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Narrative enhancement and cognitive therapy for self-stigma among youth with bipolar disorder or multiple mental health conditions: protocol for a pilot randomised basket trial

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ABSTRACT

Introduction Self-stigma occurs when individuals internalise negative stereotypes about their mental health conditions. Self-stigma is common among those with serious mental illnesses, including youth, and is considered a major barrier to recovery through its impact on hope, self-esteem and self-identity. This patient-oriented protocol aims to assess the feasibility of conducting a future full-scale randomised controlled trial (RCT) of a youth-oriented adaptation of narrative enhancement and cognitive therapy for self-stigma among youth (NECT-Y).

Methods and analysis This is a two-site, two-arm pilot basket RCT with 1:1 randomisation to NECT-Y or treatment as usual (TAU). Participants are youth, ages 16–29 diagnosed with bipolar disorder, any subtype (Basket 1) or with any two or more mental health conditions (Basket 2). After informed consent, we will conduct baseline assessments and randomisation, then either a 14-week NECT-Y group intervention or TAU. Diagnostic interviews will be used to confirm diagnosis at baseline. A range of self-report questionnaires will be administered at baseline, post-treatment and 3 month follow-up. The primary outcome is feasibility as indicated by the achievement of recruitment goals, retention and adherence, intervention fidelity and the absence of serious adverse events. Secondary outcomes include acceptability and the intervention's impact on self-stigma, wellness, symptomatology, treatment-seeking attitudes and other related constructs. A youth advisory group is informing all stages of the study process.

Ethics and dissemination The Research Ethics Board for Centre for Addiction and Mental Health (#062/2024) has approved this study protocol. Ethics is also approved at London Health Sciences Centre (Western Health Sciences Research Ethics Board (HSREB) #125812). Results will be published in international peer-reviewed journals and presented at relevant conferences. Summaries will be provided to the funders of the study, as well as to lay audiences, including study participants.

Trial registration number NCT06672562.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The basket trial design had advantages in terms of recruitment, statistical power and trial management.
⇒ From a patient-oriented research standpoint, youth advisors will inform all aspects of the trial.
⇒ As a pilot study, this trial is underpowered to detect significant differences in participant outcomes.
⇒ Generalisability cannot be confirmed outside of the populations represented in the baskets and hospital settings.

BACKGROUND

Stigma toward mental illness includes a variety of harmful negative stereotypes (eg, expectations of violence, incompetence and inability to recover) held by community members that result in harmful behaviours such as the social avoidance of, and discrimination toward, people who have been diagnosed with mental illnesses.[1] Stigma intersects with culture[2] and is found throughout society.[3]

Stigma is often conceptualised as public stigma, structural stigma and self-stigma.[4 5] Public stigma is the stigma held widely in society. Public stigma has direct impacts on people with mental illness, as well as on family members, friends, service providers and other groups.[4] Structural stigma exists at the level of institutions that institute discriminatory or restrictive practices that have negative impacts on people with mental illness.[5] In contrast, self-stigma occurs when individuals with mental illness are aware of negative stereotypes regarding mental illness and internalise them, directing them toward themselves.[4] High levels of

self-stigma are associated with a range of mental health conditions,[6] such as bipolar disorder (BD), schizophrenia and major depressive disorder. Self-stigma appears to be highest among those with serious mental illness.[7–10] Self-stigma has also been identified among youth, which is particularly concerning given that youth is a time when identity is forming.[11 12] Having multiple co-occurring mental health conditions is a common situation for many youth seeking mental health services. Some 50% of youth have at least one mental health or substance use disorder during their lifetime, while around 20% have two or more conditions.[13] There is evidence that self-stigma may be higher among individuals with comorbidities or multiple mental health conditions.[14 15]

The Illness Identity model[16] proposes that self-stigma is a major barrier to recovery: when identity is influenced by self-stigma, people believe that they cannot recover, thus reducing hope and self-esteem. This increases the risk of depression and suicide and decreases social interaction. It may also lead to more passive coping styles, limiting treatment engagement. As individuals use more avoidant coping strategies, they may also avoid other activities, such as work, which can further reduce social connectedness and functioning. Avoidant coping, reduced treatment engagement, social isolation and decreased vocational functioning may increase symptom severity. A comprehensive review of 111 studies[17] showed consistent evidence for a relationship between self-stigma and treatment engagement (eg, medication adherence, psychosocial treatment attendance, working alliance).

Young people have expressed that stigma is a barrier to service seeking, despite the promise of early intervention.[12 18 19] In fact, research with youth receiving services following a first episode of psychosis (FEP) and their family members found that concern with stigma was associated with increased ambivalence about engaging in FEP services.[20] Reducing stigma is among the public health strategies identified to promote service seeking among youth.[21] Stigma, including self-stigma, has been identified by in Canada as a major public health priority and a key social determinant of health.[22] An enhanced Action Framework[23] sets out the goal of creating a more inclusive healthcare system and improving health and well-being.

Narrative enhancement and cognitive therapy (NECT) is a novel intervention that was developed in the USA, with some work conducted in Israel, Sweden, Denmark, France, Taiwan and Italy.[24] It is a manualised, structured group intervention that targets self-stigma in severe mental illness, from a trauma-informed lens. NECT integrates evidence-based psychotherapies. Internalised negative stereotypes are addressed by increasing patients' understanding of stigma (psychoeducation), helping them to restructure unproductive thoughts (cognitive therapy) and helping them build a meaningful life narrative and self-identity, where the illness is a component of their experience but does not encompass their entire identity (narrative therapy). NECT involves 20 individual sessions, each lasting one hour, conducted by two clinicians. A patient guidebook is complemented by a facilitator manual and fidelity supports.

