

# Effectiveness of a Stand-alone Telephone-Delivered Intervention for Reducing Problem Alcohol Use

## A Randomized Clinical Trial

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**IMPORTANCE** Despite the magnitude of alcohol use problems globally, treatment uptake remains low. Telephone-delivered interventions have potential to overcome many structural and individual barriers to help seeking, yet their effectiveness as a stand-alone treatment for problem alcohol use has not been established.

**OBJECTIVE** To examine the effectiveness of the Ready2Change telephone-delivered intervention in reducing alcohol problem severity up to 3 months among a general population sample.

**DESIGN, SETTING, AND PARTICIPANTS** This double-blind, randomized clinical trial recruited participants with an Alcohol Use Disorders Identification Test (AUDIT) score of greater than 6 (for female participants) and 7 (for male participants) from across Australia during the period of May 25, 2018, to October 2, 2019. Telephone assessments occurred at baseline and 3 months after baseline (84.9% retention). Data collection was finalized September 2020.

**INTERVENTIONS** The telephone-based cognitive and behavioral intervention comprised 4 to 6 telephone sessions with a psychologist. The active control condition comprised four 5-minute telephone check-ins from a researcher and alcohol and stress management pamphlets.

**MAIN OUTCOMES AND MEASURES** The primary outcome was change in alcohol problem severity, measured with the AUDIT total score. Drinking patterns were measured with the Timeline Followback (TLFB) instrument.

**RESULTS** This study included a total of 344 participants (mean [SD] age, 39.9 [11.4] years; range, 18-73 years; 177 male participants [51.5%]); 173 participants (50.3%) composed the intervention group, and 171 participants (49.7%) composed the active control group. Less than one-third of participants (101 [29.4%]) had previously sought alcohol treatment, despite a high mean (SD) baseline AUDIT score of 21.5 (6.3) and 218 (63.4%) scoring in the probable dependence range. For the primary intention-to-treat analyses, there was a significant decrease in AUDIT total score from baseline to 3 months in both groups (intervention group decrease, 8.22; 95% CI, 7.11-9.32;  $P < .001$ ; control group decrease, 7.13; 95% CI, 6.10-8.17;  $P < .001$ ), but change over time was not different between groups (difference, 1.08; 95% CI, -0.43 to 2.59;  $P = .16$ ). In secondary analyses, the intervention group showed a significantly greater reduction in the AUDIT hazardous use domain relative to the control group at 3 months (difference, 0.58; 95% CI, 0.02-1.14;  $P = .04$ ). A greater reduction in AUDIT total score was observed for the intervention group relative to the control group when adjusting for exposure to 2 or more sessions (difference, 3.40; 95% CI, 0.36-6.44;  $P = .03$ ) but not 1 or more sessions (per-protocol analysis).

**CONCLUSIONS AND RELEVANCE** Based on the primary outcome, AUDIT total score, this randomized clinical trial did not find superior effectiveness of this telephone-based cognitive and behavioral intervention compared with active control. However, the intervention was effective in reducing hazardous alcohol use and reduced alcohol problem severity when 2 or more sessions were delivered. Trial outcomes demonstrate the potential benefits of this highly scalable and accessible model of alcohol treatment.

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Alcohol consumption is a leading cause of preventable morbidity and mortality globally, resulting in 5.3% of all deaths (3 million) and 5.1% of all disease burden in 2016.<sup>1,2</sup> Alcohol use disorders are estimated to affect 5.1% of the adult population worldwide.<sup>2</sup> Yet, the magnitude of alcohol consumption and attributable harms remains in sharp contrast to the low rates of treatment use,<sup>3</sup> with the treatment gap attributable to a range of structural (eg, treatment coverage, distance to services) and individual (eg, readiness for change, fear of shame or stigma) barriers.<sup>2,4-6</sup> Moreover, since 2020, access to treatment has been severely disrupted by the COVID-19 pandemic, which has further driven alcohol consumption and related harms among vulnerable groups,<sup>7-10</sup> including an increase in alcohol-induced death rates in several countries.<sup>11,12</sup> Telehealth has the potential to overcome many of the individual and structural barriers to accessing treatment for alcohol problems. Yet, until now, it has been underused and understudied in substance use populations.<sup>13,14</sup> With the rapid expansion in the use of telehealth globally in response to government policies aimed at containing COVID-19 transmission (eg, social distancing), it is critical to determine the effectiveness of psychosocial treatments offered via these methods to ensure evidence-based service delivery.<sup>15</sup>

