BMJ Open Protocol: a cluster randomised control trial study exploring stigmatisation and recovery-based perspectives regarding mental illness and substance use problems among primary healthcare providers across Toronto, Ontario

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ABSTRACT

Introduction Primary care settings are often the first and only point of contact for persons with mental health and/or substance use problems. However, staff experience and training in this area are often limited. These factors as well as a multitude of other components such as structural and systemic stigma experienced by staff can lead to clients being stigmatised, leading to poorer outcomes. By developing a comprehensive intervention for primary care staff working at community health centres (CHCs) aimed at reducing stigma towards people with mental health and substance use problems (MHSUP), we sought to test an innovative and contact-based intervention consisting of staff training, raising awareness, a recovery-focused art programme and an analysis of internal policies and procedures. All of these components can inform and support staff so they can provide better care for people who are experiencing MHSUP. CHC staff members and clients will be included in this project as active participants.

Methods and analysis This mixed-methods project will consist of repeated surveys of staff and clients, as well as in-depth, semistructured interviews with a sample of clients and staff. A cluster randomised control trial design will test the effectiveness of an antistigma intervention for CHCs in Toronto, Canada. Six CHCs—three receiving the intervention and three controls—will be included in the study. Using a variety of measures, including the Opening Minds Scale for Health Care Providers (OMS-HC), Mental Illness: Clinicians Attitudes (MICA) Scale, Modified Bogardus Social Distance Scale, Perceived Devaluation-Discrimination Scale, Discrimination Experience subscale of the Internalized Stigma of Mental Illness (ISMI) Scale and the Recovery Assessment Scale (RAS), we hope to gain a thorough understanding of staff members’ attitudes and beliefs and clients’ perceptions of staff beliefs and behaviours. In-depth interviews will reveal important themes related to clients’ experiences of stigma both within and outside the healthcare setting.

Strengths and limitations of this study

- It will be the first Canadian cluster randomised controlled trial to test the effectiveness of a standardised intervention aimed at reducing stigmatising attitudes and practices of primary care providers towards persons with mental health and substance use problems (MHSUP).
- Using a mixed-methods approach, this study will measure how both staff and clients evaluate their own ideas and beliefs about people with MHSUP. Using standardised tools, clients will also be asked to evaluate primary care staff at the health centre they frequent.
- This study may only be applicable to primary care staff at community health centres in Toronto, Canada. There are variables specific to this population and region, and therefore the effectiveness of this intervention may not be duplicated elsewhere. Further study in other regions/environments would need to be investigated.

Ethics and dissemination If demonstrated to be successful, this intervention can be used as a model for future initiatives aimed at reducing MHSUP-related stigma among healthcare providers in an organisational context. Adapting this work in other settings is a key strategic goal of this project. The project will also advance knowledge about stigma reduction and the experience of encountering stigma within a healthcare setting.

Trial registration NCT03043417; Post-results.

INTRODUCTION

Stigma towards persons with mental health problems and substance use problems (MHSUP) is well documented in Canada and can affect people in various situations.
such as within their families or in the healthcare system. By stigma we are referring to negative attitudes and behaviours experienced by people with a mental illness or substance use disorder. Stigma towards persons with MHSUP is a public health issue that can result in: (1) continuing problems in accessing resources and opportunities, for example, employment and housing; (2) social isolation due to exclusion from activities and (3) low levels of service utilisation. Stigmatisation can also increase isolation: many people with MHSUP are ostracised from their families or communities, which, in turn, can affect their ability or desire to seek appropriate services. At a structural level, stigma can result in a lack of resources, inappropriate care and barriers to healthcare access. Stigma associated with mental health and substance use plays a key role in the under-detection of such problems worldwide. It can increase stress and add to the burden of disease or disability.

