





# BMJ Open Realist evaluation of the impact, viability and transferability of an alcohol harm reduction support programme based on mental health recovery: the Vitae study protocol

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## ABSTRACT

**Introduction** Addiction is considered a chronic disease associated with a high rate of relapse as a consequence of the addictive condition. Most of the current therapeutic work focuses on the notion of relapse prevention or avoidance and the control of its determinants. Since only a small portion of patients can access alcohol addiction treatment, it is crucial to find a way to offer new support towards safe consumptions, reductions or cessations. The harm reduction (HR) approach and mental health recovery perspective offers another way to support the patient with alcohol addiction. Vitae is a realist evaluation of the impact, viability and transferability of the IACA! programme, an HR programme based on the principle of psychosocial recovery for people with alcohol use disorders.

**Methods and analysis** The Vitae study adheres to the theory-driven evaluation framework where the realist evaluation method and contribution analysis are used to explore the effects, mechanisms and influence of context on the outcomes and to develop and adjust an intervention theory. This study is a 12-month, multi-case, longitudinal descriptive pilot study using mixed methods. It is multi-centred, and carried out in 10 addiction treatment or prevention centres. In this study, outcomes are related to the evolution of alcohol use and the beneficiaries trajectory in terms of psychosocial recovery during these 12 months after the start of IACA!. The target number of participants are 100 beneficiaries and 23 professionals.

**Ethics and dissemination** This research was approved by the Committee for the Protection of Persons Ouest V n : 21/008-3HPS and was reported to the French National Agency for the Safety of Health Products. All participants will provide consent prior to participation. The results will be reported in international peer-reviewed journals and presented at scientific and public conferences.

**Trial registration numbers** NCT04927455; ID-RCB2020-A03371-38.

## INTRODUCTION

### Scientific context and issues

In 2016, an estimated 80 000 people died of alcohol-attributable cancer, and about 1.9

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Consistent with bottom-up approaches, our study is a realist evaluation based on a natural experiment.
- ⇒ Mobilising mixed-models methods this study will evaluate the impact, viability and transferability of a complex harm reduction intervention (IACA!).
- ⇒ This study will mobilise multiple modes of data collection: interviews with four samples, observations and questionnaires.
- ⇒ We anticipate a potential risk of attrition during the study due to structural and circumstantial situations.
- ⇒ The Vitae study will not use any kind of biological or medical information and will rely on declarative data.

million years of life were lost due to premature mortality or disability in the European Union (EU).<sup>1</sup> Alcohol use is a well-known risk factor of disease and injury.<sup>2 3</sup> A large contribution to this burden is alcohol use disorders (AUDs) (Defined as alcohol dependence (AD) and harmful use of alcohol (see International Classification of Disease 10th revision).) and AD.<sup>4</sup> In France, in 2015, more than 27 000 and almost 8% of all new cancer cases were estimated to be attributable to alcohol, whereas they were estimated to be 5.8% worldwide in 2012.<sup>5</sup> Heavy drinking was responsible for 4.4% of all new cancer cases<sup>6</sup> and was the second leading cause of so-called preventable cancers.<sup>7</sup> A recent review also showed that, worldwide, alcohol use can explain up to 27% of the socioeconomic inequalities in mortality.<sup>8</sup>

Subjects with alcohol addiction (or AUD) are known to experience a range of social harms because of their own excess drinking, including family disruption, employment

problems, criminal convictions and financial problems.<sup>9</sup> Assessments of these problems are scarcer, but social cost studies give some hints of the alcohol-attributable consequences in selected countries.<sup>10-11</sup>

Addiction is considered a chronic disease<sup>12-13</sup> associated with a high rate of relapse as a consequence of the addictive condition. In this perspective, treatment, whatever the addiction, aims to obtain and maintain abstinence, or at least a significant reduction in use or a controlled consumption, by avoiding situations presenting the risk of relapse and through the management of craving. Most of the current therapeutic work focuses on the notion of relapse prevention or avoidance and the control of its determinants.<sup>13-15</sup>

Since only a small portion of patients can access alcohol addiction treatment, it is of paramount importance to find a way to offer new support towards safe consumptions, reductions or cessations. The harm reduction (HR) approach and mental health recovery perspective offers another way to support the patient with alcohol addiction. HR refers to interventions that aim to reduce the adverse health and socioeconomic consequences of substance use without focusing on abstinence, reduced use or addiction management.<sup>16</sup> The HR approach is based on:

