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Access to care for people with alcohol use disorder in France: a mixed-method cross-sectional study protocol (ASIA)

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Access to care for people with alcohol use disorder in France: a mixed-method cross-sectional study protocol (ASIA).

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Abstract

Introduction: Alcohol use disorder (AUD) is a major public health concern worldwide. In France only 10% of people with AUD (PWAUD) receive medical care. General practitioners (GP) are one of the main entry points for AUD care. The present ongoing study, entitled ASIA (Access to Care and Indifference toward Alcohol, *Accès aux Soins et Indifférence à l'Alcool* in French), aims to improve knowledge about factors associated with access to care for AUD by exploring related GP and PWAUD practices, experiences and perceptions.

Methods and Analysis: The ASIA project is an ongoing cross-sectional multi-site study based on a complementary mixed-method approach (quantitative and qualitative) using a convergent parallel design.

For the PWAUD quantitative study, 260 PWAUD will be interviewed using a telephone-based questionnaire. For the qualitative study, 36 PWAUD have already been interviewed. The GP quantitative study will include 100 GP in a 15-minute survey. Fifteen GP have already participated in semi-structured interviews for the qualitative study.

Logistic regression will be used to identify predictors to access to care. With respect to data analyses, qualitative interviews will be analysed using semantic analysis while quantitative logistic regression will be used for quantitative interviews.

Ethics and dissemination: This study was approved by the French National Commission on Informatics and Liberties (CNIL) (approval reference number: C16-10 Date of approval: July 17, 2017), the Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS) and the Evaluation and Ethics Committee (approval reference number: 16-312 Date of approval: July 8, 2016) (CEEI) of the French National Institute of Health and Medical Research (INSERM). We believe results from ASIA will be of great use in the development of future recommendations and the updating of care guidelines for GP, as well as in the improvement of prevention and medical management of PWAUD.

Key words:

Alcohol Use Disorder, Access to Care, General practitioners, Alcohol Use Disorder treatments, Mixed-method study, Protocol

Strengths and limitations of this study

- The originality of this study is that it cross-analyses GP and PWAUD data regarding a common issue. Its results will be very useful for improving AUD management in primary care, and consequently, for improving access to care for PWAUD in general
- The major strength of this study is its mixed use of qualitative and quantitative data, which enables us to collect subjective data - such as perceptions - as well as data on measurable variables, both elements being involved in the patient's AUD care trajectory.
- Another strength is the recruitment of both PWAUD involved and PWAUD not involved in AUD care, so that barriers as well as levers to access to care can be identified.
- The study population with AUD enrolled in the study may not be completely representative of the general population with AUD in France, and data may need appropriate weighting during analysis.

Introduction

Alcohol Use Disorder (AUD) is a major health and social concern and is responsible for approximately 3.3 million deaths (or 5.9% of all global deaths) annually (1). It is estimated that AUD contributes to over 200 diseases and injury conditions, especially liver cirrhosis and cancer (1). The prevalence of alcohol dependence in Europe has been evaluated at 6.4% among men and 1.2 % among women (2). Only 10% of people concerned by AUD receive medical care for AUD in France (3).

According to a report on alcohol use, published by the French Observatory on Drugs and Drug Addiction (OFDT) in 2014 (4,5), 10 % of people interviewed in the country (n= 15635) reported daily alcohol consumption. A report published in 2015 (6) estimated the annual external cost of alcohol abuse at 114 399 billion euros, in terms of lost lives, reduced quality of life and production losses.

In France, it is difficult to obtain accurate figures on care for AUD due to the different AUD management entry points (7) (specialized centres, general practitioners, hospitals, associations), but the proportion of PWAUD linked to medical care for this disorder is definitely small (8).

Although medical care for substance use disorders is easily accessible in specialized addiction centres (CSAPA), general practitioners (GP) constitute the main first line of care for AUD screening. Primary healthcare provided by GP is the first-choice option for preventing, screening and managing AUD and its consequences. Indeed, in addition to being the first point of contact, GP are numerous and provide comprehensive and coordinated care (9,10).

Depending on the severity of the disorder, different psychosocial approaches can be used to help PWAUD reduce or stop alcohol, including motivational interviews, mindfulness interventions, social-skills training, behavioural self-control training (11). In addition, 5 different pharmacological treatments can be prescribed: acamprosate, disulfiram, naltrexone, nalmefene and baclofen (12). Acamprosate and disulfiram are prescribed to help maintain abstinence in people who have already stopped drinking. Naltrexone is approved for abstinence maintenance, but has also been used off-label to reduce consumption (13). Nalmefene is prescribed to reduce consumption as it reduces craving. Baclofen is also used to reduce craving but unlike the other 4 drugs, which are legally available in France, it can only be prescribed off-label, as part of France's regulatory drug-evaluation framework (called "Temporary Recommendation Use (TRU)"). A review published in 2016 concluded that all 5 treatments show different safety profiles and must be adapted to each patient's

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3 alcohol consumption goal and individual profile (14). Another review reported that all 5
4 treatments are still underused and that barriers to their prescription need to be investigated
5 (15).
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8 It is important to note that we are in a transitional period between one paradigm and
9 another. More specifically, although until very recently, the standard of care for AUD was
10 based on stopping consumption, maintaining abstinence, preventing chronic complications
11 related to excessive alcohol consumption and managing withdrawal symptoms, we now see
12 that alcohol-related risk reduction, including controlled drinking (CD), is becoming an
13 acceptable therapeutic goal for caregivers and patients (17). The licensing of nalmefene and
14 the prescription of baclofen within France's TRU framework confirms this paradigm shift (18).
15 For many patients who might not be immediately ready for total abstinence, reducing
16 consumption may constitute a realistic achievable goal (16).
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19 Lack of awareness of having AUD and apprehension towards total alcohol abstinence are
20 two important barriers to treatment seeking (19). It is possible that a lack of knowledge
21 about the different AUD therapeutic options currently available (20) also constitutes a
22 barrier.
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25 Given this dynamic context, an in-depth evaluation of access to care for PWAUD in France
26 would seem necessary. The present study, ASIA, aims to improve knowledge about factors
27 associated with seeking, receiving and providing care for AUD by exploring related GP and
28 PWAUD practices, experiences and perceptions.
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30

31 *General study design*

32 ASIA is an ongoing multi-site cross-sectional study which started in France in 2016. It aims to
33 explore barriers to and facilitators of access to care for PWAUD in France, and to provide a
34 better understanding of the individual and contextual factors associated with the currently
35 poor level of access to care for those who wish to stop or reduce their alcohol consumption.
36 The study uses a mixed approach which comprises (i) a qualitative study, and (ii) a
37 quantitative study for two populations: PWAUD (I) and GP (II).
38
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40 The complementary mixed-method approach (quantitative and qualitative) implemented
41 here uses a convergent parallel design (21). This type of study design provides a more
42 comprehensive view of a phenomenon, as it separately cross-analyses data collected
43 concomitantly using these two study approaches from each of two different studies (in our
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3 situation PWAUD and GP). For the present work, comparing data from the resulting four
4 sub-studies will shed greater light on the mechanisms leading or not to AUD care.
5

