Author's response to reviews

Title: Ending homelessness among people with mental illness: The At Home/Chez Soi randomized trial of a Housing First intervention in Toronto.

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Version: 2 Date: 15 June 2012

Author's response to reviews: see over
Dear Editor(s),

The authors would like to extend our thanks to both of the reviews for their helpful comments on the manuscript. For each suggestion, we have provided a highlighted response. In addition, we have added a third section which outlines other changes we have made to the manuscript which allowed us to improve clarity, consistency and update our results with the most accurate data.

Reviewer’s report

Title: Ending homelessness among people with mental illness: The At Home/Chez Soi randomized trial of a Housing First intervention in Toronto.

Reviewer: dyanne semogas

Version: 1 Date: 12 March 2012

Reviewer's report:

Questions & Reviewer’s Comments
1. Is the question posed by the authors well defined? Yes.
2. Are the methods appropriate and well described? No.
   a) Target population inclusion criteria and definitions are sound and meets target population example-absolute homelessness. But authors do not define mental illness: does it include conduct disorders, axis II: personality disorders? Is it any mental illness for inclusion?

Response: Mental illness, as defined by the At Home/Chez Soi study is now defined in the methods section on page 10 which now reads:

Page 11-12:

Study Eligibility and Establishment of Need Level

In order to meet study inclusion criteria, participants had to 1) be 18 years of age or older; 2) be either absolutely homelessness or precariously housed (for definitions see Table 1); and 3) have a serious mental disorder with or without a co-existing substance use disorder. Participants were excluded if they 1) were current clients of another Assertive Community Treatment or Intensive Case Management program; 2) did not have legal status in Canada as a citizen, landed immigrant, refugee, or refugee claimant; 3) were relatively homeless (for definition see Table 1).

The presence of a serious mental disorder was established at the time of screening for study entry and was defined by diagnosis and disability based on several lines of evidence: 1) behavioural observations made by referral sources, 2) indicators of functional impairment, 3) history of recent psychiatric treatment and 4) current presence of an eligible diagnosis, as identified by the DSM-IV criteria in the Mini International Neuropsychiatric Interview 6.0 (MINI). Participants with a documented
prior diagnosis or a MINI diagnosis made at study entry of at least one of the following Axis I diagnoses were considered eligible for this study: major depressive episode, manic or hypomanic episode, mood disorder with psychotic features, panic disorder, post-traumatic stress disorder and psychotic disorder [36].

Randomization

b) Use of MINI is a large part of the protocol. The authors don’t tell us anything about the MINI: is it structured versus semi-structured, what’s its reliability and validity? what are its limitations?

Response: We have included more information about the MINI in the methods section. We have also revised and clarified the methods section which outlines the establishment of need level groups among the participants. We also provided more information about the MCAS scale which was used as part of the needs level assessment. The following sections of the text have been modified to reflect these changes:

Page 12-14:

The AH/CS study is a randomized controlled trial (RCT) that follows participants for 24 months. The randomization procedures have been described in detail elsewhere [36]. Prior to randomization, all eligible participants were stratified based on the extent of disability and severity of psychiatric problems into “high needs” or “moderate needs” for mental health services groups, based on an algorithm described elsewhere and summarized in Figure 1 [36]. The criteria for establishing need level included community functioning, mental disorder diagnosis, co-morbid conditions, prior hospitalizations and incarcerations, as well as results from the MINI and the Multnomah Community Ability Scale (MCAS) (see Measures below). In order to be considered “high needs”, participants had to have a MCAS score of less than 62 and have a MINI diagnosis of psychotic or bipolar disorder or an observation of psychotic disorder on the eligibility screening instrument (i.e., answered “yes” to at least two of Questions 6-10, see Appendix) and had to meet one of following three criteria: 1) had indicated “yes” (or “don’t know” or declined) to having been hospitalized for mental illness two or more times in any one year in the last five years; or 2) have indicated co-morbid substance use; or 3) have answered “yes” (or “don’t know” or declined) to recent arrest or incarcerations. All other participants who met study eligibility criteria but did not meet the criteria for the “high needs” group were considered “moderate needs”[36]