- ▶ Suspension of the moral judgement on uses.
- ▶ The implementation of a proximity approach, based on reaching people who use alcohol 'where they are' (going to them or through outreach, implemented through mobile teams, street work or even intervention in a festive environment) and, on the other hand, on the unconditional reception of people 'where they are' with their current consumption (ie, without any requirement for a commitment to stop drug use or to a care or integration approach).
- ▶ The participation, from a community health perspective, of people who use drugs in the development and implementation of interventions and the recognition of their knowledge of the experience (knowledge of products and their effects, use practices, consumption scenes, lifestyles and peer group codes, ability to define and relay low-risk practices).

In some respects, this concept is very similar to that of mental health recovery,<sup>17</sup> which articulates cure and care, autonomy and dependence, vulnerability and capacity. It is a non-medical process of getting better, clinically, socially and functionally. It aims at seeking and supporting the person's resources to build solutions. This process focuses on the positive transformations that the person experiences when recovering and the environmental factors that facilitate or hinder them.<sup>18</sup>

Even though this is not their primary objective, HR and mental health recovery are likely to influence the severity of addiction and relapse.

Since 2013 the organisation Santé! (Marseille, PACA region, France) has developed a risk and HR programme (IACA!) based on the principle of psychosocial recovery used in the 'Housing First' programme<sup>19</sup> for people with AUD. This programme aims to reintegrate the person

with problem alcohol use into a path of care, by removing the psychological contributors to medical and social isolation (shame, guilt, feeling of failure), stabilising alcohol use (sometimes including access to alcohol) and providing security and support for psychosocial recovery. The IACA! intervention has already shown its effects on alcohol consumption in the centre where it was implemented and is now being extended to new sites. In order to assess the conditions under which such an intervention is deployed in other centres and how its initial effect is generalisable, we developed the Vitae study. This pilot study is a realist evaluation of the impact, viability and transferability of the IACA! programme. This pilot study will be used to collect data prior to implementation of a fully controlled effectiveness trial.

## METHODS

This protocol is consistent with the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement: defining standard protocol items for clinical trials.

### Aim, design and setting of the study

#### Aim of the study

The IACA! intervention proposes intervention likely to secure factors that are predictive of relapse (feelings of dissatisfaction, anxiety, stress management, family and social support, etc), thus facilitating spontaneous cessation while promoting the well-being of individuals. The IACA! intervention has already shown its effects on alcohol consumption in the centre where it was tested. The question now is to confirm the results observed over the last 2 years and to explain them in a perspective of scaling up. As the IACA! intervention was only tested in one centre, operating on an associative model and not on a care model, the question arises as to its transferability. For this reason, we decided to conduct a pilot study<sup>20</sup> prior to an effectiveness trial.

The aims of the present study are:

- ▶ To evaluate the transferability of IACA! to various centres that take care of people that have problems related to excessive alcohol use (in 10 different treatment centres -addictions treatment centres and/or psychosocial support centres- in the Nouvelle-Aquitaine and PACA regions, see online supplemental table 1) in terms of results.
- ▶ To assess the conditions of transferability, included viability, of IACA! in these 10 centres.
- ▶ To evaluate the feasibility of a multi-centred controlled efficacy trial.

#### Theoretical framework

Transferability is the extent to which the measured effectiveness of an applicable intervention could be achieved in another setting.<sup>21</sup> It depends on multiple factors such as population and stakeholders' characteristics, contextual factors, modalities of intervention deliverance and

the modalities and conditions of implementation.<sup>22</sup> When studying transferability, an analysis of viable validity is also essential.<sup>23</sup> As defined by Chen, viability evaluation ‘assesses the extent to which an intervention program is viable in the real world. More specifically, it evaluates whether the intervention:

- ▶ Can recruit and/or retain ordinary clients,
- ▶ Can be adequately implemented by ordinary implementers
- ▶ Is suitable for ordinary implementing organizations to coordinate intervention-related activities,
- ▶ Is affordable,
- ▶ Is evaluable, and
- ▶ Enables ordinary clients and other stakeholders to view and experience how well it solves the problem’.<sup>23</sup>

