Author’s response to reviews

Title: Evaluation of the Housing First Program in patients with severe mental disorders in France: study protocol for a randomised controlled trial

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Author’s response to reviews: see over
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To: Doug Altman, Curt Furberg, Jeremy Grimshaw and Peter Rothwell
    Editors-in-Chief of Trials journal.

Dear Editors,

Please find enclosed a copy of our revised manuscript entitled: “Evaluation of the Housing First Program in patients with severe mental disorders in France: study protocol for a randomised controlled trial.”

We are honoured by the attention you have given to our manuscript, and we are grateful to the reviewer for his meticulous review of the paper.

We responded point-by-point to the comments and requests of the reviewer, documenting any changes we made to the original manuscript.

We hope that the new version is deemed worthy of publication in Trials.

Yours sincerely,

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Editor
1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format: study protocol for a randomized controlled trial.
2) Please remove the conclusion section; this is not required for a protocol.
3) Please include a trial status section. This should state the status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials, provided they have not completed patient recruitment at the time of submission.

Authors
1) The title is now in agreement with the journal style for study protocol articles: Evaluation of the Housing First Program in patients with severe mental disorders in France: study protocol for a randomised controlled trial.
2) We removed the conclusion section.
3) We included a trial status section at the end of the manuscript line 408: “Trial status. The study started recruiting participants in August 2011, and the recruitment is ongoing.”
Reviewer 1

Reviewer’s point 1.
1. Page 2, Paragraph 2: The authors should clearly state in the abstract how they define “costly health services” (e.g., from page 7: number of hospital admissions, days in hospital, and emergency department visits).

Authors
We thank the reviewer for this comment (and comments 8 and 9). We defined our primary outcome more precisely and we revised the abstract at line 41: “The primary outcome criterion is the use of high-cost health services (i.e., number of hospital admissions and number of emergency department visits) during the 24-month follow-up period.” (See comments 8 and 9 for primary outcome corrections).

Reviewer’s point 2.
2. Page 2: The authors should state in the abstract the anticipated total number of participants to be enrolled in the study.

Authors
The anticipated total number of participants to be enrolled in the study is now added in the abstract at line 48: “A total of 300 individuals per group will be included.”

Reviewer’s point 3.
3. Page 4, Paragraph 2: The authors describe Housing First as model offering stable housing with no treatment, follow up or abstinence conditions. The phrasing of this sentence may confuse readers. Readers should be clear that appropriately matched services are an important part of the Housing First approach.

Authors
We rephrased the sentence (“In contrast to this model which predominates in many European countries including France, the Housing First model reverses this sequence by offering stable housing at an early stage with no treatment, follow up or abstinence conditions [20].”) as follows in line 81: “In contrast to this model, which predominates in many European countries, including France, the Housing First model reverses this sequence by offering immediate access to stable housing [18]. Individuals can exercise some degree of choice regarding the location and type of housing they receive. No pre-conditions, such as being stabilised on medications or bringing substance abuse under control, are necessary. In addition, homeless people in the Housing First model access support from a multidisciplinary team, following a well-defined intensive case management (ICM) program for people with moderate needs (i.e., participant/staff ratio = 20:1; availability: 5 days/week, 8 hours/day) or assertive community treatment (ACT) for those with greater needs (i.e., participant/staff ratio = 10:1; availability: 7 days/week, 24 hours/day).”

Reviewer’s point 4.
4. Page 4, Paragraph 2: Choice (the idea that individuals can exercise some degree of choice regarding the location and type of housing they receive) is a key principle of Housing First, and should be included in authors’ description of the model.

Authors
We agree with the reviewer, the choice is a key principle of Housing First, and we added this issue to line 81: “Individuals can exercise some degree of choice regarding the location and type of housing they receive.”
Reviewer’s point 5.
5. Page 4/5, Background: Please include the following in the background section:
   a) A clear description of what constitutes TAU in the current context.
   b) Details about the funding/funders and partners for the current project.
   c) A description of the makeup and function of the ACT and ICM teams (e.g., staffing ratios).
Much of this information is left to the discussion and should be moved to the background section.
Authors
We agree with the reviewer that this information should be included at the beginning of the article.
   a) Line 103: “We thus designed a prospective randomised trial to assess the impact of a Housing First intervention in comparison with treatment-as-usual (i.e., control group receiving existing supports and services in each site) on health outcomes and costs for homeless people with severe mental illness.”
   b) Line 105: “This project is supported both by private (less than 10%) funding sources and public funding sources, issued from different policymakers in charge of medical, social, housing and research services.” The details of the funding are presented at the end of the manuscript.
   c) Line 86: “In addition, homeless people in the Housing First model access support from a multidisciplinary team, following a well-defined intensive case management (ICM) program for people with moderate needs (i.e., participant/staff ratio = 20:1; availability: 5 days/week, 8 hours/day) or assertive community treatment (ACT) for those with greater needs (i.e., participant/staff ratio = 10:1; availability: 7 days/week, 24 hours/day).”

