Study Protocol

Title: Effect of Music Breathing, a programme based on mindful breathing and music therapy for promoting sense of coherence in young people: A randomized controlled trial

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Introduction

Stress arises when individuals perceive that they are powerless to cope with the demands placed on them (Lazarus, 1993). Chronic stress may lead to physiological (Pan et al., 2015) and psychological illnesses (Chernomas & Shapiro, 2013): adversely impacting interpersonal relationship and quality of life (Ribeiro et al., 2018). Young people are vulnerable to stressors associated with academic challenges, work and relationships (Sagy & Braun-Lewensohn, 2009; Ribeiro et al., 2018). Currently, these challenges have been exacerbated by the effects of the covid-19 pandemic, which has increased concerns associated with academic challenges, financial burdens, relationships and uncertainty about the future (CDC, 2020). Current research has found that young people's mental well-being was adversely affected and perceived more stress as the pandemic took hold in 2020 (Tang et al. 2021; Anwer et al., 2021). Coping with this stressful event has never been so imperative in order to maintain a healthy mental state in young people.

According to Lazarus and Folkman's Stress, Appraisal, and Coping Theory (1984), the type of coping strategy is influenced by the evaluation of options for coping, referred to as 'secondary appraisal' (Lazarus & Folkman, 1984). Secondary appraisal involves evaluation of the personal resources or coping strategies that can be used to manage situations. Therefore, the results of secondary appraisal will determine the coping strategies in the form of behavioural actions, which in turn influence individuals' emotional responses and mental well-being. Individuals with personal resources that can facilitate positive coping strategies and behaviours are therefore more adaptive to stressful situations. Sense of coherence (SOC) can be considered as a personal resource important to resolve stress and tension (Ängarne-Lindberg & Wadsby, 2011). SOC is defined as an enduring tendency individuals view life is comprehensible, manageable and meaningful (Antonovsky, 1993). It is a central component of the Salutogenic Model which plays a great emphasis on the role of personal resources and positive qualities in promoting well-being (Antonovsky, 1993). Therefore, a person with a strong SOC is more likely to perceive stressful situations less threatening and can mobilize resources that are available to promote well-being. Further, Posadzki, and Glass (2009) argued that the sense of manageability and meaningfulness in SOC is corresponded to the behavioral and emotional components, respectively, of self-efficacy in Bandura's Self-Efficacy Theory (1977). According to Bandura's (1977), self-efficacy is the confidence in one's ability to successfully complete a task. These two approaches

reflect a common feature is that people who have strong beliefs in their capabilities to tackle life events as challenges rather than threats (Posadzki, & Glass, 2009). The stronger SOC may engender the individuals' confidence to manage daily hassles, and hence increase the coping self-efficacy. Coping self-efficacy can be termed as the confidence of an individual in their ability to effectively cope with the potential threats (Luzzo & McWhirter, 2001). SOC could be a component in the process of secondary appraisal that influences the coping options and enhances self-efficacy of coping in meeting the demands from the environments.

To this end, SOC is therefore considered as a personal resource that can facilitate individuals to use resources available to manage stressful situations (Eriksson et al., 2017) and promote resilience against adversities (Mayer, 2011). In fact, previous studies with young people showed that SOC is associated with their quality of life, health behaviour, and mental health (Länsimies et al., 2017). It has been noted that SOC has a mediating effect between perceived stress and health status (Jeong & Koh, 2021), and a better SOC is associated with positive coping styles (Konaszewski et al., 2019). Furthermore, SOC and self-efficacy are closely related constructs in the context of self-management of chronic disease (Hourzad et al., 2018). Therefore, young people with a strong SOC may be more likely to perceive stressful situations less threatening and can facilitate coping strategies to cope with stressors, and thus attain a better mental well-being.

The proposed intervention

The proposed intervention, namely, music breathing (MB), was developed by Dag Körlin (co-investigator [Co-I] of the proposed study) as an adaptation of the Bonny Method of Guided Imagery and Music (GIM) (Bonny, 1975). As founded by Helen Bonny, GIM is an 'in-depth approach to music psychotherapy in which specifically programmed classical music is used to generate a dynamic unfolding of inner experiences' (Goldberg, 1995, p. 112). In GIM, music is used to evoke imagery and acts as a 'container' for the imagery experience. The therapist uses music with enough variability to stimulate flow and movement during the imagery experience, but avoids using excessive variability that would dysregulate the ANS. During the session, the therapist provides grounding and focus through an ongoing active dialogue with the client. The music used in GIM serves as a link between the self and the outer consciousness, and aspects of musical language, such as rhythm, melody and timbre, can enhance the feelings and imagery that arise from the unconscious self (Maack, 2012). GIM could allow individual to get into their previous emotions that require further processing; accordingly, it can help people to reconnect the non-integrated self during deep music listening, as the inner resources become conscious (Goldberg, 1995).

Although GIM was developed mainly for people with traumatic stress and ANS dysregulation, MB can be used by people without dysregulation, including those experiencing adjustment disorders and developmental crises and those seeking self-actualisation. The aim of MB is to help the person to learn affect regulation through breathing while listening to selected pieces of music (Körlin, 2019b).