NECT has demonstrated efficacy in reducing stigma and improving a number of mental health and well-being metrics in a randomised controlled trial (RCT) among adults with schizophrenia in the USA.[25] It was associated with reduced hopelessness, social withdrawal and use of avoidant coping strategies, as well as increased narrative insight and enhanced treatment engagement. Another RCT, conducted in Taiwan, found positive impacts on self-stigma among adults with schizophrenia.[26] NECT has also been shown to be effective in a mixed group of adults primarily with psychotic disorders in a quasi-experimental study in Israel,[27] with reductions in self-stigma and improvements in quality of life, hope and self-esteem. It has been shown to be acceptable for implementation in a Swedish adaptation for adults with psychosis using a stakeholders-engaged process.[28] This is backed by a sizeable evidence base on the constituent parts of NECT, that is, group psychoeducation and cognitive therapies, with promising findings for youth populations,[29–31] but a paucity of rigorous research on narrative approaches to psychotherapy.[32] Although it has been successfully adapted for youth receiving FEP services, empirical findings related to NECT's wider adaptation with youth have yet to be published.

Our team brought together a youth lived experience panel to generate youth-oriented adaptations of NECT.[33] The youth team improved the fit with the lived experience of young people in Canada, reduced the number of sessions from 20 to 14 and the reading level for accessibility and enhanced the strengths-based lens. They further integrated peer support, added a goal-setting module and created an engaging graphic design. The result is the new NECT-Youth (NECT-Y). After the adaptation phase, the next stage in this line of work is to establish the feasibility of conducting a trial and the acceptability of the newly adapted NECT-Y. The current pilot basket RCT aims to meet that need.

The basket trial is an innovative master protocol design.[34] The basket trial design involves recruiting multiple samples of individuals with different health conditions ('baskets') and treating them with the same intervention within a single trial. This master protocol design provides efficiencies in terms of recruitment, power and trial management.

Objective

The primary objective of this pilot basket RCT is to assess the feasibility of conducting a future definitive RCT of NECT-Y for youth with BD or multiple mental health conditions (without BD), represented by the achievement of recruitment goals, treatment retention/compliance, study retention/compliance, fidelity and the absence of serious adverse events. The intervention will be compared with treatment as usual (TAU) as a pragmatic choice within the treatment settings, given that no established treatments address self-stigma in these settings. It is

hypothesised that a pilot basket RCT in this study setting will be feasible. Secondary objectives are to examine whether the adapted intervention is acceptable to patients and the NECT-Y facilitators, with an exploratory analysis of participant outcomes on aspects of stigma, wellness, symptomatology, treatment-seeking attitudes, medication adherence and other related constructs.

METHODS

A mixed-methods, patient-oriented, parallel-arm pilot basket RCT will be conducted to compare NECT-Y to TAU, with a 1:1 randomisation. Two participant populations ('baskets') have been selected for the trial: (1) youth with BD (Basket 1), and (2) youth mental health multimorbidity (henceforth 'multiple mental health conditions' as per youth and family preference in terminology; MMHC, Basket 2). The selection of diagnostic groups was driven by the literature on high levels of self-stigma associated with BD and, potentially, multiple mental health conditions,[14 15 35] the promise of group interventions, the gaps in the evaluation of NECT to date, and local clinical and research interest and opportunities in line with an associated longitudinal cohort study focusing on multiple mental health conditions in youth. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[36] The SPIRIT checklist is provided in online supplemental material. The trial is registered at ClinicalTrials.gov (NCT06672562) as of 1 November 2024, with an anticipated date of enrolment of the first participant in November 2024. The public title is 'Narrative Enhancement and Cognitive Therapy for Self-Stigma in Youth'. The scientific title is 'A mixed methods randomised pilot basket trial of Discovering Our Best Selves: Narrative Enhancement and Cognitive Therapy for self-stigma among youth'. It is overseen by a Trial Governance Committee that meets approximately monthly to make study design and operational decisions, as well as a Youth Advisory Group that meets approximately monthly to guide study components. Patient-oriented research procedures will be followed in line with Canada's Strategy for Patient-Oriented Research.[37]

Study setting

This trial is conducted at the Centre for Addiction and Mental Health (CAMH) in Toronto, Canada, as the lead site, with additional recruitment occurring at the London Health Sciences Centre (LHSC), in London, Canada. All assessment and NECT intervention activities will occur at CAMH. Both are hospital-based settings.

Participants and recruitment

The BD basket will consist of a target of 48 youth participants with BD (any subtype), who are connected with one of two distinct hospitals in Toronto (CAMH) and London (LHSC), Ontario, Canada. The MMHC basket will consist of a target of 48 participants with MMHC connected with CAMH. Participants are currently being recruited and enrolled as of November 2024.

