

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Realist evaluation of a theory-based life skills program aiming to prevent addictive behaviors in adolescents: The ERIEAS study protocol
AUTHORS	Martin-Fernandez, Judith; Affret, Aurelie; Martel, Emma; Gallard, Romain; merchadou, Laurence; Moinot, Laetitia; Termote, Monique; Dejarnac, Vincent; Alla, François; Cambon, Linda

VERSION 1 - REVIEW

REVIEWER	LI Xiang The Hong Kong Polytechnic University
REVIEW RETURNED	31-Dec-2019

GENERAL COMMENTS	<p>Thank you for inviting me to review this manuscript. I appreciate the efforts of the authors in writing this protocol. However, I wonder the significance and novelty of this study after reading this manuscript. Since the EA program has launched in 2015, why do you write a protocol rather than directly evaluating it?</p> <p>I list a number of comments as below.</p> <p>As the authors want to evaluate the EA program, I think more information on EA should be introduced. For example, the authors only wrote “the EA program involves supervised animated short movies and talks”. What is the content of the movies and talks? How to supervise?</p> <p>As EA is a theory-based life skills program aiming to prevent addictive behaviours, what are specific life skills that are useful to reduce addictive behaviours? Why these life skills are chosen to prevent addictive behaviours? For example, the authors refer to resistance skill. Why this skill is helpful? What is middle-range theory? More introduction is expected.</p> <p>The literature is not very comprehensive. For example, the authors wrote “there are many programs focused on addiction prevention implemented in schools” on page 5. However, they didn’t introduce any of them. Additionally, the authors listed many aims of the program in the last paragraph on page 5. However, no literature in this manuscript supports these aims. Why and how the program can reach these aims?</p> <p>The methods used in this study should be more detailed. For example, the authors wrote “the case-study method will be used as it</p>
-------------------------	--

	<p>involves..." on page 7. What is about the case study? How to conduct the case study? What is a double-blind review on page 14? What is a cross-case analysis on page 19? What is bottom-up approaches advocated in health promotion? Why and how "these first data will help and guide a second qualitative phase (i.e. IP2, IE2) and the DCE questionnaire elaboration" on page 21?</p> <p>Overall, I think this protocol is general and not specific. It is expected to be more concise and clearer.</p>
--	---

REVIEWER	Amelia Usher Ryerson University Canada
REVIEW RETURNED	31-Jan-2020

GENERAL COMMENTS	<p>I commend the authors on the ambitious study described here and in their desire to evaluate a substance use prevention intervention using a theory-driven realist approach. This is an important topic and once completed, the study will add value to the extant literature.</p> <p>1) Please elaborate on what is meant by contribution analysis paradigm. What methods are involved? How does this contrast/complement/support/enhance the realist approach to evaluation? It would be helpful for the reader to have a better understanding of what you mean and how contribution analysis relates to the realist paradigm.</p> <p>2) It is not immediately clear that the mechanisms proposed in your protocol are indeed mechanisms. Recall that mechanisms are internal responses to an intervention, that generate outcomes in the presence of particular contextual factors. Please more clearly articulate how and why you hypothesize that the EA intervention will trigger the mechanisms you have identified. It would be helpful to elaborate on how and why your hypothesized mechanisms were selected and why they might generate outcomes.</p> <p>3) Please clarify how outcomes will be measured. Is it a pre-post analysis (will the same individuals complete the questionnaires at T0 and T1)? Over what period of time are you hoping that the EA intervention will be effective in reducing or delaying substance use? Will there be any comparison or control groups to help in establishing outcomes?</p> <p>4) Please discuss the limitations of your study.</p> <p>5) The paper is quite long and could benefit from careful editing. The paper could be written more succinctly and summarized.</p>
-------------------------	--

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Li Xiang

Institution and Country: The Hong Kong Polytechnic University

Please state any competing interests or state 'None declared': none declared

Please leave your comments for the authors below

Thank you for inviting me to review this manuscript. I appreciate the efforts of the authors in writing this protocol. However, I wonder the significance and novelty of this study after reading this manuscript. Since the EA program has launched in 2015, why do you write a protocol rather than directly evaluating it?

Dear Reviewer, thank you for your comments and for accepting to review this manuscript. Indeed, the EA program started in 2015, as a field based program it has changed and is, since 2019, stabilized. We are currently evaluating the EA program and, here we submit the protocol of this evaluation. The evaluation we propose being quite complex, we wanted to expose it in a protocol paper in order to present our specific design and contribute to scientific knowledge about realistic evaluation.

I list a number of comments as below.

As the authors want to evaluate the EA program, I think more information on EA should be introduced. For example, the authors only wrote “the EA program involves supervised animated short movies and talks”. What is the content of the movies and talks? How to supervise?

We rewrote this section in order to be more precise and accurate. More details regarding the film and the session are now integrated to the description of the EA program p 8.

