CLINICAL STUDY PROTOCOL

The Effect of a Group Music Therapy Advocacy Recording Intervention (MTAR) on Internalized Stigma in Adult Psychiatric Inpatients in Acute Care

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Abbreviations

Abbreviation	Explanation
ACU	Acute Care Unit
APA	American Psychiatric Association
DSM-5	*Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; American Psychiatric Association, 2013)
HMHCC	Hackensack Meridian Health Carrier Clinic
ISMI	Internalized Stigma of Mental Illness Inventory
MT	Music Therapist or Music Therapy
MTAR	Music Therapy Advocacy Recording

Summary

The primary objective of this study is to determine the effect of a systematic music therapy intervention on internalized stigma of mental illness. The secondary objective is to evaluate the potential for the treatment effect to vary across subject diagnostic categories. This study will also examine the ability of the treatment effect to persist after 3 weeks as an exploratory objective.

Data collection will be conducted in the Acute Care Unit (ACU) of Hackensack Meridian Health Carrier Clinic (HMHCC) over a period of ten months. Subjects will be drawn from the pool of patients admitted to the HMHCC ACU during that time. Adults aged 18-65 with severe mental illness with a diagnosis of bipolar or a related disorder, depressive or anxiety disorder, or schizophrenia spectrum or other psychotic disorders as defined by the DSM-5 (5th ed.; American Psychiatric Association, 2013), of prolonged duration with a significant degree of disability or social dysfunction (Ruggeri et al., 2000) are eligible to participate. Eligible participants must be able to provide informed consent as determined by the doctor.

1 – Introduction

This study will be investigating the effects of the Music Therapy Advocacy Recording intervention (MTAR) on internalized stigma in adult inpatients in acute psychiatric care. MTAR is a sequence of group music therapy songwriting and recording sessions framed as a mental health awareness project to be shared with the general public. Internalized stigma is the subjective, nonconscious process of assimilating socially transmitted stereotypes and negative messages about mental illness into one's own belief system (Corrigan, 2005; Link, 2001; VandenBos, 2007). It is distinct from direct experiences and perceptions of social stigma (Corrigan, 2005; Hinshaw, 2009). Internalized stigma is negatively associated with quality of life (Degnan et al., 2021; Picco et al., 2016), self-esteem (Lysaker et al., 2008; Segalovich et al., 2013), recovery orientation (Yanos et al., 2008), morale (Ritsher & Phelan, 2004), social adaptation (Firat, 2020; Link, 1987; Lysaker et al., 2007; Perlick et al., 2001), general functioning (Yanos et al., 2012; Muñoz et al., 2011), symptom severity (Corrigan, 2004; Livingston & Boyd, 2010; Lysaker, 2010; Tesfaye, 2020), treatment adherence (Fung et al., 2009), and medication adherence (Semahegn et al., 2021), and it is positively associated with delayed treatment seeking (Fox et al., 2018; Sirey et al., 2001; Tucker et al., 2013; Vogel et al., 2013; Wade et al., 2015) and greater risk of suicide (Schomerus et al., 2015). Considering the scope and gravity of related outcomes, developing treatment strategies for internalized stigma has naturally become a topic of considerable interest in current mental health research.

Five recently published meta-analyses and systematic reviews (Alonso et al., 2019; Büchter & Messer, 2017; Tsang et al., 2016; Wood et al, 2016; Yanos et al., 2015) have drawn mixed conclusions about the efficacy of interventions designed to address internalized stigma. Tsang et al. (2016) assert that "most internalized stigma reduction programs appear to be effective", while Büchter & Messer (2017), "did not find any encouraging results". Authors' conclusions and recommendations for optimal intervention development and approach are similarly varied. Alonso et al. (2019) posit that psychoeducation and interventions combining elements of psychoeducational, cognitive-behavioral, narrative, motivational, peer support, and empowerment strategies showed the best results. Wood et al. (2016) recommend that interventions target specific demographics, while Tsang et al. (2016) call for more innovation. For Büchter & Messer (2017), the most important aspects of developing new approaches are systematic literature review and involvement with people from stigmatized groups. The wide array of recommendations from these authors highlights the need for more research in this area, including the need for new evidence-based interventions to address internalized stigma.

None of these systematic reviews and meta-analyses evaluate music therapy approaches. Music therapy is currently used in a wide range of mental health settings with diverse and varied populations (Eyre, 2013). Recent Cochrane reviews of music therapy and depression (Aalbers et al., 2017) and schizophrenia (Geretsegger et al., 2017) found that music therapy can improve functioning and quality of life, and reduce depressive and anxiety symptoms in patients with depression and schizophrenia. Sparse but promising research has suggested the potential efficacy of music therapy for addressing internalized stigma (Silverman, 2013; Woofenden, 2020) with songwriting, improvisation, and community performance-based methods. The intervention designed for this study combines elements of these methods in a way that is informed by the music therapy literature, and expands upon these approaches with the added component of a music therapy recording session aimed at creating music for mental health awareness.

