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A novel community-based therapeutic education program for reducing alcohol-related harms and stigma in people with alcohol use disorders: A quasi-experimental study (ETHER study)

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Abstract

Introduction: Alcohol use disorder (AUD) is associated with a significant disease burden in France, where alcohol use is deeply rooted in culture. However, the treatment gap is large because of several barriers, including stigmatisation and drinkers' apprehension about total abstinence. However, standardised and evidence-based interventions based on controlled-drinking for people with AUD are lacking. We aimed to assess the effectiveness of a novel community-based French therapeutic patient education (TPE) program for people with AUD named Choizitaconso.

Methods: A before-after non-randomised quasi-experimental study, named ETHER, was designed and implemented with people living with AUD, over a period of 6 months. The primary outcome was percentage change in the number of alcohol-related harms experienced. Secondary outcomes were percentage changes in psycho-social patient-reported and community-validated outcomes.

Marion Coste and Patrizia Carrieri equally contributed to this study.

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Participants in the intervention group ($n = 34$) benefited from the 10-week TPE program Choizitaconso, while the comparison group ($n = 58$) received standard care. The Kruskal–Wallis and chi-squared or Fisher's exact tests were used to compare before-after changes in variables in both groups. Linear regression models were used to test for the effect of study group on each outcome and to test for the effect of alcohol consumption as a confounder.

Results: At 6 months, all outcomes but one either remained stable or numerically improved in both groups. Internalised stigma significantly improved in the intervention group ($p = 0.026$) but not in the comparison group ($p = 0.207$), with a significant group effect ($p = 0.014$).

Discussion and Conclusions: This study demonstrates the effectiveness of the Choizitaconso TPE program on community-validated outcomes, especially internalised stigma.

KEYWORDS

alcohol use disorder, France, harm reduction, psychosocial skills, therapeutic patient education

1 | INTRODUCTION

Alcohol use is a leading risk factor for disease burden worldwide and can lead to a substantial loss of health [1]. Alcohol use disorder (AUD) is the world's most prevalent substance use disorder [2]. In France, it was estimated that 7% of deaths in 2015 were attributable to alcohol consumption in people 15 years old and over [3]. It has been forecast that by 2050, age-standardised alcohol-attributable mortality (in deaths per 100,000 persons) in France will be between 10.5 and 17.6 for men and between 1.1 and 1.8 for women [4]. The prevalence of AUD in France was 7% in 2016 [5]. However, the few associated data available reveal that less than half of people with AUD (PWAUD) received appropriate treatment [6, 7]. This illustrates the large treatment gap generally observed for this condition [8].

Common barriers to seeking treatment in France, and in Europe generally, are a lack of awareness about living with AUD, fear of stigmatisation and apprehension about total abstinence [9, 10]. With regard to the latter, a paradigm change has recently occurred in terms of therapeutic strategies for treating AUD. Specifically, increased emphasis is being placed on reducing alcohol consumption—as opposed to exclusively targeting total abstinence—in order to better meet PWAUD preferences and needs [11]. In this context, 'controlled drinking', (i.e., a sustained drinking pattern within consciously chosen pre-defined limits for low-risk consumption) has emerged as a viable treatment goal for AUD [12, 13].

People with mental disorders, especially those with AUD [14], are still severely stigmatised and little improvement has been observed in attitudes towards these populations in recent decades [15, 16]. Stigma is

associated with poorer quality of life in PWAUD [17, 18]. It can negatively impact feelings and beliefs about treatments and treatment-seeking decisions, increase risk behaviours, and lower treatment adherence and treatment outcomes [19–24], including poor liver disease outcomes [25].

Few data on interventions for PWAUD based on alcohol harm reduction principles are reported in the literature. In Canada, managed alcohol programs aim to reduce the harms of severe alcohol use without expecting abstinence and positive results have been highlighted [26, 27]. In Europe, controlled-drinking programs have been implemented in Switzerland and Germany, with positive impacts on alcohol users in terms of alcohol intake and quality of life [28, 29]. While the need for further assessment of anti-stigma interventions for people with mental illness has been highlighted [30], to our knowledge, in France's specific socio-cultural context, no alcohol harm reduction intervention has been evaluated to date, and no intervention has been implemented which focuses on alcohol-related harms and/or stigma-related outcomes.

Therapeutic patient education (TPE) was defined by the World Health Organization in 1998 as 'educational activities essential to the management of pathological conditions, managed by health care providers duly trained in the field of education, designed to help a patient (or a group of patients and their families) to manage their treatment and prevent avoidable complications, while keeping or improving their quality of life' [31]. TPE is therefore a patient-centred, multidisciplinary approach that aims to promote autonomy, improve health-related quality of life (HRQoL) and strengthen coping skills. The therapeutic effectiveness of TPE has

been documented for several chronic diseases [32–34]. Its cost-effectiveness has also been documented [35]. However, interventions applying TPE principles in the field of substance use disorders are relatively scarce and their effectiveness is rarely assessed. For instance, of the 3378 TPE programs listed by the Regional Health Authorities in France in January 2014, only 35 were related to substance use disorders [36].

In this context, the ETHER (Education Thérapeutique pour la Réduction des dommages en alcoologie or Therapeutic education for alcohol-related harm reduction) study aimed to assess the effectiveness of the French TPE program Choizitaconso, which focuses on alcohol-related harm reduction and stigmatisation of PWAUD.

2 | METHODS

2.1 | ETHER study design

The ETHER study was designed to evaluate the effectiveness of the Choizitaconso program. The study protocol has been extensively described elsewhere [37]. ETHER comprises a quantitative study, whose results are presented in the present paper, and a qualitative study, whose results have been published elsewhere [38]. For convenience, in the present paper, the term ETHER hereafter refers exclusively to the quantitative component of the study.