6 **Methods and analysis**

7 *Objectives*

8
9 The specific objectives of the study are presented below, relationship between project
10 objectives and study components are resumed in table 1.
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14 1) Identify socio-demographic characteristics and health experiences associated with access
15 to care (PWAUD)

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18 2) Determine socio-demographic and professional characteristics associated with AUD
19 management and screening, acceptance of CD and AUD pharmacological treatment
20 prescription (GP).
21

22
23 3) Assess whether barriers found in other studies were relevant in the current French
24 context (PWAUD and GP)
25

26
27 4) Identify other barriers and levers which could have been missed in the quantitative study
28 (GP and PWAUD)
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30 5) Illustrate and examine in depth the findings of the quantitative study (GP and PWAUD)
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Table 1. Relationship between project objectives and study components

	PWAUD Qualitative study	PWAUD Quantitative study	GP Qualitative study	GP Quantitative study
1) Identify socio-demographic characteristics and health experiences associated with access to care (PWAUD)		X		
2) Determine socio-demographic and professional characteristics associated with AUD management and screening, acceptance of CD and pharmacological treatment prescription (GP)				X
3) Assess whether barriers found in other studies were relevant in the current French context (PWAUD and GP)		X		X
4) Identify other barriers and levers which could have been missed in the quantitative study (GP and PWAUD)	X		X	
5) Illustrate and examine in depth the findings of the quantitative study (GP and PWAUD)	X		X	

Definition of AUD

The main tool used by the World Health Organization to measure alcohol consumption is the Alcohol Use Identification Test (AUDIT) (22). This 10-item questionnaire provides an alcohol consumption score from 0 to 40. Scores between 8 (7 for women) and 15 suggest hazardous alcohol consumption, 16 to 19 harmful alcohol consumption, and >20 alcohol dependence (15). We chose to include only people with a score > 15, because above this, medical care is recommended (11).

Definition of care

In this study, we decided to define “receiving care” as follows:

- Receiving non-pharmacological therapeutic interventions from a healthcare professional to reduce or stop alcohol consumption

And/or

- Participating in an alcohol-related support group (such as Alcoholics Anonymous)

1
2
3 And/or:

4
5 - Taking one of the five approved AUD pharmacological drugs

6
7 *Patient and Public Involvement statement*

8
9 Neither patients nor the general public were involved in the design of this study.

10
11 In order to respect patient confidentiality, we will not keep participants' contact information.
12
13 Consequently, the results of the study will not be personally disseminated to participants.
14
15 However, participants are informed in the consent form that if they wish, they can contact
16
17 the main investigator to obtain the study results.

18
19 *Sampling strategy and data collection*

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21 As of May 2018, data collection for the qualitative sub-studies has already been performed
22
23 for the PWAUD and GP. Analysis of qualitative GP data has also been completed. More in-
24
25 depth details can be found in this section.

26
27 **I. PWAUD population**

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29 *Inclusion criteria*

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31 For both sub-studies (i.e. quantitative and qualitative), the following inclusion criteria are
32
33 used: aged over 18, French speaking and AUDIT score >15.

34
35 **i. Qualitative sub-study**

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37 *Recruitment and data collection*

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39 From June 2016 to May 2017, 36 patients were recruited in 4 medical services: the Saint-
40
41 Barnabe substance disorder clinic in Marseille, two CSAPA (Care, Prevention, and Support
42
43 Center for Addiction) in Avignon and Nîmes, and the CISIH (Information and Care Center for
44
45 Human Immunodeficiency) in Saint-Marguerite Hospital in Marseille (patients recruited
46
47 through this service were not already receiving AUD care at enrolment)). Medical staff
48
49 informed their patients of the study and introduced potential participants to the study
50
51 investigator.

52
53 After providing information about the study, the study investigator performed a face-to-face
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55 interview in a closed office to ensure confidentiality. The interview was semi-structured and
56
57 conducted according to the guide described in Table 2.

58
59 Interviews lasted between 30 and 75 minutes and were recorded. Recordings were
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transcribed using word processing software. Transcripts of interviews were not returned to

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3 PWAUD participants for comments or correction. Only the qualitative sub-study investigator
4 has access to these records. Information concerning participants' confidentiality and
5 anonymity is presented in the "Ethics and Dissemination" section.
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Table 2. Semi-structured PWAUD interview guide

Qualitative sub-study for PWAUD	
Standard data collected	Audit score Enrolment site Year of birth Gender Personal situation (e.g., living in a couple, having children, etc.) Professional situation (e.g., employment status) Substance use (Yes/No, and if applicable, consumption frequency)
Semi-structured PWAUD interview guide	
Opening question	You are experiencing difficulties with your alcohol consumption. I imagine it is difficult to deal with that. Could you tell me about your experience with alcohol since you started drinking, including, if applicable, your experience with health professionals for this specific problem?
If the interviewee does not mention these topics spontaneously, the interviewer must do so.	<ul style="list-style-type: none"> ➤ How long have you been drinking, how did it start? ➤ How did you realize that you had a drinking problem? ➤ Who have you talked to about your drinking problem? ➤ Have you talked about it with your family physician or another physician? ➤ What do you think prevents you from reducing or stopping your alcohol consumption? ➤ What are your goals: to stop drinking altogether? To drink less? ➤ What steps have you taken to try to change your consumption? (treatment, consultation with specialists, alternative medicines, etc.) ➤ Have you ever taken medication to stop drinking? Which medication(s) precisely? ➤ Have you looked for information concerning treatments to stop or reduce alcohol consumption? ➤ Have you heard of baclofen? Of nalmefene? ➤ Do you visit medical websites and / or online forums? Does this help you? How ?

Data analysis

The qualitative data for the PWAUD interview corpus has yet to be analysed (as of June 2018). The text analysis software Iramuteq (Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires) (Version 0.7 Alpha 2) will be used. Iramuteq provides different processing and statistical analysis options for produced texts and ensures accurate analyses for qualitative health research.

Descending hierarchical classification will be performed, whereby calculations are performed on the concurrence of words in the text (23). The results come in the form of speech classes that are described from the lexicon that is statistically overrepresented in the segments gathered in the classes. Each of the lexical classes is described in detail by the lexicon that defines it, the characteristic segments that represent it, and the associated variables (24)

ii. Quantitative sub-study

Recruitment and data collection

Recruitment started in September 2017 and is ongoing (as of June 2018). PWAUD are recruited in several different medical services such as CSAPA, clinics, hospitals, addiction care services and ELSA (translated from French as “Team for Linkage to Addiction Care”, ELSA is an organisation of trained addiction care professionals, created in 2000 to increase screening and care for patients with AUD in hospitals. Patients recruited through ELSA are not already receiving AUD care at enrolment.)

Medical staff inform their patients of the study and provide them with the consent form. They collect the phone number of patients who agree to participate and provide related information to the investigators.