Though a rich precedent exists for utilizing recording technology in music therapy, its clinical potential and therapeutic relevance have not been systematically investigated. Kirkland & Nesbitt (2019) offer a model of therapy-oriented recording as a medium for self-reflection and personal narrative review for patients with concurrent psychiatric disorders. When framed as a mental health advocacy project to be released to the general public, recording the patient-composed song in the MTAR treatment sequence offers patients an opportunity to proactively work together in a socially supportive context to change public perception of mental illness, to refute self-relevance of stereotypes by strengthening and broadening self-concept, and empower themselves and each other with creative, expressive tools to confront and adapt to the "experience, perception, or anticipation of negative social reactions" (Livingston & Boyd, 2010) to mental illness that initiate stigma internalization.

In this study, subjects will work together with a certified music therapist (MT) in groups of 5 to 7 subjects per group to compose, rehearse, and record a song to be released to the general public for the purpose of generating anti-stigma mental health awareness. The primary objective is to reduce internalized stigma from baseline relative to the control group as measured by the 29-item Internalized Stigma of Mental Illness Inventory (ISMI; Ritsher et al., 2003). The secondary objective, examining the association between treatment effect and diagnostic category, can assist in generating hypotheses related to effective implementation. The exploratory goal of the study is to examine the potential for the treatment effect of the music therapy intervention to persist after 21 days from baseline.

The mechanism of change in this study is rooted in the aesthetic decision-making intrinsic to the musical experiences of songwriting, active music-making, and music recording. In making these decisions, subjects integrate symbolic representations of the lived experience of stigma into a healthy and expanded self-concept. This process is aided by the mutual social support in collaborating on the artistic product, transforming the negative experiences and perceptions of social stigma into an object of beauty and a catalyst for social change. The recording also serves as a post-treatment reminder of the subject's successful attainment of a meaningful goal and their agency to effect positive change.

2 – Background

2.1. Background/literature review

There is substantial literature examining the processes related to stigma internalization and approaches to address it. The impact of internalized stigma upon a person's recovery is connected to how they make sense of their subjective experience and diagnosis of mental illness in the context of widely-held beliefs (Yanos et al., 2010). The "Illness Identity" model (Lysaker et al., 2007; Yanos et al., 2008, 2010, & 2020) describes how internalized stigma precipitates poor outcomes via the "insight paradox" (Lysaker et al., 2007) which posits that the interaction between stigma internalization and increased awareness of one's mental illness results in increased hopelessness and decreased self-esteem. Hopelessness and low self-esteem contribute to increased avoidant coping, leading to increased risk of suicide, social interaction, and vocational functioning, which can amplify symptom severity (Lysaker et al., 2007; Yanos et al., 2008, 2010, 2020).

Recent meta-analyses offer insight into theoretical foundations of programs seeking to address internalized stigma. Degnan et al (2021) conclude that "psychological interventions should target improvements in [self-concept and social networking] to reduce the negative impact of stigma on quality of life in psychosis". Yanos et al. (2015) assert that "tools and experiences designed to increase or elicit hope, empowerment, and motivation to act toward one's goals and according to one's values" are important components of interventions aimed at reducing internalized stigma. In alignment with these recommendations, this music therapy approach offers subjects opportunities to expand self-concept by highlighting their innate aesthetic sensibilities as expressed in the creative process, provides tools to engage in self-advocacy which can transform "illness identity" into an empowered self-concept, and utilizes the intrinsic motivation of musical experiences to instill hope in the accomplishment of

a specific goal. The collaborative group format provides opportunities for participants to build social skills that can be used to strengthen post-treatment support networks.

Drapalski et al. (2013) identify four clinical "pathways" intended for use as a basis for developing interventions targeted at reducing internalized stigma. The MTAR intervention utilizes each of the four in a distinct phase: Songwriting and Arrangement, Rehearsal, Recording, and Review (see Table 1).

Clinical "pathway", Drapalski et al. (2013)	Related MTAR phase(s)	Description of MTAR phase
Undermine the perceived accuracy and self-relevance of stereotypes	Verbal Processing; Songwriting and Arrangement	Confront and refute stereotypes by sharing personal perspectives and experiences of stigma in lyric writing.
Reinforce the inaccuracy of stereotypes by broadening self-concept	Rehearsal	Build a sense of competence and mastery rooted in intrinsic musicality, aesthetic sensibility, and creative expression.
Realistically assess rejection probability	Recording	Experience acceptance, social support, and group cohesion in the face of potential judgment and rejection; access vulnerability by making musical decisions based on personal aesthetic.
Connect with non-stigmatizing others	Editing and Review	Work together to achieve a sense of pride and connectedness in accomplishing a goal; connect with others in the pursuit of betterment on intrapersonal, interpersonal, and societal levels.

