.6, SD = 10.1) and 'Heavy' (mean = 2.2, SD = 9.8).

Abstinence-related messages

Eleven TA participants (4.6%) opted into the abstinence program to receive abstinence-only-related messages instead of moderation messages.

Continued messaging

Of the 581 participants who responded to the question of whether they would like additional messages for 6 months, 402 (69.2%) opted

^aMen: ≤14 drinks per week; women: ≤7 drinks per week.

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Assessment adherence

Eighty-seven per cent (n = 638) of the sample completed at least one weekly assessment, with an average of 15.0 (SD = 9.5) completed assessments. Overall, we had weekly and/or monthly assessment data from 93% of the sample. Weekly and monthly data were highly correlated (range = 0.68-0.8608; average = 0.79). Group assignment was not statistically significantly associated with the number of weekly assessments completed (TS versus DT P = 0.612, TA versus DT P = 0.163).

Other resources

Of the 559 participants who completed the 6M assessment, 405 (72.5%) reported using at least one other resource (e.g. moderation management and SMART recovery) during the previous 90 days, 303 (74.8%) of whom attributed positive changes in their drinking exclusively to the study.

Other drug use

Of the 559 participants who completed the 6M assessment, 246 (44.0%) reported using at least one other substance during the previous 90 days, with marijuana (n = 202) being most prevalent (36.1%). Of those who used another substance, 67% reported using four or fewer times in the 90 days prior to 6M.

Within-group drinking changes

As shown in Table 3, during the course of the study all groups made significant within-group drinking reductions from baseline to 1M, 3M, 6M and 12M (P < 0.0001), except DT, which was not significant between BL and 1M follow-up. The largest changes were observed across groups from BL-1M (P < 0.0001), except DT, and 1M-3M (P < 0.0001), while at 3M-6M, there was a differential within-group reduction TA (P = 0.09), TS (P = 0.36), DT (P < 0.05). At 6M-12M, there were no significant within drinking changes in any condition.

Moderation analyses

We conducted secondary analyses testing baseline severity, gender and race as moderators of the association between intervention group and primary outcomes of SSD and HDD at 6 months. Baseline severity was operationalized as participants' baseline SSD and HHD, split at the median value. Baseline severity, gender and race were not

TABLE 2 Intervention effects on 6-month drinking outcomes, intent-to-treat and completers.

Variable	Intent-to-treat (n = 723)	Completers (n = 535)
Primary outcome		
Weekly sum of	standard drinks—risk ratio (959	% CI)
DT (ref.)		
TS	0.89 (0.79, 1.00)	0.86 (0.75, 1.00)*
TA	0.80 (0.71, 0.91)***	0.82 (0.70, 0.96)*
Secondary outcom	nes	
Heavy drinking	days (≥ 4 drinks) over month—	risk ratio (95% CI)
DT (ref.)		
TS	0.88 (0.73, 1.07)	0.86 (0.67, 1.10)
TA	0.87 (0.71, 1.05)	0.83 (0.65, 1.08)
Drinks per drink	king day—risk ratio (95% CI)	
DT (ref.)		
TS	0.95 (0.86, 1.04)	0.92 (0.82, 1.03)
TA	0.84 (0.77, 0.92)***	0.84 (0.74, 0.94)**
Drinking days p	er week—beta (95% CI)	
DT (ref.)		
TS	-0.20 (-0.48, 0.08)	-0.18 (-0.52, 0.16)
TA	-0.39 (-0.67, -0.10)**	-0.32 (-0.67, 0.02)
Largest drinks in	n one sitting—risk ratio (95% C	I)
DT (ref.)		
TS	0.97 (0.90, 1.03)	0.98 (0.90, 1.06)
TA	0.91 (0.85, 0.97)**	0.95 (0.87, 1.03)
Drinking-related	d consequences—beta (95% CI)
DT (ref.)		
TS	0.02 (-0.06, 0.11)	0.04 (-0.06, 0.14)
TA	-0.06 (-0.15, 0.02)	-0.04 (-0.15, 0.06)
Self-efficacy ^a —l	oeta (95% CI)	
DT (ref.)		
TS	1.06 (-2.74, 4.86) ^a	1.17 (-3.46, 5.81)
TA	2.86 (-0.95, 6.68)	1.52 (-3.14, 6.18)