Participants are then contacted for a phone-based interview. Computer-assisted interviews are conducted by trained investigators and answers are collected using Sphinx software (version IQ 2).

Interviews follow a questionnaire based on the framework detailed in Table 3. This questionnaire was built by exploring the literature on similar topics.

Table 3. PWAUD Questionnaire

Section number	Main theme	Specific themes
1	General information	Age, gender, family situation, educational status, income, employment status, quality of housing, receiving ordinary healthcare, access to transportation, internet access.
2	Alcohol consumption	Craving level, health issues related to alcohol consumption, withdrawal symptoms, alcohol consumption perceptions
3	Substances use other than alcohol	Tobacco, opioids, benzodiazepines, cocaine, synthetic drugs
4	Experiences and perceptions related to alcohol consumption	Feelings, discrimination, drinking environment (place, peers).
5	AUD aims concerning personal alcohol consumption	(e.g., abstinence, reduction, etc.)
6	Care received	Having a regular GP, quality of relationship with regular GP, receiving/having received care (in the 3 years prior to enrolment), having already sought AUD care through regular GP or in general, and, if applicable, reasons for not having sought AUD care.
7	Methods used to stop or reduce alcohol consumption	Medical methods, alternative therapies, association support. For each method, participants are asked if it was/is helpful and if it is ongoing.
8/9	Pharmacological treatments	Pharmacological treatments: Question 8 is designed for PWAUD who have already had at least one experience with pharmacological treatment, while question 9 is for people who have never taken any pharmacological treatment. For each of the 5 prescribed pharmacological treatments for maintaining abstinence or reducing alcohol consumption, participants are asked 1) if they have heard of it (if applicable where/from whom), 2) if they have taken the treatment (if applicable, who prescribed it to them), 3) reasons for deciding to take or not to take this treatment, 4) the treatment's efficacy, and 5) (if appropriate) their personal opinion about the causes for failure using this treatment.

Statistical considerations

Collected variables considered to be potentially associated with access to care include socio-demographic factors, characteristics of family members (with AUD or not), drinking patterns, perceived stigma, and perception about treatment for AUD (Table 3).

In order to calculate the sample size, we want to over-represent those who have received care for AUD by a factor of 2 in order to compare possible “care subgroups”. A sample size of 110 vs. 55 will allow us to highlight a strength of association with an OR=2.77 between potential correlates and receiving care for AUD (alpha =5% and a power= 80 %.)

Data will be analysed with STATA (*Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP). In order to control for possible recruitment biases, the socio-demographic characteristics of PWAUD will be compared between individuals recruited in the ASIA study and individuals in the French general population identified with AUD in the 2016 Health Barometer Survey, which was conducted by the Health Prevention and Education National Institute (INPES). The results obtained will be used to decide if a weighting procedure is needed to make our data more representative of PWAUD living in France.

The main correlates of access to care for PWAUD, including potential barriers and levers, will be identified using univariate and multivariable logistic regression models, the outcome being “Having access to care for AUD in the 3 previous years medical care for AUD (yes/no)”. In order to control for heterogeneity depending on the type of care accessed by PWAUD, the outcome will also be expressed as a categorical ordinal variable and multinomial logistic regression will be used. Possible missing data in the outcomes can be managed using selection models (such as the Heckman model) (25).

Sensitivity analyses will be performed on specific subgroups (e.g. those never treated vs. those receiving pharmacological treatment for AUD) to verify results’ robustness.

II. General practitioner (GP) population

Inclusion criteria

For both sub-studies (i.e. quantitative and qualitative), the following criteria are used: working as a general practitioner and following at least 3 PWAUD in the 3 years prior to the interview (even if they did not consult for AUD)

1
2
3 **i. Qualitative study**

4 *Recruitment and data collection*

5
6 From December 2016 to August 2017, 15 GP were recruited from a GP network.
7 Recruitment took place using a “snowball method” as follows: a member of the study’s
8 research team first provided the study investigator with the contact information for 2 GP,
9 who were then contacted by email. Both agreed to participate. These first participants were
10 then asked for 2 other colleagues’ emails, so that they too could be invited, and so on.
11 Information about the study and the consent form to be completed were sent to all GP by
12 email.
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15 Interviews took place in GP offices or were performed over the telephone and were
16 recorded in both cases. The interviews were semi-structured and conducted according to
17 the guide described in Table 4.
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Table 4. Semi-structured GP interview guide

Qualitative sub-study among GP	
Standard data collected	Year of birth Gender Beginning date of professional practice Workplace category (urban, rural, or semi-rural)
Semi-structured GP interview guide	
Opening question	Can you tell me about your experience with patients with alcohol use disorder, especially how you handle them?
If the interviewee does not mention these topics spontaneously, the interviewer must do so:	<ul style="list-style-type: none"> ➤ Are you currently following patients with alcohol use disorder? ➤ How do you screen for alcohol use disorder? Do you use a specific scale or test? ➤ Do you treat patients by yourself for substance abuse or do you refer them to a colleague or a specialized centre? ➤ Do you prescribe pharmacological treatments to help with the suppression / reduction of alcohol consumption? Which ones? ➤ What motivates this choice of treatment? ➤ Do you think it is possible to stop drinking without treatment? ➤ Do you think that abstinence is the only possible answer for people who have a drinking problem? ➤ Do you consider that reducing consumption is an acceptable therapeutic objective (with respect to abstinence)? ➤ What do you think about baclofen and nalmefene?

Data analysis

Data analysis has been completed. For the GP interview corpus (10 hours), a manual sequenced thematic analysis (26) was performed. To ensure the results' reliability, four transcribed interviews were randomly selected, read repeatedly, analysed, coded and then categorised separately by the main investigator and her supervisor. They then discussed their respective findings together to identify discourse themes. The main investigator then conducted the initial coding of all fifteen transcribed interviews according to the previously identified themes. After preliminary analysis, the coding framework was discussed and approved by all the study group members. The main investigator then conducted the final coding.

ii. Quantitative sub-study

Recruitment and data collection

Recruitment started in May 2017 and is ongoing (as of May 2018). GP are recruited randomly from the French professional phonebook. Inclusion criteria are the same as for the qualitative study. After receiving information on the study and providing consent, participants are contacted to perform the survey. Just as for the PWAUD quantitative study, computer-assisted interviews are conducted by trained investigators and answers are collected using Sphinx software (version IQ2). Interviews follow a questionnaire based on the guide detailed in Table 5. The questionnaire was built by exploring the literature on similar topics.

In order to calculate the sample size, we assumed a 50% prevalence of GP not providing AUD. Furthermore, to be able to identify an odds ratio (OR) equal to 3.5 when comparing the risk of not providing care when being exposed or non-exposed to a potential correlate, with 80% power and a 0.05 alpha risk, we calculated that we need to recruit at least 46 GP who provide AUD care and 46 who do not. We rounded this total to 50 and 50 (100 GP in total).