ETHER was a 6-month quasi-experimental non-randomised study with a nonequivalent comparison group, which compared the evolution of patient-reported outcomes (including alcohol-related harms) in Choizitaconso participants (from the beginning of the 10-week program to 14 weeks after it ended) with the same outcomes in a comparison group who did not participate in Choizitaconso program.

ETHER was approved by the local ethics committee ('Comité de Protection des Personnes SUD-EST IV') based in Lyon, on 9 April 2019 and is registered under the ID RCB number 2019-A00715-52. Confidentiality of participant data were guaranteed for people with AUD in every step of the study.

2.2 | Participants

Study inclusion criteria were as follows: at least 18 years old, able to provide written informed consent, fluent French speaking, reachable by phone and followed for AUD or a history of AUD in one of the study's three recruitment centres. These criteria mirror those for participation in Choizitaconso. Exclusion criteria were

cocaine or opiate dependence, pregnancy, being a legally protected adult (tutorship, curatorship), already participating or planning to participate in another study during ETHER's 6-month follow-up period, and having severe cognitive impairment or psychiatric disorders which could hamper an appropriate assessment of the program's impact during the interviews at the end of the 6 months.

Participants in the intervention group were recruited among PWAUD participating in Choizitaconso program, which is run in the specialised service for substance use disorders (called CSAPA in France) in Avignon in the south of France.

Participants in the comparison group were recruited in the three recruitment centres: Avignon CSAPA (the same CSAPA as for the intervention group but from a different department), Dignes-les-Bains CSAPA (a structure similar to Avignon CSAPA) and a private hospital clinic in Marseille. Eligible participants were identified by medical staff working in the three centres who then presented the study and invited them to participate.

2.3 | Modalities of treatment groups

2.3.1 | Intervention group

Choizitaconso is a TPE program co-constructed with PWAUD which aims to reduce alcohol-related harms and improve participants' health conditions and HRQoL, by teaching psychosocial skills which help them (re) establish self-determined controlled drinking [37, 39]. The program focuses on reinforcing self-efficacy and the freedom to think. It was designed in Avignon CSAPA and is implemented there. It lasts 10 weeks and is composed of five mandatory modules plus an optional module. Peer educators (former PWAUD) collaborate in the program's continuous development.

Each module consists of two to four collective workshops that each last 120 min and involve 5–10 persons. The five mandatory modules are: (i) understanding the mechanisms that trigger and/or maintain alcohol-related difficulties; (ii) planning and evaluating personalised controlled-drinking strategies; (iii) understanding and identifying external and internal influences (e.g., thoughts and emotions); identifying and managing risk situations; (iv) identifying alcohol effects and alcohol-related expectations (by developing self-observation skills); and (v) family environment: learning how to observe and evaluate familial situations in order to best position oneself and take care of oneself (e.g., learning how to better express feelings).

Doing away with vertical teaching, the program is based on cooperation between caregivers and participants, with the differences between these two stakeholder types but also between the participants themselves in terms of their expertise and experience of AUD being fully acknowledged. Choizitaconso avoids discussing any moral perspectives and adapts the program framework to the participants' current psychological, cognitive and pathognomonic resources. Each workshop is built around a specific theme and has an objective to reach (e.g., 'the participants will be able to...'). Starting from a concrete daily life situation, participants are invited to work together, mostly in small groups, to explore the elements of this situation and how to manage it. A peer educator is present at each workshop. The program includes a range of workshop facilitation techniques and focuses on progressively reducing theoretical inputs in favour of increased collaborative work, with a view to enhancing patients' skill-sets.

Participants also attend several individual meetings with medical staff before, during and after the program. Furthermore, follow-up takes place at 3, 6 and 12 months after the program ends. The multidisciplinary team in charge of the program comprises three physicians specialised in addictology (including the program coordinator), two registered nurses, two specialised educators, a psychologist and a prevention manager. All health-care providers involved in the program have received training in TPE and substance use disorders. Peer educators also collaborate in the development and implementation of the program.

2.3.2 | Comparison group

In the two CSAPA (Avignon and Dignes-les-Bains) participating in ETHER, routine treatment consisted in tailored and patient-centred care plans. Each comparison group participant regularly came to one of the centres for social and psychosocial follow-up, and to participate in individual and/or group activities not related to the Choizitaconso program.

Study participants from the clinic in Marseille were hospitalised for a 5-week program of medically supervised withdrawal therapy. They were recruited in ETHER 1 week after hospital admission (i.e., after the acute symptomatic period). After the end of hospitalisation, participants were either followed up as outpatients at the same clinic, referred to another addictology service (such as a CSAPA) or referred to their general practitioner, depending on geographical constraints.

In all three centres, pharmacological treatments were dispensed to both the intervention and comparison

groups according to participants' individual needs. By construction, the comparison group was nonequivalent to the intervention group.

2.4 | Sample size calculation

The targeted sample size was 30 participants for the intervention group, and 60 for the comparison group. These numbers were based on the assumption of an observed 30% reduction in alcohol-related harms in the first group and a 5% reduction in the second group after 6 months, $\alpha = 5\%$ and $\beta = 20\%$ (i.e., 80% power). We had no available order of magnitude available in the literature to set our harm reduction targets. We therefore considered that harms are correlated with alcohol consumption. Thus, the threshold of 30% reduction corresponds to a moderate improvement according to some authors [28] and approaches alcohol consumption reduction obtained in another controlled-drinking-based intervention study [29].

