The At Home/Chez Soi trial protocol: A pragmatic, multi-site, randomized controlled trial of Housing First in five Canadian cities

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The At Home/Chez Soi trial protocol: A pragmatic, multi-site, randomized controlled trial of Housing First in five Canadian cities

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ABSTRACT

Introduction: Housing First is a complex housing and support intervention for homeless individuals with mental health problems. It has a sufficient knowledge base and interest to warrant a test of wide-scale implementation in various settings. This protocol describes the quantitative design of a Canadian 5 city, $110 million demonstration project and provides the rationale for key scientific decisions.

Methods: A pragmatic, mixed methods, multi-site field trial of the effectiveness of Housing First in Vancouver, Winnipeg, Toronto, Montreal and Moncton, will randomize approximately 2,500 participants, stratified by high and moderate need levels, into intervention and treatment as usual groups. Quantitative outcome measures will be collected over a two year period and a qualitative process evaluation will be completed. Primary outcomes are housing stability, social functioning and, for the economic analyses, quality of life. Hierarchical linear modeling is the primary data analytic strategy.

Ethics and dissemination: Research ethics board approval has been obtained from 11 institutions and a safety and adverse events committee is in place. The results of the multi-site analyses of outcomes at 12 months and one year will be reported in a series of core scientific journal papers. Extensive knowledge exchange activities with non-academic audiences will occur throughout the duration of the project.

Registration: This study has been registered with the International Standard Randomized Control Trial Number Register and assigned ISRCTN42520374.

SUMMARY

- An evaluation of the cost effectiveness of Housing First in comparison to treatment as usual for homeless adults with mental illness in five Canadian cities followed for two years
- Primary outcomes include housing stability, quality of life and social functioning
- The correlates of different trajectories and the critical ingredient of the intervention for sub-populations will also be investigated

Key messages

First and largest multi-site trial of this complex housing and support intervention will create knowledge about implementation and outcomes.

The addition of site specific intervention arms to a core common protocol will investigate innovative adaptations that are tailored to local context.

The inclusion of a broader homeless population receiving a less intensive service model will increase policy relevance of the findings.

Strengths and limitations

Larger sample size (n.= 2,500)) and wider range of outcome variables than previous trials

Concomitant mixed methods process evaluation that includes fidelity assessments

Variation in sample characteristics and in treatment as usual across five cities may limit opportunities for aggregate analyses.

INTRODUCTION

Background and Rationale

The prevalence of mental health problems and addictions among homeless people is significantly higher than in the general population.[1, 2, 3] Mental health problems among people who are homeless include severe and persistent mental illnesses such as schizophrenia, as well as more prevalent conditions such as mood and affective disorders.[3] The co-occurrence of mental disorders and substance abuse is also common in this group, particularly among single men.[1,2] While people with severe and persistent mental illness form a minority among the homeless population, with a pooled estimated prevalence for psychotic disorders of 12.7%[4], they are more likely to experience repeated episodes and longer periods of homelessness, as well as to require more health and social services than others experiencing homelessness.[5]

To date, a small number of controlled trials, all conducted in the United States,[6] have examined the effectiveness of housing and support interventions for people with mental illness who are homeless. This research reveals that programs providing housing combined with supports to people with severe mental illness are effective in reducing homelessness and hospitalizations and in producing other positive outcomes (e.g., well-being).

Housing First involves providing homeless people with immediate access to subsidized housing, together with supports. No pre-conditions, such as bringing substance abuse under control or being stabilized on medications, are imposed. In the 1980s, Pathways to Housing in New York City introduced a consumer-choice-oriented variant of Housing First, in which clients are offered their choice of subsidized scattered-site apartments (as opposed to one-size-fits-all congregate-housing). Clients who have severe mental illness in addition to being homeless are also offered the support of a multidisciplinary team, following a well-defined program model called assertive community treatment (ACT). A number of studies have examined the effectiveness of Pathways to Housing in delivering housing and support services to people with severe mental illness including individuals with concurrent disorders.[7, 8, 9, 10, 11]

Based on these studies, Pathways to Housing has emerged as an empirically supported intervention for people with severe mental illness who are homeless, including those with concurrent disorders. It has now been implemented in Calgary and Edmonton, Alberta and in several U.S. cities.[12]

Because of the differences in health care and social policies between the U.S. and Canada, it is not known if the Pathways to Housing approach will prove to be effective in the Canadian context, or more broadly in other international contexts. Moreover, it is not known if the approach will be equally effective among different sub-populations (e.g., defined by gender, age, presence of concurrent disorders, Aboriginal status, and immigration status) located in different cities across Canada. Further, while previous

research examining Pathways to Housing focused on outcomes such as housing stability, housing problems, psychiatric symptoms, substance use, service utilization, and perceived housing choice, none of the studies examined other important outcomes of interest, such as community integration, social functioning, employment, recovery or physical health. As well, cost-benefit or cost-effectiveness of the program compared to standard care was not evaluated. Finally, the Pathways to Housing studies did not incorporate a fidelity assessment to determine if the key elements to the approach were implemented nor did they examine how fidelity related to outcomes.

Developed independently in Toronto, Streets to Homes is a Canadian approach to Housing First[13], which Toronto City Council initiated in 2005 as a strategy for ending street homelessness. The Canadian and U.S. programs share many of the same elements of focus such as services to assist people to find and move into housing of their choice followed by supports, so they can be successfully and stably housed. However, the Streets to Homes program uses intensive case management (ICM) rather than ACT as the service delivery model and serves a broader population than Pathways to Housing, including all those who are on the streets rather than targeting only those with severe mental illness. While no published study evaluates Streets to Homes directly, two U.S. studies suggest that this approach may be effective in providing care to a lower need subgroup that has otherwise not been included in much of the published literature.[14, 15]

Both studies examined interventions targeting veterans of the armed forces in the U.S. Using an experimental design, Rosenheck et al.[15] compared the effectiveness of housing and support in the form of comprehensive case management to standard care. The study found that the combined housing and support approach was superior to standard care in achieving housing stability and reducing hospitalizations and prison stays.

In the other study, O'Connell et al.[14] used a quasi-experimental design to evaluate the effectiveness of regular housing and case management compared to the traditional approach of multistage continuum housing. Both groups showed significant improvements in housing outcomes, clinical status, community functioning, and quality of life. Multistage housing participants, who had more difficulties in these areas at baseline, experienced greater improvement to the point that they were not significantly different from participants accessing regular housing and case management after 24 months. Residents in multistage housing, however, had significantly greater health care costs, due to greater use of inpatient care.

Given the promising evidence of the Housing First model and interest in the less expensive intensive case management support approach, the present study was designed to stratify individuals by need level and evaluate these two service delivery variants.

The research design is a *pragmatic, multi-site field trial of the effectiveness* of Housing First with concomitant economic and qualitative process evaluations. It is intended to provide policy-relevant evidence about whether a complex housing and support intervention works under real life conditions in five Canadian cities. This demonstration project includes funding for the implementation of the intervention through contracts

with existing service agencies and rent supplements for participants. In order to ensure local buy-in and to develop innovative Housing First services that are tailored to local circumstances, each city had the option of defining a third intervention arm that was specific to their site (described below).

This paper describes the study protocol including core quantitative research questions and methods that are common to all sites. It also includes an adaptation of the standard CONSORT description of pragmatic[16] trials of non-pharmacologic[17] and complex interventions.[18]

Objectives

The At Home/Chez Soi study sought to involve a range of stakeholders in a collaborative research and knowledge translation process that addresses the following objectives:

1. To determine whether Housing First results in better outcomes than treatment as usual (TAU) for unaccompanied homeless adults with high and moderate needs living in five urban settings with respect to: (a) housing stability; (b) quality of life; (c) medical, psychological, and physical status; (d) social functioning; and (e) community integration.

2. To examine the cost-effectiveness of Housing First in comparison to TAU.

3. To examine the correlates of different trajectories of interest such as housing stability, mental health, medical conditions and employment over time.

4. To identify the critical ingredients of the Housing First model and what modifications are needed to effectively serve particular sub-populations (e.g. Aboriginals, ethnic groups, those living in congregate or rural settings).

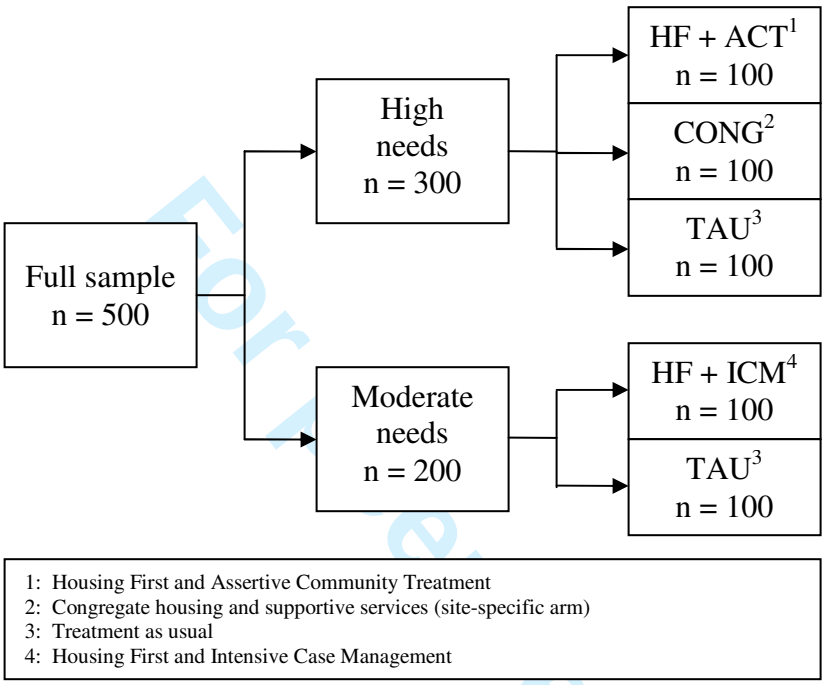
METHODS and ANALYSIS

Design

The study's basic design is a randomized controlled trial (RCT) that is being conducted in five cities in Canada: Vancouver, British Columbia; Winnipeg, Manitoba; Toronto, Ontario; Montreal, Quebec; and Moncton, New Brunswick. Prior to randomization, participants at all sites except Moncton are stratified according to the severity of their psychiatric problems into High Need or Moderate Need groups. Those in the High Need group are randomized into Housing First and ACT (HF+ACT) or TAU, while those with Moderate Need are randomized to Housing First and ICM (HF + ICM) or TAU. In Moncton, there are not enough people who are homeless to allow for a stratified design, so all participants are randomized to HF + ACT or TAU, although the team responds flexibly to individual needs. A typical design for one site is presented in

Figure 1.

Figure 1. Vancouver Study Design



In Vancouver (as indicated in Figure 1), and also in Winnipeg, Toronto, and Montreal, participants are being randomized to a third site-specific intervention arm, in addition to HF+ACT and HF+ICM. In Vancouver, this intervention consists of congregate housing (a former hotel in which all of the residents are formerly homeless people with a mental illness), or project-based housing, which is a variation on HF that has been found effective with homeless substance using clients.[19] In Winnipeg, the intervention is an Aboriginal peer support model for the moderate need group. In Toronto, an ICM intervention specifically for ethno-racial minorities is being tested for moderate need participants. In Montreal, moderate-need participants are being randomized to an institutional vs. a non-profit community-based ICM provider; both groups of participants are also invited to participate in a trial of supported employment. Moncton does not have a third arm, but there is a small, pilot project of HF in a rural setting. Details of the site-specific interventions are described in Appendix A.