Specific to the Toronto site, moderate needs participants were further stratified by ethno-racial group membership prior to randomization. Participants who did not self-identify as belonging to an ethno-racial group were randomized to either Housing First with Intensive Case Management (ICM) or a Treatment as Usual (TAU) control group. Participants who indicated membership in an ethno-racial group were allowed to choose between assignment to the regular ICM intervention or a Housing First with ethno-racial specific ICM intervention (ER-ICM). Choice was allowed as long as there was available space in both intervention arms. As a result, ethno-racial participants were assigned to both the regular ICM and ER-ICM intervention groups (Figure 1).
Participants identified as High Needs were randomized to either Housing First with Assertive Community Treatment (ACT) or TAU, regardless of ethno-racial group membership status. Since there was no unique ethno-racial intervention for participants with high needs, both non-ethno racial and ethno-racial high needs participants randomized to receive treatment were provided services by the same Assertive Case Management team (see Figure 1).

Measures
MINI International Neuropsychiatric Interview 6.0 (MINI 6.0)
The MINI 6.0 is a short, structured diagnostic interview used for psychiatric evaluation, typically administered in approximately 15 minutes. In the AH/CS study, we focused specifically on the following modules of the MINI 6.0: 1) major depressive episodes; 2) manic or hypomanic episodes; 3) post-traumatic stress disorder; 4) panic disorder; 5) mood disorder with psychotic features; 6) psychotic disorder; 7) alcohol dependence; 8) alcohol abuse; 9) substance dependence; 10) substance abuse; and 11) suicidality. Diagnosis of at least one of the first six disorders listed met the eligibility criteria for the presence of a serious mental disorder [36].

The MINI has been validated against several much longer diagnostic interviews, including the Structure Clinical Interview for DSM Diagnoses (SCID-P), and against the Composite International Diagnostic Interview for ICD-10 (CIDI) [53, 54]. In comparison to both the SCIP-P and ICD-10, the MINI has shown good or very good concordance and high sensitivity for most diagnoses, with a high level of reliability [53, 54].

Multnomah Community Integration Scale (MCAS)
The MCAS is a 17-item instrument that measures the degree of functional ability of adult clients who have severe and persistent mental disorders and who live in the community [55]. Items are rated on a 5-point scale and are grouped into four categories; 1) interference with functioning 2) adjustment to living; 3) social skills; and 4) behavioural problems. The MCAS has good internal consistency (Cronbach’s α =0.90) with high test-retest reliability (ICC=0.83 for total scale) [55]. Anchor and interview probes were developed by Dickerson et al, and increased test-retest reliability (ICC=0.96 for total scale) [56].

Barker et al (1994) proposed criterion scores for interpreting levels of disability in individuals with severe mental illness: total MCAS scores of 17 to 47 indicate severe disability, 48 to 62 moderate disability and 63 to 85 indicate mild disability [55]. Other investigators report MCAS ratings in the 40s for inpatients [57], in the 50s for ambulatory patients receiving a high level of community support [58], and in the 60s for clients in lower intensity outpatient care [57].

Other data collected as part of the AH/CS project, including additional survey elements and qualitative data elements, are described in further detail elsewhere [36].

3. Are the data sound? Yes.
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes.

5. Are the discussion and conclusions well balanced and adequately supported by the data? No.

a) “Randomization was successful in balancing the characteristics”. Described a recruitment strategy but did not outline what the criteria are for a successful recruitment strategy “balance” between intervention and control. In other words: what’s the criteria for “balance”?

Response: This sentence was altered to further clarify what we intent by the term balance. We have replaced this sentence with the following sentence:

Page 17:

Randomization at the Toronto site of the At Home/Chez Soi randomized controlled trial of Housing First was successful and resulted in no significant differences between intervention and control groups in key baseline demographic and exposure variables.

6. Are limitations of the work clearly stated? No.

a) Needs to be expanded. Barriers experienced are important to state as much as strategies for success.