2.5 | Procedure

All participants in four consecutive sessions of the Choizitaconso program were presented the ETHER study at program initiation and were invited to participate in ETHER's intervention group. Local staff identified persons attending the two CSAPAs and the private clinic who were eligible to participate in ETHER's comparison group, and invited them to participate in the study during a medical or psychosocial visit. Written informed consent was obtained from each patient who agreed to participate. The protocol was written in accordance with the Declaration of Helsinki and French law for biomedical research. It was approved by the CPP (comité de protection des personnes) Sud-Est 4 ethics committee (Lyon, France).

2.6 | Data collection

Participants in both the intervention and comparison groups were assessed at study enrolment (M0) and again 6 months later (M6) (i.e., 14 weeks after they ended the Choizitaconso program), using both a computer-assisted telephone interview (CATI) and an individual face-to-face interview. Because of the COVID-19 pandemic, data collection at M6 was performed by telephone.

The CATI questionnaire collected the following data: socio-demographics, self-assessed difficulties in making ends meet ('very comfortable' or 'comfortable' vs. 'get by' or 'difficult to get by'), living alone (yes vs. no), other

substance use (including tobacco), current anxiolytic and antidepressant drug intake, lifetime intake of drugs approved for AUD in France (disulfiram, acamprosate, naltrexone, nalmefene, baclofene and prazepam), date when participant considered that his/her alcohol use was a problem, lifetime number of withdrawal episodes and parental history of AUD (yes/no). It also included 34 dichotomous items related to different psychosocial, behavioural and physical alcohol-related harms [37]. They were chosen according to a Delphi approach as follows: first, a list of possible questions were identified by the study's researchers in the international literature from existing and validated questionnaires; second, during several working sessions, peer educators (people with a history of AUD) approved or adapted items from the list to guarantee the relevance of the study outcomes. The CATI questionnaire also collected data related to the following: stigma (anticipated and internalised, using the Substance Use Stigma Mechanism Scale [40]); alcohol consumption using the short form of the Alcohol Use Disorder Identification Test [41] (frequency and quantity of alcohol consumption, binge drinking) and HRQoL (physical and mental health, using the physical component summary and mental component summary, respectively, from the Short-Form 12-item Health Survey (version 2) [42]).

The face-to-face interview collected data on anxiety and depressive symptoms using the Hospital Anxiety and Depression Scale [43], and alcohol-related neuropsychological impairments using the Brief Evaluation of Alcohol-Related Neuropsychological Impairment [44]. The interview was conducted by a psychologist, nurse or physician.

2.7 | Study outcomes and explanatory variables

The primary outcome was the percentage change (i.e., $100 \times [M0 - M6]/M0$) in the number of alcohol-related harms experienced (this number ranged between 0 and 34, and provided a measure of the 'harm burden' of alcohol use). We hypothesised that these 34 items constituted different components of a composite measure of the extent of experienced alcohol-related harms for each participant.

The secondary outcomes were percentage changes in the following patient-reported outcomes: stigma (anticipated and internalised), HRQoL (physical and mental health), anxiety and depressive symptoms.

Explanatory variables included study group (intervention vs. comparison) and alcohol consumption (number of standard drinks/week).

2.8 | Statistical analyses

Descriptive statistics of participants' characteristics at baseline were provided between groups (intervention vs. comparison). Variables at baseline were compared using the Kruskal–Wallis test and chi-squared or Fisher's exact tests for continuous and categorical variables, respectively. Cronbach's alpha was estimated for the items used to construct the total number of alcohol-related harms. A multiple correspondence analysis was used to test for unidimensionality of the items [45].

The Kruskal–Wallis and chi-squared or Fisher's exact tests were used to compare before-after changes in variables in both groups.

Linear regression models were used to test for the effect of study group on each outcome, and to test for the effect of alcohol consumption as a confounder. Fixed models were initially built entering the group effect only. When the latter was statistically significant, the influence of alcohol consumption was tested by adding this variable in the model and verifying the change of the group effect coefficient. The threshold for statistical significance was set at $\alpha = 0.05$. However, given the relatively small sample size, effects with p -value < 0.25 were also examined.

All analyses were performed using an intent-to-treat approach: participants with missing values at M6 had the M6 values imputed with their M0 values (i.e., zero change and therefore null outcomes).

3 | RESULTS

3.1 | Participants' characteristics

The intervention and comparison group comprised 34 and 58 participants, respectively. Their characteristics are shown in Table 1. Participants were mainly male (68.5%), middle-aged (median [interquartile range] 50.4 [41.9–58.1] years) and tobacco users (65.2%). Nearly half were employed (46.7%) and 38% had already taken drugs approved for AUD. None of these characteristics were significantly different between the two groups. However, the difference in alcohol consumption approached significance ($p = 0.083$), with the comparison group having a higher consumption (Table 1). The number of alcohol-related harms, cognitive performance, and the number of years that participants considered their alcohol use to be a problem were numerically higher in the comparison group, but differences were not statistically significant ($0.05 < p < 0.25$). The lifetime number of withdrawal episodes was significantly higher in the comparison group (median of 2 vs. 1, $p = 0.033$). The prevalence of current

TABLE 1 Participants' characteristics at baseline overall and by study group (ETHER study, $N = 92$)