Table 1. Phases of MTAR treatment sequence as related to Drapalski et al.'s (2013) model

Narrative enhancement approaches are also common in interventions that address internalized stigma (Alonso, 2019; Roe et al., 2010; Yanos et al., 2012). These approaches utilize cognitive restructuring techniques (Beck, 1970) to challenge maladaptive beliefs by developing self-affirming personal narratives. This study does not utilize narrative enhancement or cognitive restructuring per se, but draws from and expands on these techniques conceptually. By centering an advocacy project on a shared group narrative in the context of aesthetic expression, the intervention offers participants opportunities to reframe their life histories from a self-affirming perspective, and to substantiate the reframing with a new experience that can build self-efficacy and a sense of mastery (Schulze, 2009), and nurture a sense of connectedness to a larger whole.

Yanos et al. (Yanos et al., 2010) suggest group advocacy work as a potential treatment for internalized stigma, and highlight the efforts of mental health consumer advocacy and self-help groups to aid mental illness recovery by empowering identity transformation. Qualitative evidence suggests that the "mental health consumer" approach can help patients integrate negative experiences into a healthy self-concept through self-disclosure combined with advocacy work (McCoy et al., 1994; Onken & Slaten, 2000). The potential for these programs to increase resistance to stigma internalization, while promising, has not been systematically studied. The proposed study draws from the self-disclosure and self-advocacy elements of the mental health consumer movement, but it is not peer-led or a self-help group. The music therapist-led format was selected because the typically higher acuity of

hospitalized subjects necessitates a consistent and coherent procedure with skilled facilitation to contain and ground the work.

Of recently developed interventions included in meta-analyses and systematic reviews that demonstrated a significant reduction of internalized stigma, the intervention most similar to the current study is Photovoice (Russinova et al., 2014). Photovoice is a peer-based photography intervention combined with psychoeducation, personal narrative construction, and community activism. Like MTAR, Photovoice aligns with Drapalski et al.'s (2013) and Degnan et al.'s (2021) recommendations for intervention development, and incorporates the identity transformation work of the mental health consumer movement (Yanos et al., 2010) by working in groups to create an artistic product aimed at effecting social change. The core principle of both MTAR and Photovoice is to integrate negative memories of stigmatizing experiences into an empowered narrative, which is then realized as an aesthetic artifact and transmitted to a wide audience as an agent of social change. However, MTAR differs from Russinova et al.'s (2014) study in a number of significant ways (see Table 2).

Though MTAR is grounded in the research literature related to internalized stigma treatment, there are two notable divergences. First, nearly all published studies included in meta-analyses examine interventions that take place as part of outpatient treatment. While outpatient approaches may be less complicated to implement and measure, they are often remedial of internalizing stigmatizing experiences related to inpatient hospitalization. MTAR is implemented during inpatient treatment, at the critical juncture when the internalization of experiences related to hospitalization is nascent. Second, most interventions include psychoeducation as a fundamental component. Psychiatric inpatients, who typically present with a higher acuity level and may be psychotic or actively decompensating, can lack the insight for significant reflexive thinking, and can rarely self-regulate to the degree required to sit for a 60- or 90-minute psychoeducation class. For this reason, psychoeducation in this study is limited to a 10-minute introduction to the concept of internalized stigma in the first session of the treatment sequence.

A major benefit of addressing internalized stigma in an inpatient setting with music therapy is that musical experiences are intrinsically motivating and pleasurable. This stands in contrast with much of the inpatient psychiatric hospital experience, which is often characterized by isolation (Lindgren et al., 2019), feeling unsafe (Berg et al., 2017), powerlessness related to a perceived lack of influence on choice of medication and treatment (Færden et al., 2020), and feeling bored or "caged in" (Stewart et al., 2015). Music therapy is a non-threatening opportunity to take part in new experiences with new people. Combined with the acquired awareness of internalized stigma in the presence of social support, engaging in new experiences can strengthen participants' resistance to stigmatization by building internal resources based on the need for novel experiences (Szcześniak et al., 2018).

In a peer-reviewed music therapy study that provides quantitative data that demonstrates a reduction in internalized stigma in an inpatient psychiatric setting, Silverman (2013) examines the effects of a songwriting intervention in which subjects compose lyrics for "The Stigma Blues".The study concluded that music therapy was significantly more effective in addressing internalized stigma relative to the control group, and the author suggests that the songwriting

Photovoice (Russinova et al., 2014) Characteristic	MTAR Characteristic	Rationale of Divergence
Narrow diversity of demographic characteristics in study sample/small sample size	Broad diversity of demographic characteristics at HMHCC; larger sample size	Greater generalizability of research findings

One-dimensional mode of creative expression (photography)	Multiple modes of creative expression: lyric-writing, composing, performing, and recording music.	Engaging in creative expression in various aesthetic modes offers opportunities to adapt to changing and evolving moods, perspectives, and feelings in real-time.
Parallel creative process	Collaborative creative process	Collaborating on a single work of art, rather than multiple individual works, requires a greater investment in social interaction.
Collection of individual narratives	Individual narratives integrated into a group narrative	Building a group narrative creates more opportunities for group cohesion
Peer-led	Music therapist as facilitator	MT can guide, contain, ground the sessions for higher-acuity inpatients; create meaningful opportunities by interfacing between patient and technology; occupy a supportive role in realizing group aesthetic
Outpatient	Inpatient	Prompt intervention to improve outcomes

Table 2. Comparison of Photovoice (Russinova et al., 2014) and MTAR Characteristics and Rationale of Divergence

process contributed to a disinhibition of self-disclosing personal histories of stigmatizing experiences (Silverman, 2013). MTAR includes a songwriting component, but also expands upon Silverman's approach (See Table 3).