The Vitae study adheres to the theory-driven evaluation framework<sup>24–27</sup> where the realist evaluation method and contribution analysis<sup>28 29</sup> are used to explore the effects, mechanisms and influence of context on the outcomes and to develop and adjust an intervention theory. This case-study method will help to set out the contribution ‘story’: in light of the multiple factors influencing the result, does the intervention contribute to an observed result and in what way?<sup>28</sup> This method is intended to provide ‘an in-depth view of how things work’.<sup>24</sup>

In realist evaluation, developed by Pawson and Tilley,<sup>30</sup> the effectiveness of the intervention depends on the underlying mechanisms at play within a given context. The realist evaluation is about identifying context-mechanism-outcome configurations (CMOs). The aim is to understand how and under what circumstances an intervention works. A middle-range theory (ie, a theory that is aimed at describing the interactions between outcomes, mechanisms and contexts) is set out to highlight the mutual influences of intervention and context.<sup>31 32</sup>

Hence, the evaluation is about identifying middle-range theories. Hypothesised and validated by empirical investigations, these CMO configurations help to understand how an intervention brings about change, bearing in mind context and target group.<sup>31 32</sup> The recurrence of CMOs is observed in successive case studies or in mixed protocols, such as realist trials.<sup>32</sup> Indeed, to consider context, realist evaluators observe in successive cases what Lawson (quoted by Pawson in 2006<sup>33</sup>) calls demi-regularities of CMOs (ie, regular although not necessarily permanent occurrences of an outcome when an intervention triggers one or more mechanisms in a given context).<sup>32</sup> Studying these recurrences in different contexts allows the isolation of key elements that are replicable in a family of contexts. This gives rise to middle-range theories that become stronger as progress is made through the cases. ‘These middle-range theories, in certain conditions, predict possible intervention outcomes in contexts different from the one in which the intervention was tested’.<sup>32</sup>

#### Applied to our case

As the realist principle is suitable for studying non-linear interactions in complex systems, we adopted this

approach. The intervention under investigation applies to an operational programme and it is therefore important to identify its key functions,<sup>34 35</sup> that is, its interventional or contextual components underpinning its effectiveness.

Where usually viability and transferability are studied with scales that list attributes and criteria in order to rate or ease the transferability of an intervention,<sup>21 36 37</sup> we chose to mobilise the realist evaluation. Indeed, studying transferability and viability through the theory-driven lens will generate a dynamic and precise analysis of the IACA! intervention because ‘theory-based evaluation is demonstrating its capacity to help readers understand how and why a programme works or fails to work. Knowing only outcomes, even if we know them with irrefragable validity, does not tell us enough to inform programme improvement or policy revision. Evaluation needs to get inside the black box and to do so systematically’.<sup>26</sup>

In this study, each institution deploying the IACA! programme, with its own context, will constitute a case. For each case, the intervention will be studied to identify the mechanisms at play in the given context along with the variation in outcomes. CMO configurations will be identified through an analysis of each case. A cross-case analysis will highlight recurrent CMO configurations and thus identify key features for possible replication.

In our study, outcomes are related to the evolution of alcohol use at 12 months after the start of IACA! and the beneficiaries’ trajectory during these 12 months in terms of psychosocial recovery.

Drawing on the literature and on the experience of professionals delivering the intervention, we will first set out initial middle-range theories,<sup>30 33</sup> which we will test in each case (ie, centres) by collecting qualitative and quantitative data.<sup>32</sup>

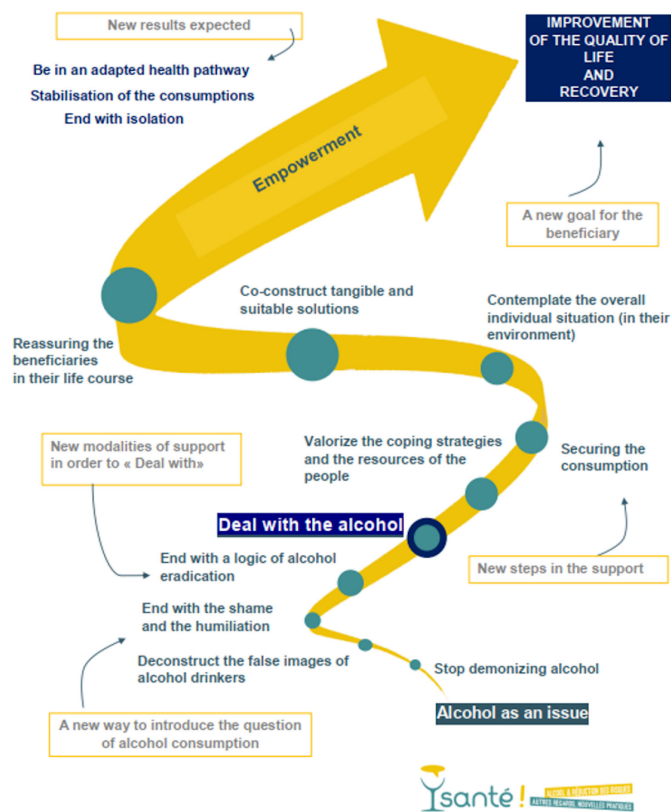
The mechanisms will be identified qualitatively according to the definition of Ridde *et al.*: ‘a mechanism is an element of reasoning and reaction of an agent with regard to an intervention productive of an outcome in a given context’.<sup>38 39</sup> It ‘characterizes and punctuates the process of change and hence, the production of outcomes’.<sup>40</sup>

