

Feasibility and preliminary efficacy of a personalized alcohol intervention integrating liver biomarkers and behavioral feedback

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Abstract

Aims: Limiting alcohol intake or not drinking at all reduces risk for multiple chronic diseases, including alcohol-associated liver disease (ALD). This research evaluated the feasibility, acceptability, and preliminary behavioral outcomes of a brief motivational interviewing (MI) intervention enhanced with personalized feedback and objective liver-health biomarkers. The intervention targeted active alcohol use disorder (AUD), including a patient subgroup diagnosed with ALD.

Setting/Design and Participants: This preliminary clinical trial enrolled 33 participants with AUD and recent heavy alcohol consumption (seven or more drinks per week for women; fourteen or more drinks per week for men). The sample was 48.5% women and 30.3% Hispanic. The primary AUD cohort ($n = 28$) was recruited via digital and community outreach, while the subgroup with ALD ($n = 5$) was recruited primarily from a hepatology clinic. Follow-up was conducted three months after the baseline intervention.

Measures and Findings: The motivational interviewing (MI) intervention integrated personalized reports combining liver-function blood tests, drinking summaries, and data from a custom smartphone application. From screening to three-month follow-up, average drinks per week decreased by 57%, and heavy drinking days decreased by 55%. Enrollment for the ALD subgroup was limited by stringent drinking inclusion criteria, primary reliance on a single hepatology clinic recruitment site, and a funding transition. Follow-up retention, however, was high across both groups (93% AUD-only; 100% ALD subgroup), demonstrating strong intervention acceptability among enrolled participants.

Conclusions: Enhancing brief MI with personalized biobehavioral data proved an acceptable and promising approach to reduce alcohol consumption over three months. While enrollment highlighted the need for expanded recruitment settings and eligibility criteria in ALD populations, these preliminary findings warrant larger trials to test long-term intervention scalability and sustainability across clinical and community settings.

Introduction

Alcohol-associated liver disease (ALD) and alcohol use disorder (AUD) are prevalent threats to health and well-being (Molzen et al., 2025; Rehm & Shield, 2019). Alcohol intake is a leading cause of steatotic liver disease, a common condition defined by an abnormal buildup of fat inside the liver, contributing significantly to the global burden of

disease and mortality (Aslam & Kwo, 2023; Staufer & Stauber, 2023). Alcohol-associated liver disease refers to a spectrum of liver damage caused by chronic alcohol intake (Ha et al., 2022). Although alcohol cessation is the best available treatment for ALD, few patients receive any form of alcohol intervention (Mellinger et al., 2018; Rogal et al., 2020). Like ALD, AUD is a progressive disease, categorized into stages of increasing severity, from mild to moderate to

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severe (Yang et al., 2022). The efficacy of behavioral interventions to reduce drinking is well-established, but research evaluations are rare among patients with ALD (Hemrage et al., 2023; Khan et al., 2016; Leggio & Lee, 2017; Oldroyd et al., 2023). As drinking levels rise worldwide, there will be earlier onset of disease and/or complex clinical comorbidities (Hingson et al., 2017; McCaul et al., 2019). Expanding the reach of brief, effective AUD interventions is critical to avoid progressive steatotic liver damage (Haque & Leggio, 2024). Without immediate attention to the extreme need for pathways to AUD treatment in primary and specialty care, the downstream health effects of drinking, the leading cause of preventable liver damage, will only worsen.

Many people, including those with AUD and ALD, underestimate their drinking level and thus the potential health sequelae of chronic alcohol consumption (Mellinger et al., 2018; Scholten et al., 2024; Watt et al., 2025). Patients with poorer understanding of their condition, and those without significant physical symptoms of liver damage, are less likely to perceive a need for support to reduce drinking (Horrell et al., 2022; Mellinger et al., 2024). In this context, personalized feedback can be a critical tool to increase motivation and self-efficacy for change (Addolorato et al., 2013; Asrani et al., 2025; DiMartini et al., 2022). Indeed, personal and/or normative drinking feedback is almost always included in brief interventions targeting alcohol use (Cadigan et al., 2015; Kahler et al., 2018; Monti et al., 2007; Morgenstern et al., 2021), and providing tangible, liver-health biomarker feedback lowers alcohol-use levels over time and increases abstinence (Berzigotti et al., 2021; Kjaergaard et al., 2024; Thursz et al., 2019). In digitally assisted interventions, behavioral feedback is a key behavior-change mechanism, particularly when delivered by a credible source such as a health provider or counselor (Garnett et al., 2018; Kuerbis et al., 2018; Mair et al., 2023). Providing personalized information on drinking and liver health also aligns with growing evidence supporting integrated care models to address both AUD and ALD (Haque & Leggio, 2024; Monnig et al., 2024).

Our multidisciplinary team of researchers and clinicians in the Northeastern area of the United States collaborated to implement *Pathways*. The study was originally designed to compare balanced groups of patients with ALD to those without an ALD diagnosis. Specifically, the primary goal was to collect initial feasibility (i.e., percentage of screening-eligible participants who enroll; percentage of participants who complete the study) and intervention acceptability/satisfaction among participants with active AUD and recent drinking, both with and without co-occurring ALD. The approach to brief motivational interviewing (MI), cultivated over decades of prior research (Bischof et al., 2021; Monti et al., 2007), added novel self-monitoring and liver-biomarker feedback to increase knowledge of liver-health status, awareness of personal precursors of drinking, and encourage motivation for change. *Pathways* aimed to remove language barriers (i.e., appropriate Spanish-language service delivery from bicultural interventionists) and recruit participants from population groups experiencing disparities in ALD

morbidity and mortality, specifically women and individuals with Hispanic ethnicity.