Health professionals of all backgrounds and positions have been found to hold stigmatising beliefs, and evidence of stigma towards people with MHSUP has been observed in a variety of healthcare settings. Our recent research revealed that the levels of stigmatisation towards persons with MHSUP among health professionals within local community health centres (CHCs) were similar to those reported among other health workers in Canada. Stigmatising attitudes and practices among health professionals are well documented throughout the literature, and clients with MHSUP have reported stigmatising treatment from a variety of healthcare professionals. One study found that stigmatisation may result in clients being threatened with coercive treatment, being provided with insufficient information, being regarded as lacking the capacity for responsible action or being patronised and/or humiliated. In addition to healthcare professionals, other staff members at health centres can contribute to positive or negative experiences among clients. Front desk staff members act as the first point of contact for most clients, and this interaction can affect how clients perceive the treatment they receive as well as their likelihood to return to the health centre.

Community health centres

Within primary health settings, CHCs are particularly appropriate locations for addressing MHSUP and stigma. In Ontario, they offer a diverse range of interdisciplinary and holistic services and health promotion programmes that are specifically designed for vulnerable populations to eliminate barriers to accessing healthcare such as poverty, geographic isolation, ethno- and cultural-centrism, racism, sexism, heterosexism, transphobia, language discrimination, ageism, ableism and other forms of social exclusion including issues such as complex mental health… As a result of this focus, CHCs offer health promotion and outreach programmes related to housing, harm reduction, youth and food security, which are key elements for serving marginalised groups, including those with MHSUP. Studies have found that stigma in primary care creates significant barriers to care for people with MHSUP.

Despite the emphasis on accessibility and quality of care for individuals with MHSUP, previous research has identified a need among CHCs to enhance efforts to address stigma associated with MHSUP. CHC workers were found to be susceptible to stigmatisation because of their limited training in mental health and substance use issues and pressures due to high workloads. Cameron et al argued that lack of training is the main reason for the proliferation of MHSUP stigma in the context of primary healthcare, especially the lack of strategies targeting health professionals. A larger consequence of this lack of training, however, is that although 25–30% of primary care clients have MHSUP, fewer than half of such cases are detected, largely as a result of a lack of knowledge and skills.

Intervention efforts to reduce stigma

Although more research is now focusing on stigma and people with MHSUP, less is known about interventions to reduce or eliminate stigma. These interventions provide short-term benefits in terms of positive attitude and behavioural changes, although less is known about improvements in knowledge. Contact-based methods means involving people with lived experience in the intervention and ensuring staff work with this group. This method has significant promise in the field of stigma reduction, but until now only short-term benefits have been documented. Few intervention studies have employed large sample sizes and few have investigated how service users perceived stigma and behavioural change.

Specific interventions implemented across entire organisations may provide supportive environments that encourage antistigmatising practices. Other interventions may include creating safe spaces for active discussion about stigma, developing creative ways to invite healthcare practitioners to reflect on problems and share with clients who expose issues surrounding their recovery process and defining protocols to identify and address existing or potential stigmatising situations and to promote stigma-free environments, policies and practices.

Research is revealing the importance of implementing organisational recovery principles and practices that are multifaceted, locally targeted, recovery-based and fully inclusive of both consumers and providers. Recovery principles and practices generally refer to an organisation’s commitment to foster hope, engender optimism and promote meaningful living by empowering individuals to take on as much responsibility as possible. The emerging consensus is that recovery-based antistigma interventions are an intrinsic feature of any effective organisational effort designed to reduce stigma and produce meaningful change.

In a pilot study involving three CHCs, we used a socio-ecological conceptual framework to develop a comprehensive, systems-level intervention targeting stigmatising...
attitudes and practices of primary healthcare providers.\textsuperscript{32} The intervention development process followed a participatory action research approach that incorporated: (1) a multmethod mixed research process (qualitative and quantitative research); (2) a knowledge translation (KT) symposium to discuss research findings and develop an evidence-based antistigma intervention model based on agreed on guiding principles and (3) tailored implementation plans for each CHC. The pilot intervention involved developing teams of local leaders, providing innovative contact-based education, raising awareness about stigma, incorporating recovery-based arts and analysing internal policies and procedures to seek and address stigmatising language and practices. Preliminary evaluation of this pilot research revealed positive changes in stigma levels among PHC staff over the course of the project.