Although there is an expansive literature demonstrating the effectiveness of low-intensity alcohol interventions delivered in primary care settings,<sup>16</sup> multiple barriers to their implementation remain (eg, lack of time, training, and confidence).<sup>17</sup> A comparatively small body of literature provides evidence for the benefits of telephone-delivered interventions in reducing substance use problems,<sup>18-21</sup> although there is strong evidence for their effectiveness in promoting smoking cessation.<sup>22</sup> Telephone-delivered interventions have been shown to be comparable to in-person treatment in reducing alcohol consumption<sup>21</sup> and to enable experiences of therapeutic alliance,<sup>4,23</sup> and there is growing evidence that they are filling a gap in service provision for health inequity groups (eg, women, people living in regional and remote areas).<sup>19,24</sup> However, these studies have typically used nonrandomized designs,<sup>4,18-20</sup> or have examined telephone support as an adjunct to standard care or continuing care after in-person treatment,<sup>21,25,26</sup> as opposed to stand-alone treatment.

The objective of this study was to examine the effectiveness of a stand-alone telephone-delivered cognitive and behavioral intervention, Ready2Change, in reducing problem alcohol use up to 3 months later among individuals with alcohol use problems from the general population.

## Methods

### Study Design

This was a single-site, double-blind, parallel-group, superiority randomized clinical trial. The Eastern Health and Monash University Human Research Ethics Committees approved the trial protocol (Supplement 1).<sup>27</sup> Participants provided verbal informed consent to participate. For the primary outcome, telephone assessments occurred at baseline and 3 months after baseline. Trial data were collected and managed using the Re-

### Key Points

**Question** Is a telephone-delivered intervention effective in reducing alcohol problem severity up to 3 months later among individuals with alcohol use problems from the general population?

**Findings** In this randomized clinical trial of 344 participants with problem alcohol use, reductions in the primary outcome—alcohol problem severity—were not significantly different between intervention and control groups at 3 months. However, the intervention was associated with a significantly greater reduction in hazardous alcohol use and a reduction in alcohol problem severity when 2 or more sessions were delivered.

**Meaning** Although reductions in alcohol problem severity were not significantly different between treatment groups at 3 months, results demonstrate the potential benefits of this highly scalable and accessible model of alcohol treatment.

search Electronic Data Capture (REDCap) web-based application (Vanderbilt University).<sup>28,29</sup> Data collection was finalized on September 10, 2020, and analyses were finalized on May 27, 2022. This study reporting followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.<sup>30</sup>

### Participants and Eligibility

The study was conducted at Turning Point, a national addiction treatment and research center in Melbourne, Victoria, Australia. Participants were recruited from across Australia via social media (including targeted recruitment of people living in regional and remote areas) and clinician referrals. The study was promoted as a trial of 2 brief support programs, which concealed group allocation when the duration of the intervention received in the other group was unknown. Participants 18 years or older with problem alcohol use (Alcohol Use Disorders Identification Test [AUDIT] score > 6 [for female participants] and 7 [for male participants])<sup>31,32</sup> were recruited between May 25, 2018, and October 2, 2019. Individuals with severe alcohol dependence requiring more intensive treatment (based on history of physical alcohol withdrawal symptoms and Severity of Alcohol Dependence Questionnaire–Community score ≥31),<sup>33</sup> low-risk alcohol consumption, a history of psychosis, active suicidality, an acquired brain injury, attending other alcohol treatment, experiencing substantial hearing impairment, and pregnant women were excluded via initial screening assessment.

### Randomization and Blinding

Participants were randomly assigned to the intervention group or active control group (1:1 allocation ratio). Randomization, stratified by sex, used a standard computer-generated permuted blocks of variable size scheme for each stratum. Participants, the researcher completing follow-up assessments, and the study statistician remained blind to treatment assignment.<sup>27</sup>

## Study Groups

### Intervention

The intervention group received 4 to 6 sessions of a telephone-delivered intervention, a manualized cognitive and behavioral intervention. After clinical assessment (session 1), 4 fundamental exercises were universally delivered (session 2): (1) a daily alcohol diary (between-session task reviewed session 2), (2) a cognitive behavioral formulation that identifies triggers and consequences, (3) managing urges with SOBER breathing (a mindfulness-based practice that includes the following steps: stop, observe, breathe, expand, respond), and (4) establishing a helpful routine. Delivery of subsequent modules was informed by participants' reasons for engaging in support and their goals (eg, reduction or abstinence), and included (1) self-monitoring, goal setting, and behavior change skills, (2) identification of strengths and motivational enhancement, (3) relapse prevention, managing urges and cravings, dealing with slip-ups and monitoring progress, and (4) psychoeducation and harm reduction (sessions 3-4, up to 6 total). Additional skills modules were delivered to address triggers identified in the cognitive behavioral formulation and included the following skills: (1) emotion regulation, (2) anger management, (3) urges and cravings management, (4) sleep hygiene, (5) mindfulness, (6) interpersonal, (7) anxiety management, and (8) depressed mood management (session 3-4, up to 6 total).<sup>19,27</sup> Sessions were typically 30 to 50 minutes long and delivered approximately weekly by the same counselor (registered/clinical psychologist). Two intervention workbooks containing exercises represented visually with node-link maps were mailed or emailed to participants to facilitate counselor-delivered exercises within sessions and contained self-help exercises to prompt between-session practice. Participants also received the alcohol consumption guidelines and stress management pamphlets provided in the active control condition.