Methods

Participants

The *Pathways* study piloted a brief MI intervention enhanced with personalized biobehavioral feedback delivered in English or Spanish in a prospective, two-arm, nonrandomized clinical trial. Funded by the Center for Addiction and Disease Risk Exacerbation, an NIGMS-funded Center of Biomedical Research Excellence (COBRE; P20GM130414; PI: Monti, subproject 8644; contact PI: Treloar Padovano), *Pathways* sought to enroll 44 adults with significant current drinking (seven or more drinks per week for women; fourteen or more for men) and AUD. *Pathways* aimed to recruit a sample of participants with AUD where half had ALD, recruited at point-of-care medical visits; and half had AUD only, recruited from community outreach. Funding stipulations truncated the study timeline and led the researchers to allow enrollment in the comparator arm to exceed that of the ALD arm. Figure 1 illustrates the parallel-group design.

Recruitment

Chart reviews at the Hepatology Clinic at Rhode Island Hospital identified patients with ALD using a standardized eligibility checklist. An attending or gastroenterology fellow introduced potentially eligible and interested patients to a research assistant who then obtained informed consent for screening. Multimethod outreach to recruit the comparator group included print and digital advertisements (social media, public spaces, buses, radio), flyers posted in the same area as the hepatology clinic, and mailings to local healthcare providers with waiting-room materials. Interested patients signed medical release and HIPAA forms prior to sharing any identifiable information with researchers outside of the clinic. Total participant compensation was up to \$532. Compensation included a fixed amount for in-person screening (\$60) and baseline (\$60), escalating compensation for weekly visits (\$40, \$50, \$60), a fixed payment for follow-up (\$70), and variable payments for daily phone reports (up to \$112). Bonuses (up to \$80) encouraged adherence to study procedures.

General Inclusion Criteria. Eligibility criteria required participants be 21 years of age or older and meet the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria for AUD (American Psychiatric Association, 2013). Participants had to report alcohol intake exceeding risk thresholds, i.e., fourteen or more drinks per week for men and seven or more drinks per week for women, during any seven-day period in the past 90 days. Participants were able to read and speak English and/or Spanish; those fluent in both selected their preference for intervention delivery and study assessments.

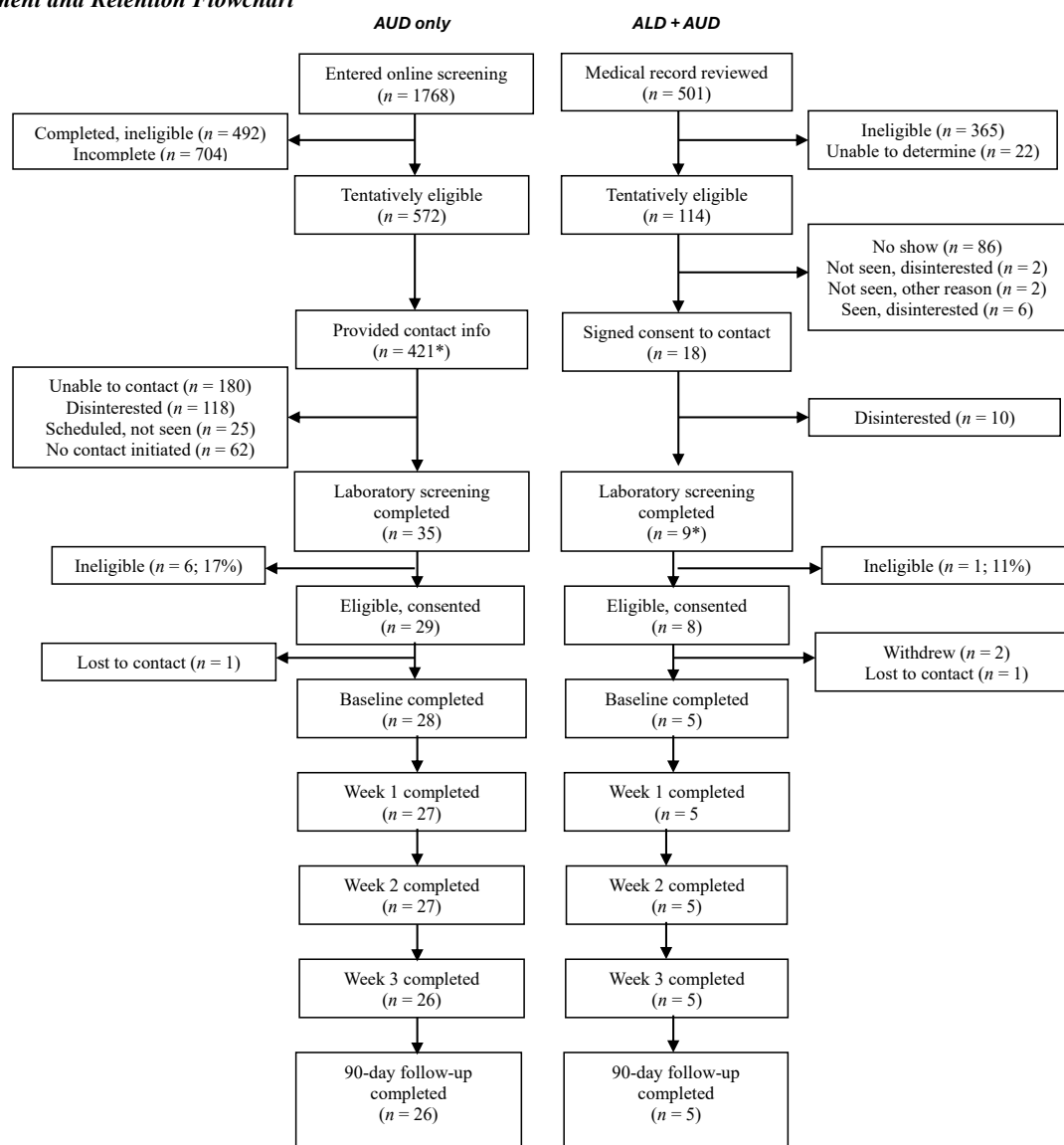
General Exclusion Criteria. Participants were excluded if they: had a current psychotic disorder; were receiving formal treatment for alcohol or substance use; were pregnant or nursing (if female); required medical detoxification; had