Participants will be followed for two years after enrollment. There will be face-to-face follow-up interviews at 6, 12, 18, and 24 months, and telephone interviews at 3, 9, 15, and 21 months. The schedule of instruments administered at each interview session is presented in Table 1. Participants will be paid $20.00 to $30.00 CAD for each face-to-face interview (less for shorter, telephone interviews), and provided with bus fare and money for telephone calls if needed. The number and timing of the interview sessions were dictated by two considerations: a desire to track the longer term trajectory of change for each individual; and recognition of the fact that it is likely that, due to the nature of

their problems, some participants, especially in the TAU groups, may miss appointments. The statistical techniques that will be used (described below) can deal with missing data, as long as there are at least three data collection points for a given outcome measure, so that the frequency of the interviews maximizes the number of people whose data can be analyzed.

Table 1. Key outcome domains and administration schedule

Outcome Domain	Variables	Instruments
Housing	Stability Perceived Quality Observer-rated Quality	Residential Time-Line Follow-Back Inventory[20]* Perceived Housing Quality Scale[21,22] Purpose developed Observer-rated Housing Quality Scale
Health Status	Mental Physical	Modified Colorado Symptom Index (CS)[23] Global Assessment of Individual Needs GAIN Substance Problem Scale[24,25] EQ-5D Visual Analog Scale[26,27,28]
Functioning incl. Community Integration, Recovery and Vocational attainment	Independent Living Response to Stress Money Management Social Meaningful Activity etc.	Multnomah Community Ability Scale (MCAS)[29, 30, 31] Adapted community integrations scales (physical and psychological integration)[32,33,34] RAS[35,36,37] Vocational Time-Line Follow-Back[38]*
Quality of Life	Generic quality of life Disease-specific quality of life	EQ-5D [36, 37, 38] SF-12[39,40,41] SF-6D[42] Qoli-20[43]
Healthcare, Social Services and Justice System Use and Costs	e.g. ER visits, hospital admissions, primary and specialist care visits,social agency visits, charges,court appearances, nights in jail or remand	Composite checklists of service use and justice system-related events to which costs will be attached using standard costing methods

* Indicates which are instruments are administered every 3 months; all others are every six months, except Housing Quality Scale which is only at 21 months

Sample Size

Although the aim is to combine participants across sites within each condition, it is recognized that (a) there will most likely be baseline differences across sites, reflecting the different demographic composition of each city; and (b) each site will want to analyze data from their site-specific arm. Consequently, the study is powered so that each site would be able to detect an effect size of 0.5 between TAU and the treatment arms for the major outcome variables. With an alpha of .05 and beta of .20, sufficient power for analysis will require 63 participants per treatment arm. Given the challenges in following a homeless population over a two year follow-up period, an attrition rate of 40% was estimated and recruitment targeted at 100 participants per arm. The exception to this recruitment target is the small pilot study in a rural region adjacent to Moncton, which draws on a matched control design with 25 individuals in each group.

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The combined sample size of approximately 2,500 (which allows for additional participants in some of the site-specific arms) will also allow for the use of hierarchical linear modeling (described below) as the primary data analytic strategy.

Participants

Criteria for inclusion are:

- Legal adult status (aged 18 or older/19 in British Columbia);
- Housing status as absolutely homelessness OR precariously housed, according to definitions in Appendix B;
- The presence of a mental disorder with or without a co-existing substance use disorder, determined by DSM IV criteria on the MINI[44] at the time of entry (details in Appendix B)

Exclusion criteria are:

- Currently a client of another ACT or ICM program
- No legal status as a Canadian citizen, landed immigrant, refugee or refugee claimant
- Those who are *relatively homeless* (as defined in Appendix B).

Randomization

During the initial eligibility and baseline interviews, participants will be administered the MINI[44] and the MCAS[45, 46], as well as answer questions about service and housing history. Based on an algorithm that includes information about diagnosis, social functioning and service use, they will be assigned to the high-need or moderate-need condition. If they meet all of the other criteria, they will be randomized to a housing intervention or TAU. Randomization is performed via computer by the central data gathering centre, using adaptive randomization procedures.[47] This approach to randomization continually changes the probability of being assigned to each group, depending on the number of participants in each. Because each arm of the trial has a maximum of 100 participants, adaptive randomization better insures balance between the groups than strict randomization. Block randomization was considered infeasible, as it is desirable for participants to know their group assignment immediately after the interview; using block randomization, they would have to wait until enough people are enrolled to complete the block, which could take a few weeks.

Interventions

Housing First as defined in the Pathways to Housing and Street to Homes approaches creates a recovery-oriented culture that puts participant/tenant choice at the centre of all its considerations with respect to the provision of housing and support services. It operates on the principle that all homeless individuals with mental illness should be offered the opportunity to live in permanent housing of varying types that is otherwise available to people without psychiatric or other disabilities. Assertive in-reach and outreach identifies and engages potential participants avoiding any coercive tactics. Rent supplements are provided so that participants pay 30% or less of their income for housing if in the private market[i]. Participants may also live in social, supported or alternative housing and in those locales the rent supplement is not required. Participants must also be provided access to furniture. Treatment and support services are offered by clinicians/providers who are based off-site. Legal rights to tenancy are in place. Whenever possible, leases are in the name of the participant, not the program, to empower participants/tenants in their recovery and autonomy, and assist them in achieving full independence. In essence, it is a housing program with supports delivered without any conditions of housing readiness such as engagement in treatment. However, participants must agree to have 30% of their income paid directly as rent and to be visited in their unit a minimum of once a week by program staff for a length of time that is appropriate to their level of need. The program has control over participant access to housing stock, primarily by facilitating access to rental apartments from community landlords. For housing in the private market (scattered site), a maximum of 20% of the total units in any one building is dedicated to the program to facilitate community integration.

The service array provides support and treatment for mental illness and, where necessary, substance abuse, and differs depending upon the level of individual severity and disability. All services are individualized based upon participant need and preference, including cultural adaptations. Services are provided in the home or community. Service teams work with participants to obtain and maintain housing, promote mental and physical health and to reduce the negative impacts of substance use.

For those individuals with high needs who have not been able to access traditional housing and services, these services are provided using a modified ACT team as exemplified by Pathways to Housing and described in more detail elsewhere.[48]

For individuals with moderate needs, services are provided using ICM as exemplified the Streets to Homes program[ii] In this model, consumers are linked primarily to one worker rather than a whole team.

Table 2 outlines the key features of the Housing First experimental intervention model and the unique elements of the two service delivery modalities.

[i] In Canada, households expending more than 30% of before tax income on shelter are classified as being in Core Housing Need. For specific CHN criteria see http://www.cmhc-schl.gc.ca/en/corp/faq/faq_002.cfm

[ii] The Streets to Homes program serves clients with high and moderate needs. For the purposes of this study, the focus is solely on those aspects of the program that serve clients with moderate needs.

Table 2. Key Features of the Experimental Intervention

<table>
<tr><th colspan="2">Housing First Model</th></tr>
<tr><td colspan="2">
Recovery oriented culture
Based on consumer choice for all services
Only requirements: income paid directly as rent; visited at a minimum once a week for pre-determined periods of follow-up supports
Rent supplements in private market: participants pay 30% or less of their income or the shelter portion of welfare
Treatment and support services voluntary - clinicians/providers based off site
Legal rights to tenancy (no head leases with agency rather than individual)
No conditions on housing readiness
Program facilitates access to housing stock
Apartments are independent living settings primarily in scattered sites
Services individualized, including cultural adaptations
Reduce the negative consequences of substance use
Availability of furniture and possibly maintenance services
Tenancy not tied to engagement in treatment
</td></tr>
<tr><th>ACT - High Need</th><th>ICM - Moderate Need</th></tr>
<tr><td>
Recovery-oriented ACT team
Participant/staff ratio of 10:1 or less and includes a psychiatrist and nurse
Program staff are closely involved in hospital admissions and discharges
Teams meet daily and include at least one peer specialist as staff
Seven day a week, 24 hour crisis coverage
</td><td>
Intensive case management for a minimum of one year once housed
Participant/staff ratio of 20:1 or less
Integrated efforts across multiple workers and agencies
Workers accompany participants to appointments
Centralized assignment and monthly case conferences
Seven day a week, 12 hours per day coverage
</td></tr>
</table>

The elements described above define the program model from which fidelity is being measured, using a new Housing First scale[48] developed during the formative evaluation phase of this study. It is recognized that there may be justifiable deviations from complete fidelity due to tailoring to local conditions. The intervention is delivered by 12 existing service agencies who were the successful applicant from each of the five pre-selected cities to a request for proposals that was issued by the Mental Health

Commission of Canada (MHCC). The agencies had to demonstrate their ability to hire, train and supervise staff for the housing and support teams and be financially accountable in the 6 month start-up period. Technical assistance and training on the Housing First intervention is provided on an ongoing basis by a centralized team of experts. Fidelity visits and qualitative interviews are conducted as a part of an extensive process evaluation (Macnaughton E, Goering P, Nelson G. Using Mixed Methods within the At Home/Chez Soi Housing First project: A strategy to evaluate the implementation of a complex population health intervention for people with lived experience of homelessness and mental illness. Under review, CJPH).

Usual Care. In each city, the housing intervention(s) will be compared to TAU. The intent is to compare a complex new service delivery approach to the "real life" experience that exists in current systems of care. This means that there will be no active intervention introduced by the study for the TAU group. "Usual care" does not mean "no care;" it is what people would normally get if this project did not exist. It is recognized that some individuals in the TAU group may over time, through new or existing programs, access some of the same components that make up the housing intervention. It is also likely that the usual care service patterns will differ across cities. This unpredictable mix of service packages is a phenomenon of interest. It is measured through the common protocol and included in the analysis of process and outcomes.

Outcomes

The key outcome domains for measuring the effectiveness and cost effectiveness of the intervention are those that have consistently been found to be relevant in studies of housing interventions for individuals with mental health issues. These are listed in Table 1. As is acknowledged in the guidelines for evaluations of complex interventions,[18] more than one outcome is needed to reflect the multiple effects that are expected. The primary outcomes for assessment of effectiveness are housing stability and social functioning; secondary outcomes include mental and physical health status, community integration, and quality of life. For the economic analyses, system use and costs will be used to calculate the costs of improvements in the primary outcomes of quality of life and days housed.

Statistical Analyses

Within each of the high- and moderate-need groups, participant data will be clustered within site, and over time. Missing data are expected due to missed appointments, drop-outs, and death. One technique to deal with missing data when the outcome is continuous, is hierarchical linear modeling (HLM; also called random effects regression, latent growth curve analysis, and many other names).[49] In brief, a regression line is fitted to each person's data, resulting in two parameters: a slope and an intercept, and the analysis focuses on variables that affect these. A minimum of three data points are necessary to fit a straight line, in order to give an estimate of the error of the fit. If there are more than three data points, more complex lines can be fitted (e.g., quadratic, cubic), which may better approximate the actual trajectories of change.

We do not anticipate differences in the intercept within each site, as randomization is expected to balance out baseline differences between the groups. However, there may be differences in the intercepts between sites, reflecting differences within the client populations served in each city. We anticipate that the primary factor affecting the slope (i.e., the rate of change of the outcome measure) will be group membership (i.e., housing intervention or TAU). If there is any significant unexplained variance after baseline differences and group membership have been accounted for, we can look for other factors influencing the slope, such as gender, age, amount of time spent on the streets, diagnosis, and so forth. Another analytic option that will be considered is generalized estimating equations (GEE),[50] which can also accommodate clustered, serially correlated data with missing values. The choice of techniques will be based on the nature of the data and the research question.

The analysis plan will combine the TAU groups within need level and across sites. However, it may turn out that the demographic characteristics of participants and available treatments differ so widely from city to city that this will not be possible. In that case, it will be necessary to compare each treatment group to its site-specific TAU group.