Note: Weekly sum of standard drinks, heavy drinking days, drinks per drinking day and largest drinks in one setting were modeled using negative binomial regressions with DT as the comparator. Drinking days per week, drinking-related consequences and self-efficacy were modeled using linear regressions and reporting the raw regression coefficients. All models controlled for participant gender, race, number of weekly assessments and baseline value. Results were equivalent with and without controlling for age. Abbreviations: 95% CI = 95% confidence interval; DT = drink tracking mobile assessment; RR = risk ratio; TA; tailored adaptive; TS = tailored statically.

significant moderators for either outcome. However, Black/African American participants (n = 91; 12.6%) had significantly lower SSD and HDD than White participants (n = 574; 79.4%) at 6M (SSD aRR = 0.74, 95% CI = 0.65, 0.84; HDD aRR = 0.56, 95% CI = 0.46, 0.69).

^aExcluding one participant with missing baseline self-efficacy data. *Risk ratio or beta was statistically significant at P < 0.05; **risk ratio or beta was statistically significant at P < 0.01; ***risk ratio or beta was statistically significant at P < 0.001.

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TABLE 3 Within-group change and ITT between group differences in alcohol consumption at baseline, 1, 3, 6 and 12 months.

Outcome	Baseline (n = 723) Mean (SD)	1 month (n = 590) Mean (SD)	1 month	3 months (n = 556) Mean (SD)	3 months	6 months (n = 559) Mean (SD)	6 months	12 months (n = 598) Mean (SD)	12 months
Primary outcor	me								
Weekly sum	of standard drin	ks (SSD)							
DT (ref.)	25.8 (14.1)	22.7 (13.3) ^t		15.9 (11.6) ^t		14.6 (11.0) ^t		14.4 (12.3) ^t	
TS	26.1 (13.3)	20.2 (13.7) ^t	*	13.7 (10.5) ^t	*	13.2 (10.4) ^t		13.8 (11.9) ^t	
TA	28.7 (19.0)	19.1 (11.0) ^t	***	13.6 (12.9) ^t	***	12.5 (9.2) ^t	***	13.8 (13.8) ^t	
Secondary out	comes								
Heavy drinki	ing days (≥ 4 drin	ks) over month	(HDD)						
DT (ref.)	13.4 (8.9)	9.2 (8.3) ^t		7.4 (8.5) ^t		6.6 (7.9) ^t		5.5 (7.8) ^t	
TS	12.5 (9.3)	7.9 (8.3) ^t		5.5 (7.3) ^t	*	5.9 (7.5) ^t		5.5 (8.1) ^t	
TA	15.2 (9.3)	7.8 (8.0) ^t	*	6.0 (7.4) ^t		5.7 (7.0) ^t		5.4 (7.7) ^t	
Drinks per d	rinking day (DDE	D)							
DT (ref.)	5.0 (2.5)	4.8 (2.1)		3.8 (2.1) ^t		3.5 (2.0) ^t		3.4 (2.3) ^t	
TS	5.1 (2.3)	4.5 (2.2) ^t		3.4 (2.0) ^t		3.3 (3.3) ^t		3.3 (2.2) ^t	
TA	5.3 (2.9)	4.4 (1.9) ^t	**	3.2 (2.2) ^t	***	3.1 (1.7) ^t	***	3.3 (2.3) ^t	*
Drinking day	s per week (NDI	O)							
DT (ref.)	5.3 (1.5)	4.6 (1.8) ^t		4.3 (1.8) ^t		4.0 (1.8) ^t		3.9 (1.9) ^t	
TS	5.3 (1.6)	4.3 (1.9) ^t	**	3.9 (1.8) ^t		3.9 (1.9) ^t		3.8 (1.9) ^t	
TA	5.5 (1.4)	4.2 (1.9) ^t	***	4.0 (1.9) ^t	**	3.8 (1.9) ^t	**	3.8 (2.1) ^t	
Largest drink	ks in one sitting								
DT (ref.)	8.2 (3.8)	7.8 (3.4) ^t		7.3 (3.9) ^t		6.7 (3.7) ^t		7.1 (4.0) ^t	
TS	8.0 (3.6)	6.8 (3.3) ^t	*	6.2 (3.5) ^t	*	6.4 (3.5) ^t		6.5 (4.2) ^t	
TA	8.6 (3.7)	7.2 (3.5) ^t	**	6.2 (3.7) ^t	***	6.4 (3.6) ^t	**	6.6 (4.2) ^t	*
Met NIAAA	guidelines for no	n-risky drinking	1						
DT (ref.)	17 (7.0)	31 (12.7) ^t		64 (26.2) ^t		70 (28.7) ^t		83 (34.0) ^t	
TS	15 (6.3)	45 (18.8) ^t		75 (31.3) ^t		85 (35.4) ^t	*	89 (37.1) ^t	
TA	8 (3.3)	39 (16.3) ^t	*	76 (31.8) ^t	**	75 (31.4) ^t		84 (35.2) ^t	
Drinking-rela	ated consequenc	es							
DT	1.1 (0.6)	-		-		0.7 (0.6) ^t		-	
TS	1.1 (0.6)	-		-		0.7 (0.6) ^t		-	
TA	1.1 (0.6)	-		-		0.6 (0.5) ^t		-	
Self-efficacy	,								
DT	42.4 (21.0)	50.9 (21.6) ^t		58.1 (23.0) ^t		62.8 (23.4) ^t		63.7 (25.4) ^t	
TS	44.8 (22.4)	57.0 (21.6) ^t	***	60.4 (22.5) ^t		65.2 (24.3) ^t		66.1 (22.6) ^t	
TA	40.0 (21.7)	52.9 (21.5) ^t	*	58.3 (24.6) ^t		62.9 (24.9) ^t		65.1 (25.6) ^t	