The use of recording technology to address internalized stigma is a novel approach. A qualitative music therapy study based on a community music therapy approach (Solli & Rolvsjord, 2015) which included recording, mixing, and producing music, subjects emphasized that music therapy "represented freedom from illness, stigma, and treatment". This suggests that a music therapy recording session can provide a locus for transforming a participant's illness identity. Using recording technology creates the opportunity to utilize the public relations and social media infrastructure of the hospital to to promulgate the work as part of a mental health awareness project. Participants' belief in their potential to effect large-scale societal change via musical expression of their personal experiences is the central mechanism for instilling feelings of empowerment and motivation in this study.

"The Stigma Blues" (Silverman, 2013) Characteristic	MTAR Characteristic	Rationale of Divergence
Single-session intervention	Four-phase treatment sequence over five sessions	Build trust, group cohesion, engagement with the musical process
Blues format	Open musical format	Broad scope of musical

		expression
No advocacy component	Advocacy-based	Identity transformation through empowerment
MT performs the music	Subjects rehearse and perform the music	Identity transformation through competence and mastery
No recording component	Includes Recording and Review Phases	Extend treatment effect by monumentalizing the work for reflection and insight
Demographic data (diagnosis) not collected	Demographic data (diagnosis) collected	Investigate potential relationships between treatment effect and diagnoses to inform future developments and implementation

Table 3. Comparison of “The Stigma Blues” (Silverman, 2013) and MTAR Characteristics and Clinical Rationale of Divergence

Using recording technology creates a record of subjects’ achievement that can be accessed at any time in the future and serve as a post-inpatient treatment reinforcement of an empowered identity, potentially extending the treatment effect. MTAR’s actual capacity to induce systemic change is out of scope for this study.

The proposed study fills the gap between Photovoice (Russinova et al., 2014), the mental health consumer movement (McCoy et al., 1994; Onken & Slaten, 2000), and the music therapy research of Silverman (2013) and Solli & Rolvsjord (2015) with an inpatient treatment sequence that combines elements of artistic collaboration to bolster self-esteem, self-concept, and social support; and community activism building a sense of agency, self-efficacy, and empowerment. It will focus on how the music therapy group, in nurturing expressive and aesthetic modes-of-being centered on mental health advocacy in the context of peer support, can diminish or prevent internalized stigma.

3 – Rationale, Objectives and Hypothesis

3.1. Study Rationale/Problem Statement/Research question or Study significance

What are the effects of a music therapy intervention focused on writing, recording, and releasing music to the general public for the purpose of mental health advocacy on internalized stigma of mental illness among adult inpatients in acute care?

3.2. Hypothesis

Adult psychiatric inpatients on an acute care unit who participate in music therapy groups focused on writing, recording, and releasing music to the general public for the purpose of mental health advocacy will report less internalized stigma from baseline relative to the control group upon completion of the treatment sequence, regardless of subject diagnosis. The effect will persist when measured at 3-weeks post-baseline.

3.3. Primary Objective

Reduce internalized stigma of mental illness among adult inpatients in acute care with a music therapy intervention focused on writing, recording, and releasing music to the general public for the purpose of mental health advocacy.

3.4. Primary Outcome Variables

ISMI score pre-treatment, ISMI score post-treatment

3.5. Secondary Objective

Reduce internalized stigma of mental illness across subject diagnostic categories. ISMI

scores will be compared between subjects with no diagnosis or diagnosed with schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, depressive disorders, and anxiety disorders, as classified by the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM–5; American Psychiatric Association, 2013).

3.6. Secondary Outcome Variable

ISMI score pre-treatment, ISMI score post-treatment, ISMI score 3 weeks post-treatment, Diagnostic Category: No Diagnosis, Diagnostic Category: Schizophrenia Spectrum and Other Psychotic Disorders, Diagnostic Category: Bipolar and Related Disorders, Diagnostic Category: Depressive Disorders, and Diagnostic Category: Anxiety Disorders

3.7. Exploratory Objective

Examine the persistence of the treatment effect, to be measured at 3 weeks after completion of the treatment sequence.

3.8. Exploratory Outcome Variables

ISMI score 3 weeks post-treatment

4 - Study Design

4.1 General Design

This prospective clinical trial's pseudo cluster randomized controlled design (Borm et al., 2005) will take advantage of the unit's two separate residential areas ("wings", ACU West and ACU East) to minimize contamination and selection bias by randomizing treatment and control conditions to each wing, rather than each individual subject (see Figure 1).