For the BD basket, multiple recruitment sources have been identified to recruit youth with BD, with or without additional mental health conditions. At CAMH, participants will be recruited from other CAMH studies if they have provided consent to be re-contacted, as well as from a clinical pool. Participants from LHSC will be recruited from among the clinical pool of youth with BD. For the MMHC basket, participants will be recruited from CAMH only, from among participants recruited to other CAMH studies who have consented to be contacted about other research. Study flyers will be circulated to potential participants by the staff of the referring study or clinic, who will connect interested potential participants to the NECT-Y study staff member for screening and enrolment. For the qualitative study component, all NECT-Y participants and facilitators will be invited to participate. Recruitment will take place over the course of approximately 1 year until the sample size is complete.

Eligibility criteria

To be eligible for inclusion, potential youth participants must be between 16 and 29 years, be connected with research or clinical care at CAMH (both baskets) or LHSC (BD basket only). They must have a primary diagnosis of a BD of any subtype for the BD basket, or they must meet diagnostic criteria for at least two mental disorders excluding BD for the MMHC basket. For the BD basket, participants can also have one or more comorbid diagnoses; diagnostic confirmation for this basket will take place at screening using the Structured Clinical Interview for DSM-5[38] (SCID-5), or will be confirmed via data shared from the referring trial. Depending on the referring trial and the age of the participant, these data will either be SCID-5 for participants age 18 and older or the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS)[39] for participants under age 18. For the MMHC basket, the diagnosis will be confirmed using either the SCID-5, the K-SADS or the Diagnostic Assessment for the Health Spectrum (DASH), which is a newly adapted assessment based on the core structure of the Schedule for Affective Disorders and Schizophrenia and the K-SADS, and will be shared from the referring study.[39 40] Included diagnostic categories are affective disorders, anxiety disorders, behavioural/impulse disorders, eating disorders, substance use disorders, psychosis/schizophrenia, suicidal behaviour disorder, non-suicidal self-injury disorder, language-thought disorders and post-traumatic stress disorder. An additional inclusion criterion requires that participants screen positive for mild-to-severe internalised stigma using the Internalised Stigma of Mental Illness Scale – 9-item version (ISMI-9),[41] with a score of greater than 2.00. As per our ethics approval, all participants are eligible to provide informed consent and parental assent will not be sought.

Excluded will be individuals who have visited an emergency department or have been admitted to a hospital for

Table 1 Inclusion and exclusion criteria for youth participants

Inclusion criteria	Exclusion criteria
Bipolar disorder (any subtype) or ≥2 mental health conditions (excluding bipolar disorder)	Emergency department visit or hospitalisation for mental health in the month prior to intake
Age 16–29	Initiation of a new psychotherapy in the month prior to intake
Mild-to-severe self-stigma (>2.00)	Unable to communicate in English
	Enrolled in another clinical trial for mental health/substance use

psychiatric reasons in the month prior to intake, are incapable of consenting, have initiated a new psychotherapy in the month prior to intake, who are participating in another clinical trial for mental health/substance use, or who are unable to consent or communicate in English. Other than the very recent initiation of a new psychotherapy, any concomitant psychological and pharmaceutical care is permitted. No other exclusions have been placed on the types of treatment participants may be receiving before, during or after NECT-Y study participation. Exclusion criteria are intentionally limited to ensure a pragmatic and inclusive study. All NECT-Y participants and facilitators will be considered eligible for inclusion in the qualitative study component. Inclusion and exclusion criteria are listed in table 1.

Procedure

Participants in both baskets will follow the same study design. Study screening and enrolment will be offered sequentially to all interested potential participants in the treatment settings during the recruitment period, until the target sample size is reached. For both sites, CAMH study staff will gauge interest, assess eligibility, seek consent, conduct screening and pretreatment questionnaires, then randomisation. Written, informed consent will be collected by study staff member using the REDCap data capture system,[42] either virtually or in-person using a study laptop. Follow-up assessments will occur at post-treatment (T2) and 3 months later (T3), for a total study duration of about 6 months for each participant.

To minimise participant burden, diagnostic interviews obtained in the referring studies will be transferred from the original study. If not available, diagnostic interviews will be conducted by study staff to determine eligibility. Demographic characteristics will be collected either in self-report format from the participant or via data transfer from the referring study when available. Participants will also complete a self-report custom screening form for additional inclusion and exclusion criteria. Participants will receive a secure survey link to REDCap[42] via their preferred method of communication (ie, email, text message). They will then directly enter self-reported data into REDCap, hosted on a secure CAMH server. Study staff will verify the completeness of study data on an ongoing basis and encourage completion, while acknowledging the voluntary nature of responding to the surveys.

Qualitative focus groups of approximately 90 min to 2 hours will be conducted by the research staff at post-treatment. Participants will be consented a second time, specific to their participation in the focus groups; electronic informed consent will be collected in the same manner as the primary study consent. Post-treatment individual interviews (approximately 45 min to 1 hour) will be conducted with the NECT-Y facilitators, including peer co-facilitators, to understand the appropriateness of the adapted intervention from the facilitator perspective. Facilitators will complete electronic informed consent following the same procedure. Focus groups and individual interviews will be audio-recorded and transcribed. NECT-Y sessions will be audio-recorded and transcribed to rate fidelity in facilitating the intervention. The focus group guide is provided in the online supplemental material.

Retention

Various mechanisms will be put into place to foster participant retention. We took this question to our Youth Advisory Group for ideas, which we implemented.

