Aim

To conduct a proof-of-concept study to examine the effect of genetic counseling (GC) on treatment adherence and illness management-related self-efficacy in people with serious mental illness (SMI).

Background

Approximately 3% of the population (around 960,000 Canadians) is affected by serious mental illness (SMI) like schizophrenia, bipolar, and schizoaffective disorder. Among individuals with SMI, 50% (or more) do not take their psychotropic medications as prescribed[1-4]. The human cost associated with medication non-adherence for affected individuals and their families is huge - non-adherence can increase risk of relapse of psychiatric illness –which can result in more emergency room visits, hospitalizations, poorer course of illness[5], and completed suicide attempts[4]. Further, the economic burden associated with non-adherence to psychotropic medication is also enormous - it has been estimated that up to a quarter of all healthcare expenditure associated with treating schizophrenia is directly related to medication non-adherence[2].

Predictors of psychotropic medication non-adherence in SMI

Since reducing medication non-adherence has been recognized as a critical factor in improving outcomes for people with SMI, and potentially in reducing health care related costs, many studies have investigated factors that correlate with treatment non-adherence in the context of SMI (for reviews of these studies see Lacro et al 2002[6] and Perkins et al 2002[2]). Despite this, perhaps at least in part because he causes of treatment non-adherence in SMI are many and varied, a clear understanding of the full range of factors that infuence treatment adherence and how they exert their effects is currently lacking. While demographic factors (age, sex, education level, etc) have not been reliably shown to be important predictors of medication adherence[6], the evidence supporting factors such as insight into illness[6], medication side effects[2, 6], beliefs about cause of illness[2, 7], communication and therapeutic alliance with a healthcare professional[6] is strong.

Beliefs about cause of illness

Research has shown that SMIs are usually caused by genetic and environmental factors acting together[8], but despite this knowledge and advances in psychiatric genetics, there has been little progress in systematically translating this knowledge for people with SMI in a thorough and individualized manner. Having an explanation regarding why one developed an illness is so critical to the process of adaptation, that in the absence of being provided with a comprehensible explanation for the cause of illness, affected individuals will develop their own explanatory model[9]. Self Regulation Theory[10] suggests that an awareness of the nature of one's illness, including an understanding of its causes, is important in determining how one behaviourally responds to that illness[11-13]; indeed previous work has consistently shown that beliefs that pertain to cause of illness influence treatment adherence[7]. Fundamentally, people are more likely to actively participate in treatment or other behaviours if these are seen to directly address what the individual perceives to be the cause of their illness[14].

Communication and therapeutic alliance with a healthcare professional

Research shows that adherence to prescribed medications and/or adoption of healthful behaviours improves in the presence of a positive therapeutic alliance with a healthcare professional[4, 15], particularly when the healthcare professional is skilled/trained in interpersonal communication[16]. Fundamentally, it seems that treatment adherence improves when individuals

understand why a treatment is being recommended, and when they feel that the healthcare professional genuinely has their best interests at heart.

Interventions to improve medication adherence in SMI

There is currently no intervention that is generally accepted as the "gold standard" for improving medication adherence in SMI. However, both group-based and individual approaches to improving treatment adherence have been tested, with interventions that have ranged from single to multiple sessions[2, 4, 17, 18]. The interventions found to be most likely to show positive effects were those which were longer, combined educational, behavioural, and affective strategies and emphasized therapeutic alliance[4]. However, to date, it appears that no interventions that focus primarily on beliefs about cause of illness have been tested in relation to their effect on treatment adherence.

A recent review concluded that "current methods of improving medication adherence for chronic health problems are mostly complex, labor-intensive, and not predictably effective"[17] Thus, there is an urgent need for the development and evaluation of simple strategies which aim to improve adherence to psychotropic medications among people with SMI. One simple, novel strategy that our data suggest could be used to improve adherence to psychotropic medications among people with SMI is genetic counseling.