There are no universally accepted methods for dealing with missing data; the only consensus is that sensitivity analyses should be conducted using different methods and comparing the results. In this study, data can be missing at four levels – individual items within instruments, the instruments themselves, specific appointment or data points, and people, due to loss to follow-up or death. We do not expect many individual items to be missing, as most of the instruments will be computer-administered. However, people may refuse to answer a specific question. In such cases, we will either follow the recommendations (if any) of the scale developer or use multiple imputation. If an instrument or appointment is missed, we will attempt to gather the information at a later visit. Irregular timing of instruments administered multiple times is not a problem for HLM, as it can account for this in deriving the slope for each person. Drop-outs and deaths, though, are a different matter. We cannot assume that these data are missing at random or missing completely at random,[51] which is an assumption of most imputation methods. If there are at least three data points for these people, we will analyze them separately to determine if their slopes differ significantly from those of people who remained in the study. If they do not, we will be somewhat more comfortable including them in the analyses; otherwise, they will need to be analyzed separately. As previously noted, though, we will analyze the missing data in a number of ways, including HLM, multiple imputation, and last observation carried forward.

The cost-effectiveness analysis (CEA) will be conducted using net benefit regression.[52] The regression framework allows the implementation of the statistical plans described above. Furthermore, the net benefit regression framework features parametric and non-parametric options to characterize uncertainty in the CEA data.[53] In addition to incremental net benefit by willingness to pay curves, we will also present our results using cost-effectiveness acceptability curves (CEACs) and scatterplots on the cost-

effectiveness plane. Net benefit regression has been used to analyze the cost-effectiveness of various programs for study participants such as those in our study.[54]

ETHICS AND DISSEMINATION

This study has been registered with the International Standard Randomised Control Trial Number Register and assigned ISRCTN42520374. Research Ethics Board (REB) approvals have been received from universities or healthcare institutions in each of the five sites (a total of 10 institutions, mostly universities). Additionally, we have REB approval from the university-affiliated teaching hospital in which the coordinating centre is based to conduct secondary analyses and move the data across provincial lines and store them in a central, secure location.

A study of this nature raises ethical issues not faced by more traditional interventions, such as medications or psychotherapy. These include the possibility of harm to the participants, research staff, and clinical personnel, due to the nature of the participants' psychiatric problems and their living situations. Analogous to the Data Safety Monitoring Boards which are established in trials of medications, the At Home/Chez Soi Project has set up a Safety and Adverse Events Committee, composed of representatives from the national research group, participants, clinical staff, and an ethicist.[55] It is charged with receiving and reviewing reports regarding any serious events associated with the project.

The results of the multi-site analyses of outcomes at 12 months and one year will be reported in a series of core scientific journal papers. Extensive knowledge exchange activities with non-academic audiences will occur throughout the duration of the project.

AUTHOR'S CONTRIBUTIONS

PG and JB conceived the study. CA and DS lead the design of the quantitative common protocol with the involvement of all authors. SH, EL, TA, JD and JS lead the design of site specific components. All authors, including JK and DZ, participated in the preparation of the manuscript by providing comments to drafts written by PG and DS and reading and approving the final version.

FUNDING STATEMENT

This work was supported by a contract from Health Canada administrated by the Mental Health Commission of Canada

COMPETING INTERESTS STATEMENT

None of the authors have competing interests.

Appendix A

Description of Site-Specific Interventions

The third arm intervention in Toronto combines a Housing First philosophy with an anti-racism/anti-oppression framework and practice which has been developed to engage and treat people from racialized groups suffering from mental illness and addictions. The anti-racism/anti-oppression framework, developed by the Toronto mental health agency Across Boundaries, is built on three core values: that racism and oppression have profound negative effects on health and mental health; that clients need to heal in ways that are meaningful and relevant to them; and that racism and oppression can occur at individual and system levels and that intervention is needed at both levels.

The Moncton site includes a small pilot study in which the effectiveness of HF + ACT is being evaluated using a quasi-experimental design in the Southeastern rural region of New Brunswick. For the study, 25 participants who are living in Special Care Homes or with their families or who are homeless have been recruited to receive HF + ACT services. Subsequent to this recruitment, a control group of 25 participants is also being recruited from the mental health clinic. The two groups are being matched in pairs on the variables of sex, age, and living situation at study entry.

Winnipeg's third arm intervention is focused on the Aboriginal experience. The intervention is delivered by Aboriginal Health and Wellness, a primary health care centre that provides service to Aboriginal peoples in Winnipeg's inner city. Key components include a drop-in centre as well as educational, employment and life skills training. Services are holistic and culturally-based, using both contemporary and traditional philosophies of the Medicine Wheel and the universal principles of sharing, caring, kindness, humility, trust, honesty and respect. These principles make up the Seven Sacred Teachings and all of these principles exist within the Medicine Wheel or the Circle of Life.

In Vancouver the congregate housing and support intervention consists of housing provided in a building with 100 self-contained units with private bathrooms. Kitchenettes are not included in the individual units. However, shared meal and amenity spaces are provided with meals offered on site three times per day. Support staff include a psychiatrist, a general practice physician, a licensed practical nurse, a registered nurse, a pharmacist, a peer employment coordinator, two social workers/case managers, two peer support workers, three mental health workers, and a team leader. In addition, one staff person is present at all times to oversee the secure entrance into the building. A number of therapeutic and recreational activities are also offered including: acupuncture, art therapy, a nutritional program, a Health & Wellness group, a Seeking Safety group, a 16-Steps to Recovery group, yoga as well as other sports activities. Individual and/or group counseling is also available on site.

In Montreal, moderate need participants are randomized to receive ICM services either from an institutional provider or from a non-profit, community-based provider.

Institutional provider staff are unionized and subject to a significant number of institutional rules that both protect and constrain staff and thus may have an impact on the way the intervention is delivered, compared to the non-profit. In addition the institutional provider is more costly due to higher wage rates and greater administrative oversight. Participants assigned to either of these groups are also invited to participate in a randomized trial of the Individual Placement and Support (IPS) model of supported employment. Several randomized trials demonstrate that IPS is more effective than other approaches at helping people with severe mental illness obtain competitive jobs.[56] No published trial of IPS, however, has evaluated its effectiveness specifically in the context of a Housing First type of intervention for homeless people with mental illness.

Appendix B

Definitions of Inclusion Criteria

Absolute Homelessness: Homelessness refers to those who lack a regular, fixed, physical shelter. This (conservative) definition is known as *absolute* homelessness according to the United Nations, and includes those who are living rough in a public or private place not ordinarily used as a regular sleeping accommodation for a human being (e.g., outside, on the streets, in parks or on the beach, in doorways, in parked vehicles, squats, or parking garages), as well as those whose primary night-time residence is a supervised public or private emergency accommodation (e.g., shelter, hostel).[iii] Specifically, being homeless is defined as currently having *no fixed place to stay for more than seven nights and little likelihood of obtaining accommodation in the upcoming month*[iv] or being discharged from an institution, prison, jail, hospital with no fixed address.

Precariously Housed: This refers to people whose primary residence is a Single Room Occupancy (SRO), rooming house, or hotel/motel. In addition, precariously housed individuals in the past year have had two or more episodes of being absolutely homeless, as defined above, in order to meet the criteria for inclusion.

Relatively Homeless. This includes people whose regular housing fails to meet basic standards, such as (i) living in overcrowded or hazardous conditions, (ii) those *at risk* of homelessness, such as people who reside informally/non-permanently with friends or relatives (e.g., doubling-up, couch surfing); (iii) those *in transition* (e.g., women, youth fleeing to transition houses/shelters from domestic abuse); (iv) those who are *temporarily* without a dwelling (e.g., home lost for a relatively short period of time due to disasters such as a fire, or a change in economic or personal situation such as marital separation, or job loss; and (v) those living in long-term institutions.

Serious mental disorders are defined by diagnosis, duration and disability using observations from referring sources, indicators of functional impairment, history of recent psychiatric treatment and current presence of eligible diagnosis as identified by the MINI (major depressive, manic or hypomanic episode, PTSD, mood disorder with psychotic features, psychotic disorder).

[iii] The UN definition of homelessness originally included individuals in transition using transition homes and hostels. The present project modified the definition to exclude this subgroup.

[iv] Definition adopted from Tolomiczenko & Goering (2000). Gender differences in legal involvement among homeless shelter users.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-7
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7,8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	10,18
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11,12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	na

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13,14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13,14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13,14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	15
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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The At Home/Chez Soi trial protocol: A pragmatic, multi-site, randomized controlled trial of a Housing First intervention for homeless individuals with mental illness in five Canadian cities

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The At Home/Chez Soi trial protocol: A pragmatic, multi-site, randomized controlled trial of a Housing First intervention for homeless individuals with mental illness in five Canadian cities

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ABSTRACT

Introduction: Housing First is a complex housing and support intervention for homeless individuals with mental health problems. It has a sufficient knowledge base and interest to warrant a test of wide-scale implementation in various settings. This protocol describes the quantitative design of a Canadian five city, $110 million demonstration project and provides the rationale for key scientific decisions.

Methods: A pragmatic, mixed methods, multi-site field trial of the effectiveness of Housing First in Vancouver, Winnipeg, Toronto, Montreal and Moncton, is randomizing approximately 2,500 participants, stratified by high and moderate need levels, into intervention and treatment as usual groups. Quantitative outcome measures are being collected over a two year period and a qualitative process evaluation is being completed. Primary outcomes are housing stability, social functioning and, for the economic analyses, quality of life. Hierarchical linear modeling is the primary data analytic strategy.

Ethics and dissemination: Research ethics board approval has been obtained from 11 institutions and a safety and adverse events committee is in place. The results of the multi-site analyses of outcomes at 12 months and two years will be reported in a series of core scientific journal papers. Extensive knowledge exchange activities with non-academic audiences will occur throughout the duration of the project.

Registration: This study has been registered with the International Standard Randomized Control Trial Number Register and assigned ISRCTN42520374.

SUMMARY

- An evaluation of the cost effectiveness of a Housing First in comparison to treatment as usual for homeless adults with mental illness in five Canadian cities with a two year follow-up.
- Primary outcomes include housing stability, quality of life and social functioning
- The correlates of different trajectories and the critical ingredient of the intervention for sub-populations will also be investigated

Key messages

The first and largest multi-site trial of this complex housing and support intervention will create knowledge about implementation and outcomes.

The addition of site specific intervention arms to a core common protocol will investigate innovative adaptations that are tailored to local context.

The inclusion of a broader homeless population receiving a less intensive service model will increase policy relevance of the findings.

Strengths and limitations

Larger sample size (n= 2,500)) and wider range of outcome variables than in previous trials

Concomitant mixed methods process evaluation that includes fidelity assessments

Variation in sample characteristics and in treatment as usual across five cities may limit opportunities for aggregate analyses.

INTRODUCTION

Background and Rationale

The prevalence of mental health problems and addictions among homeless people is significantly higher than in the general population.[1, 2, 3] Mental health problems among people who are homeless include severe and persistent mental illnesses such as schizophrenia, as well as more prevalent conditions such as mood and affective disorders.[3] The co-occurrence of mental disorders and substance abuse is also common in this group, particularly among single men.[1,2] While people with severe and persistent mental illness form a minority among the homeless population, with a pooled estimated prevalence for psychotic disorders of 12.7%[4], they are more likely to experience repeated episodes and longer periods of homelessness, as well as to require more health and social services than others experiencing homelessness.[5]

To date, a small number of controlled trials, all conducted in the United States,[6] have examined the effectiveness of housing and support interventions for people with mental illness who are homeless. This research reveals that programs providing housing combined with supports to people with severe mental illness are effective in reducing homelessness and hospitalizations and in producing other positive outcomes (e.g., well-being).