Table 5. GP Questionnaire

GP questionnaire		
Section number	Main theme	Specific themes
1	General information about GP and their practice	Gender, age, practice duration (years), number of regular patients, consultation duration, addictology training, participation in an addictology network, opioid maintenance treatment prescription, interest in addictology, tobacco cessation management.
2	Alcohol consumption screening: alcohol cessation /reduction management	Performs screening (yes or no, alone or with another healthcare professional, and if applicable, which category of professional), reason for not managing patient alcohol cessation, number of patients with AUD, prescribes blood analysis to screen for AUD (yes or no), AUD spontaneous assessment (if applicable, with which tool/scale), uses a brief intervention (yes or no), knowledge of specialised alcoholism network structures (for nine different structures, GP are asked if they know the structure and if they collaborate with it).
3	AUD management (if applicable)	AUD management motivations, treatment/orientation/advice provided, pharmacological treatment prescription (yes or no, and if applicable, the reason for not prescribing pharmacological treatment to stop or reduce alcohol consumption), prescription of one of the 5 pharmacological treatments indicated to stop or reduce alcohol consumption (for each treatment: treatment prescription intention, prescription motivation, treatment risk-benefit opinion, opinion about causes for treatment failure, opinion about causes for poor adherence and treatment cessation).
4	Opinion question	“Do you think that abstinence is the only acceptable therapeutic goal for PWAUD? (Yes, no, I don’t know)”, and: “Do you think that CD is a realistic therapeutic goal for PWAUD? (Yes, no, I don’t know)”.

Statistical considerations

Outcomes and potential correlates (See Table 5)

The four following outcomes will be explored:

- 1) Systematic AUD screening (Table 5, Section 2)
- 2) AUD management (Table 5, Section 3)
- 3) Acceptance of CD as a therapeutic goal (Table 5, Section 4)
- 4) Prescription of pharmacological treatment (Table 5, Section 3)

Potential variables that will be considered for analysis include demographic and professional characteristics/practices, number of patients with AUD, and perceived barriers to engaging patients in care for AUD (lack of training, patient's denial of AUD, lack of time, complexity of AUD patients' profile (i.e., several concurrent psychological and physiological comorbidities)).

Percentages, median and interquartile ranges will be used to describe the characteristics of the study group. In order to identify correlates of the three outcomes, we will use logistic regression models.

Potential explanatory variables of all four outcomes are described in the questionnaire outlined in Table 5. Logistic regression models will be used to compute both crude and adjusted odds ratios and their 95% confidence intervals in order to obtain an estimate of the strength of the association between each explanatory variable and each outcome.

Variables with a liberal p-value <0.20 will be considered eligible for the multivariable models which will be built using a backward procedure based on the likelihood ratio test ($p < 0.05$). Perceived barriers to AUD engagement in care will be eligible for the final multivariable model independently of the p-value obtained in the bi-variable analysis, due to the high risk of confounding.

All the analysis will be performed using STATA SE/12.1.

Identifying GP who are likely to prescribe treatment for AUD and those who are not, may help target future interventions to improve screening and treatment for PWAUD.

Discussion

The originality of the present protocol lies in the use of the combination of a mixed-method and a "double-perspective" design. Various studies exploring both healthcare providers' and patients' points of view have highlighted differences in expectations, priorities and perceptions of each of the two populations, and identified the need to develop patient-centred care strategies (27–29). We believe that our study will confirm these findings and

bring to light some new concerns in the field of AUD care. The use of a qualitative and quantitative mixed-method approach is, in our opinion, very pertinent, as alcohol consumption is highly integrated into various socio-cultural patterns and differs greatly from one context to another (30). Qualitative study approaches are especially useful to increase socio-cultural understanding (31). The replication of this study would be of great value for several reasons: the use of the mixed-method approach permits an in-depth exploration of the different aspects of access to care in a specific context, and the double-perspective design leads to a greater understanding of the differences between the two populations' views and perceptions.

The use of two different qualitative analysis methods may seem questionable but can be justified by the difference between the volume of data for GP and for PWAUD. More specifically, as the PWAUD interview corpus was very large (35 hours), the use of a software-assisted thematic and lexical content analysis seemed an appropriate choice. As the GP qualitative data was less substantial, manual thematic analysis seemed more appropriate. Data obtained using these two methods can easily be compared and researchers aiming to reproduce this study have the choice of using one or both of these same methods to analyse qualitative data.

We believe results from ASIA will be of great use in the development of future recommendations and the updating of care guidelines for GP, an important element being clear information about AUD care networks. The ASIA study's results will be disseminated via peer-reviewed publications, conference presentations, and in general public media.

Ethics and dissemination

The confidentiality and anonymity of participant data will be guaranteed for both GP and PWAUD in every step of the study: no information will be kept which could result in participants being identified. Audio-recorded interviews will be transcribed and deleted within 3 months after recording. Only the main investigator will have access to the recordings. For both populations, participation in the quantitative and/or the qualitative substudy will only occur if written consent is given after the individual has been provided with a document explaining ASIA modalities and objectives.

This study was approved by the French National Commission on Informatics and Liberties (CNIL) (approval reference number: C16-10 Date of approval: July 17, 2017), the Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS) and the Evaluation and Ethics Committee (approval reference number: 16-312 Date of

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2
3 approval: July 8, 2016) (CEEI) of the French National Institute of Health and Medical
4 Research (INSERM).
5

6 **Declarations**

7 *Authors' contributions*

8
9 MPC, SN, MC1, FM, PR, MM, TB, MC2 and GM designed the study and wrote the protocol.
10 MC and MPC managed the literature searches and formulated the research questions. MC
11 wrote the first draft of the manuscript. NS, PP, CC, DC, SLB and MT reviewed the manuscript
12 and gave their approval.
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14
15

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17
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22
23

24 *Competing interests*

25
26 The commercial company Ethypharm provides financial support - in the form of a salary – to
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28 preparation of the manuscript.
29
30

31 *Consent for publication*

32
33 The corresponding author confirms that all authors have read and approved the paper.

34
35 All authors contributed to and approved the current version of the manuscript.

36
37 This work has not been published previously and is not under consideration for publication
38 elsewhere. If accepted, this work will not be published elsewhere in English or in any other
39 language, without the written consent of the copyright holder.
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41
42

43 *Availability of data and material*

44
45 Not applicable
46

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Access to care for people with alcohol use disorder in France: a mixed-method cross-sectional study protocol (ASIA)

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Manuscripts

Access to care for people with alcohol use disorder in France: a mixed-method cross-sectional study protocol (ASIA).

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Abstract

Introduction: Alcohol use disorder (AUD) is a major public health concern worldwide. In France only 10% of people with AUD (PWAUD) receive medical care. General practitioners (GP) are one of the main entry points for AUD care. The present ongoing study, entitled ASIA (Access to Care and Indifference toward Alcohol, *Accès aux Soins et Indifférence à l'Alcool* in French), aims to improve knowledge about factors associated with access to care for AUD by exploring related GP and PWAUD practices, experiences and perceptions.