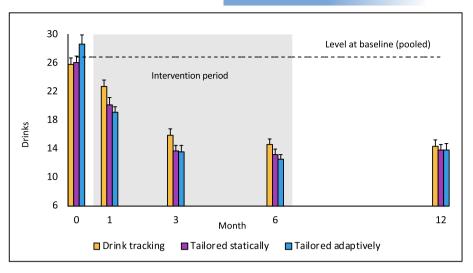
Note: Weekly sum of standard drinks, heavy drinking days, drinks per drinking day and largest drinks in one setting were modeled using negative binomial regressions with DT as the comparator. Within-group changes using t-tests from baseline to follow-up period included as significant at tP < 0.05. Met NIAAA guidelines for non-risky drinking was modeled using logistic regression with DT as the comparator. Drinking days per week, drinking-related consequences and self-efficacy were modeled using linear regressions and reporting the raw regression coefficients. All models controlled for participant gender, race, number of weekly assessments and baseline value. Results were equivalent with and without controlling for age. All follow-up means, standard deviations and percentages are based on completers only.

Abbreviations: Drinking-related consequences = Short Inventory of Problems mean score; DT = drink tracking mobile assessment; NIAAA = National Institute on Alcohol Abuse and Alcoholism; Self-efficacy = Brief Situational Confidence Questionnaire mean score; TA = tailored adaptive; TS = tailored statically.

^aMen: ≤ 14 drinks per week; women: ≤ 7 drinks per week. Variables missing data: drinking-related consequences at baseline (n = 119) and 6 months (n = 60); self-efficacy at baseline (n = 78).

*Risk ratio or beta was statistically significant at P < 0.05, using the intent-to-treat sample; **risk ratio or beta was statistically significant at P < 0.01, using the intent-to-treat sample; ***risk ratio or beta was statistically significant at P < 0.001, using the intent-to-treat sample.