One key retention factor is compensation.[43] Participants will be compensated $C30 or $C60 for the consent and screening process depending on the length of the visit, $C10 for attending each intervention session in lieu of snacks given the virtual nature of the intervention, $C60 for each assessment (ie, baseline, post-treatment, follow-up) and $C50 for the completion of focus groups. Each facilitator will receive $C30 in compensation for completing the individual interview. Compensation will be provided to promote participant retention and completion of follow-up.

During the recruitment process, participants may receive a newsletter update to maintain engagement in the study, informing them of the state of recruitment. They may also receive a friendly greeting card, with a small treat. At randomisation, they will receive a youth-friendly study flyer introducing the study team and the study procedures. To facilitate group adherence, cameras must remain on during each session, and youth co-designed group-building activities will occur at the start of every session. To support the participants in cases of distress, virtual breakout rooms will be available for use together with one of the co-facilitators, and individual debrief sessions will also be provided.

Sample size

The sample size is determined based on the desired precision of the estimated feasibility measures as the

Table 2 Estimated Clopper-Pearson 95% CIs for feasibility metrics

Feasibility metric	Target success rate	Expected 95% CI
Recruitment success	n=96/160 (60%)	(52.0%, 67.7%)
Treatment retention	n=77/96 (80%)	(70.8%, 87.6%)
Study retention	n=77/96 (80%)	(70.8%, 87.6%)
Study compliance	n=86/96 (90%)	(81.7%, 94.9%)

primary objective of the pilot trial, as recommended by the Consolidated Standards of Reporting Trials extension.[44] Table 2 below illustrates the sample size calculations for each feasibility metric. The sample size is n=96 across two baskets and two arms (24 per basket per arm). This equates to four rounds of NECT-Y, at about 12 participants per group, with the same number of control participants. A recruitment success of 60% means that 96 participants will be recruited out of 160 approached, which generates a 95% CI of 0.520 to 0.677. Across all four feasibility metrics, the CI width is not expected to exceed 0.168, which is sufficiently narrow to be confident in our estimates of feasibility. This pilot/feasibility trial is intentionally not powered to detect statistically significant differences between arms on clinical outcome measures. Interpretations will therefore be secondary in nature and will focus on estimating between-group effect sizes (with 95% CIs).

Randomisation

A computerised randomisation module will be generated to randomise participants 1:1 to NECT-Y or TAU. It will use random block sizes and randomisation will be stratified by treatment site and by basket. The allocation sequence will be generated by the study statisticians. It will then be uploaded into REDCap[42] by team members unconnected to study participants. It will be accessed electronically by the research staff only at the time of randomisation as they will be responsible for randomly assigning participants to either group. Allocation concealment will be achieved since the staff making the random assignment will have no awareness of or control over the randomisation schedule. Participants and study staff will not be blinded to the randomisation result after the randomisation occurs, given the psychosocial nature of the intervention. Data analysts will be blinded to group assignments.

Interventions

NECT-Y consists of 14 individual sessions of 90 min each, which will be delivered via a secure institutional teleconferencing system (WebEx) over the course of 14 weeks. The intervention combines psychoeducation, cognitive therapy, narrative therapy, goal-setting and peer support. Each group meeting includes educational materials, reflections and active exercises that participants are guided through verbally by facilitators to personalise the content to their experiences, with a supportive workbook.

Table 3 Description of the sessions involved in NECT-Y

Session number	Content
Session 1	Orientation to the group, group agreement, concept of recovery
Sessions 2–4	Psychoeducation on stigma, self-stigma, myths vs facts, impacts, disclosure
Sessions 5–8	Cognitive therapy on self-stigma, thought-feeling-behaviour connections, cognitive restructuring, self-talk
Sessions 9–12	Narrative enhancement, ie, developing a self-story that considers challenges as well as strengths and successes
Session 13	Goal-setting exercise: short-term and long-term goals
Session 14	Reflections about the group as a whole and closure

Participants will receive a print copy of the intervention workbook, which will allow them to follow the activities. The sessions are described in table 3.

NECT-Y will be delivered by clinicians embedded in the clinical setting and co-facilitated by peer support workers, who will add selective sharing of lived experience consistent with the values of peer support to increase the relevance of the intervention for participants. Three clinician facilitators together with three peers have been trained in NECT-Y by the NECT developer, for staffing flexibility in administration. The training is described in a study by Yanos *et al*.[25] Training events included familiarisation, role play and corrective feedback; the NECT fidelity scale,[25] with NECT-Y adaptations, was used as a framework for training competence.

TAU typically consists of psychiatric consultation and follow-up, medication management, basic group psychoeducation about the index diagnosis, and group or individual psychotherapy and/or addiction therapy, as indicated. TAU does not explicitly focus on stigma. TAU was selected as a comparator as a pragmatic choice to compare the active intervention with the type of care youth would normally receive in the study sites and to achieve equipoise. Typical TAU will be described by the clinical site lead. Specific services received will be documented through service utilisation questions asking participants to describe the services they have received during the trial period. Participation in any concomitant therapies will not be prevented. All participants can request to withdraw from the study at any time, and this decision will not affect their current or future care at CAMH or LHSC. No further data will be collected from the participant from the time of their discontinuation from the study.