Methods and Analysis: The ASIA project is an ongoing cross-sectional multi-site study based on a complementary mixed-method approach (quantitative and qualitative) using a convergent parallel design. The double-perspective design of the study will enable us to collect and compare data regarding both PWAUD and GP points of view.

For the PWAUD quantitative study, 260 PWAUD will be interviewed using a telephone-based questionnaire. For the qualitative study, 36 PWAUD have already been interviewed. The GP quantitative study will include 100 GP in a 15-minute survey. Fifteen GP have already participated in semi-structured interviews for the qualitative study.

Logistic regression will be used to identify predictors to access to care. With respect to data analyses, qualitative interviews will be analysed using semantic analysis while quantitative logistic regression will be used for quantitative interviews.

Ethics and dissemination: This study was approved by the French National Commission on Informatics and Liberties (CNIL) (approval reference number: C16-10 Date of approval: July 17, 2017), the Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS) and the Evaluation and Ethics Committee (approval reference number: 16-312 Date of approval: July 8, 2016) (CEEI) of the French National Institute of Health and Medical Research (INSERM). Results from ASIA will be disseminated in peer-reviewed publications, conference presentations, reports and in a PhD thesis.

Key words:

Alcohol Use Disorder, Access to Care, General practitioners, Alcohol Use Disorder treatments, Mixed-method study;

Article summary

- The originality of this study is that it cross-analyses GP and PWAUD data regarding a common issue. Its results will be very useful for improving AUD management in primary care, and consequently, for improving access to care for PWAUD in general
- The major strength of this study is its mixed use of qualitative and quantitative data, which enables us to collect subjective data - such as perceptions - as well as data on measurable variables, both elements being involved in the patient's AUD care trajectory.
- Another strength is the recruitment of both PWAUD involved and PWAUD not involved in AUD care, so that barriers as well as levers to access to care can be identified.
- The study population with AUD enrolled in the study may not be completely representative of the general population with AUD in France, and data may need appropriate weighting during analysis.

Introduction

Alcohol Use Disorder (AUD) is a major health and social concern and is responsible for approximately 3.3 million deaths (or 5.9% of all global deaths) annually (1). It is estimated that AUD contributes to over 200 diseases and injury conditions, especially liver cirrhosis and cancer (1). The prevalence of alcohol dependence in Europe has been evaluated at 6.4% among men and 1.2 % among women (2). Only 10% of people concerned by AUD receive medical care for AUD in France (3).

According to a report on alcohol use, published by the French Observatory on Drugs and Drug Addiction (OFDT) in 2014 (4,5), 10 % of people interviewed in the country (n= 15635) reported daily alcohol consumption. A report published in 2015 (6) estimated the annual external cost of alcohol abuse at 114 399 billion euros, in terms of lost lives, reduced quality of life and production losses.

In France, it is difficult to obtain accurate figures on care for AUD due to the different AUD management entry points (7) (specialized centres, general practitioners, hospitals, associations), but the proportion of PWAUD linked to medical care for this disorder is definitely small (8).

Although medical care for substance use disorders is easily accessible in specialized addiction centres (CSAPA), general practitioners (GP) constitute the main first line of care for AUD screening. Primary healthcare provided by GP is the first-choice option for preventing, screening and managing AUD and its consequences. Indeed, in addition to being the first point of contact, GP are numerous and provide comprehensive and coordinated care (9,10).

Depending on the severity of the disorder, different psychosocial approaches can be used to help PWAUD reduce or stop alcohol, including motivational interviews, mindfulness interventions, social-skills training, behavioural self-control training (11). In addition, 5 different pharmacological treatments can be prescribed: acamprosate, disulfiram, naltrexone, nalmefene and baclofen (12). Acamprosate and disulfiram are prescribed to help maintain abstinence in people who have already stopped drinking. Naltrexone is approved for abstinence maintenance, but has also been used off-label to reduce consumption (13). Nalmefene is prescribed to reduce consumption as it reduces craving. Baclofen is also used to reduce craving but unlike the other 4 drugs, which are legally available in France, it can only be prescribed off-label, as part of France's regulatory drug-evaluation framework (called "Temporary Recommendation Use (TRU)"). A review published in 2016 concluded that all 5 treatments show different safety profiles and must be adapted to each patient's

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3 alcohol consumption goal and individual profile (14). Another review reported that all 5
4 treatments are still underused and that barriers to their prescription need to be investigated
5 (15).
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8 It is important to note that we are in a transitional period between one paradigm and
9 another. More specifically, alcohol-related risk reduction, including controlled drinking (CD),
10 is becoming an acceptable therapeutic goal for caregivers and patients (16), while until very
11 recently, the standard of care for AUD was based on stopping consumption, maintaining
12 abstinence, preventing chronic complications related to excessive alcohol consumption and
13 managing withdrawal symptoms. The licensing of nalmefene and the prescription of
14 baclofen within France's TRU framework confirms this paradigm shift (17). For many
15 patients who might not be immediately ready for total abstinence, reducing consumption
16 may constitute a realistic achievable goal (18).
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19 Lack of awareness of having AUD and apprehension towards total alcohol abstinence are
20 two important barriers to treatment seeking (19). It is possible that a lack of knowledge
21 about the different AUD therapeutic options currently available (20) also constitutes a
22 barrier.
23
24

25 Given this dynamic context, an in-depth evaluation of access to care for PWAUD in France
26 would seem necessary. The present study, ASIA, aims to improve knowledge about factors
27 associated with seeking, receiving and providing care for AUD by exploring related GP and
28 PWAUD practices, experiences and perceptions.
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31 *General study design*

32 ASIA is an ongoing multi-site cross-sectional study which started in France in 2016. It aims to
33 explore barriers to and facilitators of access to care for PWAUD in France, and to provide a
34 better understanding of the individual and contextual factors associated with the currently
35 poor level of access to care for those who wish to stop or reduce their alcohol consumption.
36 The study uses a mixed approach which comprises (i) a qualitative study, and (ii) a
37 quantitative study for two populations: PWAUD (I) and GP (II).
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40 The complementary mixed-method approach (quantitative and qualitative) implemented
41 here uses a convergent parallel design (21). This type of study design provides a more
42 comprehensive view of a phenomenon, as it separately cross-analyses data collected
43 concomitantly using these two study approaches from each of two different studies (in our
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3 situation PWAUD and GP). For the present work, comparing data from the resulting four
4 sub-studies will shed greater light on the mechanisms leading or not to AUD care.
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6 **Methods and analysis**

7 *Objectives*

8
9 The specific objectives of the study are presented below, relationship between project
10 objectives and study components are resumed in table 1.
11
12

13
14 1) Identify socio-demographic characteristics and health experiences associated with access
15 to care (PWAUD)
16

17
18 2) Determine socio-demographic and professional characteristics associated with AUD
19 management and screening, acceptance of CD and AUD pharmacological treatment
20 prescription (GP).
21

22
23 3) Assess whether barriers found in other studies were relevant in the current French
24 context (PWAUD and GP)
25