Variable	All participants ($N = 92$) N (%) or median (IQR)	Intervention group ($N = 34$) N (%) or median (IQR)	Comparison group ($N = 58$) N (%) or median (IQR)	p -value ^a
Gender				
Men	63 (68.5)	21 (61.8)	42 (72.4)	0.289
Women	29 (31.5)	13 (38.2)	16 (27.6)	
Age, years	50.4 [41.9–58.1]	53.6 [45.1–59.5]	48.5 [41.8–57.0]	0.322
Employment status				
Employed	43 (46.7)	18 (52.9)	25 (43.1)	0.361
Unemployed	49 (53.3)	16 (47.1)	33 (56.9)	
Difficulties in making ends meet ^b				0.596
No	40 (43.5)	16 (47.1)	24 (41.4)	
Yes	52 (56.5)	18 (52.9)	34 (58.6)	
Living alone				0.631
Yes	43 (46.7)	17 (50.0)	26 (44.8)	
No	49 (53.3)	17 (50.0)	32 (55.2)	
Tobacco use				0.845
Never	14 (15.2)	6 (17.6)	8 (13.8)	
Former	18 (19.6)	7 (20.6)	11 (19.0)	
Current	60 (65.2)	21 (61.8)	39 (67.2)	
Cannabis use: previous month				1.000
No	86 (93.5)	32 (94.1)	54 (93.1)	
Yes	6 (6.5)	2 (5.9)	4 (6.9)	
Other psychoactive substance use: previous month				1.000
No	88 (95.7)	33 (97.1)	55 (94.8)	
Occasionally	3 (3.3)	1 (2.9)	2 (3.4)	
Weekly	1 (1.1)	0 (0.0)	1 (1.7)	
Parental history of AUD				0.999
No	46 (50.0)	17 (50.0)	29 (50.0)	
One parent	35 (38.0)	13 (38.2)	22 (37.9)	
Two parents	11 (12.0)	4 (11.8)	7 (12.1)	
Time since participant considered his/her alcohol use to be a problem, years ^l	11 [5–21]	8.5 [4–18]	14 [7–24]	0.091
Lifetime number of withdrawal episodes	2 [1–3]	1 [0–2]	2 [1–3]	0.033
Lifetime intake of drugs approved for AUD ^c				0.636
No	57 (62.0)	20 (58.8)	37 (63.8)	
Yes	35 (38.0)	14 (41.2)	21 (36.2)	
Intake of drugs approved for AUD ^c at M6 ^d				0.903
No	79 (85.9)	29 (85.3)	50 (86.2)	
Yes	13 (14.1)	5 (14.7)	8 (13.8)	
Current anxiolytic treatment ^m				0.108
Yes	22 (23.9)	12 (35.3)	10 (17.2)	
No	64 (69.6)	21 (61.8)	43 (74.1)	

(Continues)

TABLE 1 (Continued)

Variable	All participants (<i>N</i> = 92) <i>N</i> (%) or median (IQR)	Intervention group (<i>N</i> = 34) <i>N</i> (%) or median (IQR)	Comparison group (<i>N</i> = 58) <i>N</i> (%) or median (IQR)	<i>p</i> -value ^a
Current antidepressant treatment				0.669
Yes	24 (26.1)	16 (27.6)	8 (23.5)	
No	68 (73.9)	42 (72.4)	26 (76.5)	
Number of alcohol-related harms ^e	11 [7–14]	9 [5–14]	11 [8–14]	0.243
Anticipated stigma ^{f,i}	2.2 [1.8–2.8]	2.2 [2.0–2.8]	2.2 [1.8–2.6]	0.327
Internalised stigma ^g (0)	3 [2.3–3.8]	3.01 [2.2–4.0]	3 [2.3–3.3]	0.510
Alcohol consumption (standard drinks/month)	120 [12–240]	70 [12–240]	180 [30–300]	0.083
HRQoL physical component summary ^{h,i}	52.4 [46.5–56.1]	52.7 [44.7–56.1]	52.3 [48.6–55.7]	0.744
HRQoL mental component summary ^{h,i}	45.0 [35.4–51.4]	42.6 [34.1–49.9]	45.9 [35.7–51.7]	0.491
Anxiety ^{i,l}	10 [7–13]	10.5 [7–13]	10 [7–12]	0.367
Depression ^{i,l}	6 [4–9]	7 [5–9]	6 [3–9]	0.426
Cognitive performance ^{j,n}	12 [9.8–15.3]	13 [10.5–16.5]	11.5 [9.5–14.0]	0.176
Cognitive impairment ^{j,n}				0.199
None	2 (3.2)	2 (9.1)	0 (0.0)	
Mild	20 (31.7)	7 (31.8)	13 (31.7)	
Moderate-to-severe	41 (65.1)	13 (59.1)	28 (68.3)	

Abbreviations: AUD, alcohol use disorder; HRQoL, health-related quality of life; IQR, interquartile range; MCS, mental component summary; PCS, physical component summary.

^aChi-squared test or Fisher's exact test for categorical variables, and Kruskal–Wallis test for continuous variables.

^b'Very comfortable' or 'comfortable' vs. 'get by' or 'difficult to get by'.

^cOnly disulfiram, acamprosate, naltrexone, nalmefene, baclofene and prazepam were taken into account, as they are the only drugs approved for AUD in France.

^dThis information was collected only at M6 (unavailable at M0).

^eNumber of items checked out of a list of 34 ad hoc dichotomous items related to psychosocial, behavioural and physical harms related to alcohol use [37].

^fAnticipated stigma was assessed through the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.

^gInternalised stigma was assessed through the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.

^hAssessed using Short-Form 12-item Health Survey (version 2) [42]. Scores range from 0 to 100.

ⁱAnxiety and depression subscales from The Hospital Anxiety and Depression Scale [43].

^jTotal score of the Brief Evaluation of Alcohol-Related Neuropsychological Impairment [44]. Impairments were categorised using cut-off values varying with the educational level of participants (≤ 15 [≤ 16] for mild and ≤ 11.5 [≤ 12.5] for moderate-to-severe impairments for participants without [respectively with] upper secondary school certificate).