Reviewer’s point 6.
6. Page 6/7, Study Design: The authors should clearly state that they are using both quantitative and qualitative methods. In the first sentence on page 7, when the authors begin describing the qualitative methods, it is unclear whether they are describing a specific component of the data collection or characterizing the entire study.
Authors
We agree with the reviewer that we have to clearly state that we are using both quantitative and qualitative methods and that qualitative methods characterise the entire study. We added the following sentence at the beginning of the study design section, line 140: “The present study is a 24-month, prospective, randomised, controlled, open-label, and multi-site study, based on a mixed approach combining quantitative and qualitative methods.”

Reviewer’s point 7.
7. Page 7, paragraph 1: The first two sentences describing the qualitative methods should be reviewed. The authors should clarify the following in this description:
   a) What constitutes a “generalizable study design”?
   b) How will qualitative data be collected and at what intervals will these methods be administered?
   c) Will information regarding a participant’s culture be collected for demographic reasons or will qualitative interviews explore issues relating to the participants’ culture?
Authors
   a) We clarified what “generalizable study design” indicates in line 154: “to determine whether the Housing First model evaluated in this study may be transposed to other real-life settings in the French context.”
   b) We added the following information in line 160: “Interviews and focus groups will be recorded and transcribed verbatim. These methods will be administered at (baseline; T0) and then at 6 (T1), 12 (T2), 18 (T3) and 24 months (T4).”
   c) The qualitative interviews will explore issues relating to the participants’ culture, which is important in a perspective of generalisation of Housing First to the French context.

Reviewer’s point 8.
8. Page 7: The authors define costly health services as: number of hospital admissions, number of days in hospital, and number of emergency department visits. The authors should clarify if they will treat these as separate outcomes or how they plan to model them together? Hospital admissions and length
of stay are highly correlated. The authors should explain their rationale for specifying both of these outcomes.

Authors

We agree with the reviewer that this point concerning the primary outcome should be clarified. Our primary outcome is the impact of a Housing First intervention in comparison with treatment-as-usual on the use of high cost health services (i.e., number of hospital admissions and number of emergency department visits) over a 24-month period in homeless people with severe mental illness in France.

By mistake, we noted in the initial manuscript that the length of stay was part of the primary endpoint when it is actually a secondary endpoint. We have now corrected this mistake in the Abstract (line 41), objective (line 111/114) and Methods (line 180).

For example:

Study Objectives

“The Housing First intervention provides immediate access to independent housing and community care. The primary outcome criterion is the use of high-cost health services (i.e., number of hospital admissions and number of emergency department visits) during the 24-month follow-up period.”

“The secondary objectives are (1) to assess the impact of the Housing First intervention on the number of days in hospital and (…).”

Finally, concerning the analysis of the primary outcome, we will conduct an intention-to-treat analysis for each of the outcomes (number of hospital admissions and number of emergency department visits). We added this point to line 278: “We will conduct analyses for each of the outcomes separately (i.e., number of hospital admissions and number of emergency department visits).”

Reviewer’s point 9

9. Page 10: The authors should provide expected values or rates at baseline for primary outcomes (e.g., how many hospitalizations or emergency visits) in order to establish reference points for the 20% differences they hope to detect.

Authors

In accordance with our previous answer (comment 8), we estimated two sample sizes for each criterion of the primary outcome (number of hospital admissions and number of emergency department visits) and chose the largest sample. Sample size was calculated to obtain 90% power to detect a 20% difference in the use of costly health services (reference points = 3.6 for the number of hospitalisations and 5.7 for the number of emergency department visits [56]) at 24 months between the two groups. With a significant p-value of 0.05, these calculations showed that a total of 250 individuals per group was required; allowing for a potential 20% of patients being lost to follow-up, a total of 600 will need to be included, i.e. 150 at each site.