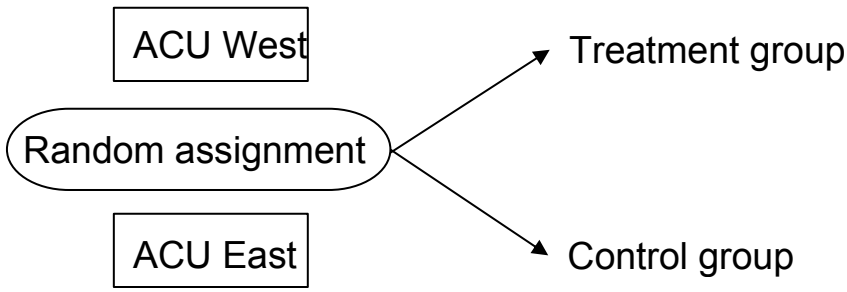

Figure 1. Pseudo Cluster Randomization Procedure

Patients on the unit currently receive opportunities to take part in several groups per day focused on topics of coping skills, mindfulness, journaling, creative arts, wellness recovery, recreation, and at least one music therapy group, as part of the standard of care. The current study improves upon the standard of care by providing a protocolized intervention sequence targeted at reducing internalized stigma of mental illness.

The intervention consists of a sequence of five music therapy songwriting and recording groups, one per day. Internalized stigma will be assessed within 3 days of admission (pretest/baseline), at ten days (posttest), and at 3 weeks from baseline (follow-up), using the Internalized Stigma of Mental Illness Inventory (Ritsher et al., 2003; Appendix 2).

4.1.1 Study Duration

The proposed study duration is one year, with eight months allotted for data collection, and four months allotted for data analysis. Subjects will be involved for a period of 21 days, including follow-up data collection (See Table 4). Results of this study can help inform the feasibility of collecting follow-up data from this population, as patient adherence to aftercare plans can be unpredictable.

Day	Treatment Group	Control Group

1-3	Enrollment, Pre-Test/Baseline	Enrollment, Pre-Test
4-10	Treatment Sequence	No Treatment Sequence
8-10	Post-Test	Post-Test
21	Follow-up data collected	Follow-up data collected

Table 4. Study Timeline Per Cohort

4.1.2 Number of Study Sites

This study will take place at Hackensack Meridian Health Carrier Clinic, 252 County Road 601, Belle Mead, NJ 08502

4.2 Study Population

All patients who are anticipated to remain admitted to the unit for at least 7 days will be considered regardless of gender or racial/ethnic background with the exception of those less than 18 years of age. Additional exclusion criteria will include S1 status (1:1 patient observation), evidence of organic brain disease, severe acute symptomatology, hearing deficit, and intellectual disability. Eligible patients must be able to read and comprehend the ISMI questionnaire, and provide informed consent as determined by their doctors.

4.2.1. Number of Participants

Based on power analysis (power=80%, see other assumptions in section 5.8.1) and the design of the study, 50 patients will be accrued to each group (n=100).

4.2.2. Eligibility Criteria

Eligible patients include adults age 18-65 who have been admitted to the HMHCC ACU, and must be able to read and comprehend the ISMI questionnaire, provide informed consent, and have severe mental illness of prolonged duration with a significant degree of disability or social dysfunction (Ruggeri et al., 2000).

Exclusion criteria will include patients younger than 18 or older than 65, patients on S1 status (1:1 patient observation) or isolation protocol, evidence of organic brain disease, severe acute symptomatology, hearing deficit, and intellectual disability.

4.2.3. Vulnerable populations

Patients on medical isolation protocol (such as those who test positive for COVID-19 while hospitalized) and patients that are unable to provide their own consent will be excluded from the study.

4.2.4. Withdrawal criteria

Subjects may withdraw from the study at any time by stating their wish to withdraw to research staff. No new data will be collected from withdrawn subjects. However, all data that have already been collected for study purposes will remain.

4.3. Study procedures

Patients will be identified and referred upon admission to the Acute Care Unit at HMH Carrier Clinic by the treatment team (attending doctors, nurses, and social workers). All subjects who are anticipated to remain admitted to the unit for at least 7 days will be considered regardless of gender or racial/ethnic background with the exception of those less than 18 years of age.

Internalized stigma will be assessed within 3 days of admission (pretest/baseline), at ten days (posttest), and at 3 weeks from baseline (follow-up), using the Internalized Stigma of Mental Illness Inventory (Ritsher et al., 2003; Appendix 2). The ISMI is a widely-used measure with acceptable internal consistency (α = .72-.90) and test–retest reliability (r = .68-.92; Boyd et al., 2014; Chang et al., 2016). It was selected over the Perceived Devaluation

and Discrimination Scale (PDD; Link, 2987) and Self-Stigma in Mental Illness Scale (SSMOI; Tucker et al., 2013) due to concerns about internal consistency and psychometric properties of these measures (Brohan et al., 2010). Data collection will include the subject's name, diagnoses, treatment ID number, and ISMI score. Treatment effect will be measured by using a two-factor, mixed-design analysis of variance (ANOVA). A P value of less than 0.05 will be considered to indicate statistical significance.