To facilitate intervention fidelity, counselors underwent comprehensive training, conducted by one of the intervention developers (K.H.). Adherence was facilitated by the intervention manual to guide delivery, the intervention workbooks to guide session content (containing participant instructions and counselor scripts for each exercise), and a checklist of delivered intervention modules completed after the session by counselors. Competence was monitored via case discussions conducted in monthly group supervision facilitated by K.H., checklist review to confirm participants uniformly received core modules, and review of recorded intervention sessions by K.H. to inform supervision discussions.

### Active Control

The active control group received alcohol consumption guidelines and stress management pamphlets, and 4 telephone check-ins less than or equal to 5 minutes in length from a researcher (I.V.). Participants in the control group were provided with information on how to access further support when required (eg, state helplines).

### Main Outcomes

The primary outcome was change in alcohol problem severity at 3 months after baseline, assessed using the AUDIT total

score<sup>31,32</sup> (previously modified and validated to use a past-month time frame).<sup>19,34</sup> Key secondary outcomes were AUDIT hazardous use, dependence symptoms, and harmful use domains.<sup>31,32</sup> Hazardous use items are the same as those that constitute the AUDIT-consumption (AUDIT-C) scale (alcohol use frequency, quantity, heavy drinking frequency), validated for identifying problem drinking and alcohol use disorders.<sup>35,36</sup> Other secondary outcomes were change in past-month drinking patterns (drinking days, days >2 standard drinks consumed, days >4 standard drinks consumed [heavy drinking days], total standard drinks), assessed using the Timeline Followback (TLFB) instrument.<sup>37</sup> Drinking pattern variables corresponded to the Australian alcohol guidelines in place at the time the study was conducted, which recommended that adults drink no more than 2 standard drinks per day, and no more than 4 standard drinks on any 1 occasion (an Australian standard drink contains 10 g of alcohol).<sup>38</sup>

### Statistical Analysis

#### Power and Sample Size Calculation

The sample size was calculated using pilot study data (ie, estimated decrease in AUDIT total score: intervention  $\geq 8$  units, control = 4 units; between-participant variance = 23.8, within-subject variance = 49.8)<sup>18</sup> and was based on the power of the *F* test for the overall treatment-by-time interaction and the power of the *t* test for the interaction contrast of primary interest (ie, the difference between treatment groups in their changes from baseline to 3 months). The sample size estimate allowed for a 30% attrition rate and 85% power for the 2-sided *t* test ( $\alpha = .05$ ) of the interaction contrast.

#### Intention-to-Treat and Per-Protocol Analyses

The primary outcome, change in alcohol problem severity at 3 months after baseline, was analyzed using intention-to-treat (ITT) principles. With the exception of participants who withdrew from the trial, follow-up data collection was attempted with all participants at each time point. Per-protocol sensitivity analyses of the primary outcome and AUDIT secondary outcomes were restricted to those participants with 1 or more postbaseline assessments and, for participants randomly assigned to the intervention group, participation in 1 or more sessions. Prespecified exploratory analyses of the primary outcome and AUDIT and TLFB secondary outcomes were conducted adjusting for exposure to treatment sessions in each group ( $\leq 1$  session,  $\geq 2$  sessions). The repeated measurements of the outcome variables were analyzed by fitting linear mixed models, with fixed effects for treatment and time, and their interaction, and random effects for participants and assessments within participants, using restricted maximum likelihood. All analyses were based on the missing at random assumption and used restricted maximum likelihood to calculate predicted means that were based on estimated effects. The variance-covariance model for the repeated measures was selected using Akaike information criterion<sup>39</sup> and, unless otherwise stated, the unstructured model was selected. The *F* test was used to test for an overall treatment-by-time interaction, and the comparison, between groups, of their changes from baseline to 3 months was based on a *t* test of the correspond-

ing interaction contrast. All *t* tests used the predicted means, variances, and covariances that were recovered from the fitted mixed model. Diagnostic plots of residuals were assessed and, if deemed necessary, variance-stabilizing transformations were applied to the outcome variables and inferences were based on the transformed scale. A 2-sided *P* value of  $< .05$  was used as the level of significance for statistical analyses, conducted using Genstat, version 21.1<sup>40</sup> (VSN International), and SAS, version 9.4<sup>41</sup> (SAS Institute) (Supplement 1).