Response: In the current manuscript, we do not report on many of the major findings of this study (only demographics), so there are few limitations to mention. However, we do mention several barriers to the implementation of the study in the discussion. In particularly we mention the following barriers:

1. Barriers to recruitment (page 20):

   Challenges to recruitment arose in the early days of the study. There were delays in building a research team with the needed training, educating potential referral sources about the study and eligibility criteria, and developing recruitment protocols acceptable to all. This resulted in an unexpectedly low rate of intake for service providers early in the study and the need to negotiate the flow of referrals to meet both recruitment timelines and service provider needs. However, this wait time also allowed for extensive training of the service team and research staff, which allowed for a more smooth recruitment process once the research study was initiated. Later on, as the research team quickly increased recruitment rates in an effort to reach target numbers, the service team’s capacity to intake participants became a limiting factor. Intake visits typically required two case managers, which put additional pressure on teams that were already trying to cope with the unexpectedly high needs of the study population.

2. Barriers to project implementation (page 21-22):

   However, some community members and service providers initially felt ambivalent towards the project. In particular, there was substantial opposition to the randomization of participants to the treatment as usual group and a fear of letting participants down at the conclusion of project intervention in 2013. Active outreach to service providers that were potential referral sources and ongoing dialogue were important components of the community engagement strategy and helped to address some of these concerns.
3. Participant disappointment at being randomized to control group (page 22):

Many study participants experienced disappointment during the process of the study, particularly those who were randomized to the TAU group. Efforts were made to ensure that existing support services in Toronto were available and accessible for these individuals, either through their referral sources or research team members. Because the referral sources often had close relationships with the participants, they were able to provide support after the randomization process took place, and were often able to suggest or offer other available services to the participants external to the services provided through the study. Additionally, research staff explained the important role the participant’s contribution would have in increasing knowledge to help other homeless individuals.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? No.

a) Authors reference other studies that have done this intervention. Does not address what gaps these other studies have identified other than “it’s not Canadian”.

Response: The key gaps in knowledge have been more clearly stated in the following paragraph on page 6-7:

Studies have shown that the Housing First model can result in positive housing and health outcomes for participants and for society in general [14, 21, 24-35]. However, the Housing First model has only been systematically assessed by a few randomized controlled studies, and there is little evidence to date regarding the effectiveness, cost-effectiveness and critical elements of this model within a Canadian context [28, 36-38]. Both health care and social policy differences exist between the United States and Canada, and while the Housing First approach has shown to be an effective intervention in the United States, it is not clear if the model will be equally effective in Canada. In addition, several gaps remain in our knowledge regarding the effectiveness of the Housing First model. First, it is not known if the Housing First approach will be equally effective among different subpopulations (including individuals of different age, sex, those who are Aboriginal or belong to other racialized ethnicities, immigrants, or those with concurrent disorders). Second, to date, no cost-benefit analysis or cost effectiveness analysis has been completed that compares the Housing First model to standard care. Third, there has been a lack of fidelity assessment among Housing First programs; these could be used to determine if elements of the approach have been implemented and how they relate to key outcomes. Fourth, an Intensive Case Management-based Housing First has been proposed as a less costly alternative for meeting the needs of homeless individuals with moderate mental health needs; this approach has not been evaluated for effectiveness compared to standard care, and will be evaluated as part of the At Home/Chez Soi project.

b) Why is Toronto of interest? 4 sites identified: can you generalize from Toronto to other parts of the world?
**Reponse:** The findings from the Toronto site of At Home/Chez Soi would be generalizable to other large service-rich urban centres worldwide. A sentence outlining this has been added in the introduction on page 7:

*The findings from the Toronto site of the AH/CS project, in particular, will provide knowledge on how to best implement a Housing First approach in other large service-rich urban centres worldwide. Because of the ethnic diversity of the Toronto homeless population, the findings from this site will also better inform the effectiveness of the Housing First model in various subpopulations.*

8. Do the title and abstract accurately convey what has been found? Yes.
9. Is the writing acceptable? Yes. Strengths: A particular strength of this manuscript is the inclusion of community stakeholders and consumers in the research process.