Description of Procedures

The music therapy treatment group will utilize a certified music therapist to facilitate a series of 5 group music therapy sessions over the course of 5 to 7 consecutive weekdays. Groups will be composed of 5 to 7 patients and the MT. There is no standard number of sessions for interventions addressing internalized stigma, and the available literature varies from one session in a single day to twenty sessions over a period of months. Since the average length of stay for acute care unit patients is 7 to 10 days, 5 sessions is the maximum feasible number of sessions to complete the treatment sequence for shorter stays. Though patients typically receive daily music therapy groups as part of the standard of care, this study improves upon the standard of care by providing a protocolized intervention sequence targeted at reducing internalized stigma of mental illness.
After enrollment and consent, research staff will administer the ISMI in hard copy to establish a pretest baseline. After the treatment sequence of 5 group music therapy sessions, research staff will administer the ISMI in hard copy for post-test data. The ISMI will be administered by phone or in person by research staff for 3-week follow-up data.

4.3.1. Study discontinuation
Subjects may stop taking part in this research study at any time without any penalty.
If a participant withdraws from the study, no new data about them will be collected for study purposes. All data that have already been collected for study purposes will remain. This will not affect their ability to receive care at any HMH hospitals or to receive any benefits to which they are otherwise entitled.

4.4. Risks and Benefits

There are no perceived medical risks to subjects in this music therapy study. Potential benefits related to music therapy in this population include improving functioning and quality of life, and reducing depressive and anxiety symptoms. The primary potential benefit for this study is reduced internalized stigma of mental illness, with secondary potential benefits of improving symptoms associated with internalized stigma described above

The potential for loss of private information always exists; there will be procedures in place to minimize this risk (see below).

5 – Methods

5.1. Screening

Patients will be screened for eligibility each morning during the treatment team meeting. See section 6.5 ("Informed Consent") for more information.

5.2. Recruitment, enrollment and retention (including screen failures as applicable)

The consent process will take place in a private room in the acute care unit and will be overseen by Zachary D. Fischer, PhD, MT-BC, the principal investigator. The process will take 15 to 20 minutes, during which time research staff will orient the participant to the study and go over the study protocols in detail as indicated in the consent form, making sure that participant understands its content. Potential participants will be provided with the opportunity to ask any questions or take the consent form to their room and make a decision later. The participant will sign the informed consent upon complete understanding of its content and agreement on participation in the study.

Subjects who are discharged or noncompliant during the treatment phase will be dropped from the study, and no further data will be collected from these subjects. Data that has been collected will remain.

5.3. Study intervention

A board-certified music therapist will facilitate the five sessions constituting the treatment sequence as follows:

1) verbal processing of a) subjects' individual experiences and perceptions of stigma, and how those experiences have impacted their relationships, available resources, mental health, and treatment; and b) the specific misconceptions and inaccuracies that contributed to those experiences; culminating in a collaboratively composed song title;
2) reflection upon themes, metaphors, images, and symbols drawn from the discussion will inform collaborative lyric-writing. Additionally, the group will begin to make musical decisions based on discussion of preferred and relevant musical styles and genres, including the selection of one or more reference tracks. A reference track is an existing song that can be used as a stylistic or structural model.
3) group composition and arrangement;
4) rehearsing and recording the song; and
5) editing (mixing and mastering) and review.

The standard of care for ACU patients at HMH Carrier Clinic includes psychoeducational and verbal processing groups, and music therapy groups. MTAR exceeds the standard of care by offering a targeted treatment sequence that includes music therapy recording and self-advocacy.

5.4. Assignment / randomization

This prospective clinical trial's pseudo cluster randomized controlled design will take advantage of the unit's two separate residential areas ("wings") to control for contamination bias by randomizing treatment and control conditions to each wing, rather than each individual subject (see Figure 1 above).

5.5. Section of instruments (to include for all studies with a social behavioral intervention)

Internalized stigma will be assessed after enrollment, within 3 days of admission to the hospital (pretest/baseline), at ten days (posttest), and at 3 weeks after baseline (follow-up), using the Internalized Stigma of Mental Illness Inventory (Ritsher et al., 2003; Appendix 2). The ISMI is a widely-used measure with acceptable internal consistency (α = .72-.90) and test–retest reliability (r = .68-.92; Boyd et al., 2014; Chang et al., 2016). It was selected over the Perceived Devaluation and Discrimination Scale (PDD; Link, 2987) and Self-Stigma in Mental Illness Scale (SSMOI; Tucker et al., 2013) due to concerns about internal consistency and psychometric properties of these measures (Brohan et al., 2010).