As requested by the reviewer, we have now added this information in line 251:

“Sample size was calculated to obtain 90% power, to detect a 20% difference in the use of costly health care services (reference points = 3.6 for the number of hospitalisations and 5.7 for the number of emergency department visits [54]) at 24 months between the two groups. With a significant p-value of 0.05, these calculations showed that a total of 250 individuals per group was required; allowing for a potential 20% of patients being lost to follow-up, a total of 600 will need to be included, i.e., 150 at each site.”

Reviewer’s point 10

Minor Essential Revisions

10. This submission will require careful editing for readability, grammar and syntax issues. For example:

- Page 4: Tense in sentence 1, paragraph 1.
- Page 4: Sentence 6, paragraph 1 is a run on sentence
- Page 7: sentence 3, paragraph 1: “direct observational” should be “direct observation.”
Authors
We corrected the tense of the sentence 1, paragraph 1. We removed sentence 6. We replaced “observational” with “observation.”
Additionally, the manuscript has been now edited by a native English speaker (see certificate from American Journal Experts).

Reviewer’s point 11.
11. Page 6, paragraph 2: The term “evaluations” is incorrectly applied here. The sentence should be revised to state that quantitative data will be collected by trained research assistants during face-to-face interviews.

Authors
In accordance with the reviewer, we replaced “evaluations” with “quantitative data” in line 149: “Quantitative data are collected during face-to-face interviews by the trained research assistants at five different points in time…”

Reviewer’s point 12.
12. Page 4: The authors should clarify what percentage of people who are homeless in France suffer from severe and persistent mental illness.

Authors
We added the following estimation in line 60: “An estimated 100,000 people live on the streets in France (Source: http://www.emmaus-france.org.uk, 2007.)”

Reviewer’s point 13.
13. Page 9: The reference to Table 1. Assessment Schedule should be moved into the section detailing the study design.

Authors
The reference to Table 1 Assessment Schedule has been moved into the section detailing the study design in line 163.

Reviewer’s point 14.
14. Page 9: The authors should clarify membership of steering committee.

Authors
As suggested by the reviewer, we clarified the membership of the steering committee in line 234: “The following parameters are also recorded by research assistants using ad-hoc questionnaires elaborated by the steering committee composed of economists, psychiatrists, psychologists, social workers and sociologists.”

Reviewer’s point 15.
Discretionary Revisions:
1. We recommend adding “mental illness” and “evaluation” as key words.

Authors
As proposed by the reviewer, we added “mental illness” and “evaluation” as key words.

Reviewer’s point 16.
2. Do the authors anticipate different rates of attrition between control and treatment participants? Have they considered the possibility of using different incentives for TAU participants as these individual should be expected to have greater rates of attrition?

Authors
We agree with the reviewer that we can expect different rates of attrition between the control and treatment participants. Twenty percent was the expected number in the control group, and we have arbitrarily chosen the same figure for the Housing First group, although it was expected to be less. The different incentives are used for both the control and treatment participants, but the incentives are actually aimed at reducing attrition for the control group because participants in the Housing First
group will be tracked more easily because of immediate housing. However, the participants of group 2 (control) will receive a supplementary incentive different from the Housing First group, including 21 euro of food coupons for each interview. We added this information to line 270: “In addition, participants of the second group will receive 21 euro worth of food coupons for each interview.”

Reviewer’s point 17.
3. Page 6: How will researchers assess a person’s intent to stay within the same city for the follow up period? How will researchers follow participants if/when participants move to another jurisdiction?

Authors
Concerning the first point, the research assistants are certified or have received specific training by existing mental health outreach teams and other services taking care of homeless individuals. These contacts and their knowledge of the field are important to assess the stability of the homeless. Thus, they may know some homeless people (or ask for information about them when necessary), the existence of a social network, and/or their stability in the past, and then be able to assess their potential stability during the study.

Concerning the second point, when participants move to another jurisdiction or city, researchers may be informed by the social network about the new location of the participants. If they can be contacted, interviews will be performed by telephone (or the researchers can go to see the individuals if the city is not too far). Otherwise, they will be considered lost to follow-up.

Reviewer’s point 18.
4. Page 12: The authors highlight 2007 legislation introducing a theoretically enforceable right to housing for all citizens. How has this affected France’s homeless population and what are the implications for assessing the impact of the Housing First model?

Authors
This legislation will not constitute a bias in our study. However, we may expect that this legislation can lead to a less important difference between the two groups than that within the experiments in Canada or the United States. Moreover, the Housing First model offers immediate access to stable housing with support from a multidisciplinary team, which is not the case in the 2007 legislation.