26
27 4) Identify other barriers and levers which could have been missed in the quantitative study
28 (GP and PWAUD)
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31 5) Illustrate and examine in depth the findings of the quantitative study (GP and PWAUD)
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Table 1. Relationship between project objectives and study components

	PWAUD Qualitative study	PWAUD Quantitative study	GP Qualitative study	GP Quantitative study
1) Identify socio-demographic characteristics and health experiences associated with access to care (PWAUD)		X		
2) Determine socio-demographic and professional characteristics associated with AUD management and screening, acceptance of CD and pharmacological treatment prescription (GP)				X
3) Assess whether barriers found in other studies were relevant in the current French context (PWAUD and GP)		X		X
4) Identify other barriers and levers which could have been missed in the quantitative study (GP and PWAUD)	X		X	
5) Illustrate and examine in depth the findings of the quantitative study (GP and PWAUD)	X		X	

Definition of AUD

The main tool used by the World Health Organization to measure alcohol consumption is the Alcohol Use Identification Test (AUDIT) (22). This 10-item questionnaire provides an alcohol consumption score from 0 to 40. Scores between 8 (7 for women) and 15 suggest hazardous alcohol consumption, 16 to 19 harmful alcohol consumption, and >20 alcohol dependence (15). We chose to include only people with a score > 15, because above this, medical care is recommended (11).

Definition of care

In this study, we decided to define "receiving care" as follows:

- Receiving non-pharmacological therapeutic interventions from a healthcare professional to reduce or stop alcohol consumption

And/or

- Participating in an alcohol-related support group (such as Alcoholics Anonymous)

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2
3 And/or:

4
5 - Taking one of the five approved AUD pharmacological drugs

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7 *Patient and Public Involvement statement*

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9 Neither patients nor the general public were involved in the design of this study.

10
11 In order to respect patient confidentiality, we will not keep participants' contact information.
12
13 Consequently, the results of the study will not be personally disseminated to participants.
14
15 However, participants are informed in the consent form that if they wish, they can contact
16
17 the main investigator to obtain the study results.

18
19 *Sampling strategy and data collection*

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21 As of May 2018, data collection for the qualitative sub-studies has already been performed
22
23 for the PWAUD and GP. Analysis of qualitative GP data has also been completed. More in-
24
25 depth details can be found in this section.

26
27 **I. PWAUD population**

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29 *Inclusion criteria*

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31 For both sub-studies (i.e. quantitative and qualitative), the following inclusion criteria are
32
33 used: aged over 18, French speaking and AUDIT score >15.

34
35 **i. Qualitative sub-study**

36
37 *Recruitment and data collection*

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39 From June 2016 to May 2017, 36 patients were recruited in 4 medical services: the Saint-
40
41 Barnabe substance disorder clinic in Marseille, two CSAPA (Care, Prevention, and Support
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43 Center for Addiction) in Avignon and Nîmes, and the CISIH (Information and Care Center for
44
45 Human Immunodeficiency) in Saint-Marguerite Hospital in Marseille (patients recruited
46
47 through this service were not already receiving AUD care at enrolment)). Medical staff
48
49 informed their patients of the study and introduced potential participants to the study
50
51 investigator.

52
53 After providing information about the study, the study investigator performed a face-to-face
54
55 interview in a closed office to ensure confidentiality. The interview was semi-structured and
56
57 conducted according to the guide described in Table 2.

58
59 Interviews lasted between 30 and 75 minutes and were recorded. Recordings were
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transcribed using word processing software. Transcripts of interviews were not returned to

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3 PWAUD participants for comments or correction. Only the qualitative sub-study investigator
4 has access to these records. Information concerning participants' confidentiality and
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6 anonymity is presented in the "Ethics and Dissemination" section.
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For peer review only

Table 2. Semi-structured PWAUD interview guide

Qualitative sub-study for PWAUD	
Standard data collected	Audit score Enrolment site Year of birth Gender Personal situation (e.g., living in a couple, having children, etc.) Professional situation (e.g., employment status) Substance use (Yes/No, and if applicable, consumption frequency)
Semi-structured PWAUD interview guide	
Opening question	You are experiencing difficulties with your alcohol consumption. I imagine it is difficult to deal with that. Could you tell me about your experience with alcohol since you started drinking, including, if applicable, your experience with health professionals for this specific problem?
If the interviewee does not mention these topics spontaneously, the interviewer must do so.	<ul style="list-style-type: none"> ➤ How long have you been drinking, how did it start? ➤ How did you realize that you had a drinking problem? ➤ Who have you talked to about your drinking problem? ➤ Have you talked about it with your family physician or another physician? ➤ What do you think prevents you from reducing or stopping your alcohol consumption? ➤ What are your goals: to stop drinking altogether? To drink less? ➤ What steps have you taken to try to change your consumption? (treatment, consultation with specialists, alternative medicines, etc.) ➤ Have you ever taken medication to stop drinking? Which medication(s) precisely? ➤ Have you looked for information concerning treatments to stop or reduce alcohol consumption? ➤ Have you heard of baclofen? Of nalmefene? ➤ Do you visit medical websites and / or online forums? Does this help you? How ?

Data analysis

The qualitative data for the PWAUD interview corpus has yet to be analysed (as of June 2018). The text analysis software Iramuteq (Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires) (Version 0.7 Alpha 2) will be used. Iramuteq provides different processing and statistical analysis options for produced texts and ensures accurate analyses for qualitative health research.

Descending hierarchical classification will be performed, whereby calculations are performed on the concurrence of words in the text (23). The results come in the form of speech classes that are described from the lexicon that is statistically overrepresented in the segments gathered in the classes. Each of the lexical classes is described in detail by the lexicon that defines it, the characteristic segments that represent it, and the associated variables (24).

Iramuteq descending hierarchical classification includes 5 stages:

- 1) The full corpus is divided into text segments composed of 40 words (by default).
- 2) Lemmatization: grouping of the inflected forms of a word so they can be analysed as a single item (verbs in the infinitive, nouns in the singular and adjectives in the masculine singular (Unlike English, the French language has masculine and feminine endings for adjectives.)
- 3) Definition of a contingency table of “analyzable” reduced forms and text segments
- 4) Top-down hierarchical classification analysis: performed to obtain stable classes and significant associated words (tested by chi-square
- 5) Production of class description to enable interpretation.

ii. Quantitative sub-study

Recruitment and data collection

Recruitment started in September 2017 and is ongoing (as of June 2018). PWAUD are recruited in several different medical services such as CSAPA, clinics, hospitals, addiction care services and ELSA (translated from French as “Team for Linkage to Addiction Care”, ELSA is an organisation of trained addiction care professionals, created in 2000 to increase screening and care for patients with AUD in hospitals. Patients recruited through ELSA are not already receiving AUD care at enrolment.)