An introduction to genetic counseling

Genetic counseling (GC) emerged as a concept in the 1940s; the term was defined by Sheldon Reed as "a kind of genetic social work without the eugenic connotations"[19]. Today, it is an established health service that provides people with information and support related to causes of illness and the chances for their children to become affected[20-22]. In Canada and the US, it is a service that is typically provided by specialist trained (MSc level) individuals (genetic counselors), who are certified by the American Board of Genetic Counseling and/or the Canadian Association of Genetic Counselors[23]. GC has traditionally been offered to people who: are pregnant (e.g., when there is an increased chance for a genetic syndrome), have illnesses that are caused entirely by genes (e.g., cystic fibrosis), or have illnesses that are caused *in part* by genetics *and* for which there is genetic testing (e.g., hereditary breast/ovarian cancer). However, it is important to note that genetic *counseling* and genetic *testing* are not synonymous concepts. While many argue that genetic testing should always be accompanied by genetic counseling, the converse is not true; that is, genetic counseling need not be accompanied by genetic testing. Indeed, GC is best conceptualized (as defined by the National Society of Genetic Counselors) as "a process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease"[21]. When understood in this way, it is clear that regardless of whether or not genetic testing is possible, GC is applicable to all individuals who have a multifactorial health condition (i.e., a condition that arises as a result of genetic and environmental factors acting together, like SMI or diabetes).

GC is based on a Rogerian (person-centred) approach[24], and unless predictive genetic testing is provided, typically involves a single, 1-2 hour session with a client (and partner if appropriate)[25]. Genetic counselors do not advise regarding child-bearing decisions, but instead provide information and support to help people make the best decisions for themselves. GC is neither purely educational, nor purely counseling-based; it is a hybrid[26]. Contrary to the implication inherent to its name, GC does not only involve discussion of *genetic* contributions to illness. Rather, when it is relevant (as it is in the case of SMI), both the genetic and environmental

contributions to illness are discussed together in a holistic fashion. GC involves gathering information from, and providing information and support to the client[27-30]. The information-gathering component of GC entails uncovering the client's existing explanation for cause of illness, and eliciting and documenting a detailed family history. The information-provision component involves discussing risk for family members (e.g., existing or potential children) to develop the indicated condition and providing research-based information about the factors that have been associated with the indicated condition. Using visual aids and active encouragement of discussion, questions and interaction to facilitate comprehension, the genetic counselor relates this information to the client's own family history, their existing explanation for cause of illness, and (in the context of GC for SMI) how illness self-management strategies and psychotropic medications can help to reduce symptoms and/or risk of relapse. This information is not neutral, it is in fact "…loaded, creating affective, cognitive and behavioral reactivity"[24] in clients – and therein lies the importance of the support/counseling component of GC. Much of this affective reactivity typically relates to guilt, fear and shame, which the counselor attempts to identify and to begin to address in the session. Although psychoeducation programs typically provide a cursory overview of the causes of SMI, this topic is usually neither the main focus of these programs, nor is the information individualized (i.e., related to the client's unique family history and existing explanation for cause of illness) or well integrated into explaining the rationale for different therapeutic approaches.

Genetic counseling: an intervention ideally suited to improving medication adherence in SMI?

Genetic counselors are trained to communicate complex concepts in lay language, and the service they provide, GC, is founded on the establishment of a therapeutic alliance. GC aims to deeply and thoroughly help individuals integrate a meaningful and personal new understanding of the cause of their illness, and can explicitly relate concepts about the cause of illness to the treatment approaches (both psychotropic medications, and self management strategies like ensuring adequate regular sleep, good and regular nutrition, and exercise) that have been prescribed or recommended. For these reasons, we propose that GC is ideally suited to improving medication adherence among individuals with SMI.

Although it is well established as a health service, to date, there has been limited research concerning the effects, efficacy or effectiveness of GC, and no more than a handful of RCTs[31]. Further, almost all of the research that has been conducted in relation to the effect of GC has been in the realm of hereditary cancer. Although the majority of individuals with SMI have expressed a desire for GC, very few have accessed the service[32-34]. And, beyond our own recently completed RCT, no studies have assessed the effects of GC in this population. In this era of evidence-based medicine, there is increasing recognition that healthcare services should ideally only be provided when there are sound data supporting their therapeutic effects[35].