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**Reviewer’s report**

**Title:** Ending homelessness among people with mental illness: The At Home/Chez Soi randomized trial of a Housing First intervention in Toronto.

**Version:** 1 Date: 1 April 2012

**Reviewer:** John Song

**Reviewer’s report:**

In terms of the reporting criteria as constructed by the editors, this reviewer did not believe that this manuscript has either major compulsory revision or minor essential revisions. What follows are my comments which are best characterized as discretionary revisions. I hope that it is clear why I would classify these suggestions, while not minor, as discretionary.

As the authors clearly explain in their introduction, there currently are two major, widely divergent, philosophies and approaches to homeless individuals with mental illness and/or substance abuse. The traditional approach emphasizes stabilizing or treating an individual’s mental illness or substance abuse before attempting to house them permanently. The latter approach, which reverses the order temporally and in emphasis, is more recently developed and has not been widely accepted yet. However, early empirical work has demonstrated great promise in this approach for some individuals.

A large scale randomized controlled trial is needed to illuminate which approach is most effective for which kinds of individuals, especially in Canada, a country that suffers from high rates of homelessness. Data from this kind of study would be extremely beneficial for service providers, municipalities, funding agencies, and other organizations to best utilize their resources efficiently and effectively.

The focus of this manuscript is more limited – it is a mainly descriptive paper reporting the recruitment strategies and challenges, as well as the community engagement activities of the project. In other contexts, this limited focus might not warrant a separate manuscript;
however, there are several unique aspects about the project as located in Toronto, which is the site the authors describe: a large array of services geared toward homeless persons; municipal commitment; and a unique intervention that addresses the large percentage of immigrants among the homeless populations of Canada.

There is no hypothesis per se; rather, it is, as noted earlier, a description of the recruited sample and of the recruitment process. These aims of the manuscript is clearly articulated. To fulfill these aims, appropriate methodology is taken and well-described, although, as I’ll discuss shortly, I believe they could be further illustrated. The data is sound and interesting. However, for purposes of this manuscript -and its aims -the results section was a little too detailed. It might be more appropriate to condense this section considerably and refer readers to Table 2. The discussion was excellent, and the area that could be expanded. The background section is very complete and well-referenced and serves as a useful reference in itself. Finally, the article is well-written and organized.

Response: We have made substantial cuts to the results section to reflect this comment.

The main suggestions that this reviewer would make is to decrease the space devoted to reporting descriptive statistics and increase reporting of the investigators’ experiences and lessons learned, as well providing further context to some of their assertions.

For example, the authors should further detail the challenges faced in terms of recruiting. This group is an experienced one, and sharing their challenges and solutions would be the greatest benefit of this manuscript. For example, when they write of “developing recruitment protocols acceptable to all,” it would be illustrative and helpful to describe the major conflicts between researchers and service providers in terms of recruitment protocol. They also write of the “need to negotiate the flow of referrals to meet both recruitment timelines and service provider needs.” This statement begs the question: What needs did the service providers have that may have conflicted with the recruitment timelines? The manuscript hints about misunderstandings about the project – which elevated to the level of “myths” – and it would be again informative to describe the misunderstandings and the strategies enlisted by the investigators to overcome them. Reading between the lines, the reader senses that understanding, acceptance, and recruitment of this project was difficult, but that these difficulties were overcome with some degree of hard work and innovation. It would be educational for readers, fellow investigators, and service and health care providers to have further insight into the challenges and solutions.