Contextual elements will be included among all the elements collected qualitatively that satisfy the following definition: elements located in time and space that may affect the intervention and the outcomes produced, and whether they relate to the centres, the professionals, the beneficiaries or the operational setting. In a realist approach, interventional elements are part of the context. Therefore, we can distinguish between Ci (for contextual factors linked to the intervention) and Ce (for contextual factors not linked to the intervention, ie, external factors).

#### IACA! intervention and its implementation

##### IACA! intervention

Created in 2013 in Marseille by an addictology professional and a social support professional, the association Santé! in the PACA region is developing a risk and HR



**Figure 1** Management process implemented by Santé!.

approach for people who consume alcohol, based, among other things, on the principle of psychosocial recovery as used in the ‘Housing First’ programme.<sup>19</sup>

The intervention, called IACA!, aims to reintegrate the person into a healthcare pathway by removing the barriers that cause medical and social isolation (shame, guilt, feelings of failure), stabilising the person’s use and ensuring their safety, and supporting their psychosocial recovery. As shown in **figure 1** and depending on the person’s needs, the intervention aims to:

1. Provide advice, reassurance, listening, appeasement.
2. Secure and/or reorganise consumption in order to avoid periods of withdrawal syndrome (vulnerability factors).
3. Activate rights to maintain/obtain appropriate and satisfactory social integration.
4. Provide psychological support.
5. Adapt, build and coordinate a health path (to avoid break-up or non-recourse).
6. Promote social links.
7. Consolidate long-term alcohol consumption strategies.
8. IF REQUESTED: accompaniment for a cessation experiment.

This support is organised in four sequences:

1st phase—*reception/build the alliance*: unburden people in relation to their issues (lifting shame): valuing their strategies without judging their consumption; inform and define the IACA! support in a break with traditional support.

2nd phase—*securing*: with the person, identify the situations that reinforce consumption and act on them: securing consumption to avoid risk situations (stress, periods of lack, dehydration, etc); avoiding peaks in consumption; ensuring basic needs such as food, hydration, safety, sleep, etc.

3rd phase (in parallel with or following phase 2)—*stabilisation*: support a project and reconstruction objectives over several months; stabilise consumption; re-engage the person in a care pathway adapted to his needs and projects; tackle social, family and professional isolation, and secure the environment by identifying a set of professionals needed to solve the main difficulties identified.

4th phase—*progressive reduction of support*: monitoring with regard to sustainability and autonomy; checking that the support is satisfactory.

The initial results of this programme over 1 year were promising since, of the 17 people who received the intervention, all had a social or health benefit, and 13 of these benefits were associated with stabilisation (n=4), reduction (n=7) or cessation (n=2) of alcohol use after 1 year. Thus, in addition to the positive results in terms of psychosocial recovery, and even if the goal is not the cessation of alcohol consumption, the programme is potentially promising since it sometimes leads to the cessation of consumption and secures/reduces consumption for half of the people (back to occasional consumption). The programme therefore initially provides what is recommended in any attempt to quit, which could explain this spontaneous reduction or cessation.

#### Implementation in 10 new centres

The 10 centres will be supported by Santé! in the implementation of IACA! according to the following procedures:

- ▶ Training of 10 pairs of professionals (2/centre) in charge of accompanying beneficiaries in the centres.
- ▶ Anchoring an alcohol RH support practice: support for the implementation and adaptation of the IACA! method within each centre.
- ▶ Adaptation and improvement: changes to the IACA! method and its tools.