Genetic counseling for SMI and treatment adherence: preliminary work

We recently completed recruitment for an RCT of GC in a cohort of individuals with SMI. Final data have not yet been analyzed, but preliminary data (from n=33) demonstrate that compared to a rigorous control intervention, GC reduced internalized stigma in people with SMI when measured 1-month post-intervention ($p<0.05$, mean pooled SD = 13.9, effect size (d) = 0.6). This finding is of particular relevance to the study proposed here because internalized stigma has been shown in a recent meta-analysis to be significantly inversely correlated with medication adherence[36]. Thus, as we have shown that GC can decrease internalized stigma, based on this correlation, we might expect that it can also increase medication adherence.

Furthermore, qualitative data from our RCT indicated that GC can have a powerful positive impact on psychotropic medication adherence at the level of the individual with SMI. This effect is well illustrated by the story of a participant called "Sue". The PI provided GC for Sue, a woman with schizoaffective disorder who was an inpatient in a psychiatric ward, and was fighting with her psychiatrist about medications: Sue felt they wouldn't help. Sue told the PI that she felt that "weak character and bad life decisions" caused her illness, and that she didn't need medications to get better, she just needed to try harder. The PI drew out Sue's family history and showed her that both of her parents had experienced significant mental health problems themselves, and that it was very likely that she had inherited genetic vulnerability to SMI from both of her parents. Sue broke down into tears, saying "a huge weight of guilt lifted". She was able to articulate that once she understood that the cause of her illness was in part genetic, then a biological treatment made more sense to her. One month after the GC session, Sue had agreed to take her psychotropic medications, and her mental health was much improved.

Rationale Summary

Medication non-adherence is a serious problem in the context of SMI, both for affected individuals who have higher chances for illness relapse and poorer long-term prognosis, and in terms of economic burden associated with SMI. Despite considerable research into interventions to improve adherence, one recent review concluded that "current methods of improving medication adherence for chronic health problems are mostly complex, labor-intensive, and not predictably effective"[17]. Thus, there is an urgent need for the development and evaluation of simple novel interventions which aim to improve adherence to psychotropic medications among people with SMI.

Previous work has shown beliefs about cause of illness influence treatment adherence; people want the treatment for their illness to address what they perceive to be the cause. However, despite advances in psychiatric genetics, people with SMI have been provided with little in the way of thorough, individualized information about the causes of their illness. Medication adherence is also better when people have a good therapeutic alliance with a healthcare professional, and understand exactly why and how the medication prescribed should help. GC is an established healthcare service that is delivered by specialist trained healthcare professionals who are skilled in interpersonal communication, which aims to help people understand the causes of their illness and how this relates to recommended treatments. GC has not traditionally been routinely offered to people who have SMI, but conceptually, is ideally suited to improving medication adherence in SMI. Further, our own preliminary data suggest from a recently completed study suggest that GC could improve medication adherence among individuals with SMI.

Methods

Summary

As this is a new area of study, we have opted for a single-group, repeated-measures proof-of-concept study design which will generate critical preliminary data that will inform the development of a future randomized controlled trial (RCT) in which we will assess the effect of GC on treatment adherence in SMI using the highest standards of rigour. We have designed this single group study such that participants complete the outcome measures at two time points during a "control" period prior to receiving the intervention, which will allow us to observe change in treatment adherence over time in the absence of an intervention. We will recruit 112 people with SMI (according to DSM-IV criteria). Participants will complete a baseline (T1) assessment,

which will include a structured clinical interview to confirm psychiatric diagnosis, documentation of demographic/current medication prescription information and completion of the Brief Adherence Rating Scale (BARS), the Medication Adherence Rating Scale (MARS), the Self-efficacy (SE) scale, and questions relating to their causal attributions for mental illness. Two weeks later (at T2), immediately after completing the BARS, MARS, and SE again, participants will receive GC. All participants will complete outcome measures at T3 (one month after T2) and T4 (one month after T3). After attrition (~ 25%), our final sample size (n=83) will provide 80% power to detect a small effect size.