Response: We have made the following changes to reflect the suggestions in the previous paragraph:

1. We have expanded the section (in bold) that describes the conflicts between the researchers and service providers in terms of the recruitment protocol on page 19:

   **Challenges to recruitment arose in the early days of the study. There were delays in building a research team with the needed training, educating potential referral sources about the study and eligibility criteria, and developing recruitment protocols acceptable to all. This resulted in an unexpectedly low rate of intake for service providers early in the study and the need to negotiate the flow of referrals to meet both recruitment timelines and service provider needs. However, this wait time also allowed...**
for extensive training of the service team and research staff, which allowed for a more smooth recruitment process once the research study was initiated. Later on, as the research team quickly increased recruitment rates in an effort to reach target numbers, the service team’s capacity to intake participants became a limiting factor. Intake visits typically required two case managers, which put additional pressure on teams that were already trying to cope with the unexpectedly high needs of the study population.

2. On page 21, we have removed the sentence that speaks of the “myths” surrounding the project.

3. With regards to describing the challenges and solutions of this project: we are currently preparing another manuscript which has this topic as its main focus and will include a more detailed description of many of these challenges. Furthermore, there is another manuscript in preparation that outlines some of the challenges of implementing a cross-site project in different cities, including the necessary adaptations to the model that had to take place.

Many individuals and groups were instrumental to the project’s success, but it was hard for this reader to fully understand the relationships and duties; a chart demonstrating all the groups involved in this project might be helpful.

Response: A figure showing the project governance at the Toronto site has been added in an Appendix to help address this issue and a line has been added on page 9 with reference to the project governance chart:

The project governance chart is provided in the Appendix.

It is not clear why there wasn’t any unique ethno-racial intervention for those individuals with high needs. As the authors argue in their introduction, these individuals might be of greatest vulnerability. It is this reviewer’s assumption that there is a valid reason, thus it would be helpful to explain this design. Was it because there are more high needs individuals who are native Canadian?

Response: We agree with the reviewer in that it would have been ideal to have both an ACT and ICM intervention for the ethno-racial participants, however funding was only available for an additional moderate needs (ICM) third arm intervention at each of the sites. Not changes have been made to the text.

With respect to native Canadians, the Winnipeg site of the AT Home/Chez Soi project has a third arm focused on this group in particular.

It would be helpful to give demographics in general of Toronto in Table 2 for comparison.

Response: The findings of this study are meant to be generalizable for populations of homeless individuals with serious mental disorder and unfortunately, previous detailed data on this population are not available. In addition, some of these variables may not be
appropriate for the general population: for example, the MCAS scale is specifically designed to assess the functioning of individuals with serious and persistent mental illness.

The following sentence is unclear and should be clarified: “A high degree of commitment to ensure meaningful involvement of consumers and community members was a major characteristic of the Toronto site of the AH/CS project.” On whose part? And why more than others? This sentence is representative of some of the questions that arise from the text, which, if answered, would be beneficial to the reader.

Response: This sentence was removed due to its lack of clarity.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests

Other changes:

Guided and inspired by the reviewer's suggestions we have made additional changes in the text and corresponding tables/figures to improve the clarity of the manuscript.

The following list outlines some of the minor and more substantive changes we have made to the manuscript, organized by manuscript section:

Abstract:

1. In the abstract methods, we have clarified that Housing First was offered at two different service delivery levels:

   Housing First interventions were offered at two different mental health service delivery levels: Assertive Community Treatment for high needs participants and Intensive Case Management for moderate needs participants.

2. In the abstract results, we have clarified that there were no significant differences between intervention and control participants within the High Needs and Moderate Needs Housing First interventions:

   Randomization produced similar demographic, mental health, cognitive, and functional impairment characteristics in the treatment and control groups for both the high needs and moderate needs groups.
3. We have also condensed the description of demographic results in the results section of the abstract, which now states (pg. 2-3):

The effectiveness of the recruitment strategy was influenced by a carefully designed referral system, targeted recruitment of specific groups, and an extensive network of pre-existing services. Community members, potential participants, service providers, and other stakeholders were engaged through active outreach and information sessions. Challenges related to the need for different sectors to work together were resolved through team building strategies. Randomization produced similar demographic, mental health, cognitive, and functional impairment characteristics in the intervention and control groups for both the high needs and moderate needs groups. The majority of participants were male (69%), aged >40 years (53%), single/never married (69%), without dependent children (71%), born in Canada (54%), and non-white (64%). Many participants had substance dependence (38%), psychotic disorder (37%), major depressive episode (36%), alcohol dependence (29%), post-traumatic stress disorder (PTSD) (23%), and mood disorder with psychotic features (21%). More than two-thirds of the participants (65%) indicated some level of suicidality.