#### Study design

This study is a 12-month, multi-case, longitudinal descriptive pilot study using mixed methods (quantitative and qualitative). It is multi-centred and national, and carried out in 10 addiction treatment or prevention centres (4 in the PACA region and 6 in the Nouvelle-Aquitaine region). These sites, all in the health and social sector, are heterogeneous (see online supplemental table 1) in their aims, organisation and target populations. Among the 10 centres there are 5 CSAPAs (addiction treatment, support and prevention centre providing information, medical, psychological and social evaluations of requests and needs, and orientation), 1 CAARUDs (reception and accompaniment centres for harm reduction for drug users), 4 CHRS (accommodation and social rehabilitation

centres) and 1 IML (intermediation rental programme). The CSAPAs have a target population which is less vulnerable than that of the other centres. Indeed, most of the CSAPAS receive users who, although they may be followed up by care, whether specialised in addictology or not, generally have more problematic and less 'controlled' uses than the general population. They also often live in more precarious social situations.

### Characteristics of participants

To validate the implementation of IACA! and highlight the conditions of transferability of this programme, we will collect data from three types of population:

- ▶ Individuals receiving support from the IACA! intervention (called beneficiaries).
- ▶ Professionals implementing the IACA! intervention, that is, the pairs in charge of accompanying the beneficiaries in the centres as well as the persons in charge of these centres.
- ▶ Professionals from Santé! supporting the deployment of the IACA! intervention.

The beneficiaries are all persons integrating the programme in the project's partner sites and who consume alcohol.

The professionals will be specialised educators, social workers, nurses, social and solidarity economy advisors, etc.

The inclusion criteria will be as follows:

- ▶ *For the beneficiaries:* being over 18 years old, willing to participate, having started the IACA! programme 15 days beforehand or less, and being followed up by one of the 10 centres in the study. Beneficiaries will be excluded if they have a severe somatic or psychiatric pathology that is incompatible with a good understanding of the assessment tools; if they have difficulty understanding and/or writing French; if they are unreachable by telephone; if they are participating in another research project with an ongoing exclusion period; if they are placed under court protection; and if they are pregnant.
- ▶ *For professionals from centres implementing IACA!:* having been trained at IACA!, willing to participate, and working in the centres participating in the implementation of IACA!.
- ▶ *For the professionals in charge of the centres:* having participated in the implementation of the IACA! method in their centres, and willing to participate.
- ▶ *For the Santé! professionals:* participating or having recently participated in the implementation of IACA!.

### Data collection

In order to collect information from multiple complementary sources we will use quantitative and a qualitative data collection methodologies.

#### Quantitative data

The aim is to collect longitudinal data concerning the effects of IACA!. The effects of IACA! involve quality of life, mental health recovery and alcohol consumption.

All participants who meet the eligibility criteria will be offered participation in the study. The centres' professionals will inform patients being treated with IACA! of the existence of the Vitae study and the possibility of participating in it. A meeting will then be organised between the patients and the research team, in order to offer them the opportunity to participate in this research and to inform them of:

- ▶ The purpose of the study.
- ▶ The computerised processing of data on the participant that will be collected in the course of this research, and his/her rights of access to, opposition to and rectification of this data.

The baseline M0 will then be scheduled (maximum 15 days after starting the IACA! programme).

Online supplemental table 2 shows the different data that will be collected on 100 patients (10 per centre), prospectively, by trained clinical research staff. During the baseline inclusion (M0), participants will be interviewed using:

- ▶ The Addiction Severity Index (ASI).
- ▶ The Treatment Service Review (TSR).
- ▶ The Mini International Neuropsychiatric Interview (MINI).
- ▶ The Empowerment Scale.

At each follow-up, participants will be assessed with a follow-up ASI, TSR interview, craving assessment and Empowerment Scale.

The ASI is a semi-structured interview designed to assess impairments that commonly occur due to substance-related disorders.<sup>41</sup> A modified and validated 45 min French version of the ASI will be used to take into account tobacco and addictive behaviours.<sup>42</sup> The ASI explores six areas that may be affected by addiction: medical status, employment/support status, substance and behavioural addiction, family and social relationships, legal status and psychological status. These data are used to generate composites scores (CSs) for each domain, thereby reflecting the severity of the subject's condition. CSs range from 0 to 1, with a worsening severity as the scores move closer to one.<sup>42-44</sup>

ASI will be used at inclusion and then every 3 months during the 12-month intervention period.