Measures

Primary outcomes: Feasibility indicators are the primary outcome of interest. These include the following metrics: recruitment success (objective: >60% of those approached consent), recruitment rate (objective: 24/2 months),

Table 4 Schedule of assessments

Assessment	Screening visit	Baseline assessment	Post-treatment assessment	3-month follow-up assessment
Demographics (where needed)	X			
SCID-5 (where needed)	X			
Internalised Stigma of Mental Illness Scale – 9-item screening version	X			
Custom screening questions	X			
Internalised Stigma of Mental Illness Scale		X	X	X
Altman Self-Rated Mania Scale		X	X	X
Patient Health Questionnaire – 9		X	X	X
Coping Orientation to Problems Experienced Inventory		X	X	X
WHO Quality of Life Scale		X	X	X
EuroQol-5 Dimensions-5 Levels		X	X	X
Mental Help Seeking Attitudes Scale		X	X	X
Adult State Hope Scale		X	X	X
Medical Outcomes Study Measures of Patient Adherence		X	X	X
Stages of Recovery Instrument		X	X	X
Generalised Anxiety Disorder Scale		X	X	X
Rosenberg Self-Esteem Scale		X	X	X
Personal goals and Goal Progress Chart		X	X	X
Personal reflection		X	X	X
Custom medications and service utilisation questionnaire		X	X	X
Focus group/qualitative interview			X	

SCID-5, Structured Clinical Interview for DSM-5.

treatment retention (objective: >80% of sessions attended), study retention (objective: >80% at T2, >70% at T3), study completion (objective: >90% assessment completion among retained participants), serious adverse events (objective: none) and facilitator fidelity (objective: ≥4 overall fidelity on the fidelity scale).[25]

Secondary outcomes: Secondary outcomes will be acceptability and participant self-reported outcomes on a battery of measures. The schedule of assessments is provided in table 4. Self-report measures were selected by the team on the basis of relevance to the clinical profiles of participants, relevance to stigma and recovery concepts, psychometric properties and validation among young adult samples, as well as inclusion in previous studies of NECT in some cases. Completion of participant self-reported measures will serve to evaluate the feasibility of study compliance as a primary outcome, but will also be assessed directly as secondary outcomes. Change from baseline to T2, baseline to T3, and from T2 to T3 will be evaluated for all assessments. A custom

form will be used to collect demographic information. An important measure in the current study and the anticipated primary outcome of the future definitive RCT is the Internalised Stigma of Mental Illness Inventory (ISMI).[45] Additional secondary outcomes encompass mental health/symptom scales including the Altman Self-Rating Mania Scale[46] for (hypo)manic symptoms, the Patient Health Questionnaire[47] for depressive symptoms, and the Generalised Anxiety Disorder Scale[48] for anxiety symptoms. Quality of life will be measured with the WHO Quality of Life,[49] as well as the EuroQol-5 Dimensions-5 Levels[50] for a utility measure. Other constructs include coping, measured with the Coping Orientation to Problems Experienced Inventory[51] and hope measured with the Adult State Hope Scale.[52] Help-seeking attitudes are measured with the Mental Help Seeking Attitudes Scale,[53] while adherence to medical treatments is measured with the Medical Outcomes Study Measures of Patient Adherence Survey.[54 55] Self-esteem will be measured with the Rosenberg Self-Esteem Scale.[56] Psychosocial recovery will be measured with the Stages of Recovery Instrument.[57] Participants will be asked to set personal goals prior to the intervention phase and evaluate their goal achievement at follow-up using the Goal Progress Chart.[58] They will also be asked to reflect on their life using a personal reflection form.[59] A custom service utilisation questionnaire will be used to enable participants to describe the services they receive during the trial period.

Acceptability to patient participants and facilitators will be assessed qualitatively following a co-designed semi-structured interview guide. The interview guide will focus on the acceptability of each section of the intervention and of the intervention as a whole from the perspective of the participants and facilitators, leveraging the implementation, adoption and maintenance components of the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework for implementation science.[60 61]

Data management

Data will be collected by study staff using the REDCap data capture system,[42] either virtually or in-person using a study laptop, at baseline (week 1), post-treatment (week 15) and at 3-month follow-up (week 28). At each time point, feasibility indicator data will be entered into the system by research staff, and participant response data from questionnaires will be entered directly into the REDCap system by the participant. Data will be monitored by the study staff, with periodic monitoring reviews and quality checking. The biostatistics team will be consulted on an ad hoc basis as needed. The final dataset will be accessible to the study leads, the study staff and the biostatistics team. Study data will be deposited in the accessible CAMH BrainHealth Databank. The data from the multiple mental health conditions basket will also be deposited in the Brain-CODE open-access database managed by the Ontario Brain Institute. For both databases, with participant consent, research ethics approval and committee review, data may be accessed by third parties for secondary research.

Data analyses

Data analyses will be conducted upon the completion of data collection, without interim analyses. Analyses will be conducted for each site, each basket, and together, with overall study findings based on all site and basket data interpreted together. All estimates of feasibility metrics will be calculated as frequencies, proportions and average proportions and range, with 95% CIs to plan the future definitive RCT. Participant quantitative outcomes will be analysed descriptively, with 95% CIs to understand sociodemographic and clinical profiles. We will model patient outcomes using linear mixed models for continuous variables and Generalised Estimated Equations for dichotomous variables, which are robust to missing data. Time since the onset of symptoms may be considered as a possible moderator on an exploratory basis, if sample sizes allow. Statistical analyses will adhere to the intention-to-treat principle.