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3 Medical staff inform their patients of the study and provide them with the consent form.
4 They collect the phone number of patients who agree to participate and provide related
5 information to the investigators.
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8 Participants are then contacted for a phone-based interview. Computer-assisted interviews
9 are conducted by trained investigators and answers are collected using Sphinx software
10 (version IQ 2).
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13 Interviews follow a questionnaire based on the framework detailed in Table 3. This
14 questionnaire was built by exploring the literature on similar topics.
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Table 3. PWAUD Questionnaire

Section number	Main theme	Specific themes
1	General information	Age, gender, family situation, educational status, income, employment status, quality of housing, receiving ordinary healthcare, access to transportation, internet access.
2	Alcohol consumption	Craving level, health issues related to alcohol consumption, withdrawal symptoms, alcohol consumption perceptions
3	Substances use other than alcohol	Tobacco, opioids, benzodiazepines, cocaine, synthetic drugs
4	Experiences and perceptions related to alcohol consumption	Feelings, discrimination, drinking environment (place, peers).
5	AUD aims concerning personal alcohol consumption	(e.g., abstinence, reduction, etc.)
6	Care received	Having a regular GP, quality of relationship with regular GP, receiving/having received care (in the 3 years prior to enrolment), having already sought AUD care through regular GP or in general, and, if applicable, reasons for not having sought AUD care.
7	Methods used to stop or reduce alcohol consumption	Medical methods, alternative therapies, association support. For each method, participants are asked if it was/is helpful and if it is ongoing.
8/9	Pharmacological treatments	Pharmacological treatments: Question 8 is designed for PWAUD who have already had at least one experience with pharmacological treatment, while question 9 is for people who have never taken any pharmacological treatment. For each of the 5 prescribed pharmacological treatments for maintaining abstinence or reducing alcohol consumption, participants are asked 1) if they have heard of it (if applicable where/from whom), 2) if they have taken the treatment (if applicable, who prescribed it to them), 3) reasons for deciding to take or not to take this treatment, 4) the treatment's efficacy, and 5) (if appropriate) their personal opinion about the causes for failure using this treatment.

Statistical considerations

Collected variables considered to be potentially associated with access to care include socio-demographic factors, characteristics of family members (with AUD or not), drinking patterns, perceived stigma, and perception about treatment for AUD (Table 3).

In order to calculate the sample size, we want to over-represent those who have received care for AUD by a factor of 2 in order to compare possible “care subgroups”. A sample size of 110 vs. 55 will allow us to highlight a strength of association with an OR=2.77 between potential correlates and receiving care for AUD (alpha =5% and a power= 80 %.)

Data will be analysed with STATA (*Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP). In order to control for possible recruitment biases, the socio-demographic characteristics of PWAUD will be compared between individuals recruited in the ASIA study and individuals in the French general population identified with AUD in the 2016 Health Barometer Survey, which was conducted by the Health Prevention and Education National Institute (INPES). The results obtained will be used to decide if a weighting procedure is needed to make our data more representative of PWAUD living in France.

The main correlates of access to care for PWAUD, including potential barriers and levers, will be identified using univariate and multivariable logistic regression models, the outcome being “Having access to care for AUD in the 3 previous years medical care for AUD (yes/no)”. In order to control for heterogeneity depending on the type of care accessed by PWAUD, the outcome will also be expressed as a categorical ordinal variable and multinomial logistic regression will be used. Possible missing data in the outcomes can be managed using selection models (such as the Heckman model) (25).

Sensitivity analyses will be performed on specific subgroups (e.g. those never treated vs. those receiving pharmacological treatment for AUD) to verify results’ robustness.

II. General practitioner (GP) population

Inclusion criteria

For both sub-studies (i.e. quantitative and qualitative), the following criteria are used: working as a general practitioner and following at least 3 PWAUD in the 3 years prior to the interview (even if they did not consult for AUD)

1
2
3 **i. Qualitative study**

4 *Recruitment and data collection*

5
6 From December 2016 to August 2017, 15 GP were recruited from a GP network.
7 Recruitment took place using a “snowball method” as follows: a member of the study’s
8 research team first provided the study investigator with the contact information for 2 GP,
9 who were then contacted by email. Both agreed to participate. These first participants were
10 then asked for 2 other colleagues’ emails, so that they too could be invited, and so on.
11 Information about the study and the consent form to be completed were sent to all GP by
12 email.
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15 Interviews took place in GP offices or were performed over the telephone and were
16 recorded in both cases. The interviews were semi-structured and conducted according to
17 the guide described in Table 4.
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Table 4. Semi-structured GP interview guide

Qualitative sub-study among GP	
Standard data collected	Year of birth Gender Beginning date of professional practice Workplace category (urban, rural, or semi-rural)
Semi-structured GP interview guide	
Opening question	Can you tell me about your experience with patients with alcohol use disorder, especially how you handle them?
If the interviewee does not mention these topics spontaneously, the interviewer must do so:	<ul style="list-style-type: none"> ➤ Are you currently following patients with alcohol use disorder? ➤ How do you screen for alcohol use disorder? Do you use a specific scale or test? ➤ Do you treat patients by yourself for substance abuse or do you refer them to a colleague or a specialized centre? ➤ Do you prescribe pharmacological treatments to help with the suppression / reduction of alcohol consumption? Which ones? ➤ What motivates this choice of treatment? ➤ Do you think it is possible to stop drinking without treatment? ➤ Do you think that abstinence is the only possible answer for people who have a drinking problem? ➤ Do you consider that reducing consumption is an acceptable therapeutic objective (with respect to abstinence)? ➤ What do you think about baclofen and nalmefene?

Data analysis

Data analysis has been completed. For the GP interview corpus (10 hours), a manual sequenced thematic analysis (26) was performed. To ensure the results' reliability, four transcribed interviews were randomly selected, read repeatedly, analysed, coded and then categorised separately by the main investigator and her supervisor. They then discussed their respective findings together to identify discourse themes. The main investigator then conducted the initial coding of all fifteen transcribed interviews according to the previously identified themes. After preliminary analysis, the coding framework was discussed and approved by all the study group members. The main investigator then conducted the final coding.

ii. Quantitative sub-study

Recruitment and data collection

Recruitment started in May 2017 and is ongoing (as of May 2018). GP are recruited randomly from the French professional phonebook. Inclusion criteria are the same as for the qualitative study. After receiving information on the study and providing consent, participants are contacted to perform the survey. Just as for the PWAUD quantitative study, computer-assisted interviews are conducted by trained investigators and answers are collected using Sphinx software (version IQ2). Interviews follow a questionnaire based on the guide detailed in Table 5. The questionnaire was built by exploring the literature on similar topics.

In order to calculate the sample size, we assumed a 50% prevalence of GP not providing AUD. In order to be able to identify an odds ratio (OR) equal to 3.5 when comparing the risk of not providing care when being exposed or non-exposed to a potential correlate, with 80% power and a 0.05 alpha risk, we calculated that we need to recruit at least 46 GP who provide AUD care and 46 who do not. We rounded this total to 50 and 50 (100 GP in total).