The current project seeks to provide more evidence on the effectiveness of this intervention. In addition to staff data, client data will also be collected to determine if clients report less stigmatising attitudes and behaviours by staff at their CHC. By conducting a randomised control cluster trial, we will be comparing the effectiveness of the intervention among six CHCs in Toronto using the same components developed in the pilot project. Using a variety of measurements (both quantitative and qualitative), we will determine if staff have increased their knowledge and awareness of MHSUP and if stigma has been reduced.

Specific hypotheses
1. Participation in the experimental group will result in a significant decrease in stigmatising attitudes among CHC staff towards individuals with MHSUP compared with the control group as measured by the Opening Minds Scale for Health Care Providers (OMS-HC).
2. Participation in the experimental group will result in a significant decrease of clients’ experiences of stigma conveyed by CHC staff compared with the control group as measured by the Perceived Devaluation-Discrimination Scale.

Secondary hypothesis
Changes in attitudes and behaviours within the experimental group will be sustained over time (3-month follow-up).

The proposed research is unique in several respects:
1. It will be the first Canadian study to rigorously evaluate a comprehensive antistigma intervention targeting CHC providers at an organisational level.
2. It will be the first Canadian cluster randomised controlled trial to test the effectiveness of a standardised intervention aimed at reducing stigmatising attitudes and practices of CHC providers towards persons with MHSUP.
3. If successful, it will yield a model for an evidence-based, standardised, validated, recovery-oriented antistigma intervention targeting CHC providers, which can be scaled up and implemented in other healthcare settings across Canada.

METHODS AND ANALYSIS
Study design
The study’s cluster randomised controlled trial design will test the effectiveness of an antistigma intervention for CHCs in Toronto, Canada. The study will include six CHCs: three receiving the intervention and three controls. The target groups include all staff members at selected CHCs, regardless of their position. The intervention will incorporate the same processes used in the pilot project as described below.

Sample
The study population will include all staff members at the six participating CHCs, as well as some of their clients with MHSUP. Participating clients with MHSUP will complete a questionnaire at four time points during the 2-year project (see figure 1). All staff members at participating CHCs will complete a questionnaire at the same four time points. All staff members will be expected to participate at each time point, regardless of when they begin employment at the CHC during the project timeline.

Staff surveys
All staff members at each CHC are expected to participate at all time points of data collection. This includes new staff members who may not have provided data at the initial time points. Based on the lists of staff members who have been provided by each CHC, we expect that approximately 490 staff members will participate.

Client surveys
We will recruit at least 13 clients from each CHC. These clients must be over the age of 18, be actively receiving some kind of service or participating in any programme at the CHC and have a mental health and/or substance use problem. Due to the nature of this project, we will rely on staff recruitment of clients as well as self-recruitment. Staff members who work with clients who meet the project’s eligibility criteria will provide them with project information, and they can either provide research staff with the client’s contact information or ask the client to contact research staff directly. Posters with contact information for research staff also will be placed at all CHCs to attract interested clients. MHSUP may be diagnosed by a health practitioner or self-diagnosed. Because stigma is a barrier to seeking and receiving help, it is important not to exclude participants who have not been formally diagnosed by a healthcare provider. The research team will ask a series of screening questions to ensure all client participants meet the inclusion criteria. In total, we expect a minimum of 78 client participants.

Randomisation of CHCs
Six CHCs in Toronto will participate in this project; they will not include the CHCs that participated in the pilot study. The six CHCs will be selected based on three main criteria: (1) serve marginalised populations; (2) located in the city of Toronto and (3) willing to participate.

Research staff have reached out to CHCs in the Toronto area and six centres have expressed interest. Although
there are differences in some of the programming and demographics, the centres are the same in terms of the overall services they provide, the governing structures and the populations they serve. To evaluate the effectiveness of the intervention, the research team will recruit CHCs and randomly assign them to intervention and control conditions. This will be done at a meeting with representatives from all CHCs. The name of each CHC will be put into a hat and drawn at random by meeting participants. As all CHCs will be aware of the intervention, we want to ensure that control CHCs do not implement any aspect of the intervention during the project period. CHCs will be asked to conduct regular activities and if stigma programmes or initiatives are required as a result of this, they may do this. They must inform the project team if they conduct any antistigma programmes or any mental health/substance use initiatives. The nature of the intervention requires application to the entire CHC, not to individual staff members. This will result in a study with a cluster randomised design, with each CHC being one cluster.