^k<5% missing.

^l<10% missing.

^m15–32% missing data.

anxiolytic treatment was higher in the intervention group, but not significantly ($p = 0.108$).

Cronbach's alpha for the 34 alcohol-related harms was 0.73. The multiple correspondence analysis confirmed the unidimensionality of the set of 34 items (64.8% of total inertia for dimension 1) (data not shown).

Among the 34 between-group comparisons of alcohol-related harm prevalence performed at M0, eight had a p -value <0.25. All but one of the latter were associated with a higher prevalence in the comparison group

(Table 2). Participants in the comparison group hurt themselves because of alcohol more than participants in the intervention group ($p = 0.021$).

Participants with missing (and therefore imputed) data for primary outcomes ($n = 24$, with $n = 1$ for alcohol-related harms, $n = 22$ and 14 for anticipated and internalised stigma, respectively) were 8 years older and had a longer history of problem with alcohol use than participants without missing data (20 vs. 10 years, data not shown).

TABLE 2 Distribution of alcohol-related harms at baseline overall and by study group (ETHER study, $N = 92$)

	All participants ($N = 92$) N (%)	Intervention group ($N = 34$) N (%)	Comparison group ($N = 58$) N (%)	p-value^a
There have been times when I have not fulfilled my role at work as well as I would have liked ^b				
No	76 (82.6)	29 (85.3)	47 (81)	0.603
Yes	16 (17.4)	5 (14.7)	11 (19)	
There have been times when I have not fulfilled my role as a parent as well as I would have liked				
No	68 (73.9)	26 (76.5)	42 (72.4)	0.669
Yes	24 (26.1)	8 (23.5)	16 (27.6)	
There have been times when I have not fulfilled my role as a partner as well as I would have liked				
No	70 (76.1)	26 (76.5)	44 (75.9)	0.947
Yes	22 (23.9)	8 (23.5)	14 (24.1)	
A close friendship has been damaged				
No	67 (72.8)	24 (70.6)	43 (74.1)	0.712
Yes	25 (27.2)	10 (29.4)	15 (25.9)	
My romantic relationship has been damaged				
No	60 (65.2)	25 (73.5)	35 (60.3)	0.200
Yes	32 (34.8)	9 (26.5)	23 (39.7)	
A family relationship has been damaged				
No	64 (69.6)	23 (67.6)	41 (70.7)	0.759
Yes	28 (30.4)	11 (32.4)	17 (29.3)	
I have said or done things that I later regretted				
No	43 (46.7)	20 (58.8)	23 (39.7)	0.075
Yes	49 (53.3)	14 (41.2)	35 (60.3)	
I have driven a motor vehicle while unfit to do so (alcohol or other drug use)				
No	61 (66.3)	24 (70.6)	37 (63.8)	0.506
Yes	31 (33.7)	10 (29.4)	21 (36.2)	
I have had legal problems				
No	84 (91.3)	31 (91.2)	53 (91.4)	1.000
Yes	8 (8.7)	3 (8.8)	5 (8.6)	
Difficulties falling asleep				
None/slight/moderate difficulties	74 (80.4)	27 (79.4)	47 (81)	0.850
Major/severe difficulties	18 (19.6)	7 (20.6)	11 (19)	
Difficulties staying asleep (nighttime awakenings)				
None/slight/moderate difficulties	69 (75)	25 (73.5)	44 (75.9)	0.803
Major/severe difficulties	23 (25)	9 (26.5)	14 (24.1)	

(Continues)

TABLE 2 (Continued)

	All participants (N = 92) N (%)	Intervention group (N = 34) N (%)	Comparison group (N = 58) N (%)	p-value ^a
Problems waking up too early in the morning				
None/slight/moderate problems	80 (87)	29 (85.3)	51 (87.9)	0.717
Major/severe problems	12 (13)	5 (14.7)	7 (12.1)	
I have had problems with sweating or feeling hot while sleeping				
No	35 (38)	15 (44.1)	20 (34.5)	0.358
Yes	57 (62)	19 (55.9)	38 (65.5)	
After drinking, I have sometimes gotten sick/ vomited/had a hangover				
No	53 (57.6)	18 (52.9)	35 (60.3)	0.488
Yes	39 (42.4)	16 (47.1)	23 (39.7)	
Because of drinking, I have hurt myself				
No	72 (78.3)	31 (91.2)	41 (70.7)	0.021
Yes	20 (21.7)	3 (8.8)	17 (29.3)	
Sometimes my hands have shook				
No	39 (42.4)	17 (50)	22 (37.9)	0.258
Yes	53 (57.6)	17 (50)	36 (62.1)	
Sometimes I have not remembered things I did the day before				
No	30 (32.6)	14 (41.2)	16 (27.6)	0.180
Yes	62 (67.4)	20 (58.8)	42 (72.4)	
I have neglected my health in general				
No	39 (42.4)	15 (44.1)	24 (41.4)	0.798
Yes	53 (57.6)	19 (55.9)	34 (58.6)	
I have neglected my physical appearance				
No	56 (60.9)	22 (64.7)	34 (58.6)	0.564
Yes	36 (39.1)	12 (35.3)	24 (41.4)	
I have not taken care of myself (hygiene, etc.)				
No	68 (73.9)	26 (76.5)	42 (72.4)	0.669
Yes	24 (26.1)	8 (23.5)	16 (27.6)	
I have often been involved in risky situations (crossing a road without looking, getting into a fight, having unprotected sex, etc.)				
No	76 (82.6)	29 (85.3)	47 (81)	0.603
Yes	16 (17.4)	5 (14.7)	11 (19)	
I have eaten quite regularly (morning, noon, evening)				
No	40 (43.5)	14 (41.2)	26 (44.8)	0.733
Yes	52 (56.5)	20 (58.8)	32 (55.2)	
I have regularly skipped meals				
No	53 (57.6)	23 (67.6)	30 (51.7)	0.136
Yes	39 (42.4)	11 (32.4)	28 (48.3)	