## Results

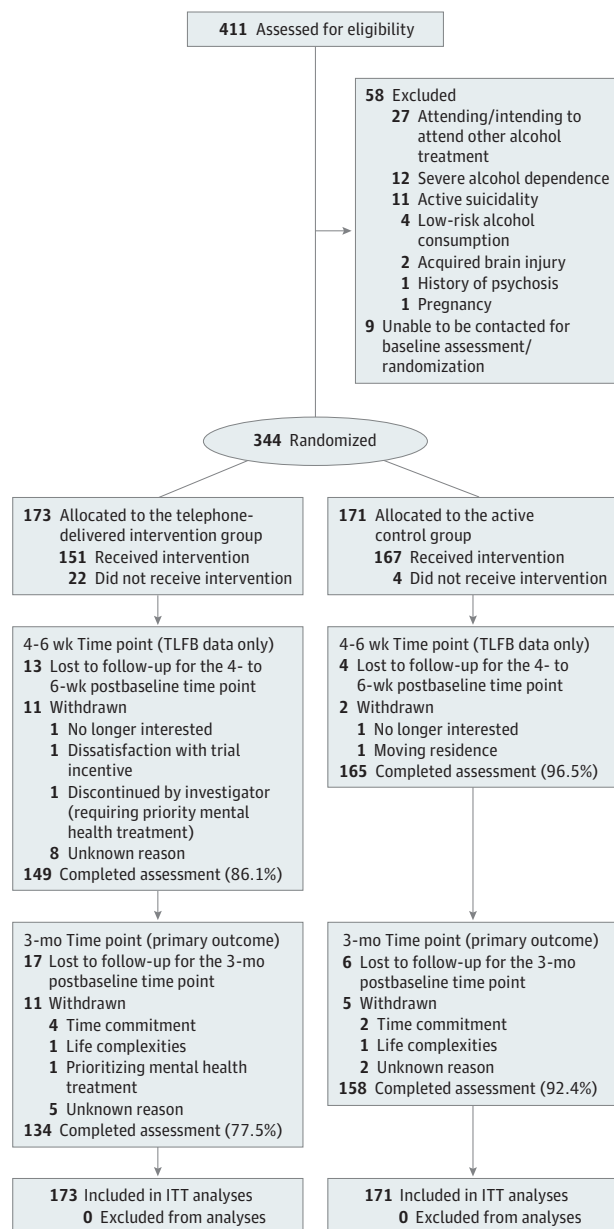
Of 411 people screened, 344 (mean [SD] age, 39.9 [11.4] years; range, 18-73 years; 177 male participants [51.5%]; 167 female participants [48.5%]; 28 being culturally and linguistically diverse participants [8.1%]; 9 participants identified as being of Aboriginal and/or Torres Strait Islander descent [2.6%]) met inclusion criteria and were randomly assigned (173 participants [50.3%] in the intervention group; 171 participants [49.7%] in the active control group) (Figure). Of those participants randomly assigned to groups who did not receive the allocated intervention (*n* = 26), 5 withdrew before their first session, with the remaining not able to be engaged despite multiple contact attempts per the study protocol. Retention at 3 months was 84.9%. Group characteristics at baseline were similar (Table 1).

Participants consumed alcohol a mean (SD) of 19.9 (8.1) days in the past month and had a mean (SD) of 15.5 (9.1) heavy drinking days (ie, days consuming  $>4$  standard drinks); two-thirds of participants (218 [63.4%]) had an AUDIT score corresponding to the highest symptom category of probable dependence. Just one-third of participants (101 [29.4%]) had previously sought alcohol treatment (mean [SD] treatment episodes, 1.3 [0.6]; predominantly counseling, support or case management, and pharmacotherapy) despite a high mean (SD) baseline AUDIT score of 21.5 (6.3). Participants randomly assigned to the intervention group completed a mean (SD) of 3.6 (2.1) sessions, with 113 (65.3%) completing the program (ie, defined as participating in  $\geq 4$  sessions). Participants randomly assigned to the control group completed a mean (SD) of 3.7 (0.9) sessions, with 137 (80.1%) completing 4 or more sessions.