Housing First involves providing homeless people with immediate access to subsidized housing, together with supports. No pre-conditions, such as bringing substance abuse under control or being stabilized on medications, are imposed. In the 1980s, Pathways to Housing in New York City introduced a consumer-choice-oriented variant of Housing First, in which clients are offered their choice of subsidized scattered-site apartments (as opposed to one-size-fits-all congregate housing). Clients who have severe mental illness in addition to being homeless are also offered the support of a multidisciplinary team, following a well-defined program model called assertive community treatment (ACT). A number of studies have examined the effectiveness of Pathways to Housing in delivering housing and support services to people with severe mental illness including individuals with concurrent disorders.[7, 8, 9, 10, 11]

Based on these studies, Pathways to Housing has emerged as an empirically supported intervention for people with severe mental illness who are homeless, including those with concurrent disorders. It has now been implemented in Calgary and Edmonton, Alberta and in several U.S. cities.[12]

Because of differences in health care and social policies between the U.S. and Canada, it is not known if the Pathways to Housing approach will prove to be effective in the Canadian context, or more broadly in other international contexts. Moreover, it is not known if the approach will be equally effective among different sub-populations (e.g., defined by gender, age, presence of concurrent disorders, Aboriginal status, and immigration status) located in different cities across Canada. Further, while previous research examining Pathways to Housing focused on outcomes such as housing stability, housing problems, psychiatric symptoms, substance use, service utilization, and

perceived housing choice, none of the studies examined other important outcomes of interest, such as community integration, social functioning, employment, recovery or physical health. As well, cost-benefit or cost-effectiveness of the program compared to standard care was not evaluated. Finally, the Pathways to Housing studies did not incorporate a fidelity assessment to determine if the key elements of the approach were implemented nor did they examine how fidelity related to outcomes.

Developed independently in Toronto, Streets to Homes is a Canadian variant of Housing First[13], which Toronto City Council initiated in 2005 as a strategy for ending street homelessness. The Canadian and U.S. programs share many of the same elements such as services to assist people to find and move into housing of their choice followed by supports, so they can be successfully and stably housed. However, the Streets to Homes program uses intensive case management (ICM) rather than ACT as the service delivery model and serves a broader population than Pathways to Housing, including all those who are on the streets rather than targeting only those with severe mental illness. While no published study evaluates Streets to Homes directly, two U.S. studies suggest that this approach may be effective in providing care to a lower need subgroup that has otherwise not been included in much of the published literature.[14, 15]

Both studies examined interventions targeting veterans of the armed forces in the U.S. Using an experimental design, Rosenheck et al.[15] compared the effectiveness of housing and support in the form of comprehensive case management to standard care. The study found that the combined housing and support approach was superior to standard care in achieving housing stability and reducing hospitalizations and prison stays.

In the other study, O'Connell et al.[14] used a quasi-experimental design to evaluate the effectiveness of regular housing and case management compared to the traditional approach of multistage continuum housing. Both groups showed significant improvements in housing outcomes, clinical status, community functioning, and quality of life. Multistage housing participants, who had more difficulties in these areas at baseline, experienced greater improvement to the point that they were not significantly different from participants accessing regular housing and case management after 24 months. Residents in multistage housing, however, had significantly greater health care costs, due to greater use of inpatient care.

Given the promising evidence of the Housing First model and interest in the less expensive intensive case management support approach, the present study was designed to stratify individuals by need level and evaluate these two service delivery variants.

The research design is a *pragmatic, multi-site field trial of the effectiveness* of Housing First with concomitant economic and qualitative process evaluations. It is intended to provide policy-relevant evidence about whether a complex housing and support intervention works under real life conditions in five Canadian cities. This demonstration project includes funding for the implementation of the intervention through contracts with existing service agencies and rent supplements for participants. In order to ensure local buy-in and to develop innovative Housing First services that are tailored to local

circumstances, each city had the option of defining a third intervention arm that was specific to their site (described below).

This paper describes the study protocol including core quantitative research questions and methods that are common to all sites. It also includes an adaptation of the standard CONSORT description of pragmatic[16] trials of non-pharmacologic[17] and complex interventions.[18] Planning for the study began in the spring of 2008, first participants were recruited in fall of 2009, and data collection is to be completed in spring of 2013.

Objectives

The At Home/Chez Soi study seeks to involve a range of stakeholders in a collaborative research and knowledge translation process that addresses the following objectives:

1. To determine whether Housing First results in better outcomes than treatment as usual (TAU) for unaccompanied homeless adults with high and moderate needs living in five urban settings with respect to: (a) housing stability; (b) quality of life; (c) medical, psychological, and physical health status; (d) social functioning; and (e) community integration.

2. To examine the cost-effectiveness of Housing First in comparison to TAU.

3. To examine the correlates of different trajectories of interest such as housing stability, mental health, medical conditions and employment over time.

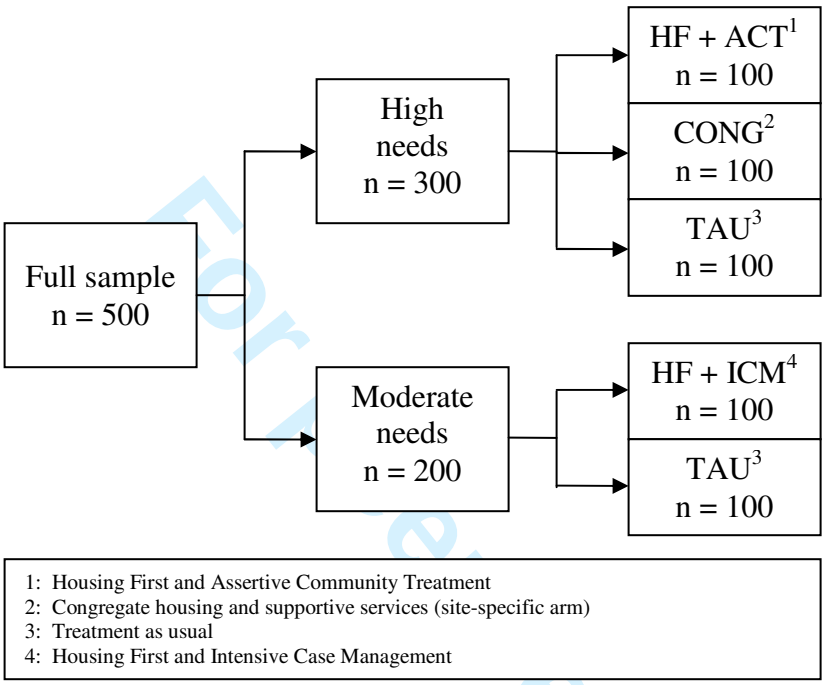
4. To identify the critical ingredients of the Housing First model and what modifications are needed to effectively serve particular sub-populations (e.g. Aboriginals, ethnic groups, those living in congregate or rural settings).

METHODS and ANALYSIS

Design

The study's basic design is a randomized controlled trial (RCT) that is being conducted in five cities in Canada: Vancouver, British Columbia; Winnipeg, Manitoba; Toronto, Ontario; Montreal, Quebec; and Moncton, New Brunswick. Prior to randomization, participants at all sites except Moncton are stratified according to the severity of their psychiatric problems into High Need or Moderate Need groups. Those in the High Need group are randomized into Housing First and ACT (HF+ACT) or TAU, while those with Moderate Need are randomized to Housing First and ICM (HF + ICM) or TAU. In Moncton, there are not enough people who are homeless to allow for a stratified design, so all participants are randomized to HF + ACT or TAU, although the team responds flexibly to individual needs. All sites have been given the option of an additional third arm. A typical design for one site is presented in

Figure 1. Vancouver Study Design



In Vancouver (as indicated in Figure 1), and also in Winnipeg, Toronto, and Montreal, participants are being randomized to a third site-specific intervention arm, in addition to HF+ACT and HF+ICM. In Vancouver, this intervention consists of congregate housing (a former hotel in which all of the residents are formerly homeless people with a mental illness), or project-based housing, which is a variation on HF that has been found effective with homeless substance using clients.[19] In Winnipeg, the intervention is an Aboriginal peer support model for the moderate need group. In Toronto, an ICM intervention specifically for ethno-racial minorities is being tested for moderate need participants. In Montreal, moderate-need participants are being randomized to an institutional vs. a non-profit community-based ICM provider; both groups of participants are also invited to participate in a trial of supported employment. Moncton does not have a third arm, but there is a small, pilot project of HF in a rural setting. Details of the site-specific interventions are described in Appendix A.

Recruitment and Data collection

Strategies to ensure adequate participation include seeking referrals from a wide variety of community agencies that serve the homeless, including shelters, drop-in centres, outreach teams, mental health teams, inpatient programs and criminal justice programs. Brochures describing the study and the eligibility criteria have been distributed and local service providers have provided advice about recruitment settings and procedures. Participants will be followed for two years after enrollment. Face-to-face follow-up

interviews are being conducted at 6, 12, 18, and 24 months, and telephone interviews at 3, 9, 15, and 21 months. Due to the inclusion of questionnaires on service use and housing trajectories (unavoidable given study objectives), blinding of interviewers was infeasible. The schedule of instruments administered at each interview session is presented in Table 1. A more detailed description of the instruments can be found in Appendix C. The number and timing of the interview sessions were dictated by two considerations: a desire to track the longer term trajectory of change for each individual; and recognition of the fact that it is likely that, due to the nature of their problems, some participants, especially in the TAU groups, may miss appointments. The statistical techniques that will be used (described below) can deal with missing data, as long as there are at least three data collection points for a given outcome measure, so that the frequency of the interviews maximizes the number of people whose data can be analyzed.

Table 1. Key outcome and process domains and administration schedule

Domain	Variables	Instruments
Housing	Stability Perceived Quality Observer-rated Quality	Residential Time-Line Follow-Back Inventory[20]* Perceived Housing Quality Scale[21,22] Purpose developed Observer-rated Housing Quality Scale
Health Status	Mental Physical	Modified Colorado Symptom Index (CS)[23] Global Assessment of Individual Needs GAIN Substance Problem Scale[24,25] EQ-5D Visual Analog Scale[26,27,28]
Functioning incl. Community Integration, Recovery and Vocational attainment	Independent Living Response to Stress Money Management Social Meaningful Activity etc.	Multnomah Community Ability Scale (MCAS)[29, 30, 31] Adapted community integrations scales (physical and psychological integration)[32,33,34] RAS[35,36,37] Vocational Time-Line Follow-Back[38]*
Quality of Life	Generic quality of life & Health related quality of life	EQ-5D [36, 37, 38] SF-12[39,40,41] SF-6D[42] Qoli-20[43]
Healthcare, Social Services and Justice System Use and Costs	e.g. ER visits, hospital admissions, primary and specialist care	Composite checklists of service use and justice system-related events, to be combined with administrative data from several mostly site-specific provincial

	visits, social agency visits, etc. Charges, court appearances, nights in jail or remand,etc	government sources to which costs will be attached using standard costing methods

*Indicates which are instruments are administered every 3 months; all others are every six months, except Housing Quality Scale which is only at 21 months

Most of the primary data are collected via participant interviews using laptop computer-assisted interviewing and entered to a highly secured central database via wireless technology. Several strategies are being used to optimize data quality. First, instruments not previously used in this population were pre-tested in three sites using cognitive interviewing techniques (these findings are reported in a separate, forthcoming publication). Second, interviewers receive ongoing face-to-face and webinar-based training. Third, type and range of data values and mandatory entry are built in to entry fields in the database. Fourth, questions from interviewers are fielded centrally and decision rules made where necessary and circulated to all sites, followed by in-depth review at annual site visits. Fifth, data managers at each site use common data checking routines and findings shared with a multi-site data quality committee. Sixth, the authority to change data elements is restricted to a limited number of personnel and all data changes are logged electronically.

Plans to promote continued participation

Previous longitudinal studies of homeless individuals have retained 60-85% of participants over follow-up periods of 18 to 36 months. Our goal is to retain 80% of participants over 2 years of follow-up, using methods that have been proven to be effective in tracking and retaining homeless and marginalized study participants.[44, 45, 46, 47, 48, 49]

Specifically, efforts have been made to establish trust and rapport with participants at first contact and to explain the importance of their participation in follow-up interviews. At the time of enrolment, participants are asked to provide contact information not only for themselves but also for friends, relatives, service providers, and case workers who are most likely to know the participant's future whereabouts and who may be contacted in order to locate them. Participants are also asked to give consent for the social services department that administers benefit payments to disclose their updated contact information to the research team.