Class III obesity (BMI ≥ 40) or Class II obesity (BMI ≥ 35) with related conditions (e.g., hypertension, diabetes); had serious medical conditions (e.g., uncontrolled infections, organ failure, GI bleeding, hepatocellular carcinoma, or other malignancies except skin cancer); had received a liver transplant; had impaired kidney function with estimated glomerular filtration rate [eGFR] < 30 ; or any condition(s) that, in the opinion of the study team, would be unsuitable

for the clinical trial by interfering with informed consent, safety, or compliance. These restrictive exclusion criteria, particularly regarding severe obesity and acute medical instability, were implemented during this initial proof-of-concept phase to prioritize participant safety and minimize confounds, though ultimately constrained the pool of eligible ALD patients.

Figure 1

Recruitment and Retention Flowchart



Group-Specific Eligibility Criteria. In the ALD group, participants had one or more diagnostic indicators of advanced-stage ALD: (a) positive liver biopsy; (b) FibroScan® score > 12.5 kPa (transient elastography measuring liver stiffness, where > 12.5 kPa indicates severe fibrosis or cirrhosis); (c) evidence of a nodular liver or portal hypertension on abdominal imaging; (d) presence of liver-related complications secondary to portal hypertension (e.g., hepatic encephalopathy [cognitive impairment], ascites

[abdominal fluid retention], or esophageal varices [dilated veins]); (e) Fibrosis-4 index ≥ 3.25 (a non-invasive score derived from age, liver enzymes [AST/ALT], and platelet count, where ≥ 3.25 indicates a high risk of advanced fibrosis); (f) aspartate transaminase-platelet ratio index [APRI] ≥ 1.0 . The following diagnostic indicators excluded potential participants from allocation to the AUD-only group: (a) Fibrosis-4 index ≥ 3.25 ; (b) APRI ≥ 1.0 (a non-invasive score calculated from AST levels and platelet

count, where a value ≥ 1.0 indicates a high risk for advanced fibrosis or cirrhosis); (c) gamma-glutamyl transpeptidase-to-platelet ratio ≥ 0.32 (a serum biomarker panel combining GGT levels and platelet count, with values ≥ 0.32 indicating significant liver fibrosis). Requiring high active drinking levels alongside documented advanced liver fibrosis, while simultaneously applying strict exclusions, limited the window for ALD inclusion and substantially impacted recruitment yield.

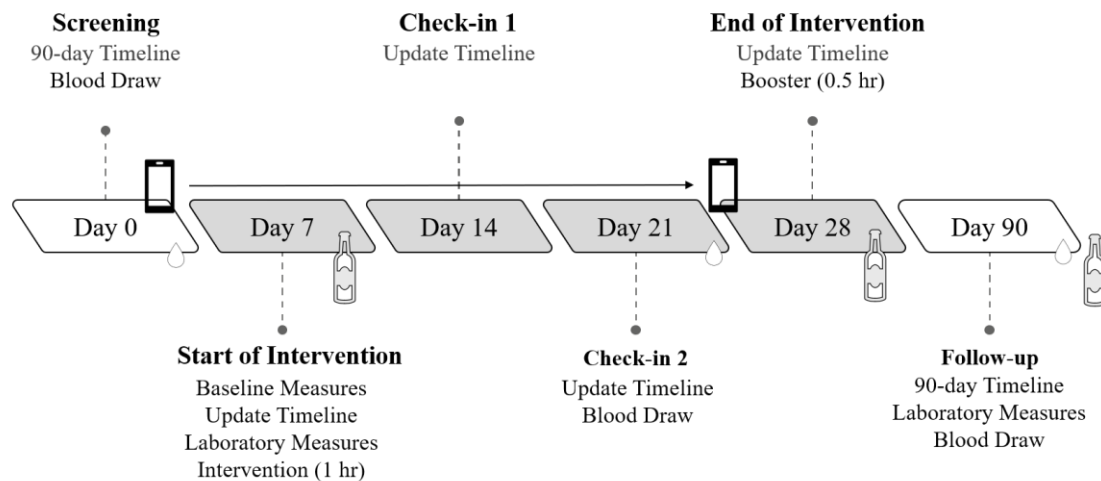
Procedures

Design Overview

Pre-registration of the study protocol is available publicly at ClinicalTrials.gov (NCT05135767). All procedures received approval from the Brown University Institutional Review

Figure 2

Study Assessment and Intervention Timeline



The *Pathways* protocol began with a screening phase (Day 0) consisting of a 90-day retrospective timeline review and a blood draw to confirm eligibility. Following this, participants entered a seven-day app-monitoring period prior to the start of intervention (Day 7), during which they completed baseline and laboratory measures and a one-hour intervention session. Participants then began a 21-day app-monitoring period punctuated by two mid-point check-ins for timeline updates (Day 14) and a second blood draw (Day 21). The active phase concluded at the end of intervention (Day 28) with a 30-minute booster session and a final timeline update. The study terminated with a three-month (Day 90) follow-up involving a final 90-day timeline review, laboratory measures, and a concluding blood draw to assess post-intervention outcomes.