(Continues)

TABLE 2 (Continued)

	All participants (<i>N</i> = 92) <i>N</i> (%)	Intervention group (<i>N</i> = 34) <i>N</i> (%)	Comparison group (<i>N</i> = 58) <i>N</i> (%)	<i>p</i> -value ^a
I have increased my use of drugs or medications (cannabis, cocaine, anxiolytics, etc.)				
No	82 (89.1)	33 (97.1)	49 (84.5)	0.085
Yes	10 (10.9)	1 (2.9)	9 (15.5)	
I have had financial difficulties				
No	58 (63)	24 (70.6)	34 (58.6)	0.251
Yes	34 (37)	10 (29.4)	24 (41.4)	
I have enjoyed participating in activities or hobbies				
No	18 (19.6)	4 (11.8)	14 (24.1)	0.181
Yes	74 (80.4)	30 (88.2)	44 (75.9)	
During this period, my alcohol consumption has been serene and without problems				
No	47 (51.1)	19 (55.9)	28 (48.3)	0.481
Yes	45 (48.9)	15 (44.1)	30 (51.7)	
I have enjoyed the taste of wine, beer, or other alcoholic beverages over this period				
No	34 (37)	13 (38.2)	21 (36.2)	0.846
Yes	58 (63)	21 (61.8)	37 (63.8)	
During the last 3 months, have you felt lonely and isolated from others?				
Not usually/not at all	65 (70.7)	21 (61.8)	44 (75.9)	0.152
Most of the time/almost all the time	27 (29.3)	13 (38.2)	14 (24.1)	
During the last 3 months, how often have you seen family members (parents, spouse or partner, children, siblings, cousins, etc.)?				
Never	2 (2.2)	0 (0)	2 (3.4)	0.529
At least once every fortnight	90 (97.8)	34 (100)	56 (96.6)	
During the last 3 months, have you been satisfied with your relationship with family members?				
Not at all satisfied/somewhat dissatisfied	17 (18.5)	7 (20.6)	10 (17.2)	0.690
Somewhat satisfied/very satisfied	75 (81.5)	27 (79.4)	48 (82.8)	
During the last 3 months, how often have you seen people outside your family circle (friends, neighbours, casual sexual partners, etc.)?				
Never	4 (4.3)	0 (0)	4 (6.9)	0.293
At least once every fortnight	88 (95.7)	34 (100)	54 (93.1)	
During the last 3 months, have you been satisfied with your relationship with people outside your family circle?				
Not at all satisfied/rather dissatisfied	5 (5.4)	2 (5.9)	3 (5.2)	1.000
Somewhat satisfied/very satisfied	87 (94.6)	32 (94.1)	55 (94.8)	

(Continues)

TABLE 2 (Continued)

	All participants (<i>N</i> = 92) <i>N</i> (%)	Intervention group (<i>N</i> = 34) <i>N</i> (%)	Comparison group (<i>N</i> = 58) <i>N</i> (%)	<i>p</i> -value ^a
Currently, when you have a health problem, do you find it easy to consult a health professional?				
Very easy/quite easy	66 (71.7)	25 (73.5)	41 (70.7)	0.770
Quite hard/very hard	26 (28.3)	9 (26.5)	17 (29.3)	

^aChi-squared test or Fisher's exact test.

^bBefore asking participants to answer those items, the telephone interviewer reminded them that they should be considered in the context of alcohol drinking.

TABLE 3 Comparisons of patient-reported outcomes between baseline (M0) and 6 months (M6) according to study group (ETHER study, *N* = 92)

Median [interquartile range]	Intervention group (<i>N</i> = 34)			Comparison group (<i>N</i> = 58)		
	M0	M6	<i>p</i> -value ^a	M0	M6	<i>p</i> -value ^a
Number of alcohol-related harms ^b	9 [5–14]	5.5 [3–9]	0.051	11 [8–14]	6 [3–10]	<10 ⁻³
Anticipated stigma ^c	2.2 [2–2.8]	2.2 [2–2.4]	0.472	2.2 [1.8–2.6]	2.2 [2–2.6]	0.369
Internalised stigma ^d	3.1 [2.2–4]	2.5 [2–3]	0.026	3 [2.3–3.3]	2.6 [2–3.3]	0.207
HRQoL physical component summary ^e	52.7 [44.7–56.1]	51.6 [45.5–54.8]	0.594	52.3 [48.6–55.7]	51.6 [43–54.8]	0.117
HRQoL mental component summary ^e	42.6 [34.1–49.9]	49.1 [42.3–51.9]	0.026	45.9 [35.7–51.7]	48.8 [44.2–54]	0.065
Anxiety ^f	10.5 [7–13]	8 [7–11]	0.027	10 [7–12]	8 [6–11]	0.049
Depression ^f	7 [5–9]	5 [2–8]	0.089	6 [3–9]	3 [1–6]	0.007
Alcohol consumption ^g	70 [12–240]	40 [12–240]	0.937	180 [30–300]	40 [2–160]	0.003

Abbreviation: HRQoL, health-related quality of life.

^aKruskal–Wallis test.

^bNumber of items checked out of a list of 34 ad hoc dichotomous items related to psychosocial, behavioral and physical harms related to alcohol use [37].

^cAnticipated stigma was assessed using the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.

^dInternalised stigma was assessed using the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.