### Intervention

The intervention will consist of five main components which address stigma at various levels within an organisational setting: developing teams of local champions, providing contact-based staff training, raising awareness about stigma, implementing a recovery-based art programme and analysing internal policies and procedures. All components of the intervention will take place during regular CHC operating hours. Management will protect time for staff to complete surveys, attend training sessions or participate in a champion role.

#### Developing a team of local champions

A team of champions at each site will include 3–5 staff members. They will liaise with project staff, assist with client recruitment and will provide input during the policy analysis. They will play a vital role in ensuring their entire CHC is well informed about the project and will help to create a supportive and inclusive institutional culture which will encourage staff to act in antistigmatising ways.

#### Providing contact-based staff training

Training will incorporate key antistigma and recovery principles along with specific mental health and addictions topics relevant to CHC providers. It will support CHC staff members in preventing stigma and promoting recovery in their practice, enhance their competency to effectively address their population’s mental health and addictions needs and foster support for health management. Key features will include a curriculum tailored to the specific requests of each intervention CHC based on a needs assessment conducted in the first year of the project, providing contact-based education to reduce prejudice and social intolerance and teaching them to provide culturally competent care for vulnerable populations. Four workshops, each lasting 3 hours, will be held at each intervention CHC. Each training session will be facilitated by two academic trainers with expertise in various areas of stigma research and practice, and one person with lived experience who will present personal experiences of encountering stigma in healthcare settings.
Raising awareness about stigma

Various forms of media will be used to increase awareness about stigma among staff and clients across the entire organisation, essentially promoting stigma-free environments within CHCs. Staff members, led by the team of champions, will determine what kind of media they wish to use: this might include film or image displays or a combination of several media pieces. Social media will not be an option, because this could negatively influence the randomised controlled trial design. Once each intervention CHC has reached consensus on their media strategy, the project team will work with the team of champions to develop and assist in showcasing the media within the CHC. This component will be incorporated throughout the duration of the project.

Implementing a recovery-based art programme

Also a form of contact-based education, this component incorporates the use of art as a powerful learning tool for staff to better understand and integrate recovery-oriented approaches into their practice. Each intervention CHC will select one staff member and recruit one local artist who will facilitate the art sessions. Each intervention CHC will select the art medium(s) they wish to use, and the project team will not influence this decision. The art programme will be held for 10 weeks, with each weekly session lasting 3 hours. Ten clients from each CHC with MHSUP and three CHC staff members will participate each week. Although the clients must have a MHSUP, they do not also have to be part of survey data collection. This will be a closed programme meaning that the same staff and clients participate each week. This allows each group to develop rapport and trust. Staff will be informed about the art programme through a presentation by the researcher and can volunteer to participate. Each intervention CHC will determine when the art programme will take place. If held during the day, the staff will need to gain permission from management to participate. Many CHCs are open late so can accommodate an evening art programme. A total of 10 themes, one for each session, will be developed with the participation and agreement of CHC champions. At the completion of the 10-week programme, each intervention CHC will host an event to showcase the artwork that has been produced. All participants, including staff and clients, will be invited to speak about their experiences in the programme and how the programme affected them. This art programme will complement the other components by encouraging increased contact with, and understanding of, individuals with MHSUP.

Data collection

Measures

The OMS-HC will be the primary outcome measure for the study. It will be applied before and after the intervention with an expected 18-month interval between applications. Given the possible total sample of 490 participants, we will be able to detect differences in OMS-HC scores of 2.1% with an alpha level of 0.05 and power of 80%.