FIGURE 2 Average weekly sum of standard drinks over the study period, by intervention arm (group). Error bars denote 1 standard error. DT = drink tracking mobile assessment; TA = tailored adaptive; TS = tailored statically.



DISCUSSION

This is the first study, to our knowledge, to examine the comparative long-term effects of different types of targeted alcohol reduction text messaging in help-seeking at-risk drinkers. There were significant sample-level reductions in drinking across treatment groups that were maintained over time. Results partially confirm a priori hypotheses that tailored text messaging interventions (compared to DT) reduce alcohol consumption in help-seeking individuals during a 6-month intervention period [23], consistent with prior trials showing reductions in harmful drinking following a digital intervention [41]. TA messaging yielded the largest effect sizes compared to DT, but was not significantly different from TS messaging. Despite significant group differences during the intervention period favoring TA messaging, DT, TS messaging and TA messaging all resulted in clinical improvement across all outcomes (except DDD for DT at 1 month) and were nearly equivalent at 12M follow-up, resulting in a 47.9% reduction from baseline in drinks per week across groups. Reducing drinking by 11.4-14.9 standard drinks a week to an average of fewer than 14 drinks a week among groups at the 12-month mark holds significant public health promise if scaled beyond this study, similar to successful scalable public health interventions such as Text4baby [54, 55].

Daily messaging versus weekly DT trajectory

While the active messaging conditions had larger effect sizes and more rapid drink reductions, the trajectory of drink reductions throughout groups was largest from baseline to 1 month and 1–3 months, with smaller reductions from 3 to 6 months and leveling off to non-significant changes following the intervention period to 12 months. Similar trends have been found in in-person interventions wherein treatment conditions and active controls or minimal interventions result in similar long-term outcomes once the intervention has been withdrawn [56]. While it is unclear whether continued daily messaging beyond 6 months would have resulted in significant differences at 12 months, at minimum the trajectory suggests a stepped reduction

of tailored text messaging towards DT or, alternatively, that variable rate messaging may be sufficient over time to keep change-goals salient [57]. Further research understanding different messaging during extensive periods of time is warranted.

Tailoring versus adaptive tailoring

The hypothesis that TA messaging related to goal achievement and just-in-time messaging would be superior to tailoring messages at baseline-only was largely not supported, apart from DDD at 6M. Several possible explanations exist. All participants actively attempted to reduce their drinking, and it is possible that because both active conditions received daily messages at critical moments (e.g. 6:00 p.m.) that fostered drink reduction goal salience, skills and support, tailoring messages at baseline-only may have been sufficient to engage in self-directed change. Unlike conditions such as depression, which have multiple time triggers and targets, moderate drinking has a single end-point of fewer drinks and usually begins in the evening for most drinkers.

It is also possible that our definition and implementation of adaptation was not sufficient to create meaningful differences. Because adaptation is a complex construct [36], weekly goal achievement may not be the only useful method. Other models of adaptive design include prescribed task interventions based on drinking goals for the evening and personalization of timing to days and times of heaviest drinking [17]. While there were no differences between groups, TA resulted in greater differences with DT for most outcomes and, given the automated nature of these interventions, should be used as a first-line automated intervention. At minimum, more research should determine the best approaches for adaptive mobile interventions for reducing alcohol consumption.

Just-in-time features rarely used

The lack of differences between TS and TA messaging may also be due to few participants in the TA group using just-in-time

messaging features. There are several possible reasons for this, including that reminders to use the features were only sent twice during the 6-month intervention period and participants may have been unaware of the different intervention features during high-risk situations where executive planning is reduced. It is also possible that just-in-time features act more like traditional, reactive, webbased and mobile application interventions, which require user effort beyond cognitive capacity to engage. While results regarding which types of just-in-time messages were used should be interpreted with caution, it appears that in-the-moment drinking support messages (e.g. 'drink') were used more frequently than preventative messages (e.g. 'tempt'), suggesting that people seek help once they are in high-risk situations rather than attempting to prevent heavy drinking before it begins [58-60].