Enhanced Motivational Interviewing Intervention

Motivational interviewing (MI) is a directive, participant-centered counseling style designed to elicit behavior change by helping individuals explore and resolve ambivalence (Bischof et al., 2021). The overall aim of the intervention was to build motivation to stop or reduce alcohol consumption, initiate a change plan, increase self-efficacy, and facilitate successful attainment of participant-specific

goals to stop or reduce drinking. A license-eligible postdoctoral interventionist ($n = 4$) or licensed psychologist ($n = 1$) delivered the intervention. All interventionists received at least eight hours of MI training: four hours of didactics by an expert trainer and four hours of supervised role-play. During the active study period, interventionists received structured feedback with weekly 1-hour supervision meetings conducted by MI expert, Dr. Magill, and the study principal investigator, Dr. Treloar Padovano, a licensed psychologist. To facilitate fidelity monitoring for the purpose of therapist training and supervision, sessions were coded with the Motivational Interviewing Treatment Integrity (MITI) Coding Manual, version 4.2.1 (Moyers et al., 2014). Calculated metrics from global scores and behavioral tallies facilitated delivery of feedback in supervision sessions (Kramer Schmidt et al., 2019; Moyers et al., 2016). See also paragraph entitled “App Usability and Compliance” under “Measures”.

The intervention was adapted from and informed by prior research and considered participants’ readiness to change (Kahler et al., 2018; Mellinger & Winder, 2019; Miller & Rollnick, 2013; Monti et al., 2007; Morgenstern et al., 2021). Phase 1 focused on building rapport and enhancing intrinsic

motivation for participants in the Precontemplation or Contemplation stages, using strategies such as reviewing pros and cons, exploring goals and values, looking forward/looking back, and using confidence and importance rulers. Phase 2 supported participants in the Action stage through strategies like recapitulation, key questions, offering advice with permission, and collaboratively creating a change plan. Interventionists recognized the participant's stage of change and applied strategies to facilitate the transition from building motivation (Phase 1) to making a change plan and strengthening commitment to change (Phase 2). The enhanced intervention included a personalized feedback report that summarized participants' self-reported drinking patterns, results of selected laboratory tests, and provided visual reports of drinking, craving, and negative mood states from app reports. The report also included common components of brief MI interventions, such as educational information on alcohol's effects on health and personalized normative feedback on drinking levels relative to gender-specific national averages. Importantly, this report articulated that learning about lower-risk drinking helps us to understand the connections of alcohol and liver health but does not mean that a drinking-reduction goal is right choice for everyone; those with signs of liver damage or other health problems were advised to stop all drinking. An example report is provided as [Supplementary Material](#).

Self-Monitoring Personalized Feedback

Participants completed two types of app reports for a 28-day monitoring period beginning the morning after the screening visit through the 29th day (to collect final drinking data for the 28th day). The custom app delivered morning reports via silent triggers daily at 4:00 a.m.; participants were instructed to complete morning reports daily upon waking. Audible triggers prompted reports at four randomly selected times within blocked intervals stratified by time of day to sample experiences across waking hours (i.e., 8:00 a.m. – 11:30 a.m., 11:31 a.m. – 3:00 p.m., 3:01 p.m. – 6:30 p.m., and 6:31 p.m. – 10:00 p.m.). Reminders included push notifications, text messages, and phone calls. Personalized feedback at the initial intervention session included self-monitoring reports aggregated for the approximately 1-week period between screening and baseline study visits. Personalized feedback at the booster intervention session included reports aggregated for the approximately three-week period between baseline and end-of-intervention study visits. Personalized feedback included daily reports of motivation and drinking precursors (e.g., alcohol craving, affect states) presented in graphical form separately by drinking and non-drinking days.

Measures

Feasibility and Acceptability

Recruitment and Retention. The primary study objectives were to establish feasibility and acceptability of procedures and satisfaction with the intervention. Specific *a priori* targets were set as follows: *Feasibility of recruitment*, i.e. total number of participants completing in-person screening sessions per month (target: two per month); *Feasibility of enrollment*, i.e., proportion of screening-eligible participants who completed the baseline session (target $\geq 60\%$);

Retention, i.e., overall and group-specific retention rates (targets $\geq 70\%$); and *Acceptability and treatment adherence*, i.e., overall and group-specific withdrawal rates (targets $\leq 20\%$).

App Usability and Compliance. Scaled scores on the System Usability Scale (SUS; Lewis, 2018) indicated the usability of the study smartphone application (MetricWire, Inc., 2023). The word “app” replaced “system” for all items. Participants rated SUS items on a scale from one (*Strongly disagree*) to five (*Strongly agree*). The standard scoring approach reverse-scores even-numbered items, then converts raw scores to score contributions from zero to four before calculating a total sum score. Multiplying the original score by 2.5 converts total sum scores to scaled scores from 0 to 100. Scaled scores in the range of 70 to 79 indicate acceptable usability, and scores of 80 or higher indicate excellent usability (Kortum & Bangor, 2013). Compliance with app reports also served as an indicator of usability and protocol adherence. In general, investigators anticipated higher compliance with once-daily morning reports, relative to prompted reports delivered at randomly selected times. Participants could miss one prompted report per day and remain fully compliant with the self-monitoring protocol and thus qualify for full compensation. An average response rate of 70% indicated acceptable compliance.

Intervention Satisfaction. Average scores, frequency counts within categories, and qualitative content on the Client Satisfaction Questionnaire-8 (CSQ-8) and supplemental items indicated satisfaction with the intervention. This measure consists of eight items designed to assess participant satisfaction with health and human services items (Larsen et al., 1979). The CSQ-8 has strong psychometric properties, operating characteristics, and internal consistency reliability; a score of 24 or above is indicative of high satisfaction (Attkisson & Zwick, 1982). The items reference a “service” received, and copyright restrictions did not allow alterations. Research staff instructed participants to rate the intervention as the “service,” and thus the CSQ-8 reflects satisfaction with the intervention as a “service,” rather than with the *Pathways* study overall.