We estimate an effect size of 10% for the intervention group, based on our experience in the pilot study. The control group will also complete the OMS-HC questionnaire at the same time points as the intervention group, but they will not receive the intervention. We anticipate that this process may cause a placebo effect of approximately 3% in the control group. The SD for the OMS-HC, calculated based on our pilot study, is consistent with previous research. In the pilot study, the association between pre-measures and post-measures was $r=0.68$. The power calculation was based on this scale, although we will also have secondary outcomes of interest.

An essential component in the power calculation for randomised cluster trials is estimating the intracluster correlation (ICC), the degree of dependence among individuals within the same CHC. We used an analysis of variance to estimate the ICC in our pilot data and found it to be negative. Although it is possible the ICC will be negative, this is unlikely considering our target population of CHC staff. The negative ICC in our pilot study might have been caused by the small overall sample size and the small number of clusters (we included three three CHCs). Our power calculation next included a range of ICC values from the literature ($0.001$–$0.05$). Finally, the power calculation also accounted for an attrition rate of 10% at the second time point.

The power calculation was conducted in two steps. In the first step, a simple random sample (SRS) was assumed and synthetic data were generated reflecting the information from pilot data and the expected effect sizes in both the control and intervention groups. This step does not account for the ICC and although we simulated the clusters, the within-cluster correlation was zero. These simulated data allowed us to fit models identical to the ones that will be used for the final analysis and assess the power for detecting the effect size under different sample sizes and a 5% significance level. Random effect models through SAS MIXED procedure were used in this simulation. The
effect of interest was defined as being the interaction between time and intervention indicator, that is, whether the difference between postscores and prescores is larger in the intervention group than the control group. This step assumes all CHCs have the same sample size. The second step involved adjusting the sample size found in Step 1 under SRS for the effect of the ICC. In this case, even with an ICC as high as 0.03, we will need only 337 completed questionnaires or 50–60 completed questionnaires per CHC to achieve 80% statistical power, which is feasible based on our pilot data.

A power calculation was conducted for the client component of the study. The primary outcome for clients will be measured using the Perceived Devaluation-Discrimination Scale. The power calculation proceeded in a similar way as for the staff component of the study, with some differences. We do not expect to be able to collect longitudinal information on clients, as we expect high attrition. Therefore, we will collect cross-sectional samples at all collection points. Time will be a fixed effect factor with two levels. A 19.5% effect was considered based on the pilot and baseline scores and their variability obtained from simulations. The ICC is likely to be smaller among clients because the community served by any given CHC is usually diverse and we would not expect as much homogeneity among clients as we would expect from staff working in the same environment. The sample of clients will be selected from those visiting the CHCs in the same month that staff members are interviewed. All of these differences were incorporated into the model and accounted for in simulations. The model still has a random effect and is fitted in a similar way as the staff model. Power was also calculated in two steps given that the design is a randomised cluster trial with CHCs as clusters. An ICC=0.01 was found and deemed reasonable considering the results of similar research, so a total sample size of approximately 78 will be needed at each time point to achieve a power of approximately 80%.

Quantitative data collection and analysis
Survey for staff members (intervention and control groups)
A self-administered questionnaire will be used to examine stigma directed at persons with MHSUP among health professionals. This questionnaire will be completed at four different time points. It will collect data related to three main components: (1) sociodemographic and other relevant general variables; (2) stigma and recovery and (3) their role at their CHC. A paper and an online version of the questionnaire will be used for data collection. For the online questionnaire, all staff will be sent a link via email with a unique code they can use to log in. They will be able to access and complete the survey online.

Survey for clients (intervention and control groups)
A supervised self-administered questionnaire will be used to examine how clients perceive stigmatising attitudes and behaviours among CHC staff. The questionnaire will collect data related to four main components: (1) sociodemographic and other relevant general variables; (2) perceived stigmatising attitudes and behaviours among CHC staff; (3) perceived recovery-oriented practices by CHC staff and (4) accessing healthcare at their CHC. A paper version of the questionnaire will be used in the data collection process, as the research coordinator will be meeting with each client individually to complete the tool. The questionnaire will take approximately 20 min to complete.