Specific Aims

a. To recruit 112 people with SMI (as defined by DSM-IV) and to retain 83 over the 10-week study period.
b. To assess the effects of GC on participants' adherence to psychotropic medications and illness management-related self-efficacy over 8 weeks.

Hypotheses

a. *Primary*: GC will increase adherence to psychotropic medications among people with SMI over 8 weeks.
b. *Secondary*: GC will increase illness management-related self-efficacy among individuals with SMI over 8 weeks.

Recruitment

We will recruit 112 individuals with SMI over 2 years, from various sources in BC. First, we have a list of 10 eligible individuals who responded (after recruitment had closed) to our advertisements about the RCT assessing the impact of GC on internalized stigma in people with SMI. Additional participants will be recruited from community-based agencies with whom we have established relationships (e.g., Schizophrenia Society of Canada, Canadian Mental Health Association, Mood Disorders Association), as well as by placing advertisements in local community centres, and coffee shops and on Craigslist, etc. We will ensure that both men and women are represented.

Inclusion criteria

Those who: a) have a diagnosis of schizophrenia, bipolar, or schizoaffective disorder (according to DSM-IV criteria), are b) ≥19 years old, c) fluent in English, and d) provide written, informed consent.

Exclusion criteria

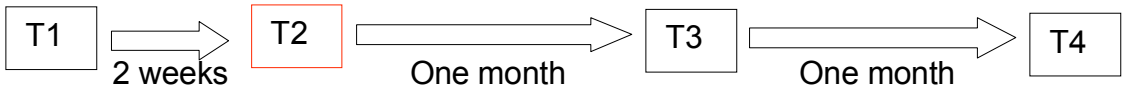
Those who have previously had GC related to their diagnosis of SMI. Note: We will NOT exclude those who are currently receiving other psychosocial interventions (e.g., psychotherapy) but will document and account for this in our analyses if necessary. For maximal ecological validity of the study, we will not exclude individuals with other co-morbid psychiatric disorders (e.g. personality disorders), but again will document this and account for it in analyses if necessary.

Procedure details (see Figure 1 and Table 1, p6)

After providing written consent, at a baseline (T1) visit, all participants will complete a structured clinical interview for DSM-IV (SCID) to confirm their psychiatric diagnosis, a demographic questionnaire, the Positive and Negative Affect Schedule (PANAS, a measure of current mood[37]) to allow us to better interpret results[38], a purpose-designed questionnaire about current psychotropic medication prescriptions, two questions specifically designed to assess the

causal attributions for SMI among affected individuals (all of which we used successfully in the recently completed RCT), and all of the outcome measures listed below.

Figure 1: Study design summary



Legend: Single group repeated measure proof-of-concept study design. For all 112 participants recruited, the intervention, GC, will be provided immediately after the completion of the outcome measures at T2 (indicated by red box). The only measurement conducted after GC at T2 will be the GC Satisfaction scale. See Table 1 for a full list of all measures administered at each time point.

At T2 (2 weeks after T1), participants will return for a genetic counseling appointment. Immediately before the GC intervention, participants will again complete the PANAS and all of the outcome measures. Immediately after the intervention, participants will complete the GC Satisfaction Scale[39] (a validated, 6-item, Likert scale rated instrument) to allow us to contextualize results. At T3 and T4 (one and two months after T2 respectively), participants will complete outcome measures at home (either by phone with a research assistant, online, or by mail according to personal preference and available resources).

Table 1: Schedule of Assessments

	Enrolment	Day 1	Day 14	Day 42	Day 70
Visit number		**T1**	**T2***	**T3**	**T4**
Consent	X				
Structured Clinical Interview for DSM-IV (SCID)		X			
Socio-demographic information		X			
Psychotropic medication prescription information		X	X	X	X
Positive and Negative Affect Scale (PANAS)		X	X	X	X
Brief Adherence Rating Scale (BARS)		X	X	X	X
Self-Efficacy Scale (SE)		X	X	X	X
Medication Adherence Rating Scale (MARS)		X	X	X	X
Genetic counselling satisfaction scale (GCSS)			X		

Table Legend: Each X in the table above marks one administration of the instrument indicated.
***** All of the measures indicated at T2 will be administered immediately before GC, except the GCSS, which will be administered immediately after GC.