Interventionist Fidelity

The MITI coding system is a tool to support interventionist training and to monitor fidelity for MI interventions (Moyers et al., 2016). For each interventionist session, researchers selected a random 20-minute segment of the audio recording. For sessions conducted in Spanish, a bilingual and bicultural research assistant translated these segments from English to Spanish prior to coding and supervision sessions. Motivational Interviewing Treatment Integrity global scores provided a holistic measure of each supervisor's general impression of the interventionist's adherence through rating technical elements (i.e., Cultivating Change Talk, Softening Sustain Talk) and relational components (i.e., Partnership, Empathy), rated on Likert scales (1 = low adherence; 5 = high adherence). Supervisors also tallied interventionist behavioral counts for the following: Giving Information (GI), Persuade (Per), Persuade with permission (Per with), Question (Q), Simple Reflection (SR), Complex Reflection

(CR), Affirm (AF), Seeking Collaboration (Seek), Emphasizing Autonomy (EA), and Confront (CO). Specifically, supervisors calculated and reviewed the following with interventionists: total MI-adherent behaviors (AF + Seek + EA), total MI-nonadherent behaviors (Per + CO), percent Complex Reflections (CR / (CR + SR)), and the ratio of Reflections to Questions (R:Q), according to the MITI 4.2.1 system (Moyers et al., 2014).

Inter-rater reliability evaluated agreement of supervisor ratings using a two-way, mixed-effect, consistency, average-measures intraclass correlation coefficient (ICC; McGraw & Wong, 1996). This approach assessed the degree to which raters (i.e., supervisors; a fixed effect) provided consistency in their MITI codes across all five interventionists (a random effect) following computational recommendations (Hallgren, 2012). Established guidelines for interpretation of ICCs were as follows (Cicchetti, 1994): < 0.40 = Poor; 0.40 to 0.59 = Fair; 0.60 to 0.74 = Good; ≥ 0.75 = Excellent.

Alcohol Consumption

Self-reported alcohol consumption in the 90 days prior to screening was the basis for calculating drinking inclusion criteria. Semi-structured Timeline Followback (TLFB) interviews assessed drinks consumed each day (Sobell & Sobell, 1992). Strategies included the use of printed monthly calendars, a weekly pattern chart (where regular drinking patterns were applicable), glassware, and a manualized script, with recent drinking corroborated by direct ethanol biomarkers from blood (i.e., phosphatidylethanol [PEth]), urine (i.e., ethylglucuronide [EtG]), and breath collected in the laboratory (Sobell et al., 1988). Phosphatidylethanol provided a highly specific and sensitive direct ethanol metabolite to corroborate reports of recent drinking at levels consistent with inclusion criteria (Rutledge & Murray, 2025). Timeline Followback queries included the number of drinks, ounces, type (e.g., beer, wine, liquor), and brand (if known). The outcome assessor and a second research assistant or investigator entered this information in a detailed Excel form which calculated total drinks per study day, with discrepancies resolved by consensus.

Results

Descriptives

In total, the *Pathways* trial recruited 37 eligible adults with AUD and recent drinking to complete informed consent and in-person screening. Twenty-nine did not have an ALD diagnosis, active symptoms, or blood biomarkers indicative of steatotic liver disease. Eight had a confirmed diagnosis of ALD at an advanced stage (i.e., F3 or greater). Of eligible participants, $n = 28$ in the comparator group (97%) and $n = 5$ in the ALD group (63%) completed baseline assessments, resulting in a total sample size of 33 in the evaluable dataset. In accordance with planned demographic targets, *Pathways* recruited a representative sample of men (51.5%) and women (48.5%), with one-third of the sample identifying as Hispanic or of Spanish origin (30.3%). Table 1 provides additional information describing participant characteristics, overall and separately by group.

Feasibility and Acceptability

Recruitment and Retention

A flowchart diagram describes recruitment and retention rates from initial contact through all study visits and follow-up (see Figure 1). The sample was representative of the population demographics (see Table 1). The pilot study originally aimed to recruit 44 participants balanced equally between two study arms ($n = 22$ AUD-only and $n = 22$ AUD+ALD), but these targets were not reached due to a slow pace of recruitment in the ALD group. The divergence from the original plan was driven by strict eligibility criteria, which required active recent drinking alongside AUD and advanced ALD indicators, as well as reliance on a single outpatient hepatology clinic site with high appointment no-show rates. Moreover, a funding transition necessitated early termination of recruitment and resulted in a decision to allow unbalanced groups so that as many participants as possible could be enrolled before the required study closure. There were approximately seven days between in-person screening and baseline assessments at the laboratory, which may account for discrepancies in group-specific enrollment rates between the AUD-only group and AUD+ALD subgroup. Although the *a priori* target of 60% enrollment was achieved overall, the rate was lower in patients with ALD and AUD (63%) than in participants with AUD only (97%). Follow-up retention was 94% across both groups, however, with 100% of the ALD patients who completed baseline assessments returning for the three-month follow-up, and 93% of the larger AUD-only cohort.