Methods:
4. On Page 9, we provide more details about the Toronto site-specific Ethno-Racial Intensive Case Management intervention:

The Toronto site has also developed a unique intervention for the AH/CS study that provides ethno-racial intensive case management (ER-ICM) for participants with moderate needs who belong to a racialized group. High rates of mental health problems have been observed in immigrants, refugees and ethno-racial individuals in Canada and worldwide [40-46]. However, reports from Canada, US, UK and Australia suggest that immigrant and ethno-racial groups use mental health services less frequently compared to non-immigrants and experience significant barriers to care [40, 47-51]. The unique Toronto-based ER-ICM intervention aims to address the unique challenges faced by this group.

5. On Page 15, we clarify that the differences are now examined between intervention and control groups within the separate High Needs and Moderate Needs interventions:

Descriptive statistics were calculated for each of the collected baseline quantitative measures. T-tests and chi-square tests, as appropriate, were used to test for significant differences between the treatment and control participants, stratified by need level, at baseline.

Results:
6. We have significantly revised Table 2 and have made revisions to the results section to reflect these changes. In particular, we no longer compare high need level
participants to moderate need level participants given that the interventions they receive are quite dissimilar and different selection criteria were used to place participants in the high vs. moderate needs level intervention groups. Instead we stratify our participants by need level prior to comparisons between intervention and control participants. In addition, we have substantially condensed the Results section of the manuscript, which now contains the following, found on pages 16-17:

**Participant Recruitment**

Between October 2009 and June 2011, a total of 1,342 referrals were received. The largest proportion of referrals was received from shelter services (39%) but drop-in centres (14%), outreach programs (12%), hospitals (11%), mental health services (7%) were also key sources of recruitment. A total of 726 (54%) referrals passed the initial review for eligibility and underwent further screening. Reasons for exclusion, prior to and after the screening interview are provided in Table 1.

A total of 575 individuals (43% of all referrals) met all eligibility requirements, provided informed consent, and completed screening and baseline interviews. Of this number, 197 were stratified to the high needs group and 378 to the moderate needs group. Randomization resulted in the assignment of 301 individuals to one of the three intervention groups and 274 individuals to a control group. Among the intervention groups, 97 were assigned to the ACT intervention group, 102 to the ICM intervention group and 102 to the ER-ICM intervention group (see Figure 1).

**Baseline Sample Characteristics**

Table 2 summarizes the baseline characteristics of participants for the sample overall and stratified by intervention group and need level group. Among study participants, the most common age group was 40-49 years old (32%), most were male (69%), born in Canada (54%), single/never married (69%), without dependent children (71%), and absolutely homeless (93%). Within each need level group, intervention and control participants did not differ in any baseline characteristics except in two instances where marginally significant differences between the intervention and control participants were noted, both within the moderate needs group. The prevalence of current alcohol dependence was higher in control participants (33%) compared to intervention participants (24%, p=0.046), and the number of participants who provided information suggesting a history of a learning disability was higher in control (41%) compared to intervention participants (31%, p=0.044).

Although this study specifically sought to recruit homeless individuals with mental illness, a large proportion of participants (70%) reported no written documentation of a mental health diagnosis. However, the prevalence of mental health conditions and concurrent disorders was high as determined by the MINI [54]. The prevalence of mental health conditions in our sample at baseline was as follows: suicidality (65%), substance dependence (38%), psychotic disorder (37%), major depression (36%), alcohol dependence (29%), post-traumatic stress disorder (PTSD) (23%), mood disorder with psychotic features (21%), panic disorder (14%), alcohol abuse (14%), mania/hypomania (11%) and substance abuse (9%).