### Primary Outcome and AUDIT Secondary Outcomes

For the primary ITT analyses, there was a significant difference in AUDIT total score for the treatment group relative to the active control group at 3 months (difference,  $-2.15$ ; 95% CI,  $-3.64$  to  $-0.65$ ;  $P = .005$ ). There was a significant decrease in AUDIT total score from baseline to 3 months in both the intervention (decrease, 8.22; 95% CI, 7.11-9.32;  $P < .001$ ) and control (decrease, 7.13; 95% CI, 6.10-8.17;  $P < .001$ ) groups, and although linear mixed modeling indicated the possibility of an overall treatment-by-time interaction ( $F_{3,285.2} = 2.59$ ;  $P = .05$ ), the changes over time from baseline to 3 months were not significantly different between groups (difference, 1.08; 95% CI,  $-0.43$  to 2.59;

Figure. Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram of Participants Recruited to the Trial



ITT indicates intention to treat; TLFB, Timeline Followback.

$P = .16$ ) (Table 2). In examining the AUDIT subscales, for AUDIT hazardous use (ie, AUDIT-C) there was a significantly greater reduction from baseline to 3 months in the intervention group relative to the active control group (difference, 0.58; 95% CI, 0.02-1.14;  $P = .04$ ) (Table 2). There were significant reductions from baseline to 3 months in both treatment groups for AUDIT dependence symptoms (intervention group decrease, 2.67; 95% CI, 2.25-3.09;  $P < .001$ ; active control decrease, 2.25; 95% CI, 1.84-2.65;  $P < .001$ ) and AUDIT harmful use (intervention group decrease, 3.10; 95% CI, 2.54-3.67;  $P < .001$ ; active control decrease, 3.02;

Table 1. Baseline Characteristics of Trial Participants and Intervention Sessions Completed

Variable	Count (%)		
	Total (n = 344)	Active control (n = 171)	Intervention (n = 173)
Age, mean (SD), y	39.9 (11.5)	41.0 (11.4)	38.7 (11.3)
Sex			
Male	177 (51.5)	88 (51.5)	89 (51.4)
Female	167 (48.5)	83 (48.5)	84 (48.6)
Geographic area <sup>a</sup>			
Major city	230 (66.9)	115 (67.3)	115 (66.5)
Inner regional	57 (16.6)	26 (15.2)	31 (17.9)
Outer regional	45 (13.1)	23 (13.5)	22 (12.7)
Remote	12 (3.5)	7 (4.1)	5 (2.9)
Education level			
<Year 12 or equivalent	39 (11.3)	24 (14.0)	15 (8.7)
Year 12 or equivalent	60 (17.4)	31 (18.1)	29 (16.8)
Vocational training, apprenticeship, certificate I, II, III, IV	66 (19.2)	32 (18.7)	34 (19.7)
Diploma, advanced diploma, associate degree	65 (18.9)	28 (16.4)	37 (21.4)
Bachelor's degree	71 (20.6)	31 (18.1)	40 (23.1)
Postgraduate degree (eg, master's or doctoral degree)	43 (12.5)	25 (14.6)	18 (10.4)
Employment status			
Full-time	151 (43.9)	76 (44.4)	75 (43.4)
Part-time	56 (16.3)	25 (14.6)	31 (17.9)
Casual	65 (18.9)	38 (22.2)	27 (15.6)
Studying	14 (4.1)	8 (4.7)	6 (3.5)
Retired	13 (3.8)	6 (3.5)	7 (4.05)
Not employed	45 (13.1)	18 (10.5)	27 (15.6)
Relationship status			
Single	116 (33.7)	57 (33.3)	59 (34.1)
In a relationship	198 (57.6)	100 (58.5)	98 (56.7)
Separated, divorced, widowed	30 (8.7)	14 (8.2)	16 (9.3)
Age first consumed alcohol, mean (SD), y	15.2 (2.5)	15.1 (2.5)	15.2 (2.5)
Age commenced regular alcohol consumption, mean (SD), y	18.2 (5.4)	18.0 (4.4)	18.5 (6.3)
Past month alcohol consumption (TLFB)			
No. of drinking days, mean (SD)	19.9 (8.1)	20.3 (7.8)	19.5 (8.3)
Days >2 standard drinks consumed, mean (SD)	18.5 (8.4)	19.1 (8.2)	17.9 (8.5)
Days >4 standard drinks consumed, mean (SD)	15.5 (9.1)	16.3 (9.1)	14.7 (9.1)
Total No. of standard drinks, ' mean (SD)	168.7 (108.2)	177.1 (111.7)	160.5 (104.3)
Intervention/active control intervention sessions completed			
None	26 (7.6)	4 (2.3)	22 (12.7)
1	26 (7.6)	6 (3.5)	20 (11.6)
2	18 (5.2)	5 (2.9)	13 (7.5)
3	24 (7.0)	19 (11.1)	5 (2.9)
4-6 <sup>b</sup>	250 (72.7)	137 (80.1)	113 (65.3)

Abbreviation: TLFB, Timeline Followback.