Outcome measures

Psychotropic Medication Adherence: Assessed using the BARS, which comprises four items: three questions relating to how many pills the individual was instructed to take per day, how many days the individual did not take their pills, and how many days they took less than the prescribed number[40]. For the latter two questions, four possible response options are provided. The last question is an overall visual analog rating scale used to report the proportion of doses taken by the patient in the past month (0-100%), The scale is internally reliable ($\propto$=0.9), has good test-retest reliability (r =.74-.86, p< .01) and scale scores correlate with measures of psychopathology, which provides evidence of construct validity. Further, the scale has been

validated against an objective measure of treatment adherence monitoring; the medication event monitoring system (MEMS), in which an electronic medication vial cap logs the date and time each time the vial is opened. Against this "gold standard", the BARS demonstrated good sensitivity (73%) and specificity (74%) in identifying non-adherence. Thus the BARS has all of the characteristics necessary to be ideally suited to reliably detect change in treatment adherence in response to the intervention provided the context of this study[41].

Self-efficacy: Is a construct that is related to internalized stigma[42], and concerns ability to cope[43]. We will assess participants' coping related to their management of their psychiatric illness (rather than global coping, which is less relevant) using the Self-Efficacy Scale (SE). This psychometrically sound self-report instrument comprises 11 items each rated on a 10-point, anchored (*1=not at all confident, 10=totally confident*) Likert scale[44, 45].

Attitudes towards medication adherence: Rather than attempting to quantify actual usage of medication, the Medication Adherence Rating Scale (MARS) assesses attitudes towards psychotropic medications and adherence behaviours[46]. It comprises10 questions (each asking about a behaviour or attitude held toward medication in the last week) to which individuals can select "Yes" or "No" responses. This scale is internally reliable ($\propto$=0.75) and has good test-retest reliability (r = 0.72). Scale scores significantly correlated with blood levels of psychotropic medication (r = 0.6, p <0.05), which supports good convergent/construct validity. Further, in a review of validation studies of adherence scales, which aimed to guide clinicians in selecting the best scale for practice[47], the MARS was recommended as a reliable indicator of non-adherence to medications in individuals with SMI.

Description of the intervention

The intervention (GC) will be delivered by a specialty-trained genetic counselor who is certified by the American Board of Genetic Counseling and/or the Canadian Association of Genetic Counselors. GC will follow the traditional, single 1-2 hour session model. GC for SMI is performed in the same way as it would be for other conditions[26]; it involves: uncovering the client's existing explanation for cause of illness, eliciting and documenting a detailed family history, discussing risk for family members (e.g., existing or potential children) to develop the indicated condition, and in lay language, relating research-based information (about the factors that have been associated with the indicated condition) to the client's family history and their existing explanation for cause of illness. The use of psychotropic medications as treatment for SMI is presented in light of what is known about the biogenetic contributions to SMI. Other strategies for self-management of illness are presented in light of what is known about environmental (or experiential) contributions to the pathogenesis of SMI. As there is no genetic testing available clinically to predict development of SMI, the current gold standard procedure involves the assessment of psychiatric family history[27-30]. The genetic counselor also attempts to identify and address the psychosocial consequences (e.g., guilt) of receiving this information. Because the emotional impact of GC can impair comprehension[24], GC typically involves the provision of written material, related to the content of the session, that the individual can take home. Thus, in this study, GC will include provision of an educational booklet that was developed, refined and piloted over a two-year period in collaboration with individuals with SMI. It contains generalized information about the causes of SMI, including pictures that illustrate key conceptual points. These same pictures are used as visual aids during the GC session.

