

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Realist evaluation of three programs aimed at reducing harm and risks associated with alcohol consumption in the Nouvelle Aquitaine region of France: the ECIAE study protocol
AUTHORS	Stevens, Nolwenn; Martin-Fernandez, Judith; Moriceau, Sarah; Serre, Fuschia; Auriacombe, Marc; Cambon, Linda

VERSION 1 – REVIEW

REVIEWER	Burkhart, Gregor European Monitoring Centre for Drugs and Drug Addiction, HEA
REVIEW RETURNED	20-Jan-2022

GENERAL COMMENTS	The paper is a study protocol, which is exhaustively described, in a clear language without relevant linguistic issues. The research method is complex and innovative, yet well explained. It seems suitable to the relative low number of participants and feasible, taking into account the complexity of the design and the demanding nature of the research tools. The limitations and expected challenges are duly described.
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REVIEWER	Martinengo, Laura Nanyang Technological University, Centre for Population Health Sciences
REVIEW RETURNED	27-Feb-2022

GENERAL COMMENTS	<p>Summary of paper</p> <p>This paper presents a protocol for a realist intervention to assess three alcohol consumption harm reduction programs in southwest France, consisting of three successive stages, and a variety of qualitative and quantitative methods. The study aims to understand how the interventions work, and circumstances, mechanisms and population that best respond to the intervention.</p> <p>Abstract</p> <p>The abstract presents a very lengthy introduction and a brief methods section. The study methodology is very broadly described, making it difficult for readers to understand how the “realist evaluation” will be carried out.</p> <p>Introduction</p> <p>- The introduction is long, and at times repetitive and unorganized. Suggest summarizing the information, focusing on topics relevant to the paper, instead of providing too much information, that although interesting and important, it does not closely relate with the paper’s focus.</p>
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	<ul style="list-style-type: none"> - It is also important to use text quotations carefully. It is observed in the text that the authors have quoted extensive paragraphs, that could be easily summarized - Authors should explain the meaning of acronyms the first time they appear in the manuscript, including those that will be explained later in the paper. - The locations where the interventions are to be evaluated should be included in the “Methods” section, not as part of the objectives - The authors list 8 study locations but later refer to 9 centres. Which one is correct? <p>Methods</p> <ul style="list-style-type: none"> - The paragraphs explaining “Theory-driven evaluation” and the “Realist evaluation method” should be part of the introduction. Information should be condensed, and quotations replaced by authors summaries. - Qualitative assessments: <ul style="list-style-type: none"> • It is unclear why the authors have decided to include more participants for the intervention deployed in only one centre. • Also, what is the rationale to select 5/10 as the number of beneficiary participants per centre? And 1/3 for professionals? • Why are the authors including just 1 professional in programs delivered in more than one centre? • Did the authors consider data saturation as a method to select the final sample size? • How would the data be analysed? Are the authors analysing data from each centre individually, as the program implementation differs, or are they planning to merge data related to each program? - Quantitative assessments: <ul style="list-style-type: none"> • What is the size of the population receiving the interventions in the included centres? • How was the number of beneficiaries to be administered the quantitative surveys/interviews decided? • Did the authors consider the validity of results if quantitative surveys/interviews were administered to 45 beneficiaries? - How will participants in the final stage seminar be selected? <p>Other comments:</p> <ul style="list-style-type: none"> - Please signpost the location of figures in the text - The administration schedule for the quantitative surveys/interviews should be mentioned when describing the instruments
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VERSION 1 – AUTHOR RESPONSE

Reviewer Reports:

Reviewer: 1

Dr. Gregor Burkhardt, European Monitoring Centre for Drugs and Drug Addiction

Comments to the Author: The paper is a study protocol, which is exhaustively described, in a clear language without relevant linguistic issues. The research method is complex and innovative, yet well explained. It seems suitable to the relative low number of participants and feasible, taking into the account the complexity of the design and the demanding nature of the research tools. The limitations and expected challenges are duly described.

Answer:

We thank the first reviewer for these comments.

Reviewer: 2

Dr. Laura Martinengo, Nanyang Technological University

Comments to the Author:

Summary of paper

This paper presents a protocol for a realist intervention to assess three alcohol consumption harm reduction programs in southwest France, consisting of three successive stages, and a variety of qualitative and quantitative methods. The study aims to understand how the interventions work, and circumstances, mechanisms and population that best respond to the intervention.