<sup>a</sup> Geographic area was classified according to the Australian Statistical Geography Standard Remoteness Structure.

<sup>b</sup> Interventions were offered as 4- to 6-week programs, with 4 or more sessions defined as completed treatment.

95% CI, 2.49-3.56;  $P < .001$ ), although no significant treatment-by-time interactions were observed. Per-protocol analyses of AUDIT total and domain scores produced similar treatment-by-time interactions as the primary ITT analyses (eTable 1 in Supplement 2).

### Primary Outcome and AUDIT Secondary Outcomes Adjusted for Exposure

Exploratory analyses of the primary outcome adjusting for exposure to treatment sessions ( $\leq 1$  compared with  $\geq 2$  sessions) indicated a greater reduction from baseline to 3 months in the



Table 2. Intention-to-Treat Analyses of Primary Outcome and AUDIT Secondary Outcomes, Treatment Group by Time

Outcome variable	Mean (SE)				Contrast <sup>a</sup> (SE)	P value
	Baseline		At 3 mo			
	Intervention (n = 173)	Active control (n = 171)	Intervention (n = 134)	Active control (n = 158)		
AUDIT total score (primary outcome)	21.0 (0.5)	22.1 (0.5)	12.8 (0.6)	14.9 (0.5)	1.1 (0.8)	.16
AUDIT						
Hazardous use (AUDIT-C)	9.2 (0.2)	9.6 (0.2)	6.7 (0.2)	7.7 (0.2)	0.6 (0.3)	.04
Dependence symptoms	4.5 (0.2)	4.6 (0.2)	1.8 (0.2)	2.3 (0.2)	0.4 (0.3)	.16
Harmful use	7.3 (0.3)	7.9 (0.3)	4.2 (0.3)	4.9 (0.2)	0.1 (0.4)	.84

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; AUDIT-C, Alcohol Use Disorders Identification Test–consumption.

each treatment group: (intervention group at baseline – intervention group at 3 mo) – (control group at baseline – control group at 3 mo).

<sup>a</sup> The contrasts and their SEs compare the changes over time from baseline in

Table 3. Primary Outcome and AUDIT Secondary Outcomes Adjusted for Exposure (1 or Fewer Compared With 2 or More Sessions), Treatment Arm by Time

Outcome variable	Mean (SE)				Contrast <sup>a</sup> (SE)	P value
	Baseline		At 3 mo			
	Intervention (n = 173)	Active control (n = 171)	Intervention (n = 134)	Active control (n = 158)		
AUDIT total score (primary outcome)	21.5 (0.6)	22.0 (1.0)	12.2 (0.8)	16.1 (1.3)	3.4 (1.6)	.03
AUDIT						
Hazardous use (AUDIT-C)	9.4 (0.2)	9.9 (0.3)	6.4 (0.3)	8.4 (0.5)	1.5 (0.6)	.01
Dependence symptoms	4.7 (0.3)	4.4 (0.5)	1.9 (0.3)	2.9 (0.4)	1.3 (0.6)	.02
Harmful use	7.4 (0.3)	7.7 (0.5)	3.8 (0.4)	4.9 (0.6)	0.7 (0.8)	.35

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; AUDIT-C, Alcohol Use Disorders Identification Test–consumption.

each treatment group: (intervention group at baseline – intervention group at 3 mo) – (control group at baseline – control group at 3 mo).

<sup>a</sup> The contrasts and their SEs compare the changes over time from baseline in

intervention group relative to the active control group (difference, 3.40; 95% CI, 0.36-6.44;  $P = .03$ ) (Table 3). The adjusted analyses also showed significantly greater reductions from baseline to 3 months in the intervention group relative to the control group for AUDIT hazardous use (difference, 1.51; 95% CI, 0.36-2.66;  $P = .01$ ) and AUDIT dependence symptoms (difference, 1.33; 95% CI, 0.19-2.47;  $P = .02$ ) (Table 3).

## Secondary Outcomes

### Drinking Patterns

No significant treatment-by-time interactions were observed for square-root transformed TLFB domains (eTable 2 in Supplement 2), although there were significant declines from baseline to 3 months in each treatment group on each of these outcomes. Exploratory analyses adjusting for exposure to treatment sessions ( $\leq 1$  compared with  $\geq 2$  sessions) showed a greater reduction from baseline to 3 months in the intervention group relative to the active control group for all TLFB domains: past-month drinking days (difference, 0.67; 95% CI, 0.09-1.25;  $P = .03$ ), days with more than 2 standard drinks consumed (difference, 0.68; 95% CI, 0.06-1.30;  $P = .03$ ), days with more than 4 standard drinks consumed (difference, 1.06; 95% CI, 0.39-1.74;  $P = .002$ ), and total standard drinks (difference, 2.51; 95% CI, 0.69-4.34;  $P = .007$ ) (Table 4).