Analyses

We will conduct a repeated-measures ANOVA (within groups) to assess the effects of genetic counseling on treatment adherence (primary hypothesis) and illness management-related self-efficacy (secondary hypothesis). Given the observed test-retest reliability of our primary outcome measure (r=0.75), with four measurement time points and at a significance threshold of 0.025 (to allow for two outcome measures), n= 83 completing participants (attrition estimated at 25% based on our experience with retaining this population over similar timeframe in other studies) will provide 80% power to detect a small effect size (f=0.1). In the event that we find significant differences, we will conduct post-hoc paired t-test comparisons between treatment adherence scores between the four time points. Further, we will (in an exploratory fashion) examine the effects of the intervention in relation to participants' baseline measurements of attitudes towards medication (measured using the MARS) and causal attributions for illness – specifically, we will be able to explore whether baseline attitudes towards medication or causal attributions mediate or moderate the effect of GC on treatment adherence.

Timeline

We will recruit 112 participants. We already have contact information for 10 eligible individuals who want to participate (as described in the Recruitment section). Based on our previous work with similar studies in this population, we anticipate recruiting four to five new participants per month such that recruitment of the remaining 102 participants will be complete in 24 months. Thus, if we begin in March 2012, recruitment will be complete by February 2014. By April 2014, T4 questionnaires will be completed for all participants. Allowing for generous attrition of 25% (in our RCT of GC in people with SMI attrition=20%) we will have 83 completing participants.

Feasibility and potential pitfalls

Our recently completed RCT (a study of similar nature and duration of follow up to that proposed here) demonstrates our ability to recruit and retain this population at the rate described. Further, the RCT showed that GC can reduce internalized stigma in people with SMI – this is a construct that has been reliably negatively correlated with medication adherence, and thus can be considered as pilot data which suggest that GC may influence medication adherence.

The intervention to be tested – GC – is targeted towards addressing two potentially modifiable factors that existing data reliably implicate in medication adherence; namely beliefs about cause of illness, and communication and therapeutic alliance with a healthcare professional. However, medication adherence is also likely to be influenced by other factors, most notably insight into illness, and perceptions of side effects. While we do not expect GC to be effective at meaningfully influencing either of these two variables, our study design is not vulnerable to failure as a result. Specifically, the nature of our method of recruitment of study participants (identical to the approach we used in the RCT) requires individuals to respond to study advertisements by contacting the study coordinator and self-identifying as having a SMI. Further, to confirm eligibility all potential participants will need to have their diagnosis confirmed by a SCID. Experience with our RCT reveals that this process effectively selects against those who lack insight. With respect to the issue relating to side effects, first, the study is powered to be able to detect even a small effect in the group as a whole. Second, we will collect information about participants' attitudes towards and behaviours relating to their medications (by using the MARS). We will be able to compare the effect of GC on those who identify side effects as an important

reason for non-adherence to those who do not identify this as an important reason for non-adherence. If in the context of this comparison we were to find a difference between groups, this could be used to inform decisions about which intervention aimed at promoting treatment adherence might be most useful to different types of individual; indeed, some authors have suggested that clinically, it is most helpful to address treatment adherence issues using a "prototypical patient" approach like this[48]. Last, it is possible that those for whom side effects is the most salient issue in medication non-adherence, GC mat encourage them to talk with their physician about the possibility of switching psychotropic medication. So, we will document whether GC prompts participants to initiate a conversation with their physician about switching medication.

It is widely acknowledged that all methods of monitoring treatment adherence (even electronic medication event monitoring systems) have their strengths and weaknesses, and none is currently considered as the "gold standard"[5]. For this proof-of-concept study, we adopted a pragmatic approach and chose to use well-validated and reliable participant self-report measures relating to treatment adherence. Should we generate data that support our central hypothesis, we intend to generate an application for funding to be submitted to CIHR or NIH for funding which would allow us to investigate the effect of GC on medication adherence in SMI using the highest standards of rigour (i.e., an RCT comparing GC to control intervention, in which medication adherence is assessed using multiple sources of information, including an electronic medication event monitoring system together with pharmacy prescription fill rates).