To facilitate tracking, participants are given a phone number to call-in for a very brief update every month that no interview is scheduled. Every three months, in addition to updating contact information, a short interview of 10 minutes is conducted asking participants about their housing and work situations since the last interview Participants receive financial compensation for all these updates as well as for interviews. Some sites

have also obtained ethics approval to offer more significant compensation for interviews of control group participants after the baseline interview, on the grounds that the opportunity cost of time is higher for TAU than for experimental group participants, who can store food provisions in their own apartment.

Participants also have the option to contact a research staff member by phone at these time points to provide updated contact information and other information. They receive the same honorarium as those contacted in-person. Participants are also encouraged to contact a research staff member whenever they move. Finally, with the consent of participants, hospitals, homeless shelters, prisons, and treatment centres can be contacted in an effort to locate those who have been lost to follow-up.

Sample Size

Although the aim is to combine participants across sites within each condition, it is recognized that (a) there will most likely be baseline differences across sites, reflecting the different demographic composition of each city; and (b) each site will want to analyze data from their site-specific arm. Consequently, the study is powered so that each site would be able to detect an effect size of 0.5 between TAU and the treatment arms for the major outcome variables. With an alpha of .05 and beta of .20, sufficient power for analysis will require 63 participants per treatment arm. Given the challenges in following a homeless population over a two year follow-up period, an attrition rate of 40% was estimated and recruitment targeted at 100 participants per arm. The exception to this recruitment target is the small pilot study in a rural region adjacent to Moncton, which draws on a matched control design with 25 individuals in each group.

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The combined sample size of approximately 2,500 (which includes additional participants in some of the site-specific arms) will also allow for the use of hierarchical linear modeling (described below) as the primary data analytic strategy.

Participants

Criteria for inclusion are:

- Legal adult status (aged 18 or older/19 in British Columbia);
- Housing status as absolutely homelessness OR precariously housed, according to definitions in Appendix B;
- The presence of a mental disorder with or without a co-existing substance use disorder, determined by DSM IV criteria on the MINI[44] at the time of entry (details in Appendix B)

Exclusion criteria are:

- Currently a client of another ACT or ICM program
- No legal status as a Canadian citizen, landed immigrant, refugee or refugee claimant
- Those who are *relatively homeless* (as defined in Appendix B).

Randomization

During the initial eligibility and baseline interviews, participants are administered the MINI[50] and the MCAS[51, 52], and are asked questions about service and housing history. If a participant meets eligibility criteria, informed written consent is obtained by the interviewer and he or she is enrolled in the study. Based on an algorithm (see Appendix D) that includes information about diagnosis, social functioning and service use, the participant is assigned to the high-need or moderate-need condition. (this allocation can be modified if relevant information becomes known within a month that changes the level of need, as determined by a central review panel) Randomization is performed via computer by the central data gathering centre, using adaptive randomization procedures.[53] The decision is immediately sent to the interviewer's laptop at the completion of the session. This approach to randomization continually changes the probability of being assigned to each group, depending on the number of participants in each. Because each arm of the trial has a maximum of 100 participants, adaptive randomization better insures balance between the groups than strict randomization. Block randomization was considered infeasible, as it is desirable for participants to know their group assignment immediately after the interview; using block randomization, they would have to wait until enough people are enrolled to complete the block, which could take a few weeks.

Interventions

Housing First as defined in the Pathways to Housing and Street to Homes approaches creates a recovery-oriented culture that puts participant/tenant choice at the centre of all its considerations with respect to the provision of housing and support services. It operates on the principle that all homeless individuals with mental illness should be offered the opportunity to live in permanent housing of varying types that is otherwise available to people without psychiatric or other disabilities. Assertive in-reach and outreach identifies and engages potential participants avoiding any coercive tactics. Rent supplements are provided so that participants pay 30% or less of their income for housing if in the private market[i]. Participants may also live in social, supported or alternative housing and in those locales the rent supplement is not required. Participants must also be provided access to furniture. Treatment and support services are offered by clinicians/providers who are based off-site. Legal rights to tenancy are in place. Whenever possible, leases are in the name of the participant, not the program, to empower participants/tenants in their recovery and autonomy, and assist them in achieving full independence. In essence, it is a housing program with supports delivered without any conditions of housing readiness such as engagement in treatment. However, participants must agree to have 30% of their income paid directly as rent and to be visited in their unit a minimum of once a week by program staff for a length of time that is appropriate to their level of need. (In practice however, participants are not required to agree to automatic withdrawal of their rent contribution from their checks, and there is some flexibility in the frequency of visits.)The program has control over participant access to housing stock, primarily by facilitating access to rental apartments from community landlords. For housing in the private market (scattered-site), a maximum of

[i] In Canada, households expending more than 30% of before tax income on shelter are classified as being in Core Housing Need. For specific CHN criteria see http://www.cmhc-schl.gc.ca/en/corp/faq/faq_002.cfm

20% of the total units in any one building is dedicated to the program to facilitate community integration.

The service array provides support and treatment for mental illness and, where necessary, substance abuse, and differs depending upon the level of individual severity and disability. All services are individualized based upon participant need and preference, including cultural adaptations. Services are provided in the home or community. Service teams work with participants to obtain and maintain housing, promote mental and physical health and to reduce the negative impacts of substance use.

For those individuals with high needs who have not been able to access traditional housing and services, these services are provided using a modified ACT team as exemplified by Pathways to Housing and described in more detail elsewhere.[54]

For individuals with moderate needs, services are provided using ICM as exemplified by the Streets to Homes program[ii] In this model, consumers are linked primarily to one worker rather than a whole team.

Discontinuation of the intervention will occur only in exceptional circumstances when an external review panel determines that there are unmanageable safety risks.

Table 2 outlines the key features of the Housing First experimental intervention model and the unique elements of the two service delivery modalities.

Table 2. Key Features of the Experimental Intervention

Housing First Model
• Recovery oriented culture • Based on consumer choice for all services • Only requirements: income paid directly as rent; visited at a minimum once a week for pre-determined periods of follow-up supports • Rent supplements in private market: participants pay 30% or less of their income or the shelter portion of welfare • Treatment and support services voluntary - clinicians/providers based off site • Legal rights to tenancy (no head leases with agency rather than individual) • No conditions on housing readiness • Program facilitates access to housing stock • Apartments are independent living settings primarily in scattered sites • Services individualized, including cultural adaptations • Reduce the negative consequences of substance use • Availability of furniture and possibly maintenance services

[ii] The Streets to Homes program serves clients with high and moderate needs. For the purposes of this study, the focus is solely on those aspects of the program that serve clients with moderate needs.

• Tenancy not tied to engagement in treatment	
ACT - High Need	**ICM - Moderate Need**
• Recovery-oriented ACT team • Participant/staff ratio of 10:1 or less and includes a psychiatrist and nurse • Program staff are closely involved in hospital admissions and discharges • Teams meet daily and include at least one peer specialist as staff • Seven day a week, 24 hour crisis coverage	• Intensive case management for a minimum of one year once housed • Participant/staff ratio of 20:1 or less • Integrated efforts across multiple workers and agencies • Workers accompany participants to appointments • Centralized assignment and monthly case conferences • Seven day a week, 12 hours per day coverage

The elements described above define the program model from which fidelity is being measured, using a new Housing First scale[54] developed during the formative evaluation phase of this study. It is based upon the Housing First logic model and draws upon previous fidelity measures of recovery-oriented assertive community treatment and supportive housing. It will be completed following annual site visits by a team of external assessors who observe team meetings, review documentation and charts and interview staff and participants. It is recognized that there may be justifiable deviations from complete fidelity due to tailoring to local conditions. The third arm, site-specific, interventions have unique, but complementary attributes which will be described more fully in reports of the comparisons within each city. The interventions are delivered by 12 existing service agencies who were the successful applicants from each of the five pre-selected cities to a request for proposals that was issued by the Mental Health Commission of Canada (MHCC). The agencies had to demonstrate their ability to hire, train and supervise staff for the housing and support teams and be financially accountable in the 6 month start-up period. Technical assistance and training on the Housing First intervention is provided on an ongoing basis by a centralized team of experts. Fidelity visits and qualitative interviews are conducted as a part of an extensive process evaluation (Macnaughton E, Goering P, Nelson G. Using Mixed Methods within the At Home/Chez Soi Housing First project: A strategy to evaluate the implementation of a complex population health intervention for people with lived experience of homelessness and mental illness. Under review, CJPH).

Usual Care. In each city, the housing intervention(s) will be compared to TAU. The intent is to compare a complex new service delivery approach to the "real life" experience that exists in current systems of care. This means that there will be no active intervention introduced by the study for the TAU group. "Usual care" does not mean "no

care;" it is what people would normally get if this project did not exist. It is recognized that some individuals in the TAU group may over time, through new or existing programs, access some of the same components that make up the housing intervention. It is also likely that the usual care service patterns will differ across cities. This unpredictable mix of service packages is a phenomenon of interest. It is measured through the common protocol and included in the analysis of process and outcomes.

Outcomes

The key outcome domains for measuring the effectiveness and cost effectiveness of the intervention are those that have consistently been found to be relevant in studies of housing interventions for individuals with mental health issues. These are listed in Table 1. As is acknowledged in the guidelines for evaluations of complex interventions,[18] more than one outcome is needed to reflect the multiple effects that are expected. The primary outcomes for assessment of effectiveness are housing stability (as defined by a joint function of number of days housed and number of moves[55]) and social functioning; secondary outcomes include mental and physical health status, community integration, and quality of life. For the economic analyses, system use and costs will be used to calculate the costs of improvements in the primary outcomes of quality of life and days housed. . Note that our focus here is on outcomes that will be informed by cross-site or multi-site data. A complementary set of outcomes will be examined through site-specific analyses, with similar analytic methods.

Statistical Analyses

Within each of the high- and moderate-need groups, participant data will be clustered within site, and over time. Missing data are expected due to missed appointments, drop-outs, and death. One technique to deal with missing data when the outcome is continuous, is hierarchical linear modeling (HLM; also called random effects regression, latent growth curve analysis, and many other names).[56] In brief, a regression line is fitted to each person's data, resulting in two parameters: a slope and an intercept, and the analysis focuses on variables that affect these. A minimum of three data points are necessary to fit a straight line, in order to give an estimate of the error of the fit. If there are more than three data points, more complex lines can be fitted (e.g., quadratic, cubic), which may better approximate the actual trajectories of change.

We do not anticipate differences in the intercept within each site, as randomization is expected to balance out baseline differences between the groups. However, there may be differences in the intercepts between sites, reflecting differences within the client populations served in each city. We anticipate that the primary factor affecting the slope (i.e., the rate of change of the outcome measure) will be group membership (i.e., housing intervention or TAU). If there is any significant unexplained variance after baseline differences and group membership have been accounted for, we can look for other factors influencing the slope, such as gender, age, amount of time spent homeless, diagnosis, and so forth. Another analytic option that will be considered is generalized estimating

equations (GEE),[57] which can also accommodate clustered, serially correlated data with missing values. The choice of techniques will be based on the nature of the data and the research question.

The analysis plan will combine the TAU groups within need level and across sites. However, it may turn out that the demographic characteristics of participants and available treatments differ so widely from city to city that this will not be possible. In that case, it will be necessary to compare each treatment group to its site-specific TAU group.