## Discussion

To our knowledge, this was the first randomized clinical trial to examine the benefits of a stand-alone telephone-delivered intervention among a general population sample with alcohol use problems. Based on the primary outcome, this trial did not find superior effectiveness of the intervention compared with active control; both groups experienced a significant decrease in AUDIT total score between baseline and 3 months, with change over time not significantly different between groups. However, the intervention was found to be effective in reducing hazardous alcohol use at 3-month after baseline. That the intervention group showed a greater reduction in AUDIT hazardous use relative to the active control group is an important finding. AUDIT hazardous use (ie, AUDIT-C) is a validated marker of alcohol use disorder severity<sup>42</sup> and is as psychometrically sound as the 10-item AUDIT,<sup>43</sup> though with excellent responsiveness to change<sup>36</sup> as it does not include items from the full AUDIT that correspond to drinking-related consequences, which are typically endorsed less frequently and therefore less sensitive to change over a shorter time frame (eg, “Have you or someone else been injured as a result of your drinking?”). This finding is consistent with the strong evidence supporting multiple-session telephone coun-

Table 4. Drinking Patterns (Square-Root Scale) Adjusted for Exposure (1 or Fewer Compared With 2 or More Sessions), Treatment Group by Time

	Mean (SE)					
	Baseline		At 3 mo			
Outcome variable	Intervention (n = 173)	Active control (n = 171)	Intervention (n = 134)	Active control (n = 158)	Contrast <sup>a</sup> (SE)	P value
TLFB drinking days	4.3 (0.1)	4.5 (0.2)	3.2 (0.2)	4.1 (0.3)	0.7 (0.3)	.03
TLFB days						
>2 Standard drinks	4.1 (0.1)	4.4 (0.2)	2.9 (0.2)	3.9 (0.3)	0.7 (0.3)	.03
>4 Standard drinks	3.6 (0.1)	3.9 (0.2)	2.2 (0.2)	3.6 (0.3)	1.1 (0.3)	.002
TLFB total standard drinks	12.2 (0.4)	12.8 (0.7)	7.8 (0.5)	11.0 (0.8)	2.5 (0.9)	.007

Abbreviation: TLFB, Timeline Feedback.

<sup>a</sup> The contrasts and their SEs compare the changes over time from baseline in

each treatment group: (intervention group at baseline – intervention group at 3 mo) – (control group at baseline – control group at 3 mo).

Abbreviation: TLFB, Timeline Feedback.

<sup>a</sup> The contrasts and their SEs compare the changes over time from baseline in

each treatment group: (intervention group at baseline – intervention group at 3 mo) – (control group at baseline – control group at 3 mo).

selling for smoking cessation<sup>22</sup> and extends findings of previous nonrandomized studies of telephone-delivered interventions for alcohol use problems.<sup>18–20</sup>

Per-protocol analyses, prespecified to occur only for those participants in the intervention group who received 1 or more sessions, yielded no treatment-by-time effects. However, in exploratory analyses adjusting for exposure to 2 or more sessions, a greater reduction in the intervention group was observed for alcohol problem severity and nearly all secondary alcohol outcomes. This approach allowed us to understand the effect of a minimal amount of treatment exposure beyond the first session, which typically consists of detailed clinical assessment only. Adjusting for exposure to 2 or more sessions may therefore be providing a more accurate representation of an as-treated or per-protocol approach and a better estimate of the true efficacy of the intervention<sup>44</sup>; this is a finding with important real-world clinical implications.

Most participants were new to alcohol treatment, despite high baseline alcohol problem severity, with two-thirds having scores indicative of alcohol dependence. Previous research is mixed regarding whether lower intensity interventions are appropriate and effective for populations with high alcohol problem severity.<sup>45–48</sup> Although telephone and online services are typically an initial point of contact with the alcohol treatment system, the results of the current study highlight the potential for telephone-delivered interventions to benefit individuals across the spectrum of alcohol use problems. These are among the first data to show that a stand-alone telephone-delivered intervention is effective among people with high alcohol problem severity who have not previously accessed alcohol treatment. From a public health perspective, given the dose-response relationship between alcohol and harms, low-intensity interventions offered to those with higher alcohol problem severity have potential for the greatest health gains.<sup>47,48</sup> The COVID-19 pandemic has increased demand for substance use treatment services<sup>49,50</sup> and has profoundly changed the ways in which this population accesses care, highlighting the urgent need to offer evidence-based telephone-delivered interventions to increase the reach and uptake of effective interventions.<sup>13</sup>