Table 5. GP Questionnaire

GP questionnaire		
Section number	Main theme	Specific themes
1	General information about GP and their practice	Gender, age, practice duration (years), number of regular patients, consultation duration, addictology training, participation in an addictology network, opioid maintenance treatment prescription, interest in addictology, tobacco cessation management.
2	Alcohol consumption screening: alcohol cessation /reduction management	Performs screening (yes or no, alone or with another healthcare professional, and if applicable, which category of professional), reason for not managing patient alcohol cessation, number of patients with AUD, prescribes blood analysis to screen for AUD (yes or no), AUD spontaneous assessment (if applicable, with which tool/scale), uses a brief intervention (yes or no), knowledge of specialised alcoholism network structures (for nine different structures, GP are asked if they know the structure and if they collaborate with it).
3	AUD management (if applicable)	AUD management motivations, treatment/orientation/advice provided, pharmacological treatment prescription (yes or no, and if applicable, the reason for not prescribing pharmacological treatment to stop or reduce alcohol consumption), prescription of one of the 5 pharmacological treatments indicated to stop or reduce alcohol consumption (for each treatment: treatment prescription intention, prescription motivation, treatment risk-benefit opinion, opinion about causes for treatment failure, opinion about causes for poor adherence and treatment cessation).
4	Opinion question	“Do you think that abstinence is the only acceptable therapeutic goal for PWAUD? (Yes, no, I don’t know)”, and: “Do you think that CD is a realistic therapeutic goal for PWAUD? (Yes, no, I don’t know)”.

Statistical considerations

Outcomes and potential correlates (See Table 5)

The four following outcomes will be explored:

- 1) Systematic AUD screening (Table 5, Section 2)
- 2) AUD management (Table 5, Section 3)
- 3) Acceptance of CD as a therapeutic goal (Table 5, Section 4)
- 4) Prescription of pharmacological treatment (Table 5, Section 3)

Potential variables that will be considered for analysis include demographic and professional characteristics/practices, number of patients with AUD, and perceived barriers to engaging patients in care for AUD (lack of training, patient's denial of AUD, lack of time, complexity of AUD patients' profile (i.e., several concurrent psychological and physiological comorbidities)).

Percentages, median and interquartile ranges will be used to describe the characteristics of the study group. In order to identify correlates of the three outcomes, we will use logistic regression models.

Potential explanatory variables of all four outcomes are described in the questionnaire outlined in Table 5. Logistic regression models will be used to compute both crude and adjusted odds ratios and their 95% confidence intervals in order to obtain an estimate of the strength of the association between each explanatory variable and each outcome.

Variables with a liberal p-value <0.20 will be considered eligible for the multivariable models which will be built using a backward procedure based on the likelihood ratio test (p<0.05). Perceived barriers to AUD engagement in care will be eligible for the final multivariable model independently of the p-value obtained in the bi-variable analysis, due to the high risk of confounding.

All the analysis will be performed using STATA SE/12.1.

Identifying GP who are likely to prescribe treatment for AUD and those who are not, may help target future interventions to improve screening and treatment for PWAUD.

Discussion

The originality of the present protocol lies in the use of the combination of a mixed-method and a "double-perspective" design. Various studies exploring both healthcare providers' and patients' points of view have highlighted differences in expectations, priorities and perceptions of each of the two populations, and identified the need to develop patient-centred care strategies (27–29). We believe that our study will confirm these findings and

bring to light some new concerns in the field of AUD care. The use of a qualitative and quantitative mixed-method approach is, in our opinion, very pertinent, as alcohol consumption is highly integrated into various socio-cultural patterns and differs greatly from one context to another (30). Qualitative study approaches are especially useful to increase socio-cultural understanding (31). The replication of this study would be of great value for several reasons: the use of the mixed-method approach permits an in-depth exploration of the different aspects of access to care in a specific context, and the double-perspective design leads to a greater understanding of the differences between the two populations' views and perceptions.

The use of two different qualitative analysis methods may seem questionable but can be justified by the difference between the volume of data for GP and for PWAUD. More specifically, as the PWAUD interview corpus was very large (35 hours), the use of a software-assisted thematic and lexical content analysis seemed an appropriate choice. As the GP qualitative data was less substantial, manual thematic analysis seemed more appropriate. Data obtained using these two methods can easily be compared and researchers aiming to reproduce this study have the choice of using one or both of these same methods to analyse qualitative data.

We believe results from ASIA will be of great use in the development of future recommendations and the updating of care guidelines for GP, an important element being clear information about AUD care networks. The ASIA study's results will be disseminated via peer-reviewed publications, conference presentations, and in general public media.

Ethics and dissemination

The confidentiality and anonymity of participant data will be guaranteed for both GP and PWAUD in every step of the study: no information will be kept which could result in participants being identified. Audio-recorded interviews will be transcribed and deleted within 3 months after recording. Only the main investigator will have access to the recordings. For both populations, participation in the quantitative and/or the qualitative substudy will only occur if written consent is given after the individual has been provided with a document explaining ASIA modalities and objectives.

This study was approved by the French National Commission on Informatics and Liberties (CNIL) (approval reference number: C16-10 Date of approval: July 17, 2017), the Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS) and the Evaluation and Ethics Committee (approval reference number: 16-312 Date of

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3 approval: July 8, 2016) (CEEI) of the French National Institute of Health and Medical
4 Research (INSERM).

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6 Results from ASIA will be disseminated at several levels: We plan to publish 4 articles in
7 peer-reviewed international scientific journals covering the fields of Public Health, general
8 practice and substance use disorders. We also plan to present our significant results in
9 national and international congresses and events for professionals working within the field
10 of alcohol use disorders and health prevention.
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15 The ASIA project will result in a PhD thesis, which will be defended in 2019.

16
17 A short report presenting ASIA main results will be distributed in PWAUD recruitment sites
18 for staff and patients.
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21 By the end of 2019, a presentation of ASIA results will be performed at the MILDECA (French
22 Inter-ministerial mission for the fight against drugs and addictive behaviours), the French
23 government organism which coordinates actions related to campaign against addictive
24 behaviours. It will enable the design of recommendations to raise the awareness of GP
25 about the necessity of improving screening and care for alcohol use disorder in their routine
26 practice.
27
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29

30 31 **Declarations**

32 *Authors' contributions*

33 MPC, SN, MC1, FM, PR, MM, TB, MC2 and GM designed the study and wrote the protocol.
34 MC and MPC managed the literature searches and formulated the research questions. MC
35 wrote the first draft of the manuscript. NS, PP, CC, DC, SLB and MT reviewed the manuscript
36 and gave their approval.
37
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39

40 *Funding statement*

41 The study received external funding from the Public Health Research Institute (IRESP).
42

43 *Competing interests*

44 The commercial company Ethypharm provides financial support - in the form of a salary – to
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46 preparation of the manuscript.
47
48
49

50 *Consent for publication*

51 The corresponding author confirms that all authors have read and approved the paper.
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All authors contributed to and approved the current version of the manuscript.

This work has not been published previously and is not under consideration for publication elsewhere. If accepted, this work will not be published elsewhere in English or in any other language, without the written consent of the copyright holder.

Availability of data and material

Not applicable

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