^eAssessed using the Short-Form 12-item Health Survey (version 2) [42]. Scores range from 0 to 100.

^fAnxiety and depression subscales from The Hospital Anxiety and Depression Scale [43].

^gNumber of standard drinks/month. Provided for descriptive purposes, alcohol consumption was not used as an outcome.

3.2 | Before-after changes in patient reported outcomes

In absolute values, all patient-reported outcomes either remained stable or improved between M0 and M6 for both groups, except for the physical component summary of HRQoL, which decreased in both groups (Table 3).

The number of alcohol-related harms reported decreased between M0 and M6 in both groups (comparison $p < 10^{-3}$ and intervention $p = 0.051$). The changes in internalised stigma and the mental component summary of HRQoL were statistically significant for the intervention group ($p = 0.026$ and 0.026 , respectively), but not for the comparison group ($p = 0.207$ and 0.065 , respectively). The change in severity of anxiety symptoms was

statistically significant for both groups, while the change in severity of depressive symptoms was significant for the comparison group only ($p = 0.089$ for the intervention group).

3.3 | Effect of the study group

When conducting the comparative analysis, the reduction in the number of alcohol-related harms was significantly lower in the intervention group than in the comparison group (regression coefficient [95% confidence interval] $-38.7 [-71.9; -5.6]$, $p = 0.023$) (Table 4). In contrast, the reduction in internalised stigma was significantly greater in the intervention group ($19.8 [4.1; 35.4]$, $p = 0.014$).

TABLE 4 Factors associated with study outcomes, linear regression models (ETHER study, $N = 92$)

Outcomes (percentage change between M0 and M6)	Number of alcohol-related harms ^a		Anticipated stigma ^c		Internalised stigma ^d		HRQoL physical component summary ^e	
	Univariable analyses ^b	Bivariable analyses ^b	Univariable analyses	Bivariable analyses ^b	Univariable analyses	Bivariable analyses ^b	Univariable analyses	Bivariable analyses ^b
Group	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]
Comparison (ref.)	0	0	0	0	0	0	0	0
Intervention	-38.7 [-71.9; -5.6]**	-35.8 [-67.2; -4.4]**	10.7 [-7.6; 28.9]	-	19.8 [4.1; 35.4]**	15.9 [1.9; 29.8]**	-11.6 [-26.9; 3.8]	-
Alcohol consumption ^f	0.1 [-0.0; 0.2]	0.1 [-0.1; 0.2]	-0.1 [-0.2; -0.0]**	-	-0.1 [-0.2; 0.0]*	-0.1 [-0.2; 0.0]*	0.1 [-0.0; 0.1]	-
HRQoL mental component summary^e								
Anxiety^g								
Outcomes (% change)	Univariable analyses ^b	Bivariable analyses ^b	Univariable analyses ^b	Bivariable analyses ^b	Univariable analyses ^b	Bivariable analyses ^b	Univariable analyses ^b	Bivariable analyses ^b
Group	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]
Comparison (ref.)	0	0	0	0	0	0	0	0
Intervention	-3.5 [-20.1; 13.2]	-	47.2 [-25.1; 119.6]	-	44.9 [-38.8; 128.5]	-	-	-
Alcohol consumption ^f	0.1 [-0.2; 0.0]*	-	-0.3 [-0.8; 0.2]	-	-0.3 [-0.9; 0.3]	-	-	-
Depression^g								
Group	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]	Coef [95% CI]	aCoef [95% CI]
Comparison (ref.)	0	0	0	0	0	0	0	0
Intervention	-3.5 [-20.1; 13.2]	-	47.2 [-25.1; 119.6]	-	44.9 [-38.8; 128.5]	-	-	-
Alcohol consumption ^f	0.1 [-0.2; 0.0]*	-	-0.3 [-0.8; 0.2]	-	-0.3 [-0.9; 0.3]	-	-	-

Abbreviations: (a)Coef., (adjusted) regression coefficient; CI, confidence interval; HRQoL, health-related quality of life; ref., reference category.

* p -value <0.100.** p -value <0.050.^aStandardised change in number of items checked out of a list of 34 ad hoc dichotomous items related to psychosocial, behavioural and physical harms related to alcohol use [37].^bAlcohol consumption variable was forced into the bivariable analyses when the group effect was statistically significant. There was no bivariate analysis if the group effect was not statistically significant.^cAnticipated stigma was assessed using the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.^dInternalised stigma was assessed using the Substance Use Stigma Mechanism Scale [40], as the mean of six items rated on a five-point Likert scale.^eAssessed using the Short-Form 12-Item Health Survey (version 2) [42]. Scores range from 0 to 100.^fNumber of standard drinks/month.^gAnxiety and depression subscales from The Hospital Anxiety and Depression Scale [43].

Adjusting for alcohol consumption did not lead to meaningful changes in these relationships. Furthermore, regression analyses did not show any difference between both groups for the variables that significantly changed between M0 and M6 in either group (i.e., HRQoL mental component summary, anxiety and depressive symptoms).

4 | DISCUSSION

We found that 6 months after starting the Choizitaconso TPE program, it had significant positive effects on internalised stigma, mental component of HRQoL and anxiety symptoms in PWAUD. It also tended to reduce alcohol-related harms and depressive symptoms in them. Compared with the comparison group, the intervention group saw a significantly great improvement in internalised stigma. However, the reduction in the number of alcohol-related harms was greater in the comparison group.