There will be an interim analysis using one year follow-up data, with the final analyses based on the two year data. In order to preserve an alpha level of .05, the one year analyses will use a nominal critical value of .01, and the two year analyses will use .04

There are no universally accepted methods for dealing with missing data; the only consensus is that sensitivity analyses should be conducted using different methods and comparing the results. In this study, data can be missing at four levels – individual items within instruments, the instruments themselves, specific appointment or data points, and people, due to loss to follow-up or death. We do not expect many individual items to be missing, as most of the instruments will be computer-administered. However, people may refuse to answer a specific question. In such cases, we will either follow the recommendations for prorating (if any) of the scale developer or use multiple imputation. If an instrument or appointment is missed, we will attempt to gather the information at a later visit. Irregular timing of instruments administered multiple times is not a problem for HLM, as it can account for this in deriving the slope for each person. Drop-outs and deaths, though, are a different matter. We cannot assume that these data are missing at random or missing completely at random,[58] which is an assumption of most imputation methods. If there are at least three data points for these people, we will analyze them separately to determine if their slopes differ significantly from those of people who remained in the study. If they do not, we will be somewhat more comfortable including them in the analyses; otherwise, they will need to be analyzed separately. As previously noted, though, we will analyze the missing data in a number of ways, including HLM, multiple imputation, and last observation carried forward.

The cost-effectiveness analysis (CEA) will be conducted using net benefit regression.[59] The regression framework allows the implementation of the statistical plans described above. Furthermore, the net benefit regression framework features parametric and non-parametric options to characterize uncertainty in the CEA data.[60] In addition to incremental net benefit by willingness to pay curves, we will also present our results using cost-effectiveness acceptability curves (CEACs) and scatterplots on the cost-effectiveness plane. Net benefit regression has been used to analyze the cost-effectiveness of various programs for study participants such as those in our study.[61]

Data access

Quantitative data is entered directly into laptops configured specifically for the project and maintained by Health Diary, a contracted service provider who will manage data

storage for the study in an off site centralized server with high levels of physical and network security. No data are stored on the hard drive and after entry hard copies are kept in secure storage at each site.

Access to the data is limited to authorized users only, using a multi-level permissions protocol that specifies roles and types of data access using a need-to-know principle. Contractual documents state that the central dataset is the property of and under the control of the Mental Health Commission of Canada to ensure access for all members of the national and local research teams. After the project is complete investigators will be able to access all or any part of the dataset for additional analyses, contingent upon appropriate Research Ethics Board approvals.

ETHICS AND DISSEMINATION

This study has been registered with the International Standard Randomised Control Trial Number Register and assigned ISRCTN42520374. Research Ethics Board (REB) approvals have been received from universities or healthcare institutions in each of the five sites (a total of 10 institutions, mostly universities). Additionally, we have REB approval from the university-affiliated teaching hospital in which the coordinating centre is based to conduct secondary analyses and move the data across provincial lines and store them in a central, secure location.

A study of this nature raises ethical issues not faced by more traditional interventions, such as medications or psychotherapy. These include the possibility of harm to the participants, research staff, and clinical personnel, due to the nature of the participants' psychiatric problems and their living situations. Analogous to the Data Safety Monitoring Boards which are established in trials of medications, the At Home/Chez Soi Project has set up a Safety and Adverse Events Committee, composed of representatives from the national research group, participants, clinical staff, and an ethicist.[62] It is charged with receiving and reviewing reports regarding any serious events associated with the project.

The results of the multi-site analyses of outcomes at 12 months and two years will be reported in a series of core scientific journal papers. Extensive knowledge exchange activities with non-academic audiences will occur throughout the duration of the project.

AUTHOR'S CONTRIBUTIONS

PG and JB conceived the study. CA and DS lead the design of the quantitative common protocol with the involvement of all authors. SH, EL, TA, JD and JS lead the design of site specific components. All authors, including JK and DZ, participated in the preparation of the manuscript by providing comments to drafts written by PG and DS and reading and approving the final version.

FUNDING STATEMENT

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COMPETING INTERESTS STATEMENT
None of the authors have competing interests.

Appendix A

Description of Site-Specific Interventions

The third arm intervention in Toronto combines a Housing First philosophy with an anti-racism/anti-oppression framework and practice which has been developed to engage and treat people from racialized groups suffering from mental illness and addictions. The anti-racism/anti-oppression framework, developed by the Toronto mental health agency Across Boundaries, is built on three core values: that racism and oppression have profound negative effects on health and mental health; that clients need to heal in ways that are meaningful and relevant to them; and that racism and oppression can occur at individual and system levels and that intervention is needed at both levels.

The Moncton site includes a small pilot study in which the effectiveness of HF + ACT is being evaluated using a quasi-experimental design in the Southeastern rural region of New Brunswick. For the study, 25 participants who are living in Special Care Homes or with their families or who are homeless have been recruited to receive HF + ACT services. Subsequent to this recruitment, a control group of 25 participants is also being recruited from the mental health clinic. The two groups are being matched in pairs on the variables of sex, age, and living situation at study entry.

Winnipeg's third arm intervention is focused on the Aboriginal experience. The intervention is delivered by Aboriginal Health and Wellness, a primary health care centre that provides service to Aboriginal peoples in Winnipeg's inner city. Key components include a drop-in centre as well as educational, employment and life skills training. Services are holistic and culturally-based, using both contemporary and traditional philosophies of the Medicine Wheel and the universal principles of sharing, caring, kindness, humility, trust, honesty and respect. These principles make up the Seven Sacred Teachings and all of these principles exist within the Medicine Wheel or the Circle of Life.

In Vancouver the congregate housing and support intervention consists of housing provided in a building with 100 self-contained units with private bathrooms. Kitchenettes are not included in the individual units. However, shared meal and amenity spaces are provided with meals offered on site three times per day. Support staff include a psychiatrist, a general practice physician, a licensed practical nurse, a registered nurse, a pharmacist, a peer employment coordinator, two social workers/case managers, two peer support workers, three mental health workers, and a team leader. In addition, one staff person is present at all times to oversee the secure entrance into the building. A number of therapeutic and recreational activities are also offered including: acupuncture, art therapy, a nutritional program, a Health & Wellness group, a Seeking Safety group, a 16-Steps to Recovery group, yoga as well as other sports activities. Individual and/or group counseling is also available on site.

In Montreal, moderate need participants are randomized to receive ICM services either from an institutional provider or from a non-profit, community-based provider.

Institutional provider staff are unionized and subject to a significant number of institutional rules that both protect and constrain staff and thus may have an impact on the way the intervention is delivered, compared to the non-profit. In addition the institutional provider is more costly due to higher wage rates and greater administrative oversight. Participants assigned to either of these groups are also invited to participate in a randomized trial of the Individual Placement and Support (IPS) model of supported employment. Several randomized trials demonstrate that IPS is more effective than other approaches at helping people with severe mental illness obtain competitive jobs.[63] No published trial of IPS, however, has evaluated its effectiveness specifically in the context of a Housing First type of intervention for homeless people with mental illness.

Appendix B

Definitions of Inclusion Criteria

Absolute Homelessness: Homelessness refers to those who lack a regular, fixed, physical shelter. This (conservative) definition is known as *absolute* homelessness according to the United Nations, and includes those who are living rough in a public or private place not ordinarily used as a regular sleeping accommodation for a human being (e.g., outside, on the streets, in parks or on the beach, in doorways, in parked vehicles, squats, or parking garages), as well as those whose primary night-time residence is a supervised public or private emergency accommodation (e.g., shelter, hostel).[iii] Specifically, being homeless is defined as currently having *no fixed place to stay for more than seven nights and little likelihood of obtaining accommodation in the upcoming month*[iv] or being discharged from an institution, prison, jail, hospital with no fixed address.

Precariously Housed: This refers to people whose primary residence is a Single Room Occupancy (SRO), rooming house, or hotel/motel. In addition, precariously housed individuals in the past year have had two or more episodes of being absolutely homeless, as defined above, in order to meet the criteria for inclusion.

Relatively Homeless. This includes people whose regular housing fails to meet basic standards, such as (i) living in overcrowded or hazardous conditions, (ii) those *at risk* of homelessness, such as people who reside informally/non-permanently with friends or relatives (e.g., doubling-up, couch surfing); (iii) those *in transition* (e.g., women, youth fleeing to transition houses/shelters from domestic abuse); (iv) those who are *temporarily* without a dwelling (e.g., home lost for a relatively short period of time due to disasters such as a fire, or a change in economic or personal situation such as marital separation, or job loss; and (v) those living in long-term institutions.

Serious mental disorders are defined by diagnosis, duration and disability using observations from referring sources, indicators of functional impairment, history of recent psychiatric treatment and current presence of eligible diagnosis as identified by the MINI (major depressive, manic or hypomanic episode, PTSD, mood disorder with psychotic features, psychotic disorder).

[iii] The UN definition of homelessness originally included individuals in transition using transition homes and hostels. The present project modified the definition to exclude this subgroup.

[iv] Definition adopted from Tolomiczenko & Goering (2000). Gender differences in legal involvement among homeless shelter users.

Appendix C

At Home/Chez Soi – Core Measures: References, Descriptions and Psychometrics

NOTE – the psychometric values reported here reflect the relevant literature in late 2008/early 2009.

Instrument and Relevant Published References	Psychometric Information
Mini International Neuropsychiatric Interview 6.0 (MINI 6.0) Sheehan, D.V., Lecrubier, Y., Harnett-Sheehan, K., Janavs, J., Weiller, E., Bonora, L.I. , Keskiner, A., Schinka, J., Knapp, E., Sheehan, M.F., Dunbar, G.C.. (1997). Reliability and validity of the MINI International Neuropsychiatric Interview (M.I.N.I.): According to the SCID-P. Eur Psychiat, 12:232-241. Lecrubier Y., Sheehan, D., Weiller, E., Amorim, P., Bonora, I., Sheehan, K., Janavs, J., Dunbar, G. (1997). The MINI International Neuropsychiatric Interview (M.I.N.I.) A Short Diagnostic Structured Interview: Reliability and validity according to the CIDI. Eur Psychiat, 12: 224-231. Sheehan, D.V., Lecrubier, Y., Harnett-Sheehan, K., Amorim, P., Janavs, J., Weiller, E., Hergueta, T., Baker, R., Dunbar, G. (1998). The Mini International Neuropsychiatric Interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview. J. Clin Psychiatry, ;59(suppl 20):22-33. Amorim, P., Lecrubier, Y., Weiller, E., Hergueta, T., Sheehan, D. (1998). DSM-III-R psychotic disorders: procedural validity of the Mini International Neuropsychiatric Interview (M.I.N.I.). Concordance and causes for discordance with the CIDI. Eur Psychiat, 13:26-34.	MINI website www.medical-outcomes.com/indexSSL.htm): "The M.I.N.I. has been validated against the much longer Structure Clinical Interview for DSM diagnoses (SCID-P) in English and French and against the Composite International Diagnostic Interview for ICD-10 (CIDI) in English, French and Arabic. It has also been validated against expert opinion in a large sample in four European countries (France, United Kingdom, Italy and Spain). According to researchers at the National Institute of Mental Health's (NIMH) Division of Clinical and Treatment Research, the M.I.N.I. is a fully validated and more time-efficient alternative to the SCID-P and CIDI." Sheehan et al. (1998) Validity Concordance of MINI-CR with SCID-P • MINI diagnoses characterized by good or very good kappa values with only one value (for current drug dependence) below 0.5. • Sensitivity 0.70 or greater for all but three diagnoses (dysthymia, OCD and current drug dependence) • Specificities and negative predictive values 0.85 or higher across all diagnoses • PPVs 0.75 or higher for major depression, lifetime mania, panic disorder, lifetime agoraphobia, lifetime psychotic disorder, anorexia, and PTSD • PPVs 0.60-0.74 for current mania, GAD, current agoraphobia, OCD, current alcohol dependence, lifetime drug dependence, and bulimia • PPVs 0.45-0.59 for dysthymia, current psychotic disorder, lifetime social phobia, and current drug dependence