Survey measures and tools
Stigmatising attitudes will be measured using a survey that includes validated scales in both intervention and control. Three existing scales were selected through consultation with an expert advisory committee comprised of national and international experts. These reflect the current state of knowledge about stigma measurement scales (with a focus on health providers and persons with MHSUP), as well as the feasibility of implementation at CHCs. They include: the OMS-HC,4 the Mental Illness: Clinicians Attitudes (MICA) Scale5 and the Modified Bogardus Social Distance Scale.

The OMS-HC is a 20-item Canadian scale that was developed specifically to measure stigma towards individuals with mental illness among healthcare providers. This scale has good internal consistency (Cronbach’s alpha=0.82), satisfactory test–retest reliability, intraclass correlation (0.66; 95% CI: 0.54 to 0.75) and sensitivity to change.41 The OMS-HC can range from 20 to 100 with higher scores indicating more negative attitudes towards those experiencing MHSUP. A sample item is ‘I am more comfortable helping a person with a physical illness than I am helping a person with a mental illness’. MICA is a 16-item scale that was also designed to measure attitudes towards individuals with mental illness among healthcare providers. The MICA Scale also has good internal consistency (Cronbach’s alpha=0.79), with a test–retest reliability (concordance) of 0.80 (95% CI: 0.68 to 0.91).48 Scores on the MICA range from 16 to 96 with higher scores indicating more negative attitudes towards those experiencing MHSUP. A sample item is ‘People with severe mental illness can never recover enough to have a good quality of life’. The Modified Bogardus Social Distance Scale is based on the Bogardus Social Distance Scale,49 which was designed to measure attitudes towards certain populations by focusing on the types of social relationships respondents would be willing to participate in with members of a specific population. Our study will use two six-item versions of the scale, focusing specifically on persons with one key mental illness (schizophrenia) and one key addiction (heroin dependence), in order to explore the effects of the intervention on both. Similar versions of this scale have been used in a

1Used with permission from Opening Minds, Mental Health Commission of Canada.
2Used with permission from Dr Graham Thornicroft.
number of different studies.50–53 Scores on the Modified Bogardus Social Distance Scales range from 6 to 24 with higher scores indicating greater desired social distance from those experiencing MHSUP. A sample item for this measure is ‘Would you feel ashamed if people knew someone in your family has schizophrenia/heroin dependence?’.

Client experiences of stigma within their CHC
Subjective experience of stigma as conveyed by CHC staff will be measured among clients using validated tools: a 12-item scale adapted from the Perceived Devaluation-Discrimination Scale.54 This scale assesses the extent to which respondents believe that other people devalue or discriminate against someone with a mental illness/addiction. This scale has shown acceptable internal consistency (alpha=0.78)53 and ranges in score from 12 to 72 with higher score indicating clients feel staff are more accepting of those with MHSUP. Respondents will be asked to describe the extent to which they agree with statements related to staff attitudes towards mental illness and addiction. A sample item is ‘Most staff members in my Community Health Centre would accept a person who has had a mental illness and/or substance use issue’. Responses are measured on a Likert scale ranging from ‘strongly disagree’ to ‘strongly agree.’

An adapted version of the Discrimination Experience Subscale of the Internalized Stigma of Mental Illness (ISMI) Scale55 was designed to measure the subjective experience of stigma, that is, respondents’ perceptions of how they are treated by others. It measures alienation, stereotype endorsement, perceived discrimination, social withdrawal and stigma resistance. The original 29-item version of the scale has shown good internal consistency (alpha=0.90).54 The current study uses a modified version of this scale with one question representing each of the five domains of the original scale. A sample item is ‘Staff members in my Community Health Centre discriminate against me because I have a mental illness and/or substance use issue’. Responses are measured on a Likert scale ranging from ‘strongly disagree’ to ‘strongly agree.’ Scores range from 5 to 20 with higher scores indicating greater internalisation of stigma.

Secondary outcome variables
Staff
Recovery-oriented attitudes about persons with MHSUP among health professionals will be measured using the Recovery Assessment Scale (RAS). The RAS has adequate test–retest reliability (r=0.88) and internal consistency (alpha=0.93).56 A sample item for this measure is ‘People with mental illness/addiction have a purpose in life’.