Significance

Approximately 960,000 Canadians are affected with SMI and treatment adherence is a substantial problem. There is a need for simple interventions that can improve treatment adherence in this population. This will be the *first and only* study to assess the impact of GC on treatment adherence in people with SMI. This study has the potential to provide an evidence base for a simple therapeutic approach to improving treatment adherence (GC) that could be readily implemented relatively inexpensively (GC can be provided by MSc-trained specialists, rather than MDs) in the near term. By improving treatment adherence, GC potentially provides a viable path toward renormalizing or compensating for biological alterations in SMI. As such, it will provide a foundation for developing best practices for applying GC in clinical settings. By improving treatment adherence in people with SMI, we could ultimately reduce risk for active episodes of illness, improving prognosis of SMI and decreasing economic burden associated with these conditions.

Further, should our hypotheses be supported, we would use the data we generate to propose to the BC Provincial Health Services Authority (PHSA) that funding be provided to support an ongoing specialist clinical GC service for people with SMI. One of the current barriers to the PHSA providing funding for such a service is a perception that there is a lack of demand – in part, because we have shown that few people are referred to general genetics services for GC related to SMI[49]. However, surveys show that most people with SMI want GC[32, 34] – our experience indicates that there are other barriers which limit this group's access to GC, namely lack of awareness of the availability and relevance of GC to individuals with SMI, and the fact that GC services are embedded in medical genetics rather than in the mental health domain. Thus, the potential impact of this study is that it could allow us to obtain funds from PHSA to <u>establish the first specialist clinical service to provide GC for people with non-syndromic SMI</u>. While there are specialist GC services for cancer, and comparatively rare conditions such as Huntingtons Disease, no specialist

GC services for SMI unrelated to genetic syndromes exist (anywhere in the world, of which we are aware). Thus, a service like this would constitute a world first, and as such would provide a model for other centers to refer to. Further, although genetic counselors are trained to routinely ask about cancer, studies show that they rarely ask about or address SMI[50], and currently, genetic counseling training programs provide little instruction in provision of GC services related to SMI. This study will allow us to build capacity to address SMI within existing GC services, thereby improving services for people with SMI. We will build capacity by offering elective internships to Canadian Genetic Counseling MSc students to join our team for periods of a few days to several weeks and observe and participate in providing genetic counseling for people with SMI. The rationale is that the experience of providing GC for people with SMI will increase the student's comfort, competence, and enthusiasm for providing GC for SMI, such that upon graduation they are motivated to uncover and address family histories of SMI with their clients in the center in which they are employed. After each internship, we will gather the student's feedback about their experience, which we will use to inform the design and implementation of future student internships.

Qualifications of the PI, and existing facilities

The PI, Dr. Austin, is an Assistant Professor in the Departments of Psychiatry and Medical Genetics at the University of British Columbia, where she holds a Tier 2 Canada Research Chair in Translational Psychiatric Genomics. *She was the PI for the recently completed RCT that generated the first ever data about the impact of GC in the context of SMI.* Dr Austin will have primary responsibility for overseeing the proposed project. She has 8 years experience of clinical interaction with individuals with a history of serious mental illnesses (SMI, like schizophrenia, bipolar disorder and schizoaffective disorder) and their family members. She is a board certified genetic counselor, and has been providing this intervention for people with SMI and their families for several years in the context of other funded research projects. Further, Dr. Austin has co-authored a book on the topic of how to talk to individuals with SMI and their families about the causes of illness (see CV). Since 2007, Dr Austin's group is growing, she currently manages a team of 7 staff and students, all of whom work on projects closely related to this one. Dr Austin will supervise the training and daily duties of the genetic counselor and research assistant who are hired for this study.

The Principal investigator has her own office (150sqft) as well as space for the genetic counselor and research assistant (semi-private carrels with their own private telephone lines) and the Genetic Counseling graduate student intern (open-plan desk space) within the Centre for Complex Disorders (which provides: a dedicated server with IT and administrative support, Internet access via the UBC high-speed network, and all telephone usage). Importantly, the PI and her team have full access to dedicated clinical interviewing space on the floor of the building below the office space.

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