#### Mini International Neuropsychiatric Interview

The MINI is a structured diagnostic interview providing a standardised assessment of 18 major psychiatric disorders defined according to Axis I DSM-IV (anxiety disorders, mood disorders, psychotic disorders, addictive disorders, eating disorders) and the diagnosis of antisocial personality disorder.<sup>45 46</sup> A 30 min version of MINI adapted for DSM-5 criteria will be used.

#### Craving evaluation scale

The craving evaluation scale developed by the University of Bordeaux Addiction Team in the SANPSY Laboratory will be used. It is a 5 min hetero-evaluation of craving for all substances and addictive behaviours manifested

now or in the past. This tool explores the frequency of craving, corresponding to the number of days craving was reported over the last 30 days, as well as the mean and maximum intensity on a scale ranging from 0 (no craving) to 10 (extreme craving).

#### Treatment Service Review

The TSR, 6th version, is an inventory of the medical, psychosocial and psycho-educational contacts of the subject over the last 30 days.<sup>47 48</sup> This instrument allows a quantitative evaluation of the effective medico-psychosocial management of a subject. It was validated in French, and is now integrated into the ASI evaluation as it was developed by the same group that developed the ASI.

#### Empowerment Scale

The Empowerment Scale measures personal empowerment by examining the concepts of hope, social acceptance and quality of life.<sup>49 50</sup> It is a 28-item scale with four points each, ranging from 'Strongly Disagree' to 'Strongly Agree'. The total empowerment score is a quantitative variable, ranging from 28 to 112. This scale can be divided into sub-dimensions measuring self-efficacy and self-esteem, power and powerlessness, community activism and autonomy, optimism and control over the future, and righteous anger.

Online supplemental table 2 shows the different data that will be collected.

#### Qualitative data

Online supplemental table 3 shows the different data that will be collected. We will identify: skills field, functioning principles, contextual conditions of success, delivering conditions of success, mechanisms and contextual elements (including techniques). The data collected will help to elaborate the principles of initial middle-range theories (to establish how the intervention works in context), and mechanisms hypothesised as key functions of IACA!. We will monitor these different data in each centre implementing IACA! to verify their integrity in target centres and to verify the initial theories (contribution analysis).

To perform this collection, we will cross two qualitative investigation methods: non-structured interviews and observations.

#### Non-directive interviews with the centres' professionals (20 interviews)

This investigation will be performed in all centres implementing IACA!. We will conduct this investigation almost 9 months after the beginning of implementation. A total of 20 interviews will therefore take place over the study period. From these professionals, the data collection will be focused on the data described in online supplemental table 3.

#### Non-directive interviews with the Santé! professionals

Interviews with Santé! professionals supporting the implementation of IACA! in the 10 investigated centres (three

interviews). We will carry out this investigation almost 6 months after the beginning of implementation. From these professionals, the data collection will be focused on the data described in online supplemental table 1.

#### Observations (10 observations)

In addition to interviews with professionals, one observation per centre will be conducted, making a total of 10 observations. The objective is to collect the following physical contextual elements, specific to each centre, presented as being potentially key. These observations will be based on an observation grid. These investigations will be performed after 6 months of implementation.

#### Non-directive interviews with beneficiaries (100 interviews)

We will perform this qualitative investigation on the beneficiaries included in the IACA! programme (10 per centre). A total of 100 interviews will be conducted. This qualitative investigation will be performed between 9 and 12 months after beginning the IACA! programme. The data collected will be focused on the data described in online supplemental table 3 (ie, mechanisms, contextual conditions of success, delivering conditions of success).

To avoid social desirability bias, we will conduct unstructured surveys. Thus, open-ended questions will be asked to the professionals and beneficiaries. The interview grids and observation log will be designed and pretested during exploratory interviews and observation sessions at the beginning of the study.

#### Patient and public involvement

The Vitae study does not include any patient or public involvement in terms of setting research priorities, defining research questions or outcomes, providing input into the study design or disseminating the results. The research participants are called on to answer questionnaires or interviews.

#### Data analysis

##### Quantitative data

Quantitative evaluations repeated every 3 months will serve to identify the impact of this intervention on the main judgement criterion (ie, the evolution of the severity of alcohol use at 12 months after the start of IACA!) and to describe the subjects and their evolution over 12 months.