Instrument and Relevant Published References	Psychometric Information
Description (with information from www.medical-outcomes.com): The MINI is a short, structured diagnostic interview that was developed in 1990 by psychiatrists and clinicians in the United States and Europe for DSM-IV and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, the MINI is often used for psychiatric evaluation and outcome tracking in clinical psychopharmacology trials and epidemiological studies. In this study, we will be using the modules for diagnosis of major depressive episode, suicidality, manic and hypomanic episodes, post-traumatic stress disorder, alcohol dependence/abuse, substance dependence/abuse, psychotic disorders, and generalized anxiety disorders.	Concordance of MINI-CR with CIDI • Kappa values good or v good for all diagnoses (only simple phobia and GAD below 0.50) • Sensitivity 0.70 or greater for all but four diagnoses (panic, agoraphobia, simple phobia, lifetime bulimia) • Specificity 0.70 or greater for all • NPV's very good (0.88 or higher) • PPVs 0.75 or higher for major depression, alcohol and drug dependence, and panic disorder • PPVs 0.60-0.74 for lifetime manic episode, agoraphobia, and simple phobia • PPVs 0.45-0.59 for current manic episode, social phobia, and lifetime bulimia • PPV poor (0.34) for GAD • For psychotic disorders, concordance was very good Reliability • Kappas listed by 23 diagnoses • Interrater kappas all above 0.75 and 70% 0.90 and higher • Test/Retest kappas 61% of values above 0.75 (one – for current mania – below 0.45) • Test/Retest was done using a second interviewer for the retest
Modified Colorado Symptom Index (CSI) Shern, D.L., Wilson, N.Z., Saranga Coen, A., Patrick, D.C., Foster, M., Bartsch, D.A., Demmler, J. (1994). Client outcomes II: Longitudinal client data from the Colorado Treatment Outcome Study. Milbank Q, 72(1), 123-148. Boothroyd, R.A., and Chen, H.J. (2008). The psychometric properties	Reliability • In Boothroyd (2008), with a sample of 3874 adult Florida Medicaid respondents, test-retest reliability r=0.71, internal consistency alpha=0.92. • In Conrad et al. (2001), with a sample of 1381 homeless adults getting treatment for substance abuse or MH issues in eight study sites, test-retest was r=0.79, internal consistency across study sites was high (alpha = 0.90) Cut-points (Boothroyd, 2008) • Using 30 as a clinical cut-off score denoting the need for further psychiatric

Instrument and Relevant Published References	Psychometric Information
of the Colorado Symptom Index. Journal of Administration and Policy in Mental Health and Mental Health Services Research, 35(5), 370-378. Conrad, K.J., Yagelka, J.R. Matters, M.D., Rich, A.R., Williams, V., and Buchanan, M. (2001). Reliability and validity of a modified Colorado Symptom Index in a national homeless sample. Mental Health Services Research, 3(3), 141-153. Greenwood, R.M., Schaefer-McDaniel, N.J., Winkel, G. Tsemberis, S. (2005). Decreasing psychiatric symptoms by increasing choice in services for adults with histories of homelessness. Am J Commun Psychol, 36(3/4), 223-238. Description (with information from Greenwood et al., 2005 and Conrad et al., 2001): This 14-item instrument assesses the presence and frequency of psychiatric symptoms participants experienced within the past month (e.g. "how often have you felt tense, nervous, worried or afraid"). Responses are coded on a 5-point likert scale with answer choices ranging from 0 (not at all) to 4 (at least every day). A higher score indicates a higher level of psychiatric symptomatology.	assessment, sensitivity was 0.76 and specificity was 0.68. • Using 30 as a cut-off PPV (proportion of individuals with positive assessment who actually have the illness) was 0.32 and NPV (proportion of individuals with a negative assessment who do not have the illness) was 0.93. • An ROC curve analysis shows that the CSI is a "fair to good" discriminator of individuals with psychiatric disabilities. Validity • Boothroyd (2008) reported that correlation between respondents' CSI scores and the reported need for assistance (i.e. functioning) was 0.50 suggesting good convergent validity with SF12. • Conrad et al. (2001) reported positive correlations with the Brief Symptom Index providing evidence of content validity.
Global Assessment of Individual Need – Substance Problem Scale (GAIN SPS) Dennis, M.L., Chan, Y., Funk, R.R. (2006). Development and validation of the GAIN Short Screener for Internalizing, Externalizing and Substance Use Disorders and Crime/Violence Problems among adolescents and adults. American Journal on Addictions, 15, 80-91.	All info from GAIN Overview from http://www.chestnut.org/LI/GAIN/index.html Reliability/Validity • Internal consistency for Substance Problem Scale (Lifetime) is 0.90 • For GAIN-I (full instrument) studies with adults and adolescents have found good reliability in test/retest situations on days of use and symptom counts (r = .7 to .8), as well as diagnosis (kappa of .5 to .7). Self-reports were consistent (kappa in the .5 to .8 range) with parent reports, on-site urine and saliva testing, and laboratory-based EMIT and GC/MS urine testing.

Instrument and Relevant Published References	Psychometric Information
Dennis, M. L., White, M. K., Titus, J. C., & Unsicker, J. I. (2006). Global Appraisal of Individual Needs (GAIN): Administration guide for the GAIN and related measures (Version 5). Bloomington, IL: Chestnut Health Systems. Retrieved April 27, 2009 Description (information from GAIN website): The GAIN Substance Problem Scale is a 16-item subscale of the larger Global Appraisal of Individual Needs (GAIN) which is a standardized biopsychosocial instrument that integrates research and clinical assessment for people presenting to substance abuse treatment or other behavioral health treatment. The GAIN SPS is composed of 16 recency items (e.g. "when was the last time you…?"): 7 based on DSM-IV criteria for dependence, 4 for abuse, 2 for substance-induced health and psychological problems, and 3 on lower severity symptoms of use (hiding use, people complaining about use, weekly use). Higher scores represent greater severity of drug problems. The scale includes physiological, psychosocial and social criteria, as well as an item on comorbid use with drugs that is likely to exacerbate the other problems.	• Self-reports on the GAIN were found to be consistent with a multi-method estimate based on any self-report or positive urine or saliva test for any drug (kappa = .56), cocaine (kappa = .52), opioids (kappa = .55), and marijuana (kappa = .75), with no one method being superior across all drugs. • Using discriminant analysis, the GAIN scales could also reliably predict independent and blind staff psychiatric diagnoses of co-occurring psychiatric disorders including ADHD (kappa = 1.00), Mood Disorders (kappa = .85), Conduct Disorder/Oppositional Defiant Disorder (kappa = .82), Adjustment Disorder (kappa = .69), or the lack of a non-substance use diagnosis (kappa = .91) and to discriminate the primary other disorders across these conditions (kappa = .65) Cut-points • 0 mild / 1-9 moderate / 10-16 severe
Multnomah Community Ability Scale (MCAS) Barker S., Barron N., McFarland B.H., et al. (1994). A community ability scale for chronically mentally ill consumer. Community Ment Hlt J, 30, 459-472. Dickerson, F.B., Origoni, A.E., and Pater, A., Friedman, B.K., Kordonski, W.A. (2003). An expanded version of the Multnomah Community Ability Scale: anchors and interview probes for the assessment of adults with serious mental illness. Community Ment	Dickerson et al. (2003) Inter-rater Reliability for MCAS with Interview Probes • ICC was 0.96 for the Total Score, 0.91 for the Interference with Functioning subscale, 0.99 for the Adjustment to Living subscale, 0.87 for the Social Competence subscale, and 0.96 for the Behavioral Problems subscale. Barker et al. (1994) Inter-rater reliability for original scale • ICC was 0.85 for Total Score, 0.70 for the Interference with Functioning subscale, 0.75 for the Adjustment to Living subscale, 0.75 for the Social

Instrument and Relevant Published References	Psychometric Information
Hlt J, 39, 131-137. Description (modified from MCAS website – www.multnomahscale.com): This 17-item scale was first created in 1983 by community mental health case managers. It measures degree of functional ability through seventeen indicators. The indicators are rated on a 5 point scale and are grouped into four sections: 1. Health: Physical, mental and emotional symptoms that interfere with daily functioning (5 indicators) 2. Adaptation: Critical abilities for coping with serious mental illness and surviving in the community (3 indicators) 3. Social Skills: How people with psychiatric disabilities interact with others (5 indicators) 4. Behavior: Personal actions that affect community tenure and positive service outcomes (4 indicators) Anchors and interview probes were developed in 2003 by Dickerson et al.	Competence subscale, and 0.78 for the Behavioral Problems subscale. Test-retest reliability for original scale • ICC was 0.83 for Total Score, 0.77 for the Interference with Functioning subscale, 0.82 for the Adjustment to Living subscale, 0.71 for the Social Competence subscale, and 0.70 for the Behavioral Problems subscale • Cronbach's alpha was 0.90 suggesting good internal consistency Validity • 17 MCAS items were compared with "criterion" variables related to state mental hospital use and were found to correlate highly with these variables. • Found that the instrument is predictive of subsequent state and local hospital admissions (instrument has substantial p< .001 prospective predictive validity – chi-squared test for trend greater than 6.05 with one degree of freedom, p=0.1) Cut-points [excerpt from Toronto site proposal] "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 indicating severe disability, 48 to 62 moderate disability and 63 to 85 indicating little disability. Other investigators similarly report MCAS ratings in the 40s for inpatients [19], in the 50s for ambulatory patients receiving a high level of community support [20], and in the 60s for clients in lower intensity outpatient care [19]. In the Community Mental Health Evaluation Initiative (CMHEI), mean MCAS scores at intake to ACT and ICM were 50.7 (6.6) and 50.9 (8.0) respectively, with approximately 99% of ACT participants and 91% of ICM participants having MCAS scores below 62 (Carolyn Dewa, personal communication)".
EQ-5D The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.	Extensive general psychometric information is available at http://www.euroqol.org/ Most relevant to our study is from Lamers et al. (2006) Utilities

Instrument and Relevant Published References	Psychometric Information
Brooks R (1996). EuroQol: the current state of play. Health Policy 37(1):53-72. Lamers, L.M., Bouwmans, C.A.M., van Straten, A., Donker, M.C.H., Hakkaart L. (2006). Comparison of EQ-5D and SF-6D utilities in mental health patients. Health Econ, 15, 1229-1236. Description (with information from EQ-5D user guide): EQ-5D is a self-administered standardized measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal. It provides a simple descriptive profile and single index value for health status. The EQ-5D descriptive system has 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems and severe problems. The visual analog scale records the respondent's self-rated health on a vertical, visual analogue scale where endpoints are labeled "best imaginable health state" and "worst imaginable health state". This information can be used as a quantitative measure of health outcome as judged by the individual respondents.	• Dutch multi-site randomized trial of 616 patients with mood and/or anxiety disorders. • EQ-5D and SF-6D utilities differed significantly between patients of adjacent severity groups. • Mean utilities increased from 0.51 at baseline to 0.68 at 1.5 years follow-up for EQ-5D and from 0.58 to 0.70 for SF-6D. For all severity sub-groups, the mean change in EQ-5D and SF-6D utilities was statistically significant. Standardized response means were higher for SF6D utilities. • Both EQ-5D and SF-6D discriminated between severity sub-groups and captured improvements in health over time but EQ-5D resulted in larger health gains and lower cost-utility ratios, especially for the subgroup with the highest severity of mental illness.
SF-12 Health Survey 1.0 (SF-12 1.0) Ware J.E., Kosinski M., Keller, S.D. (1996). A 12 Item short form health survey: Construction of scales and preliminary tests of reliability and validity. Med Care, 34, 220-233. Larson, C.O. (2002). Use of the SF-12 to measure the health of homeless persons. Health Serv Res, 37(3), 733-750. Lamers, L.M., Bouwmans, C.A.M., van Straten, A., Donker,	Extensive general psychometric information is available at http://www.qualitymetric.com/ Of relevance to our study is from Larson (2002). This study evaluated construct validity of the SF12 among users of a homeless day shelter. The study compares SF12 scores from a sample of homeless persons to scores from a sample of general population. Reliability • The internal consistency estimates of summary scores were calculated using Cronbach's alpha. Within the homeless sample these were found to be 0.82