Other outcomes

There were significant increases in drinking-related self-efficacy and reduction in consequences across all conditions despite differential outcomes during the intervention period, which is a replication of the pilot and other studies. It is possible that any change causes a marked shift in both efficacy and consequences before drink reductions [61]. It is also possible that drink reduction may be hyper-targeted to situational consequences wherein an individual reduces their drinking (when they have an important activity), becomes confident, but consumes the same for the week. Overall, understanding this relationship is important for building personalized predictive models of behavior change.

Recruitment and engagement

Of the 3944 individuals screened for the study, more than half (n = 2249) were excluded due to such reasons as too low, heavy drinking and/or medical or psychiatric comorbidities. Given the absence of adverse events when using messaging, future trials of this kind may consider less stringent eligibility criteria to enable a larger number of individuals to participate and receive treatment.

To be eligible for the study, individuals must have reported consuming at least 13 or 15 standard drinks per week (for women and men, respectively). In an effort to increase our sample size, we modified this requirement to at least nine or 11 standard drinks. The majority of our sample (n = 664; 90.8%) enrolled based on the revised criteria. Nevertheless, the average number of reported drinks per week at baseline was more than 25 drinks across the sample (more than double the required drinks to join the study). The relatively high drinking severity observed in our participants was probably related to our sample consisting of help-seeking drinkers, with several studies indicating that alcohol use severity is one of the strongest factors related to seeking treatment [62, 63]. Given the heterogeneity in the sample, this study demonstrated that there are numerous helpseekers willing to engage in a fully remote intervention to reduce their

drinking regardless of severity. However, future work can explore ways to address risky drinkers who are less severe or less motivated to pursue treatment.

Participants were moderately adherent to weekly DT with an average of 15 of 26 (SD = 9.5) weeks completed. It is noteworthy that DT engagement in TA or DT was not higher than TS, even though it partially altered TA's intervention messaging and it was DT's primary intervention. Further research is needed to understand this phenomenon. Similar to the pilot study, a larger percentage was interested in continuing the messaging after the study period, highlighting the acceptability of the intervention. However, when continuing required texting a keyword and completing a new assessment, only 7.1% signed up. When we auto-enrolled participants who expressed interest, 94% of those interested stayed enrolled. This robust difference represents a key engagement metric for future studies, based on the effort needed to engage in interventions and how we build effortoptimized interventions [64].

Population and generalizability

The study population largely replicates previous open recruitment digital alcohol studies wherein white women were the largest cohort. Our recruitment efforts included targeted advertisements to those who identified as men and people of color, which resulted in higher participation from both groups, compared to the pilot study. However, men only represented 37.5% of the sample, and the sample mainly identified as White (79.4%). Unlike with gender or severity, there was a significant effect by race in that non-White participants did significantly better than White participants regardless of condition. Studies using apps in opportunistic settings have revealed no differences between groups [30]. While this finding needs cautionary interpretation, it is possible that non-White participants have not had access to remote, digital, alcohol moderation interventions and even brief ongoing interventions may be more than what under-represented groups have received in the past, enhancing effects.

Limitations

Despite positive outcomes, more research is needed. First, we have to expand the sample's demographic characteristics to understand mediators and moderators for different populations. Secondly, while individuals made significant, meaningful overall drink reductions, most were binge drinking weekly and as a result did not meet NIAAA criteria for safe drinking. Research combining interventions specifically for heavy drinking nights with longer-term narratives is needed. Thirdly, our sample was recruited on-line without research assistant contact, and while we made significant efforts to ensure validity by manipulating measurement constructs and prospectively adding questions, data from remote samples need cautionary interpretation. Similarly, there have been recent concerns regarding an increase in 'bots'

in on-line research [65]. Although we made efforts to detect and eliminate this problem (e.g. removing those from the study who completed assessments in < 10 min), future work in this area may consider implementing a more systematic approach such as bot detection software [66]. Fourthly, our study required individuals to have an active e-mail address as well as a mobile phone, which may be a barrier to certain populations [67].