To our knowledge, this is the first community-based PWAUD-targeted TPE program relying on controlled-drinking principles to be assessed in France. Choizitaconso was tried-and-tested for 5 years before reaching its current standardised framework. It appears to be a tool that could be scaled up to improve health status and quality of life of all PWAUD. Focusing on controlled drinking, Choizitaconso may help attract PWAUD for whom abstinence has been a barrier to seeking treatment [9]. By teaching psychosocial and coping skills rather than focusing on alcohol consumption, this program may also meet PWAUD specific needs at different stages of their treatment (e.g., when initiating care or after completing an alcohol withdrawal period) irrespective of their objective in terms of alcohol consumption (i.e., abstinence vs. reduced drinking). Despite being standardised, the program remains patient-centred and is flexible enough to be adapted to each participant's needs and expectations.

The benefits yielded by the program in terms of reduced internalised stigma, together with the fact that these benefits were superior to those observed from routine treatment in the comparison group, are very important findings. The need to assess and implement anti-stigma interventions for people with mental illness has been highlighted [30]. Mental health-related stigma, including self-stigma, is negatively associated with seeking help and care [20, 22, 46]. Care avoidance and lower disease awareness participate in poorer health outcomes, such as liver disease [25], and alcohol-related damage to the central nervous system [47]. Reducing internalised stigma may therefore yield a cascade of health benefits, for example, greater use of health services, specialised

services for AUD and treatment adherence [48]. A reduction in internalised stigma is also likely to positively impact quality of life, as both are correlated, not only in PWAUD [18], but also in various populations [49–51]. Self-esteem most likely plays a mediating role in this relationship [52].

The two following excerpts from different participants to Choizitaconso illustrate this benefit. 'The more you come to the CSAPA, the more you're involved, and the more you can get away from that [i.e., the shame of coming and of alcohol]. I'm no longer ashamed now'. 'Because guilt damages your self-esteem, that's it: "yes, I'm a nothing so I drink." And this idea ... I don't like the word "control," to have the freedom to take it or not, [...] I could do it without feeling guilty'. [38]

The TPE program did not lead to a decrease in alcohol consumption and was not superior to other treatments in improving alcohol-related harms. The larger reduction in the number of alcohol-related harms observed in the comparison group 14 weeks after Choizitaconso program ended may be due to a higher (although non statistically significant) baseline level of both alcohol consumption and the number of alcohol-related harms.

It is worth noting that alcohol consumption was not an outcome in our study, as some participants attended the TPE program to learn how to manage risks and how to consume alcohol (again) occasionally and safely. Nevertheless, as alcohol use may be a confounder or effect modifier, we adjusted for it in the models.

The fact that overall improvement was for several outcomes despite alcohol consumption remaining statistically stable in the intervention group is relevant. This result would seem to contradict findings elsewhere, which established a relationship between drinking pattern and the mental component of HRQoL in PWAUD initiating treatment [53]. However, they are in line with other results for community-dwelling older patients [54]. We can hypothesise that by directly targeting psychosocial skills, the program improves psychological well-being, by increasing self-esteem and/or reducing feelings of guilt, independently of alcohol use reduction.

A Swiss-based controlled-drinking program showed that the benefits in terms of quality of life (coupled with decreased alcohol consumption) were at worst stable for most indicators between 6 weeks and 1 year follow-up [29]. Accordingly, a longer study evaluating Choizitaconso's long-term benefits would be helpful to test whether the changes reported in the present article continue over time.

The main strength of the ETHER study is its novel, timely, rigorous assessment of a controlled-drinking

based intervention for PWAUD in France. Its results justify the expansion of the use of harm reduction principles to AUD, which constitutes a major paradigm shift, especially for France. Another strength is that the study follows the principles of community-based participatory research [55]. More specifically, the program's design and the choice of ETHER's study outcomes were developed in collaboration with the PWAUD community.

The main study limitation is the relatively small sample size, which prevented us from highlighting significant differences for all outcomes. Indeed, some of them only approached statistical significance. Another major limitation is the nonequivalence between the comparison group and the intervention group. The former was originally included to verify that any deterioration of study outcomes in the latter could be compared with what was observed in participants receiving routine treatment and follow-up care in the participating specialised care centres. Our comparison group included patients followed up in specialised, hospital-based services. Accordingly, their care patterns and trajectories were not always comparable with those of the intervention group. Specifically, participants in the comparison group received mostly individual-based care interventions, while Choizitaconso is group-based by design. The comparison group exhibited higher baseline cognitive impairment scores (and non-significantly higher baseline alcohol consumption levels). An ideal comparison group would have matched the intensity and duration of Choizitaconso. However, such a group would be difficult to find, as care for AUD varies between specialised centres in France. Having said that, the ETHER study was designed to primarily focus on before-after differences [37], as there is no 'gold-standard'.

To conclude, the Choizitaconso community-based TPE program was effective in reducing internalised stigma and tended to reduce alcohol-related harms. It also improved mental quality of life, anxiety and depressive symptoms 6 months after program initiation. Further large-scale and long-term studies are needed to confirm our results and to be able to consider it as an additional therapeutic option in the spectrum of care for PWAUD.

AUTHOR CONTRIBUTIONS

Conceptualisation: Tangui Barré, Danielle Casanova, Patrizia Carrieri, Marion Coste and Fabienne Marcellin. Formal Analysis: Clémence Ramier. Writing—original draft: Tangui Barré. Writing—review and editing: Tangui Barré, Clémence Ramier, Saskia Antwerpes, Marie Costa, Marion Coste, Morgane Bureau, Gwenaelle Maradan, Vincent Di Beo, Christophe Cutarella, Jacques Leloutre, Olivier Riccobono-Soulier, Sophie Hedoire, Elodie Frot, Fabienne Vernier, Stephanie Vassas-Goyard, Sabine Dufort, Camelia Protopopescu, Fabienne Marcellin,

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CONFLICT OF INTEREST

None to declare.

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