### Strengths and Limitations

Outcome measures demonstrating the benefits of the intervention in this trial (eg, combined consumption measures [AU-

DIT/AUDIT-C], risky drinking patterns) were recently identified by an international e-Delphi study<sup>51</sup> as core outcomes appropriate for use in alcohol intervention trials, which represents a key strength of this study. The trial was adequately powered, a double-blind design was used, the recruitment target was met with a high retention rate at 3 months (84.9%), treatment fidelity was monitored, and a nationwide approach to recruitment was used that included targeted recruitment of regional and remote participants. Generalizability of this study is limited owing to the exclusion of participants with severe alcohol dependence requiring more intensive treatment. Although, overall, the intervention group exhibited good treatment adherence (65.3% of the active group completed ≥4 sessions), adherence was greater in the control group (ie, 80.1%). Although participation steps and time commitment were communicated at multiple points (with a visual participation flowchart also provided), the increased burden of the intervention condition (eg, time commitment, content) may have led to the greater attrition of intervention participants observed. Additionally, the difference in treatment adherence between groups was, at least in part, driven by the greater proportion of intervention participants failing to initiate treatment (n = 22; control n = 4), which likely reflects operational factors (eg, handover to the counseling team, with fewer appointment times available relative to the dedicated researcher providing control sessions) and may have led to a decrease in the trial's statistical power. As treatment noncompletion for alcohol use problems predicts relapse and represents a key barrier to successful treatment outcomes,<sup>52</sup> methods to optimize initiation of, and retention in, interventions of this modality require further examination. In this trial, frequency—but not amount of contact—was controlled for across treatment groups. Another goal of research in this field is to examine the comparative effectiveness of telephone-delivered and in-person interventions of similar contact frequency and duration. Although some previous studies have shown equivalence of telehealth and in-person treatment for substance use problems using metrics of therapeutic alliance, treatment satisfaction, and abstinence supported by urinalysis data and treatment retention rates,<sup>53,54</sup> randomized trials with alcohol cohorts are needed. Another potential limitation was the reliance on self-reported alcohol outcomes where consumption may be inaccurately reported (eg, due to recall bias and/or social desirability).<sup>55</sup> Although biological verification of alco-

hol consumption (eg, urinalysis, transdermal monitoring) was not feasible owing to the trial's nationwide recruitment and telephone intervention and assessment approaches, research has found high convergence between biochemical and self-report measures of alcohol consumption in community populations, supporting the validity of self-report methods in the population under study.<sup>56</sup> Further, telephone-based assessments of alcohol consumption may be more robust to the effects of social desirability as they permit a sense of privacy and anonymity.<sup>4,57</sup>

Although estimated contrasts were consistently in the expected direction favoring the intervention, significant reductions in both groups were observed on most alcohol outcomes (not attributable to other treatment, accessed by just 5 participants between baseline and 3 months). Control group reductions in alcohol consumption are a common issue in alcohol intervention research,<sup>58</sup> with data from several studies suggesting that assessment reactivity (ie, mere exposure to alcohol questions prompts awareness and behavior self-regulation) can bias trial results toward the null and lead to underestimates of true intervention effects.<sup>58,59</sup> Regression to the mean relating to recruitment of a treatment-seeking cohort,<sup>60</sup> and treatment benefits from trial participation,<sup>61</sup> may also have contributed to control group response. The active control condition in this trial experienced a greater benefit than was anticipated (AUDIT total score decrease of 7.14 instead of 4 as estimated); however, we found that the intervention group

outperformed the control group on multiple secondary analyses of problem alcohol use, particularly when 2 or more sessions were received. To minimize nonspecific effects in the control group, using briefer validated versions of outcome measures, quantitatively accounting for research participation effects, and increasing the precision of estimating control group change for power calculations<sup>58,62</sup> should be considered in future research.

## Conclusions

Results of the randomized clinical trial showed that although reductions in the primary outcome, alcohol problem severity, were not significantly different between treatment groups at 3 months, the telephone-delivered intervention was effective in reducing hazardous alcohol use and reduced alcohol problem severity, risky drinking patterns, and total consumption when 2 or more sessions were delivered. The results of this clinical trial support these benefits of a telephone-delivered intervention in a general population sample of individuals who do not typically seek treatment for alcohol use problems, despite experiencing high problem severity. Findings demonstrate the potential benefits of this highly scalable telehealth model of alcohol treatment, with potential to reduce the treatment gap for problem alcohol use.

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