Abstract

The abstract presents a very lengthy introduction and a brief methods section. The study methodology is very broadly described, making it difficult to readers to understand how the “realist evaluation” will be carried out.

Answer:

We shortened the introduction and tried to develop the study methodology in order to make it more understandable for the readers.

Introduction

- The introduction is long, and at times repetitive and unorganized. Suggest summarizing the information, focusing on topics relevant to the paper, instead of providing too much information, that although interesting and important, it does not closely relate with the paper’s focus.
- It is also important to use text quotations carefully. It is observed in the text that the authors have quoted extensive paragraphs, that could be easily summarized.

Answer: We have revised, reorganised and shortened the corresponding section.

Regarding the organization of the section, the introduction follows the following plan:

- Epidemiological data (World, Europe, France and the Nouvelle Aquitaine region)
- Available responses or support strategies (abstinence and risk and harm reduction),
- The state of play of policies in favor of the harm and risks reduction related to alcohol consumption (France, then specifically the Nouvelle Aquitaine region).

- Authors should explain the meaning of acronyms the first time they appear in the manuscript, including those that will be explained later in the paper.

Answer: Thank you for this remark it is, indeed, an oversight.

We add the meaning of the following acronym: ETP (Education Thérapeutique du Patient)

Please note that "IACA" is not an acronym but the name of the program. For less confusion we will not keep a capital letter typology. We therefore replace "IACA" by "Iaca" throughout the document.

- The locations where the interventions are to be evaluated should be included in the “Methods” section, not as part of the objectives

Answer: We have chosen to maintain the information concerning the location of the centers in this section in order to respect the plan proposed by the BMJ Open journal whose section is entitled "Study objectives and location"

- The authors list 8 study locations but later refer to 9 centres. Which one is correct?

Answer: There are 8 participating centers. We apologize for this error, as one of the centers initially identified to participate in the study eventually withdrew.

We therefore correct the following sentence: “The ECIAE study will therefore investigate 9 centers implementing one of the three programs listed above.”

We replace it with: “The ECIAE study will therefore investigate 8 centers implementing one of the three programs listed above.”

In addition, we correct the locations of these centers since the submission of this article, the participating centers in the study have changed.

We therefore correct the following sentence: "These centers are located in Agen, Bordeaux, Libourne, Limoges, Mont de Marsan and Pau."

We replace it with: "These centers are located in Agen, Bordeaux, Limoges and Pau."

Methods

- The paragraphs explaining "Theory-driven evaluation" and the "Realist evaluation method" should be part of the introduction. Information should be condensed, and quotations replaced by authors summaries.

Answer: Since the methodology of our studies are complex we usually place the theoretical framework in the methods section in order make it more readable and understandable. We suggest to keep as it is if the editor agrees.

We have summarized and rephrased the passages corresponding to quotations.

We delete the following quote: "Theory based evaluation is demonstrating its capacity to help readers understand how and why a program works or fails to work. Knowing only outcomes, even if we know them with irreproachable validity, does not tell us enough to inform program improvement or policy revision. Evaluation needs to get inside the black box and to do so systematically". (30)

We replace it with the following sentence: This is because theory-based evaluations explore how and why a program works or does not work, thus providing valuable assistance for program or policy improvement. (30)

We delete the following quote: "Theory thus provides a basis for justifying action, a framework for organizing and integrating new information, and a vehicle for transferring knowledge from one situation to another." (29)

We replace it with the following sentence: Theorizing interventions also facilitates knowledge transfer.(29)

- Qualitative assessments:

- It is unclear why the authors have decided to include more participants for the intervention deployed in only one centre.

Answer: The number of beneficiaries included in the study was decided with a pragmatic and realistic aim. Indeed, the number of beneficiaries was determined after discussions with each center, which determined the maximum number of people they thought they could accompany with the program in question. Our study protocol was therefore adapted to their possibilities and we chose to aim for the largest possible number of participants.

We added this paragraph: "The number of beneficiaries expected to participate in the study was determined in consultation with each program's representative. The different centers estimated a plausible number of participants based on their experiences. Indeed, apart from the ECIAE study, the various programs studied only involve a small number of users in the active file of each center." and this one "The number of professionals expected to participate in the study was determined in consultation with each program's representative. The participating centers do not have the same number of staff trained in the program concerned. Furthermore, we estimated together that not all trained professionals would be available to participate in the study. In addition, some may refuse to participate in the study."