The provider version of the Recovery Self-Assessment-Revised (RSA-R)57 also will be considered. The RSA-R is a 36-item measure designed to gauge the degree to which programmes implement recovery-oriented practices. It is a self-reflective tool designed to identify strengths and target areas of improvement, as agencies and systems strive to offer recovery-oriented care. The RSA has shown very good internal consistency in similar research environments (alpha=0.96). Our study employs a modified 32-item version of this scale. Scores range from 32 to 160 with higher scores indicating staff feel their workplace has a greater implementation of recovery-oriented practices. A sample item is ‘Staff in this Community Health Centre make a concerted effort to welcome people in recovery and help them to feel comfortable in this programme’.

 Clients
Clients’ perception of recovery-oriented practice in their CHC will be assessed using the person in Recovery Version of the RSA. This instrument was selected based on existing literature reviews58 59 regarding recovery measurements and the importance of measuring recovery at the organisational level considering the perspectives of both clients and staff. As with our provider version of the scale, scores range from 32 to 160 with higher scores indicating that clients feel their workplace has a greater implementation of recovery-oriented practices. A sample item is ‘Staff in this Community Health Centre encourage me to have hope and high expectations for myself and my recovery’. Responses are measured on a Likert scale ranging from ‘strongly disagree’ to ‘strongly agree.’ Clients can also indicate they ‘don’t know’ or if the question is ‘not applicable’ for them. Clients will be asked about any negative experiences they have had at their CHC and how this has affected other areas of their life (eg, self-confidence, financial situation, housing, overall mental health, etc). The scale scores range from 0 to 100 with higher scores indicating greater negative experiences and their impact. If a client has had a negative experience at the CHC, they would indicate how that impacted these areas of their life by circling a number from 1 to 10.

Other variables
Both staff and clients will complete the Marlowe-Crowne Social Desirability Scale (MCSDS). Due to the sensitive nature of the other study scales, there is some risk of social desirability bias in participants’ responses. The MCSDS will allow us to measure and control such bias. Our study uses a modified 13-item version of the scale which ranges from 0 to 13 with higher scores indicating lower chances of social desirability bias. A sample item is ‘I sometimes feel resentful when I don’t get my way’. Respondents can indicate ‘true’ or ‘false’ for each item.

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Staff
Demographic variables on the survey will include age, gender identity, self-identified race or ethnicity, country of birth and education. Variables related to their professional capacities will include their role at the CHC (clinical team, community health team, administrative, other), length of employment, additional relevant training and client contact. Other relevant variables will include personal or close (e.g., family members, friends) experiences with mental illness and/or addiction.

Clients
Demographic variables will include age, gender identity, self-identified race or ethnicity, level of education, country of birth, immigration status, income, current and past history of mental health and/or substance use issues and previous treatment regarding mental health/ addiction. A series of questions will also explore access to services at the CHC, including the length of time spent accessing at the CHC, the number of services used and the types of services used.

Data analysis
Data analysis will be carried out on SPSS 21 and R. Mixed-effect modelling will be used for both staff and client data, which will include time and CHCs as random effect and group (intervention/control) as fixed effects. The technique is appropriate to analyse randomised cluster trials because these models can account for the possible dependence between responses of clients and staff within the same CHC. Initially, a descriptive analysis will be conducted to obtain a general picture of the sample. Time and important covariates (e.g., demographics) as they relate to our outcome variable will be explored. Univariate association tests will be performed to clarify the unconditional effect of these covariates on outcomes. No adjustment for multiple tests will be made since this part of the analysis is exploratory.

Qualitative methods
Qualitative methodology will consist of interviews (with both staff and clients) at baseline and follow-up. Interviews will be semi-structured and audio-taped. An additional qualitative component will be employed during and following the art programme.