Intervention Satisfaction

Across participants, the average CSQ-8 total score was 28.2 ($SD = 3.5$), and the average scaled score was 91.7 ($SD = 11.3$), indicating high satisfaction with the intervention overall (Attkisson & Zwick, 1982). There were not notable differences in CSQ-8 total scores between patients with and without ALD (AUD+ALD: $M = 28.2$, $SD = 1.9$; AUD only: $M = 28.2$, $SD = 3.7$). Moreover, the CSQ-8 individual items indicated that the quality of the behavioral intervention was good ($n = 9$; 29.0%) or excellent ($n = 22$; 71.0%), with no participants choosing options of fair or poor. Most participants indicated that they had received the kind of intervention they wanted ($n = 28$; 90.3%), and that the intervention met most or almost all their needs ($n = 29$; 93.5%). All but one participant (96.8%) stated they would recommend the intervention to a friend. The majority (90.3%) were mostly or very satisfied with the amount of help they received, and only three were indifferent or mildly dissatisfied. Most participants (90.3%) reported positive changes as compared to how things were before they received the *Pathways* intervention. All but one said the intervention helped them deal more effectively with their problems ($n = 30$; 97.0%). All participants indicated that if they were to seek help to reduce drinking again, they would choose *Pathways*.

App Usability and Compliance

Scores on the validated System Usability Scale indicated satisfaction with the smartphone application ($n = 31$ participants who completed the intervention; 94% of total

sample). The average scaled usability score of 84.0 ($SD = 14.2$) was in the Excellent range and exceeded the *a priori* target of 70.0. In patients with ALD ($n = 5$), SUS scores

ranged from 70 to 95, $M = 81.0$, $SD = 10.1$, and among comparators ($n = 26$) SUS scores ranged from 40 to 100, $M = 84.5$, $SD = 15.0$.

Table 1

Summary of Descriptive Information for Participant Groups and Overall

Variable	AUD only ($n = 28$)	ALD + AUD ($n = 5$)	Overall ($N = 33$)
<i>Age (in years)</i>			
Observed range	21 – 63	33 – 67	21 – 67
M (SD)	45.1 (12.0)	51.0 (15.6)	46.0 (12.5)
<i>What sex were you assigned at birth (on your original birth certificate)? n (%)</i>			
Female	15 (53.6)	1 (20.0)	16 (48.5)
Male	13 (46.4)	4 (80.0)	17 (51.5)
<i>What is your race? n (%)</i>			
Asian	1 (3.6)	—	1 (3.0)
Black	3 (10.7)	—	3 (9.1)
White	15 (53.6)	4 (80.0)	19 (57.6)
Unknown	8 (28.6)	1 (20.0)	9 (27.3)
More than one race	1 (3.6)	—	1 (3.0)
<i>Are you Hispanic, Latino/Latina/Latinx, or of Spanish origin? n (%)</i>			
Yes	9 (32.1)	1 (20.0)	10 (30.3)
No	19 (67.9)	4 (80.0)	23 (69.7)
<i>What is your sexual orientation? n (%)</i>			
Asexual	2 (7.1)	1 (20.0)	3 (9.1)
Bisexual	1 (3.6)	—	1 (3.0)
Gay	—	1 (20.0)	1 (3.0)
Heterosexual	20 (71.4)	3 (60.0)	23 (69.7)
Lesbian	1 (3.6)	—	1 (3.0)
Pansexual	1 (3.6)	—	1 (3.0)
Prefer not to answer	3 (10.7)	—	3 (9.1)
<i>When did you last work for pay, even for a few days? n (%)</i>			
Within the past 12 months	21 (75.0)	4 (80.0)	25 (75.8)
1 to 5 years ago	4 (14.3)	1 (20.0)	5 (15.1)
Over 5 years ago or never worked	3 (10.7)	—	3 (9.1)
<i>Considering your own income and the income from any other people who help you, how would you describe your overall personal financial situation? n (%)</i>			
Live comfortably	8 (28.6)	—	9 (27.3)
Meet needs with a little left	10 (35.7)	1 (20.0)	10 (30.3)
Just meet basic expenses	8 (28.6)	3 (60.0)	11 (33.3)
Don't meet basic expenses	2 (7.1)	1 (20.0)	3 (9.1)
<i>What is your annual gross income (before taxes) from all sources? n (%)</i>			
\$0-\$9999	5 (17.9)	3 (60.0)	8 (24.2)
\$10,000-\$19,999	5 (17.9)	1 (20.0)	6 (18.2)
\$20,000-\$29,999	3 (10.7)	—	3 (9.1)
\$40,000-\$59,999	2 (7.1)	—	2 (6.1)
\$60,000-\$79,999	5 (17.9)	—	5 (15.2)
\$80,000-\$99,999	3 (10.7)	—	3 (9.1)
\$100,000 or more	5 (17.9)	1 (20.0)	6 (18.2)
<i>Alcohol Use Disorder Identification Test</i>			
Observed range	2 – 34	6 – 38	2 – 38
M (SD)	16.5 (8.1)	20.4 (11.6)	17.1 (8.6)

Overall, there were 3,733 completed smartphone reports and 1,231 reports marked as missed, yielding a response rate of 75.2%. Separately by report type, there were 96 missed

morning reports, yielding a response rate of 90.6%. There were 1135 missed prompted reports (sent up to four times daily), yielding a response rate of 71.3%.