A descriptive analysis will be performed to describe the severity of the subjects' alcohol use after 12 months of intervention. This evolution of the severity of alcohol use corresponds to the delta of composite scores between M12 and M0. The variables alcohol consumption, alcohol craving and severity of addiction will be described over the 12 months of the intervention in relation to the initial assessment. They will also be compared between centres.

Qualitative variables will be described according to their frequency and percentage. Quantitative variables will be described according to their means and SD.

Second, to determine the factors impacted by the intervention, we will perform repeated analyses of variance to determine whether the variables have changed during the

intervention. For the variables showing a change, we will use a comparison test on repeated measures controlling for sociodemographic variables: age, gender, work in the last 3 years, presence or absence of current mood and anxiety disorders, and the centre in which the intervention was carried out (applying the Bonferroni correction). All statistical analyses will be performed with the JMP software (Pro V.15.2.0, SAS Institute).

### Qualitative data

A content analysis by case and inter-case (centres) will be conducted. Content analysis encodes, classifies and ranks the communication in order to examine its patterns, trends or distinguishing features, in our case the recurrence of C-M configurations. The N'vivo software will be used for this, allowing us to conduct a thematic analysis of the three data sources.

The analysis performed by centre, by validating or allowing CMO adjustments, will have to answer four questions:

Question 1: in what contextual and delivery conditions does IACA! seem to produce an impact on patients? By impact we mean the targeted goals presented within the intervention section.

Question 2: to what extent is IACA! feasible and acceptable in the routines of professionals in the different centres?

Question 3: what elements considered as key are actually adaptable (and therefore are non-key)?

Question 4: what elements are mandatory to help to implement IACA!? What elements should be included in a transfer scheme?

The answers to these questions will allow us to highlight the hypothetical key functions (CMO configurations) defined with Santé! for each centre by identifying (a) the degree of integrity of the key functions in each centre and (b) the degree of adaptation in each centre. We will perform monographies, providing a specific description

of all key functions in each centre. The timeline (figure 2) presents the key steps of the Vitae study.

### QUAN/QUAL analysis

We will then conduct a QUAN/QUAL<sup>51</sup> analysis in each centre in order to compare: the results observed on patients in terms of psychosocial recovery and consumption (collected by quantitative questionnaire) and the implementation or completeness of the IACA! intervention, the contextual conditions, the principles of operation and support and the professional skills needed in the transfer scheme.

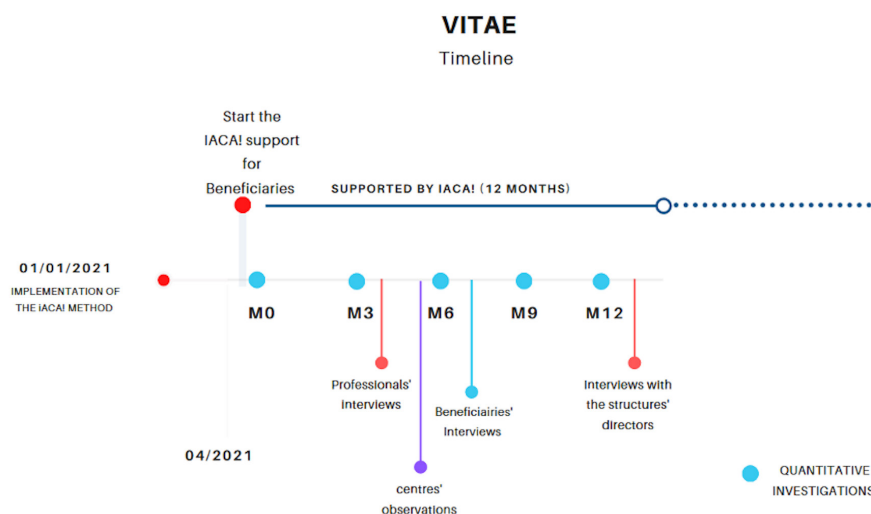
## ETHICS AND DISSEMINATION

### Ethics approval and consent to participate

The Vitae project will be carried out with full respect of current relevant legislation (eg, the Charter of Fundamental Rights of the EU) and international conventions (eg, Declaration of Helsinki). It follows the relevant French legislation on interventional research protocols involving the human person (Jardé law, category 3 research on prospective data<sup>52</sup>).

The protocol (version 1.2) was approved on March 2021 by the Comité et Protection des Personnes, that is, Committee for the Protection of Persons Ouest V n°: 21/008-3HPS and was reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (ANSM) that is, the French National Agency for the Safety of Health Products.