Qualitative data analyses will be conducted using reflexive thematic analysis,[62] following an inductive approach to the development of codes, themes and interpretations, with openness to latent themes. Tentative quantitative and qualitative data will be taken to our youth advisory group for discussion and co-interpretation, to enhance relevance, reflexivity and credibility. The analyses will be refined and finalised accordingly.

Intervention feasibility

A number of areas of intervention feasibility will be interpreted based on the study feasibility data. Notably, intervention retention will be an area of interest. It is important to note that this is a 14-session intervention, which is relatively long and may lead to dropouts over time. We discussed this with our youth advisory group for feedback. Intervention retention strategies include compensation in lieu of snacks, the requirement of maintaining cameras on for clinical engagement, youth-developed icebreaker activities at the beginning of each session, encouraging privacy in their personal space, and hiring engaging, friendly facilitators. The appropriateness of the adaptation to a youth population is also under question; while this was completed by a youth team, for youth,[33] and is expected to be largely acceptable, it is possible that more adaptation is required. The qualitative substudy will serve to confirm the youth-oriented adaptation.

Distress and adverse events

Distress experienced by youth during the sessions will be addressed by the facilitators. One co-facilitator can open a break-out session for a private discussion with the youth if necessary. Post-session individual de-briefs will also be available if needed. Research staff and clinicians will remain alert to any spontaneously reported adverse events, including if a participant expresses any current suicidal ideation or self-harm during a study visit. They

will immediately inform the study leads and the event will be taken to the governance committee for discussion. Any serious adverse events, as defined by the CAMH Research Ethics Board, will be immediately reported to the board.

Patient and public involvement

Lived experience team members will be involved in all stages of the trial, from study design to knowledge translation, in accordance with Canada's Strategy for Patient-Oriented Research.[37] A lived experience adaptation group conducted the youth-oriented adaptation of the trial.[33] The Trial Governance Committee includes two co-investigators serving in lived experience advisory roles. In addition, a Youth Advisory Group has been established, consisting of youth with lived experience of either BD or MMHC. The Youth Advisory Group is co-facilitated by two Youth Engagement Specialists and a research staff member. Young people with lived experience have contributed to the study design and will contribute to ongoing decisions about the study, including design, procedures, analysis, interpretation and knowledge translation. Lived experience engagement will be reported on using the Guidance for Reporting Involvement of Patients and the Public checklist.[63]

Future definitive RCT

The results of the current trial will be used to inform the design of a future definitive RCT. Notably, the current trial is not powered to detect efficacy; that will be the primary aim of the future definitive RCT. Rigorous interpretation of the group by time effect will focus on the future primary outcome measure (ISMI), as well as the secondary outcome measures. For that trial, a power analysis will be based on expected effect sizes, power and planned significance levels. If the different baskets in the current trial show different study results, it may be necessary to adapt the basket trial design accordingly.

Limitations

As a pilot RCT, this trial is underpowered to detect significant differences in participant outcomes, especially within baskets; a future definitive RCT will be required to rigorously assess outcomes for NECT-Y as a whole and specific to youth with BD or MMHC. Participant outcomes are in self-report format, which may differ from the results that would be obtained by interviewer-administered assessments. For example, social desirability may affect self-report scores. Participation in concomitant psychological therapies might differ across NECT-Y and TAU groups, which could mask the impacts of the intervention; we will collect information on concomitant therapies and may control for this if between-group differences are found. The study is taking place in two hospital settings and among two patient groups; generalisability cannot be confirmed outside of the hospital settings and identified participant baskets. Follow-up is only short- and medium-term. Future research protocols might include longer-term follow-up assessments. Collecting data from family caregivers or members of the social network might also be considered as an additional source of information.

ETHICS AND DISSEMINATION

This study has been approved by the CAMH Research Ethics Board (#062/2024) and is approved at the London Health Sciences Centre (Western Health Sciences Research Ethics Board (HSREB) #125812). Any future amendments will be submitted for approval prior to implementation; the ClinicalTrials.gov registry will be updated and other parties will be informed as needed, including consented participants if appropriate. Written electronic informed consent will be provided by all participants prior to beginning study activities, using the CAMH REDCap E-Consent Framework.

Personal identifying information will be collected and stored in a password-protected file on a secure CAMH server accessible only to authorised personnel, to maintain confidentiality. A master linking log will contain identifying information and a study identification number. All other participant data will be labelled only by the study identification number. Research staff will review all open-ended fields and qualitative transcripts for identifiers and will de-identify them as needed.

Any medical care required by participants will be covered by the Ontario Hospital Insurance Plan, as is common practice locally. Participants will receive a flyer presenting suggested avenues to obtain mental health support, in addition to the support they are receiving within the hospital setting.

Dissemination will include conventional academic knowledge translation activities (manuscripts, conference presentations). Several papers have been planned as part of this study, including a primary outcome paper, a qualitative paper and various secondary analyses. Authorship will be determined based on the extent of the contributions to the study, including study stages such as conceptualisation, design, implementation, data analysis, interpretation and report writing. Professional writers and artificial intelligence tools will not be used to write any reports. We will also conduct lay-friendly knowledge translation tools to be co-designed by our lived experience team; in the past, these have included infographics and social media tools.

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and thereby have informed its design and development. All authors critically reviewed the manuscript, provided feedback and approved the final version. LDH is responsible for the overall content as guarantor.