Table 2

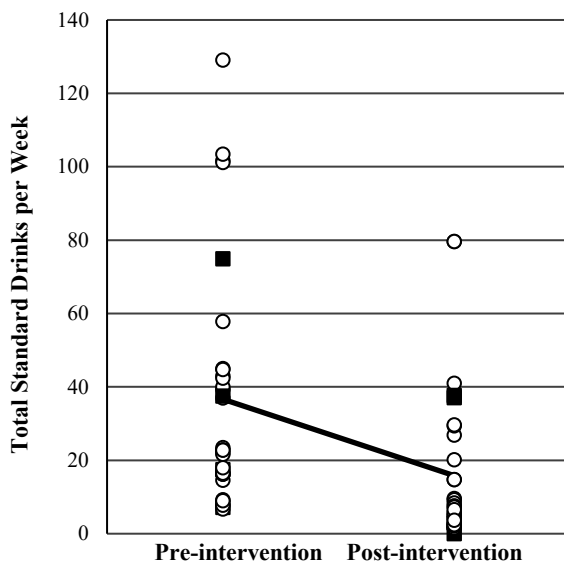
Summary of Alcohol Consumption by Group

Variable	Comparator Group: AUD only (<i>n</i> = 28)				ALD Group: ALD and AUD (<i>n</i> = 5)			
	Pre <i>M</i> (<i>SD</i>)		Post <i>M</i> (<i>SD</i>)		Pre <i>M</i> (<i>SD</i>)		Post <i>M</i> (<i>SD</i>)	
Percent drinking days	62.3	(29.3)	25.5	(23.9)	65.1	(30.5)	44.0	(40.0)
Percent heavy drinking days (4+)	43.8	(34.0)	16.2	(23.3)	50.7	(45.2)	42.2	(42.0)
Percent heavy drinking days (5+)	39.5	(34.6)	15.2	(23.4)	50.7	(45.2)	41.6	(42.4)
Average drinks per week	37.0	(33.1)	15.3	(20.8)	34.3 ^a	(29.9)	19.4 ^a	(20.8)

Note: Pre = Preintervention drinking. Post = Postintervention drinking. Timeline Follow-back interviews assessed drinking variables for the 90 days prior to intervention (at in-person screening) and 90 days after baseline (at 90-day follow-up). This is not a randomized trial, and the ALD group is too small to conduct mean comparisons. ^aExcludes one extreme outlier in the ALD and AUD group; uncorrected average drinks per week were as follows: Pre *M*=83.1 (*SD*=112.2); Post *M*=68.0 (*SD*=110.1)

Figure 3

Total Standard Drinks per Week for all Participants, After Removal of One Outlier



Note: The trendline shows average drinks per week for the sample overall for the 90 days prior to screening (i.e., preintervention) and the 90 days after baseline (i.e., post-intervention). Shaded squares indicate patients with ALD and AUD. Open circles indicate comparators with AUD only.

Interventionist Fidelity

Intervention fidelity coding was not fully crossed (Hallgren, 2012), with *n* = 13 (39%) sessions double-coded by both supervisors following established guidelines (Moyers et al., 2016). The ICC for Cultivating Change Talk was in the Excellent range (Cicchetti, 1994), ICC = 0.82, as was the ICC for Softening Sustain Talk, ICC = 0.79. These high ICCs suggest that the assessment error introduced by the

independent coders (i.e., supervisors) was minimal. Therefore, supervisor ratings were suitable for assessing MI fidelity across interventionists in the *Pathways* study. For double-coded sessions, the overall average Technical score was 4.0 (*SD* = 0.8), indicating good interventionist proficiency (Moyers et al., 2014). Likewise, the overall average Relational score was 4.2 (*SD* = 0.5), indicating good interventionist proficiency (Moyers et al., 2014). Nonadherent MI behavioral counts were rare, with a modal sum of zero (*M* = 0.3, *SD* = 0.7). The Reflection-to-Question ratio was 1.12:1 (*SD* = 0.90), on average, indicating fair proficiency (Moyers et al., 2014). Interventionists were primarily providing Complex, rather than Simple, reflections (*M* ratio of Complex-to-Simple reflections = 54.4%, *SD* = 20.6%), indicating good proficiency (Moyers et al., 2014).

Alcohol Consumption

Preliminary efficacy endpoints estimated plausible ranges for summary drinking variables and potential reductions in alcohol consumption (see Table 2), which PEth corroborated. Descriptives for average drinks per week excluded one extreme outlier. This participant was in the ALD group and did not drink more frequently than other participants but reported significantly greater drinks per drinking event. Source documents confirmed the reported average drinks per drinking day and drinks per week. Uncorrected average drinks per week are reported in the table note. Across the overall sample (*n* = 33), self-reported drinking days decreased from 62.7% pre-intervention to 28.3% post-intervention. Excluding the outlier (*n* = 32), participants showed significant reductions in alcohol consumption: drinks per week decreased by 56.7% (from 36.7 to 15.8) and drinks per drinking day decreased by 25.1% (from 7.3 to 5.4). Standard deviations in both measures (*SD* pre-intervention: 32.3 and 4.5; *SD* post-intervention: 20.5 and 3.4) highlight wide variability across all participants. Figure 3 depicts pre- and post-intervention total standard drinks per drinking day, showing ALD

patients (shaded squares), AUD-only comparators (open circles), and the trendline for the overall average (excluding the outlier).

Discussion

The *Pathways* study effectively tested recruitment strategies and study protocols for a pilot clinical trial of a brief intervention targeting AUD. The intervention, which enhanced MI with biobehavioral data (i.e., personalized feedback), showed preliminary success as a brief intervention to reduce alcohol intake for participants with AUD-only and a smaller subset with AUD+ALD. Despite meeting the enrollment benchmark for the ALD group (63%; target $\geq 60\%$), recruitment of patients still faced barriers. Challenges such as the high no-show rate (i.e., approximately 70% of appointments missed) at the hepatology clinic serving as the primary recruitment site for ALD patients made reaching patients with advanced ALD difficult. Crucially, once enrolled, all participants, including those with ALD at advanced stages, showed exceptional compliance, retention, and satisfaction with the *Pathways* intervention. Overall, the primary outcomes demonstrated acceptability of study procedures among enrolled participants, suggesting the brief intervention model is a well-received approach and warrants additional exploration in larger samples of patients with AUD and ALD.