Instrument and Relevant Published References	Psychometric Information
M.C.H., Hakkaart L. (2006). Comparison of EQ-5D and SF-6D utilities in mental health patients. Health Econ, 15, 1229-1236. Description (with information from an Australian Health Outcomes Collaboration instrument review – http://chsd.uow.edu.au/ahoc): This 12-item self-report measure of generic health status is a shorter version of the SF-36 Health Survey designed to reproduce the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. It has an administration time of 2 minutes. There are 2 questions concerning physical functioning, 2 questions on role limitations because of physical health problems, 1 question on bodily pain, 1 question on general health perceptions, 1 question on vitality, 1 question on social functioning, 2 questions on role limitation because of emotional problems, and 2 questions on general mental health (psychological distress and psychological well-being).	for physical health and 0.79 for mental health. Estimates for the general population were found to be 0.78 for physical health and 0.73 for mental health. Validity • Construct validity was assessed by method of extreme groups where multivariate analysis of variance determined if SF12 summary scores varied for individuals who differed in self-reported clinical symptoms and medical conditions. Four to 10 point differences in physical health (PCS12) and 5-11 point differences in mental health (MCS12) were found between those who reported acute symptoms and medical conditions and those who did not. A 13 point difference in PCS12 scores and a 7-16 point difference in MCS12 scores were found for those who reported none or few to several symptoms or conditions. • Convergent validity was assessed by correlating SF12 summary scores with the subscales. Summary scores and subscales yielded satisfactory convergent validity coefficients that ranged from 0.62 to 0.88. • Ware et al. (1996) found that SF-12 PCS and MCS scores correlate 0.95 and 0.96 with their SF-36 counterparts.
Quality of Life Index – 20 item (QoLI-20) Lehman, A.F. (1996). Measures of quality of life among persons with severe and persistent mental disorders. Soc Psych Psych Epid, 31, 78-88. Uttaro, T., Lehman, A. (1999). Graded response modeling of the Quality of Life Interview. Eval Program Plann, 22, 41-52. Lançon C., Auquier P., Toumi M., Launois R., Llorca PM., Lehman	Lancon et al. (2000) • Scores for nine subjective dimensions were uniformly distributed. Discrimination index ranged from 0.87 to 0.96. Objective items, had discrimination indices varying from 0.79 to 0.94. • Item scores were highly correlated with scores on subscale to which that item contributes (0.6 upwards) Lehman, A.F. (1996). • Internal consistency scores (using Cronbach's alpha) for the original scale range from 0.79 to 0.88 for the subjective scales, and from 0.44 to 0.82 for the objective scales.

Instrument and Relevant Published References	Psychometric Information
A., Bebbington P. - English version of "Evaluation de la qualité de vie des patients schizophrènes : validation de la version courte de la QoLI". Encephale 2000; 26 (4) : 11-16. Description (with information from Lehman, 1996) The original scale was designed to assess the quality of life of people with severe and persistent mental illness. It is a structured self-report interview, conducted by a trained non-clinical interviewer, and elicits participants' ratings of their quality of life. There are 7 subjective scales (living situation, everyday activities, family, social relationships, finances, safety, and satisfaction with life in general) and 4 objective scales (everyday activities, enough money, family contacts, and contacts with friends). The 20-item version was developed by Uttaro et al. (1999) using item-response theory.	• Subjective scale alpha coefficients: living situation (0.83), everyday activities (0.83), family (0.88), social relationships (0.71), finances (0.84), safety (0.84) and satisfaction with life in general (0.74) • Objective scale alpha coefficients: everyday activities (0.62), enough money (0.78), family contacts (0.69), contacts with friends (0.72) Uttaro, T. et al. (1999) • 20-item version was derived using item-response theory. Internal consistency was retained.
Recovery Assessment Scale – 22 item (RAS-22) Giffort D., Schmook, A., Woody, C., Vollendorf, C., & Gervain, M. (1995). Construction of a scale to measure consumer recovery. Springfield, IL, Illinois Office of Mental Health. Corrigan, P.W., Giffort, D., Rashid, F., Leary, M., & Okeke, I. (1999). Recovery as a psychological construct. Community Ment Hlt J, 35, 231-240. Corrigan, P.W., Salzer, M., Ralph, R., Sangster, Y., & Keck, L. (2004). Examining the factor structure of the Recovery Assessment Scale. Schizophrenia Bull, 30, 1035-1042.	Corrigan et al. (2004) • Alphas for factors ranged from 0.74 to 0.87: personal confidence and hope (0.87), willingness to ask for help (0.84), goal and success orientation (0.82), reliance on others (0.74), no domination by symptoms (0.74) Reliability • Cronbach's alpha 0.93 in initial testing • Respondents in initial testing completed the scale twice within 14 days. Pearson Product Moment Correlation was r=0.88 (n=35) Validity • RAS total score positively correlated with other measures: Rosenberg Self-Esteem Scale (r=0.55), Empowerment Scale Self-orientation (0.71), Social Support Questionnaire – short version (0.48), Quality of Life Interview – subjective component (0.62), Brief Psychiatric Rating Scale – expanded version (0.44)

Instrument and Relevant Published References	Psychometric Information
Residential Follow-Back Calendar Tsemberis, S. McHugo, G., Williams, V., Hanrahan, P. and Stefancic, A. (2007). Measuring homelessness and residential stability: The Residential Time-Line Follow-Back Inventory. J Commun Psychol, 35(1), 29-42.	• Test-retest reliability high, with coefficients ranging from 0.80 to 0.91 • Concurrent validity good, assessed by associations between agency and self-reports, with coefficients ranging from 0.84 to 0.92
Vocational Time-Line Follow-Back Latimer, E.A., Lecomte, T., Becker, D.R., Drake, R.E., Duclos, I., Piat, M., et al. (2006). Generalisability of the individual placement and support model of supported employment: results of a Canadian randomised controlled trial. Brit J Psychiatry, 189, 65-73.	The VTLFB was adapted for our study from an instrument developed by Dr. Eric Latimer (Montreal site lead investigator) for earlier studies of the outcomes of a vocational intervention – Individual Placement and Supports (IPS). See reference.
Perceived Housing Quality Items Tsemberis, S., Rogers, E.S., Rodis, E., Dushuttle, P., Skryha, V. (2003). Housing satisfaction for persons with psychiatric disabilities. J Community Psychol, 31(6), 581-590. Toro, P.A., Bellavia, C.W., Daeschler, C.V., Wall, D.D., Smith S.J. (1997). Evaluating an intervention for homeless persons: results of a field experiment. J Consult Clin Psychol, 65(3), 476-484.	For this instrument relevant items were selected from existing questionnaires for which little psychometric information is available. Some items were pre-tested in our study population.
Health, Social and Justice Service Use Inventory (HSJSU) Ambulatory Health Care Record (AHCR) Guerriere, D.N., Ungar, W.J., Corey, M., Croxford, R., Tranmer, J.E., Tullis, E., Coyte, P.C. (2006). Evaluation of the ambulatory and home care record: Agreement between self-reports and administrative data. Int J Technol Assess, 22(2), 203-210. Utilization and Cost Inventory (UAC-I) Kashner, M.T., Stensland,	The HSJSU was developed specifically for this study because no single health services use questionnaire was identified in the literature that was suitable for our research questions and study population. We used seven existing instruments (as per references) to ensure comprehensive coverage of items and then added items that were relatively unique to our study population (e.g. food bank service use). Some of the service use items for which recall was anticipated to be a problem were pre-tested and piloted for the study.

Instrument and Relevant Published References	Psychometric Information
M.D., Lind, L., Wicker, A., Rush, A.J., Golden, R.M., et al. (2009). Measuring use and cost of care for patients with mood disorders. Medical Care, 47(2), 184-190. Cornell Service Index (CSI) Sirey, J., Beyers, B.S., Teresi, J.A., Bruce, M.L., Ramirez, M. Raue, P.J., et al. (2005). The Cornell Service Index as a measure of health service use. Psychiat Serv, 56(12), 1564-1569. Health Service Utilization Inventory Browne, G.B., Arpin, K, Corey, P., Fitch, M., Gafni, A. (1990). Individual correlates of health service utilization and the cost of poor adjustment to chronic illness. Medical Care, 28(1), 43-58. Utilization of Hospital and Community Services Form Forchuk, C., Brown, S.A., Schofield, R., Jensen, E. (2008). Perceptions of health and health service utilization among homeless and housed psychiatric consumer/survivors. J Psychiatr Ment Hlt, 15, 399-407. Client Socio-Demographic and Service Receipt Inventory (CSSRI) Chishom, M.R, Knapp, M.R.J., Knudsen, H.C., Amaddeo, F., Gaite, L., van Wijngaarden, B. et al. (2000). Client Socio-Demographic and Service Receipt Inventory – European Version: development of an instrument for international research. Brit J Psychiatry, 177,s28-s33. Service Use Questionnaire for the Continuity of Mental Health Services (COMHS) Study of Alberta. Adair, C.E., McDougall, G.M., Mitton, C.R., Joyce, A.S., Wild, T.C., Gordon, A., et al. (2005). Continuity of care and health outcomes among persons with severe mental illness. Psychiatr Serv, 56, 1061-1069.	

Instrument and Relevant Published References	Psychometric Information
Health Service Access Items (ACC) Canadian Community Health Survey (CCHS) 2008 Questionnaire. Statistics Canada. Available at www.statcan.gc.ca/imdb-bmd/instrument/3226_Q1_V5-eng.pdf Khandor, E and Mason, K. (2007). The street health report 2007. Toronto, ON: Creative Commons Hwang, S. W. Ueng, J. J. M., Chiu, S. et al. (in press). Does universal health insurance ensure health access for homeless people? Am J Public Health.	These items were developed by the Toronto site team and are based on the sources in the references.
Community Integration Scale (CIS) Segal, S. P. & Aviram, U. (1978). The mentally ill in community based sheltered care: A study of community care and social integration. New York: John Wiley & Sons. Aubry, T. & Myner, J. (1996). Community integration and quality of life: A comparison of persons with psychiatric disabilities in housing programs and community residents who are neighbors. Can J Commun Ment Health , 15, 5-20. Chavis, D. M., Hogge, J. H., McMillan, D. W. & Wandersman, A. (1986). Sense of community through Brunswick's lens: A first look. J Commun Psychol, 14, 24-40.	Three sources of items (as referenced) for the concept of community integration were extensively pre-tested in our study population, given that many were not relevant or applicable. Little psychometric information was available for the original scales.

Appendix D

Operational Definitions for HIGH/MODERATE Need Groups

HIGH NEED:

MUST HAVE:

- a score on the MCAS of 62 or lower (functioning indicator) **AND**
- a MINI diagnosis of current psychotic disorder or bipolar disorder (MINI disorders 18, 21 or 22 on the Eligibility Screening Questionnaire) or an observation of psychotic disorder on the screener (at least 2 of Q 6-10 in Section DI) on the Eligibility Screening Questionnaire (diagnostic indicator) **AND** one of:

- YES (or don't know or declined) to item 20 on Demographics, Service & Housing History questionnaire; i.e. two or more hospitalizations for mental illness in any one year of the last five (service use indicator) **OR**

- Comorbid substance use (any of MINI disorders 23,24, 25, 26 on the Eligibility Screening Questionnaire) (substance use indicator) **OR**

- Recent arrest or incarceration YES (or don't know or declined) to item 22 on Demographics, Service & Housing History questionnaire (legal involvement indicator).

MODERATE NEED:

- All others who have met eligibility criteria but do not meet the criteria above.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5,6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	9,31
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10,11,12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7,13.20-30
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	na

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13,14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13,14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13,14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	15
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.