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REFERENCES

1 Corrigan PW, Roe D, Tsang HWH. *Challenging the stigma of mental Illness*. Hoboken, NJ, US: John Wiley and Sons, 2011.
2 Elkington KS, Hackler D, McKinnon K, *et al*. Perceived Mental Illness Stigma Among Youth in Psychiatric Outpatient Treatment. *J Adolesc Res* 2012;27:290–317.
3 Sartorius N, Gaebel W, Cleveland H-R, *et al*. WPA guidance on how to combat stigmatization of psychiatry and psychiatrists. *World Psychiatry* 2010;9:131–44.
4 Corrigan PW, Kerr A, Knudsen L. The stigma of mental illness: Explanatory models and methods for change. *Appl Prev Psychol* 2005;11:179–90.
5 Hatzenbuehler ML. Structural stigma: Research evidence and implications for psychological science. *Am Psychol* 2016;71:742–51.
6 Dubreucq J, Plasse J, Franck N. Self-stigma in Serious Mental Illness: A Systematic Review of Frequency, Correlates, and Consequences. *Schizophr Bull* 2021;47:1261–87.
7 Karidi MV, Vassilopoulou D, Savvidou E, *et al*. Bipolar disorder and self-stigma: A comparison with schizophrenia. *J Affect Disord* 2015;184:209–15.
8 Yen C-F, Chen C-C, Lee Y, *et al*. Self-stigma and its correlates among outpatients with depressive disorders. *Psychiatr Serv* 2005;56:599–601.
9 Curcio C, Corboy D. Stigma and anxiety disorders: A systematic review. *Stigma Health* 2020;5:125–37.
10 Bonfils KA, Lysaker PH, Yanos PT, *et al*. Self-stigma in PTSD: Prevalence and correlates. *Psychiatry Res* 2018;265:7–12.
11 Moses T. Adolescent mental health consumers' self-stigma: associations with parents' and adolescents' illness perceptions and parental stigma. *J Community Psychol* 2010;38:781–98.
12 Sheikhan NY, Henderson JL, Halsall T, *et al*. Stigma as a barrier to early intervention among youth seeking mental health services in Ontario, Canada: a qualitative study. *BMC Health Serv Res* 2023;23:86.
13 Merikangas KR, He J-P, Burstein M, *et al*. Lifetime prevalence of mental disorders in U.S. adolescents: results from the National Comorbidity Survey Replication--Adolescent Supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry* 2010;49:980–9.
14 Ociskova M, Prasko J, Kamaradova D, *et al*. Individual correlates of self-stigma in patients with anxiety disorders with and without comorbidities. *Neuropsychiatr Dis Treat* 2015;11:1767–79.
15 Vrbova K, Prasko J, Ociskova M, *et al*. Comorbidity of schizophrenia and social phobia - impact on quality of life, hope, and personality traits: a cross sectional study. *Neuropsychiatr Dis Treat* 2017;13:2073–83.
16 Yanos PT, Roe D, Lysaker PH. The Impact of Illness Identity on Recovery from Severe Mental Illness. *Am J Psychiatr Rehabil* 2010;13:73–93.
17 Yanos PT, DeLuca JS, Roe D, *et al*. The impact of illness identity on recovery from severe mental illness: A review of the evidence. *Psychiatry Res* 2020;288:112950.
18 Eisenberg D, Downs MF, Golberstein E, *et al*. Stigma and help seeking for mental health among college students. *Med Care Res Rev* 2009;66:522–41.
19 Mehra K, Hawke LD, Watson P, *et al*. Youth Perspectives on Seeking Psychotherapy: A Concurrent Mixed Methods Study. *J Can Acad Child Adolesc Psychiatry* 2021;30:165–76.
20 Hussain S, Yanos PT, Wiesepape CN, *et al*. The experience of stigma and treatment-seeking among youth and family members receiving first episode psychosis services. *Stigma Health* 2024.
21 Saporito JM, Ryan C, Teachman BA. Reducing stigma toward seeking mental health treatment among adolescents. *Stigma Res Action* 2011;1:9–21.
22 Chief Public Health Officer of Canada. The chief public health officer's report on the state of public health in Canada 2019. addressing stigma: towards a more inclusive health system Ottawa, Canada 2019. 2022. Available: https://www.canada.ca/en/public-health/corporate/publications/chief-public-health-officer-reports-state-public-health-canada/addressing-stigma-toward-more-inclusive-health-system.html [Accessed 19 Jul 2022].
23 Health Canada. Action framework for building an inclusive health system Ottawa, Canada2019, 2019. Available: https://www.canada.ca/en/public-health/corporate/publications/chief-public-health-officer-reports-state-public-health-canada/addressing-stigma-action-framework-infographic.html [Accessed 17 Aug 2022].
24 Yanos PT, Roe D, Lysaker PH. Narrative enhancement and cognitive therapy: a new group-based treatment for internalized stigma among persons with severe mental illness. *Int J Group Psychother* 2011;61:577–95.
25 Yanos PT, Lysaker PH, Silverstein SM, *et al*. A randomized-controlled trial of treatment for self-stigma among persons diagnosed with schizophrenia-spectrum disorders. *Soc Psychiatry Psychiatr Epidemiol* 2019;54:1363–78.
26 Huang L-T, Liu C-Y, Yang C-Y. Narrative enhancement and cognitive therapy for perceived stigma of chronic schizophrenia: A multicenter randomized controlled trial study. *Arch Psychiatr Nurs* 2023;44:59–68.
27 Roe D, Hasson-Ohayon I, Mashiach-Eizenberg M, *et al*. Narrative enhancement and cognitive therapy (NECT) effectiveness: a quasi-experimental study. *J Clin Psychol* 2014;70:303–12.