Fifthly, although the consent form was at an 8th-grade reading level, some of the text messages may have been more complex. While there were no differences based on education, it should be corrected in future studies. Sixthly, 44% of the sample reported other drug use during the intervention period. While most was infrequent and primarily cannabis, exploring the effects of other substances on outcomes is warranted in future papers. Seventhly, although participants seemed to engage well with the messaging programs (e.g. completing several assessments sent via text), we could not determine the extent to which they read each message delivered to their phone. Future studies may consider incorporating more interactive messages to enforce more regular responses from individuals participating in mobile messaging interventions. Lastly, and as noted above, our model of adaptation was potentially flawed in that the algorithm adapted to overall goal achievement rather than in-the-moment adaptations accounting for drinking goals.

CONCLUSIONS

Overall, results highlight the opportunity to significantly reduce risky drinking with long-term automated messaging interventions that are scalable and low-effort on participants. Given the opportunity to improve automated interventions with clinician or coach-supported messaging [68], the studies highlighting the efficacy of human-supported messaging in alcohol reduction [69] and the rise of conversational artificial intelligence, hybrid models should be explored in future studies. Given both the debilitating personal consequences of excessive alcohol consumption and the economic burden and costs to society [10], reducing binge drinking episodes by 8.2 a month and weekly drinking by 12.9 drinks per week can have a measurable impact on public health through rapid scaling without significant implementation costs.

AUTHOR CONTRIBUTIONS

Frederick Muench: Conceptualization (lead); data curation (supporting); formal analysis (supporting); funding acquisition (lead); investigation (lead); methodology (lead); project administration (supporting); resources (equal); software (equal); supervision (lead); validation (equal); visualization (supporting); writing—original draft (lead); writing—review and editing (equal). Sean P. Madden: Investigation (supporting); project administration (lead); writing—original draft (equal); writing—review and editing (equal). Sherry Oommen: Investigation (equal); project administration (equal); writing—original draft (equal); writing—review and editing (equal). Sarah Forthal: Data curation (equal); formal analysis (lead); software (supporting); visualization

(lead); writing-original draft (supporting). Aradhana Srinagesh: Investigation (equal); project administration (equal); resources (equal); supervision (equal); writing—review and editing (supporting). Gertraud Stadler: Data curation (supporting); formal analysis (equal); methodology (supporting); writing-review and editing (supporting). Alexis Kuerbis: Conceptualization (supporting); formal analysis (supporting); writing-original draft (supporting). Robert F. Leeman: Funding acquisition (supporting); investigation (supporting); writing-original draft (equal); writing-review and editing (equal). Brian Suffoletto: Conceptualization (supporting); writing-original draft (supporting); writingreview and editing (supporting). Amit Baumel: Conceptualization (supporting); investigation (supporting); writing-original draft (supporting); writing-review and editing (supporting). Cameron Haslip: Investigation (supporting); project administration (supporting). Nehal P. Vadhan: Project administration (equal): supervision (equal): writing-review and editing (equal). Jon Morgenstern: Conceptualization (equal); funding acquisition (equal); methodology (equal); supervision (equal); validation (equal).

ACKNOWLEDGEMENTS

The authors would like to acknowledge National Institute on Alcohol Abuse and Alcoholism (R01AA025058) at NIH for funding this study and the participants who devoted their time to completing the protocol and assessments.

DECLARATION OF INTERESTS

B.S. has received royalties for an exclusive license of a different health text messaging program to Health Stratica LLC. N.P.V. is a paid research consultant for Cutback Coach, LLC.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

CLINICAL TRIAL REGISTRATION

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Muench F, Madden SP, Oommen S, Forthal S, Srinagesh A, Stadler G, et al. Automated, tailored adaptive mobile messaging to reduce alcohol consumption in help-seeking adults: A randomized controlled trial. Addiction. 2024;119(3):530–43. https://doi.org/10.1111/add.16391