All participants who meet the eligibility criteria will be offered participation in the study. Professionals at the centres will inform patients being treated with IACA! of the existence of the Vitae study and the possibility of participating in it. A meeting will then be organised between the patients and the SANPSY research team, in order to offer them to participate in this research and to inform them of:



**Figure 2** Timeline of the Vitae project.



- ▶ The purpose of the study.
- ▶ The computerised processing of data concerning the participant that will be collected during the course of this research and his/her rights of access, opposition and rectification to this data.

For patients under a protective measure (ie, curatorship, tutorship, etc), the legal representative will also be informed by the Vitae team:

- ▶ Of the purpose of the study.
- ▶ Of the computerised processing of data concerning the participant that will be collected during this research and his/her rights of access, opposition and rectification to this data.

If the person agrees to participate, he or she gives oral consent (as it is specified by the Jardé law and accepted by the ethics committee<sup>52</sup>) and his or her non-opposition is documented in the participant's medical record or file. The participant may, at any time, object to the use of his or her data in the context of the research.

These information will also be given to the legal representative if the patients are under guardianship.

### Dissemination plan

The results will be disseminated in various academic and non-academic platforms. The results will be reported in international peer-reviewed journals and presented at international and national conferences. A public report will describe all the steps of the study, the results and recommendations. Eventually, a general restitution will be held in order present the final result of the study to all the participants and funders.

### DISCUSSION

Despite a high prevalence of addiction in the general population, the worldwide proportion of individuals with addictions who access addiction treatment is estimated to be less than 25% overall, and under 10% for alcohol and tobacco, including in France.<sup>53 54</sup> A recent meta-analysis identified an average dropout rate of 30% for psychosocial substance use disorder treatment and a 26% dropout rate for programmes targeting alcohol.<sup>55</sup> The low rate of access to alcohol addiction treatment and the high level of drop-out after relapse could be explained by barriers such as the stigma associated with addiction or the desire to try to cope alone. In addition, many patients do not have access to treatment, or drop out from treatment due to the pre-requisite of a period of inpatient detoxification.<sup>53 56 57</sup> This study will contribute to scaling up a potentially effective intervention for the management of tens of thousands of patients currently in a therapeutic impasse.

Our study will face some challenges and limitations, since it will start during the COVID-19 crisis which is impacting the follow-up and involvement of the people with AUD and the professionals. Therefore, we anticipate a significant risk of attrition during the study due to the turnover of staff and the discontinued monitoring of the beneficiaries while the intervention is being dispensed.

Second, all our results are declarative and the Vitae study will not use any kind of biological or medical information. Although declarative data could lead to underestimation, the use of a hetero-administered questionnaire on substance consumption should reduce this under-declaration.<sup>58</sup>

From a public health point of view, this study will explain and pinpoint the precise impact of IACA! and identify the conditions for this impact. It will allow us to define the key functions and how they work in different contexts or how they could be adapted, and eventually to define a guideline to disseminate IACA! to other centres and adapt it.

From a research viewpoint, our proposed methodology is consistent with the bottom-up approaches advocated in health promotion, starting with a real-world response to a pressing problem.<sup>23</sup> Transferability and viability studies are still underused in France, even though their pertinence has been highlighted in the international literature. Here, we propose an application of these international recommendations relative to the transferability and evaluation of complex health interventions. Mobilising the realist evaluation to analyse the transferability and the viability of an intervention is quite innovative, and will produce thorough and precise knowledge on this programme.

This pilot study will evaluate the feasibility and the pertinence of a multi-centred controlled efficacy trial. It will use the feedback from the teams conducting the evaluation and the interviews with centre managers or directors. These elements will allow us to establish: the size of the sample needed to conduct a trial; the integrity and relevance of the evaluation protocol and of the data collection tools used in this trial; and the randomisation, recruitment and consent procedures.

Transferability of complex health interventions is a major public health topic and remains a highly valuable research field. This study, focusing on an innovative intervention for people with AUD implemented in very different contexts will provide valuable information for the implementation science but also for the HR field. The results of this study will contribute to informing public decision-making in terms of support for people with AUD. In addition, it will contribute to the preparation of a large-scale trial and, ultimately, to the scaling up of an effective intervention for the management of people with psychosocial problems related to excessive alcohol use.

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