28 Hansson L, Yanos PT. Narrative enhancement and cognitive therapy: A pilot study of outcomes of a self-stigma intervention in a Swedish clinical context. *Stigma Health* 2016;1:280–6.
29 Baourda VC, Brouzos A, Mavridis D, *et al*. Group Psychoeducation for Anxiety Symptoms in Youth: Systematic Review and Meta-analysis. *J Spec Group Work* 2022;47:22–42.
30 Bevan Jones R, Thapar A, Stone Z, *et al*. Psychoeducational interventions in adolescent depression: A systematic review. *Pat Educ Couns* 2018;101:804–16.
31 James AC, James G, Cowdrey FA, *et al*. Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database Syst Rev* 2013;2020:CD004690.
32 Hawke LD, Nguyen ATP, Rodak T, *et al*. Narrative-based psychotherapies for mood disorders: A scoping review of the literature. *SSM MH* 2023;3:100224.
33 Hawke LD, Bennett R, Sheikhan NY, *et al*. Lived experience adaptation of a psychosocial intervention for young adults with bipolar spectrum disorders: Process description and adaptation outcomes. *E I Psych* 2023;17:1125–30.
34 Woodcock J, LaVange LM. Master Protocols to Study Multiple Therapies, Multiple Diseases, or Both. *N Engl J Med* 2017;377:62–70.
35 Perich T, Mitchell PB, Vilus B. Stigma in bipolar disorder: A current review of the literature. *Aust N Z J Psychiatry* 2022;56:1060–4.
36 Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
37 Canadian Institutes of Health Research. Strategy for patient-oriented research - patient engagement framework. 2019. Available: https://cihr-irsc.gc.ca/e/48413.html
38 First MB, Williams JB, Karg RS, *et al*. Structured clinical interview for dsm-5 disorders. clinician version (scid-5-cv); 2015.
39 Kaufman J, Birmaher B, Brent D, *et al*. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): initial reliability and validity data. *J Am Acad Child Adolesc Psychiatry* 1997;36:980–8.
40 Endicott J, Spitzer RL. A diagnostic interview: the schedule for affective disorders and schizophrenia. *Arch Gen Psychiatry* 1978;35:837–44.
41 Hammer JH, Toland MD. Internal structure and reliability of the Internalized Stigma of Mental Illness Scale (ISMI-29) and Brief Versions (ISMI-10, ISMI-9) among Americans with depression. *Stigma Health* 2017;2:159–74.
42 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
43 Abdelazeem B, Abbas KS, Amin MA, *et al*. The effectiveness of incentives for research participation: A systematic review and meta-analysis of randomized controlled trials. *PLoS ONE* 2022;17:e0267534.
44 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
45 Ritsher JB, Otilingam PG, Grajales M. Internalized stigma of mental illness: psychometric properties of a new measure. *Psychiatry Res* 2003;121:31–49.
46 Altman EG, Hedeker D, Peterson JL, *et al*. The Altman Self-Rating Mania Scale. *Biol Psychiatry* 1997;42:948–55.
47 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
48 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
49 The Whoqol Group. Development of the World Health Organization WHOQOL-BREF Quality of Life Assessment. *Psychol Med* 1998;28:551–8.
50 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
51 Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. *Int J Behav Med* 1997;4:92–100.
52 Snyder CR, Harris C, Anderson JR, *et al*. The will and the ways: Development and validation of an individual-differences measure of hope. *J Pers Soc Psychol* 1991;60:570–85.
53 Hammer JH, Parent MC, Spiker DA. Mental Help Seeking Attitudes Scale (MHSAS): Development, reliability, validity, and comparison with the ATSPPH-SF and IASMHS-PO. *J Couns Psychol* 2018;65:74–85.
54 DiMatteo MR, Sherbourne CD, Hays RD, *et al*. Physicians' characteristics influence patients' adherence to medical treatment: results from the Medical Outcomes Study. *Health Psychol* 1993;12:93–102.
55 Sherbourne CD, Hays RD, Ordway L, *et al*. Antecedents of adherence to medical recommendations: results from the Medical Outcomes Study. *J Behav Med* 1992;15:447–68.
56 Rosenberg M. *Society and the adolescent self-image*. Princeton: Princeton University Press, 1965.
57 Andresen R, Caputi P, Oades L. Development of a short measure of psychological recovery in serious mental illness: the STORI-30. *Australas Psychiatry* 2013;21:267–70.
58 Law D. *Goals and goal based outcomes: some useful information*. CAMHS Press, 2013.
59 Arntz A, Hawke LD, Bamelis L, *et al*. Changes in natural language use as an indicator of psychotherapeutic change in personality disorders. *Behav Res Ther* 2012;50:191–202.
60 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322–7.
61 Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Serv Res* 2018;18:177.
62 Braun V, Clarke V. One size fits all? What counts as quality practice in (reflexive) thematic analysis? *Qual Res Psychol* 2021;18:328–52.
63 Staniszewska S, Brett J, Simera I, *et al*. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ* 2017;358:j3453.