- Also, what is the rationale to select 5/10 as the number of beneficiary participants per centre? And 1/3 for professionals?

Answer: The number of beneficiaries included in the study as well as the number of professionals included in the study came from the same process: in consultation with the representant of program that expressed their possibilities.

- Why are the authors including just 1 professional in programs delivered in more than one centre?

Answer: The number of beneficiaries included in the study as well as the number of professionals included in the study came from the same process: in consultation with the representant of program that expressed their possibilities. Thus the center implementing the Consorepère ETP program offered that 3 professionals participate in the study, the three centers implementing the Alcochoix program offered that one to two professionals/center participate in the study, the four centers implementing the laca program accepted that one to two professionals/center participate in the study. The centers could not provide more participating professionals, as they did not have more professionals implementing the relevant programs within their structure.

- Did the authors consider data saturation as a method to select the final sample size?

Answer: From a scientific point of view, this would indeed have been the methodological decision we would have made, and we hope to reach data saturation with our sample. From a pragmatic point of view, as mentioned above, we only have a small maximum sample - of professionals as well as of beneficiaries - within each center.

- How would the data be analysed? Are the authors analysing data from each centre individually, as the program implementation differs, or are they planning to merge data related to each program?

Answer:

This assessment is based on multiple case studies in two nested levels.

At the first level, each center implementing the program (differently) is a unique application situation (with a set of activities conducted according to the constraints and opportunities of its environment) and will represent a case.

At the second level, each program will represent a case in which a set of activities is conducted to achieve risk reduction objectives. (methods and analysis page 7 and figure 1)

- Quantitative assessments:

- What is the size of the population receiving the interventions in the included centres?

Answer: According to the experience of the different representants of program, the number of beneficiaries of the programs varies according to the time of the year. On the other hand, the centers were able to tell us the maximum number of beneficiaries likely to be accompanied by the different programs studied: this corresponds to the number of people planned to participate in the study. The number of beneficiaries receiving the intervention is not known a priori, and depends on the capacity of each center to implement the program (number of trained staff available), as well as on the number of eligible subjects, which may vary during the year. However, discussions with the centers allow us to estimate that it will be higher than 45 (estimated number of beneficiaries to be evaluated in the quantitative part)

- How was the number of beneficiaries to be administered the quantitative surveys/interviews decided?

Answer: The number of beneficiaries included in the study was determined with a pragmatic and realistic aim, after discussions with each center, which determined the maximum number of people they thought they could accompany with the program in question. Our study protocol was therefore adapted to their possibilities and we chose to aim for the largest possible number of participants. Finally, it should be noted that not all programs are at the same stage of development or experimentation, so program representatives could not always rely on estimates from periods before the study.

- Did the authors consider the validity of results if quantitative surveys/interviews were administered to 45 beneficiaries?

Answer: Of course, the small sample available does not allow us to obtain sufficient statistical power to generalize our results. We will therefore confine ourselves to a purely descriptive analysis, with a view to understanding. The size of our sample is discussed in the article as a limitation of this study.

However, we have limited the non-inclusion criteria as much as possible in order to include a maximum of subjects receiving the intervention (to limit selection bias). We will also seek information on patients who attended the program but were not evaluated, and possible reasons for non-inclusion, in order to describe it.

▪ How will participants in the final stage seminar be selected?

Answer: All professionals participating in the study will be invited to participate in the final seminar. Addition of the following item: “All the members of the research teams involved will be present, representatives of each program will be invited as well as all the professionals participating in the study.”

Other comments:

▪ Please signpost the location of figures in the text

Answer: Figure 1 is called on page 7. Figure 2 is called on page 13. Figure 3 is called on page 20.

▪ The administration schedule for the quantitative surveys/interviews should be mentioned when describing the instruments

Answer:

We added the figure 3 in this section.

VERSION 2 – REVIEW

REVIEWER	Martinengo, Laura Nanyang Technological University, Centre for Population Health Sciences
REVIEW RETURNED	23-Jun-2022
GENERAL COMMENTS	Dear authors, thank you very much for addressing the comments. The manuscript reads very well and each part of the protocol is described with sufficient clarity and detail.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

Dr. Laura Martinengo, Nanyang Technological University

Comments to the Author:

Dear authors, thank you very much for addressing the comments. The manuscript reads very well and each part of the protocol is described with sufficient clarity and detail.

Reviewer: 2

Competing interests of Reviewer: No competing interests