Staff
Three staff members per CHC will be interviewed by the research coordinator after the first time point of data collection. Staff will be asked about their experiences of living with a mental illness and/or substance use problem and their experiences in the healthcare system. Client participants will be randomly selected from the client list of survey respondents. They will be asked if they would like to be interviewed and will be informed that they will be compensated for their time. This will yield a total of 18 one-on-one client interviews. A different group of clients will be randomly selected to be interviewed at the completion of the project (during the 3-month follow-up phase) to determine if they have noticed any changes at their CHC over the course of the project period.

Art programme
Participants (staff and client) from the art programme will be part of a qualitative component as well. Three primary methods will be used to collect participant data: observation by researcher, observation by staff and art facilitators and focus groups. The researcher will attend at least two sessions per CHC to observe the class. Observations will be recorded by pen rather than audio-recording. The goal will be to understand and record how staff and client participants engage with one another and create art using the weekly theme. The facilitators (staff and artist) will be provided with a form to document their own observations after each class. Topics to comment on will include documenting notable quotes, group discussions and any conflicts that arise. The completed forms will be returned to the researcher following the art programme. Finally, the researcher will conduct a focus group with each art class at the completion of the programme. All participants, excluding the facilitators will be invited to attend. A semistructured guide will be used to learn about group dynamics, challenges and how/if the programme will inform practice moving forward.

Qualitative analysis
All interviews and focus groups will be audio-recorded and professionally transcribed. The analysis will be conducted using NVivoPro 11 Software to identify themes. Thematic analysis is useful in identifying themes and patterns in the data, which can be explored in detail. Observational data will also be coded and used to supplement the data found in the focus groups and interviews.

Follow-up procedure
The total time required for the completion of this project is 48 months. The 18-month intervention will be conducted from month 6 to month 30 of the project. Measurements will be collected at baseline, 9 months into the intervention, at the end of the intervention (month 18 of the intervention) and 3 months after the intervention. Research suggests that interventions are often successful in the very short term but typically revert to baseline scores in the medium and long term.26 The timing of this
project will not allow for a long-term follow-up; however, the 3-month follow-up will provide meaningful insight into the direction of the scores.

Ethics and dissemination
All participants will be asked to read and sign a consent form prior to completing the survey or engaging in any other aspect of the project. In addition to reading the consent form, client participants will have the consent form explained orally prior to signing and agreeing to participate. All participants will be assigned a numerical code and therefore identification in all data analyses, reports and presentations will be anonymised. The key KT objectives are to generate and impart an awareness of this project and the importance of stigma reduction within primary care settings and to demonstrate the importance and relevance of this initiative on a global scale. Furthermore, the KT plan will seek to elicit changes in practices and behaviours within all CHCs and staff members, to lead to policy changes in CHCs and to encourage discussion within CHCs about stigma. Various tools and strategies will be used to achieve the KT goals, including webinars, social media presence, developing a community of interest and presenting at relevant conferences. KT will be measured by the number of participants at webinars and other presentations, digital media hits (eg, Retweets, web article sharing or quoting) and participation in the community of interest. Reports and articles will be shared with staff at each CHC to inform them of the results. Furthermore, a package will be developed with the components of the intervention so that CHCs can continue to implement the antistigma intervention on their own.

CONCLUSION
Globally, stigma remains a key barrier to care. Many promising initiatives have been implemented worldwide to reduce this problem, but the evidence to support the effectiveness of stigma-reducing interventions is not always strong. This project is important because it will test a comprehensive intervention and will also measure how primary healthcare professionals and clients with MHSUP perceive the effectiveness of the intervention. If successful, this intervention has the potential to be replicated in hospitals and other healthcare settings.

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AK, JCS, SJB, RM, SP, HS, PC, HH and BA conceptualised and designed the study; AK, JCS and SJB drafted the protocol; RM, EKL, MS and MvdM contributed to the draft of this manuscript; RM, SJB and EKL edited each draft version; AK edited the final draft; RM, EKL, SJB, JCS and AK approved the final manuscript and agree to be accountable for all aspects of the work.

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Competing interests
None declared.

Ethics approval
This project has been approved by the Centre for Addiction and Mental Health Research Ethics Board and Centre for Addiction and Mental Health Review Board.

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