5.6. Data collection (data points, source and storage)

Data points will include the subject's name, diagnoses, and treatment ID number, to be collected from the medical chart by research staff; and ISMI score, collected from the subject by questionnaire administered by the PI. Data will be collected by research staff and entered into REDCap, a secure web application.

The participant's file as it relates to this study will only be altered by the PI, who is also the clinician implementing the intervention. After each session (and only at this time), the PI will briefly document the group topic and the patient's affect and presentation as observed. For example: "(*Participant first name*) participated in a music therapy songwriting group focused on themes of stigma and resilience. (*Participant first name*) initially presented with a blunted, flat affect, becoming more activated and brightening by the end of the session. (*He/she/they*) participated by verbally suggesting the genre '(*genre*)' and song title '(*song title*)' for the project." Documentation related to the study will not be differentiated in the participant's file from other therapeutic group activity.

5.7. Follow-up and end-of study

Subjects will be hospitalized for at least the first two phases of data collection (pretest and posttest). The 3 week follow-up data may be collected either post-discharge or in the hospital, as required by the subject's unique treatment needs.

Subjects will be hospitalized for at least the first two phases of data collection (pretest and posttest), which will be administered in hard copy by research staff. The 3 week follow-up data may be collected by research staff either post-discharge by phone or in person in the hospital by hard copy, as required by the subject's unique treatment needs.

5.8. Statistical Method

5.8.1. Sample size calculation and justification

Based on power analysis (power=80%, see assumptions below) and the design of the study, 50 patients will be accrued to each group (*n*=100).

The study has a two-factor repeated-measures ANO*V*A design. For the power analysis, the assumption of sphericity will be made (*epsilon* = 1). Sphericity is the condition where the variances of the differences between all combinations of related groups (levels) are equal.

Assumptions and parameters of power analysis:

Sphericity: *epsilon* = 1
Type I error: *alpha* = 0.05
Type II error*: beta* = 0.2
Required power*: power* = 100(1 – *B*) = 80%
Effect size: f = 0.1, 0.25, 0.33, 0.4, 0.8
Cohen's effect size for F test, 0.1 ("small"), 0.25 ("medium"), 0.33, and 0.4 ("large"). Effect size of 0.33 was used.

5.8.2. Statistical Analysis Plan

Primary Analysis

Treatment effect on the primary dependent variable (ISMI score) will be measured by using a two-factor repeated-measures analysis of variance (ANOVA). A P value of less than 0.05 will be considered to indicate statistical significance.

Secondary Analysis

Treatment effect on the secondary dependent variables (diagnosis category) will be measured by using a two-factor repeated-measures analysis of variance (ANOVA). A P value of less than 0.05 will be considered to indicate statistical significance.

Exploratory Analysis

Treatment effect on the exploratory variable (ISMI score 3 weeks after baseline) will be measured by using a two-factor repeated-measures analysis of variance (ANOVA). A P value of less than 0.05 will be considered to indicate statistical significance.

6 - Trial Administration

6.1. Ethical Considerations - Institutional Review Board (IRB) Review

The study will be conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), the Declaration of Helsinki, Institutional Review Boards (IRB) and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

6.2. Institutional Review Board (IRB) Review (list the IRB of record)

The final study (ICF, HIPAA form as applicable) and data collection tools will be approved by the Institutional Review Board (IRB) at HMH. Approval will be received in writing before study initiation. Any changes to the study design will be formally documented in amendments and be approved by the IRB prior to implementation.

6.3. Data management (collection, storage etc.)

Hard copy data (such as paper questionnaires) will be collected and stored by research staff in a locked cabinet. Digital information will be stored on HMH password-protected computers.

6.4. Confidentiality

Patient charts, collected data, and analyses of the data will adhere to HIPAA & institutional patient confidentiality requirements. A unique identifier (study ID number) will be assigned to each patient. The study ID number will be included in the data collection tools and analysis software while the list with direct identifiers and ID numbers will be stored separately in a HMH password-protected computer and/or locked office.

If results of the study are published, individual names or other identifying information will not be used.

The completed audio recording will not contain any PHI aside from the subject's voice, which may be represented if the subject chooses to sing on the recording. Recording will include the voices of many people and individual people will not be identified in the recordings. Recordings will be posted on social media pending approval from HMH Corporate Communications, as per HMH PolicyStat ID 8270519: "The use or creation of a profile on any external social media sites for school or work-related purposes, such as blogs, groups forums, photo streaming sites, video, and audio must be reviewed and approved by the Hackensack Meridian Corporate Communications Department" (Retrieved from http://hmh.policystat.com/policy/8270519/).

6.5. Informed consent

Informed consent will be obtained prior to any research related activities. Informed consent will be documented in the study's data collection tools and hard copies of the consent form will be kept in the PI's locked office in a locked cabinet.

The majority of the psychiatric inpatient population has legal capacity to provide informed consent as well as the ability to make independent treatment decisions. There is a very small number of patients who do not have the ability to provide informed consent due to being deemed incapacitated by the psychiatrist or nurse practioner. These patients will be excluded from participation in this study.