As EA is a theory-based life skills program aiming to prevent addictive behaviors, what are specific life skills that are useful to reduce addictive behaviors? Why these life skills are chosen to prevent addictive behaviors? For example, the authors refer to resistance skill. Why this skill is helpful?

We added a section in the introduction regarding Life skills and their links with addictions hoping that it makes it clearer.

What is middle-range theory? More introduction is expected.

We rewrote this section and clarified what is a Middle range theory (p6). A middle-range theory (i.e. a theory that aims to describe the interactions between outcomes, mechanisms and contexts) is set out in order to highlight the mutual influences of intervention and context

The literature is not very comprehensive. For example, the authors wrote “there are many programs focused on addiction prevention implemented in schools” on page 5. However, they didn’t introduce any of them.

We added references line 108

Additionally, the authors listed many aims of the program in the last paragraph on page 5. However, no literature in this manuscript supports these aims. Why and how the program can reach these aims?

We changed this section and addressed this issue more clearly p 4, and added some information in the description of the program p 8.

The methods used in this study should be more detailed. For example, the authors wrote “the case-study method will be used as it involves...” on page 7. What is about the case study? How to conduct the case study?

We rewrote this section trying to be more specific. In realist evaluation a “case“ is a different context where the program can be observed and the theory tested . The cases should enable ‘testing’ of the initial program theory in all its dimensions.

What is a double-blind review on page 14?

We changed the phrasing in order to be more understandable. This review has been made by 2 searchers each one working independently from the other.

What is a cross-case analysis on page 19?

We rewrote this section in order to be very specific and accurate on these topics. (cf p 16-17).

What is bottom-up approaches advocated in health promotion?

We added explanation and a reference p.20.

Why and how “these first data will help and guide a second qualitative phase (i.e. IP2, IE2) and the DCE questionnaire elaboration” on page 21?

We added information p12, 16-18.

Overall, I think this protocol is general and not specific. It is excepted to be more concise and clearer.

We summarized the protocol. It is now more concise and clearer. Also, we asked two professional editors who are english native speakers to review the protocol and it’s English wording.

Reviewer: 2

Reviewer Name: Amelia Usher

Institution and Country: Ryerson University

Canada

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

I commend the authors on the ambitious study described here and in their desire to evaluate a substance use prevention intervention using a theory-driven realist approach. This is an important topic and once completed, the study will add value to the extant literature.

Dear Reviewer, thank you for your comments and for accepting to review this manuscript.

1) Please elaborate on what is meant by contribution analysis paradigm. What methods are involved? How does this contrast/complement/support/enhance the realist approach to evaluation? It would be helpful for the reader to have a better understanding of what you mean and how contribution analysis relates to the realist paradigm.

We rewrote this section in order to be more precise but also keeping in mind the summarizing injunction.

2) It is not immediately clear that the mechanisms proposed in your protocol are indeed mechanisms. Recall that mechanisms are internal responses to an intervention, that generate outcomes in the presence of particular contextual factors. Please more clearly articulate how and why you hypothesize that the EA intervention will trigger the mechanisms you have identified. It would be helpful to elaborate on how and why your hypothesized mechanisms were selected and why they might generate outcomes.

In order to be consistent in our manuscript we added two definitions (p 6) of mechanism that we are referring to in this research. Regarding the reason why we selected these mechanisms we added several times in the manuscript that they are extracted from a literature review. Since they are hypothetical and not confirmed by our data collection yet, we cannot confirm this choice and we just present them as research hypotheses.

3) Please clarify how outcomes will be measured. Is it a pre-post analysis (will the same individuals complete the questionnaires at T0 and T1)?

We clarified that point in the manuscript p 12

Over what period of time are you hoping that the EA intervention will be effective in reducing or delaying substance use?

Since it is one of the questions this study aims to answer, it's difficult to provide an answer to this question. Between the 2 questionnaire T0 and T1 there will be a 3 years delta i.e. 9 EA sessions. We don't know yet if this lapse will be enough to produce an effect in substance use but we are quite confident on the possible activation of mechanisms playing a role in such behaviors.

Will there be any comparison or control groups to help in establishing outcomes?

No, realist intervention design usually doesn't involve a control group. There will not be any control groups to help in establishing outcomes, but there will be a descriptive comparison between T0 and T1 which with all the limits that it includes may help in identifying and/or rejecting some hypotheses.

4) Please discuss the limitations of your study.

We added a limitations section p 20

5) The paper is quite long and could benefit from careful editing. The paper could be written more succinctly and summarized.

We summarized it and the English in this document has been checked by two professional editors, both English native speakers.

VERSION 2 – REVIEW

REVIEWER	Amelia Usher Ryerson University, Canada
REVIEW RETURNED	19-Apr-2020

GENERAL COMMENTS	I am satisfied that previous reviewer comments have been addressed.
-------------------------	---