A significant strength of the *Pathways* intervention was its availability in Spanish, delivered via telehealth videoconference by a bilingual interventionist, which increases the intervention's potential reach and generalizability. Evidence-based interventions to change drinking patterns rarely specifically address the connections of alcohol intake and progressive liver damage. Moreover, as of 2026, most US clinical trials still list "proficiency in English" as a mandatory inclusion criterion. Thus, *Pathways* takes a critical step toward increasing research representation by offering a linguistically inclusive intervention tailored to inform participants about the effects of alcohol on liver health. For low-SES populations, the healthcare system is often reactive, identifying and treating acute emergencies. By integrating evidence-based MI with personalized feedback from liver-health markers, alcohol intake, and real-world drinking precursors, interventions like *Pathways* can bridge a critical gap where hepatology practice has historically failed to diagnose early-stage ALD and provide accessible pathways to AUD treatment in primary and specialty care settings.

A central takeaway from this trial involves the methodological and practical lessons learned regarding ALD recruitment. The original ambition to recruit a balanced cohort of ALD patients integrated directly within routine care was constrained not only by a tight study timeline, but also by design features including restrictive eligibility criteria. Requiring active AUD with recent drinking alongside ALD is a tall order, particularly while also excluding individuals with acute medical instability, decompensation, or severe comorbidities (including severe obesity). In real-world clinical practice, patients with advanced ALD and AUD may have already reduced their

drinking in the near term but still would benefit from behavioral support to maintain sustained changes. Furthermore, relying primarily on an outpatient hepatology clinic, where appointment no-show rates were high, severely restricted recruitment reach. These methodological choices restricted the pool of eligible ALD patients, ultimately reducing recruitment success and weakening feasibility evidence for this subgroup. Moving the field toward a more equitable and preventive model of care is essential. To achieve this, future trials should relax exclusion criteria to include additional settings (e.g., acute care units, addiction consult services, primary care) and patients with undiagnosed liver disease and/or mildly decompensated advanced disease. Broadening the approach can reach patients at critical teachable moments and test the long-term scalability of biobehavioral MI across diverse clinical settings.

Limitations

This was a pilot study, not a randomized clinical trial (RCT). The finding that alcohol-intake reductions at the final follow-up (i.e., three months after baseline) exceeded reductions immediately after treatment (i.e., three weeks after baseline) suggest the observed benefits for participants with AUD and recent drinking were real, and not a statistical artifact that was uncontrolled by the nonrandomized design (e.g., regression to the mean). The sample included a variety of people with AUD, including some with ALD, but preliminary subgroup analyses are strictly descriptive due to the study sample size. The biobehavioral feedback was purposefully packaged within liver-related information about how progressive damage occurs and can be prevented by stopping or limiting drinking. This was relevant for the full sample and the ALD subgroup, as all can improve their health and functioning through behavioral changes. The primary goal of this trial was not to re-prove that MI works. The benefits of MI are already well-established. Rather, the *Pathways* project tested a novel approach to enhancing brief MI with personalized biobehavioral feedback. While the interventionist's Reflection-to-Question ratio was rated in the "fair" range, this may have been the result of the Elicit-Provide-Elicit framework required to discuss the personalized biobehavioral reports. This ratio reflects a successful clinical application that balanced data-driven information exchange with the relational spirit of MI.

Having shown promise, *Pathways* provides footing for a rigorous, full-scale RCT that can draw more robust conclusions. Planning is underway for such rigorous RCTs evaluating the enhanced MI intervention for population groups experiencing disparities in ALD severity and mortality, including women and people with Hispanic ethnicity (Ochoa-Allemant et al., 2023). Relatedly, whereas restrictive exclusion criteria were necessary for the pilot, they limit the generalizability of the findings to the broader ALD population, where metabolic comorbidities are common and recent drinking may have declined upon ALD diagnosis. Regardless of recent drinking, ALD patients with past-year AUD need support due to increased risk for returning to drinking. Our recent and future studies adopt more inclusive criteria to reflect the clinical reality of

metabolic dysfunction and alcohol-associated liver disease patients.

Conclusions

Efficacious behavioral AUD interventions are available and have demonstrated promise for reducing alcohol intake in patients with ALD (Addolorato et al., 2016). If treated earlier in its progression, recovery from AUD could circumvent multiple leading alcohol-related causes of death and chronic health conditions (Mathurin et al., 2012). Despite many opportunities for intervention through interactions in the healthcare system, patients rarely receive brief alcohol interventions or referrals for formalized AUD treatment (Edlund et al., 2012; Hemrage et al., 2023; Khan et al., 2016; Mellinger et al., 2019). Stopping drinking is the only known effective treatment for ALD, and brief advice alone is not a sufficient form of AUD intervention. Furthermore, the challenges of systematic bias and limited healthcare access for the population groups at greatest risk of ALD mortality require moving beyond current approaches and forming multidisciplinary collaborations to reach and help more patients (Haque & Leggio, 2024; Ochoa-Allemant et al., 2023). Avoiding drastic increases in morbidity and mortality of ALD (Gan et al., 2025) requires adaptations to meet the urgent need to identify and intervene for AUD at earlier stages.

Contributor Roles Taxonomy (CRediT) Author Statement

Treloar Padovano: Conceptualization, Methodology, Software, Formal analysis, Data Curation, Writing – Original Draft, Writing – Review and Editing, Supervision, Project administration, Funding acquisition. **Promrat:** Resources, Investigation, Writing – Review and Editing, Supervision, Funding acquisition. **Muro:** Investigation, Data Curation, Writing – Review and Editing. **Magill:** Resources, Writing – Review and Editing, Supervision. **Mellinger:** Conceptualization, Resources, Writing – Review & Editing, Supervision, Funding acquisition. **Aggarwal:** Writing – Review and Editing. **Zelaya:** Project administration, Writing – Review and Editing. **Monti:** Conceptualization, Methodology, Resources, Writing – Review and Editing, Supervision, Funding acquisition.

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