Patients in the hospital routinely sign consent forms for various reasons: release of protected information to family members and caregivers; special privileges or greater responsibility on the milieu; and certain services (e.g. electroconvulsive therapy). Capacity to sign these forms is determined by the patient's doctor on a case by case basis.

Consent and appropriateness to participate in this study will be discussed and agreed upon by the treatment team, including nurses, social workers, group counselors, doctors, and the MT, during the morning report. The treatment team's collective insight and knowledge of a person's medication, treatment, and illness based on medical records and first hand observations of one's behavior during intake and assessment will determine capacity to consent to participate in this study.

6.6. Data Quality Assurance

Data will be collected by the PI, who has completed training from the Collaborative Institutional Training Initiative (CITI).

6.7. Study Records (retention etc.)

Records will be retained in accordance with regulatory and organizational requirements, but for no less than six (6) years following the completion of the study. Disposal of records will be performed according to regulations. At the conclusion of the study, hard copy data will be stored in a locked cabinet in the PI's locked office until disposal. Digital copies of audio recordings will be stored on an HMH password-protected computer until disposal, though completed audio recordings will remain online.

6.8. Credentials, Training

All clinicians implementing the intervention will maintain active certification status from the Certification Board for Music Therapists.

6.9. Financing and Insurance

This study is funded by HMH Carrier Clinic with a grant from the American Music Therapy Association. The grant will be disbursed in two installments of $2,471.89, a total of $4943.77. HMH Carrier Clinic has agreed to cover the cost of capital improvements, including acoustic treatment of the clinical space, up to $5000.00.

6.10. Publication Plan

Upon completion of data collection, analysis, and write-up, the study will be submitted for publication to a peer-reviewed journal.

Appendices

Appendix #	Name	Title	Section	Topic
1	Data Collected			
2	ISMI Questionnaire			

Appendix 1: Data collected

PHI: Name; DSM-5 category of diagnosis: schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, depressive disorders, anxiety disorders, no diagnosis

Non-PHI: Participant ID (#); ISMI Score pre-intervention/baseline (#); ISMI Score post-intervention (#); ISMI Score 3 week follow-up (#)

Appendix 2: ISMI questionnaire

Internalized Stigma of Mental Illness Inventory (ISMI)

We are going to use the term "mental illness" in the rest of this questionnaire, but please think of it as whatever you feel is the best term for it. For each question, please mark whether you strongly disagree (1), disagree (2), agree (3), or strongly agree (4).

	Strongly Disagree	Disagree	Agree	Strongly agree
1. I feel out of place in the world because I have a mental illness.	1	2	3	4
2. Mentally ill people tend to be violent.	1	2	3	4
3. People discriminate against me because I have a mental illness.	1	2	3	4
4. I avoid getting close to people who don't have a mental illness to avoid rejection.	1	2	3	4
5. I am embarrassed or ashamed that I have a mental illness.	1	2	3	4
6. Mentally ill people shouldn't get married.	1	2	3	4
7. People with mental illness make important contributions to society.	1	2	3	4
8. I feel inferior to others who don't have a mental illness.	1	2	3	4
9. I don't socialize as much as I used to because my mental illness might make me look or behave "weird."	1	2	3	4

10. People with mental illness cannot live a good, rewarding life.	1	2	3	4
11. I don't talk about myself much because I don't want to burden others with my mental illness.	1	2	3	4
12. Negative stereotypes about mental illness keep me isolated from the "normal" world.	1	2	3	4
13. Being around people who don't have a mental illness makes me feel out of place or inadequate.	1	2	3	4
14. I feel comfortable being seen in public with an obviously mentally ill person.	1	2	3	4
15. People often patronize me, or treat me like a child, just because I have a mental illness.	1	2	3	4
16. I am disappointed in myself for having a mental illness.	1	2	3	4
17. Having a mental illness has spoiled my life.	1	2	3	4
18. People can tell that I have a mental illness by the way I look.	1	2	3	4
19. Because I have a mental illness, I need others to make most decisions for me.	1	2	3	4
20. I stay away from social situations in order to protect my family or friends from embarrassment.	1	2	3	4
21. People without mental illness could not possibly understand me.	1	2	3	4
22. People ignore me or take me less seriously just because I have a mental illness.	1	2	3	4
23. I can't contribute anything to society because I have a mental illness.	1	2	3	4
24. Living with mental illness has made me a tough survivor.	1	2	3	4
25. Nobody would be interested in getting close to me because I have a mental illness.	1	2	3	4
26. In general, I am able to live my life the way I want to .	1	2	3	4
27. I can have a good, fulfilling life, despite my mental illness.	1	2	3	4
28. Others think that I can't achieve much in life because I have a mental illness .	1	2	3	4
29. Stereotypes about the mentally ill apply to me.	1	2	3	4
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List of Tables

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