Exposure to a threat or stress is known to arouse the autonomic system. Stress reduction involves the parasympathetic system, which cooperates with the sympathetic system to regulate arousal and autonomic activity. These two systems converge in the right medial orbitofrontal cortex (mPFC) to coordinate cognitive functions, including perception, decision making and emotional regulation via the lateral-, dorsal-ventral and vertical integration of whole-brain functions. Through breathing exercises, MB emphasises the vertical integration of the ANS, which coordinates the orbitofrontal region to facilitate emotional regulation of the limbic system and regulation of the ANS in the brain stem (Körlin, 2019a, 2019b).

During MB, forceful music can be used because the window of tolerance (WoT) increases when using meditative breathing. WoT refers to the zone in which one's nervous system can regulate and handle stressors in life (Siegel, 1999a). Each person is assumed to have a WoT that enables them to process and control their thoughts, emotions and images. This concept of the WoT is crucial for managing the stages of MB, namely the grounding, modulation and working stages (Körlin, 2008). The selection of music depends on the stage experienced by the individual and involves matching two dimensions: 1) the state of arousal and level of intensity, and 2) the degree of harmonic modulation and other musical transformations. The guiding principle is to identify the musical arousal level that the client can tolerate without dysregulation. Any changes in the harmonic progression and rhythmic variations may lead to emotional modulation. Music that is highly repetitive in terms of the melody, harmony, rhythm or other music elements tends to hold arousal at a steady level. In other words, the aim of MB is to initially stabilise the client in a comfortable zone of arousal, and then to explore different qualities and degrees of modulation. The selected music must be maintained with a steady rhythm and tempo it attunes with the breath (Körlin, 2019a, 2019b).

Dag Körlin, the Co-I of proposed study, has applied MB to clients with adjustment disorders and prolonged grief, and to those seeking self-actualisation. The initial findings from nine case studies demonstrated that patients with PTSD experienced reductions in depression–anxiety symptoms and stress levels after 15–20 weekly sessions (Körlin, 2019b). Körlin (2019b) also reported that MB yielded clinically significant reductions in chronic dissociative symptoms such as flashbacks, anxiety and fear.

During MB, the level of emotional response can be regulated by intentionally controlling breathing during periods of silence and listening to music. Breathing acts like a 'volume knob' to regulate the level of arousal and quality of consciousness. By varying the depth and pace of breathing, one can control arousal from moment to moment. Through breathing, the autonomic functions can be regulated. Based on the above theoretical discussions, we hypothesise that a programme, namely, music breathing (MB), can reduce stress, foster the self-regulation of emotions and facilitate the development of awareness and personal strength, as a result, leading to improved emotional well-being.

Based on the above theoretical discussions, we hypothesise that the MB programme can facilitate the promotion of SOC leading to better coping, reduced stress and better mental well-being. Fig. 1 shows the conceptual framework of the study. In the proposed study, the efficacy of a music breathing programme (MB) will be tested using a randomised controlled trial design. The hypotheses of the proposed study are as follows:

H1: People who receive the MB programme will have better SOC, emotion regulation, coping self-efficacy and mindfulness than those receiving the control condition.

H2: People who receive the MB programme will have reduced stress-related symptoms and better physiological outcome, i.e., salivary cortisol levels than those receiving the control condition.

H3: People who receive the MB programme will have better mental well-being than those receiving the control condition.

H4: There is an association between SOC, coping self-efficacy, emotion regulation and mindfulness.

Study design. We will conduct a two-arm, parallel randomised controlled trial (RCT) to evaluate the effects of the MB programme. Randomisation involving computer-generated two-digit random numbers (even and odd) (Excel 2007, Microsoft, Redmond, WA, USA) will be used to allocate participants in sequence to either the intervention group or control group in a 1:1 ratio after they have provided consent to participate. The allocation will be blinded to the participants and the data analyst. The random allocation will be conducted by a research assistant who will not be involved in the intervention and data analysis. Participants in the experimental arm will receive a 6-week MB programme. Participants in the control arm will receive a 6-week placebo control programme and will be blinded to the study details. Data will be collected from both groups at three time points: before-intervention (T0), after-intervention (week 6; T1) and 1-month follow-up (week 10; T2), except the salivary cortisol levels which will be assessed at T0 and T1. Figure 2 depicts the flow of the study.

Subject recruitment. The participants will be recruited from universities and district

centres through emails, social media, leaflets and posters. Inclusion criteria: young people (aged 18 to 30); moderate level of stress (Perceived Stress Scale (PSS-10) score ≥14-26/40); a liking for music. Exclusion criteria: participants diagnosed with an acute mental problem; participants under the influence of drugs that affect the nervous system; having previous experience with imagery evoked by music and meditations where music is played.

Sample size. The estimated sample size has been calculated using the statistical package G*Power 3.1.9.4 (version 2019) for a multivariate analysis of variance (MANOVA) according to the effect size (Cohen's d) (between 0.43 and 0.59) of anxiety in previous study on group music-guided imagery (Torres et al., 2018). When converting to a repeated measure (Cohen's f), the effect size is considered moderate (f = 0.25), with a type I error rate of 5% (2-sided) and assuming a correlation of 0.5 between repeated measures. To achieve 90% power to measure outcome three times in two groups, 232 subjects (n=116 per group) will be required (Cohen, 1988). Assuming a 20% attrition rate (Porter et al., 2012), the trial will require at least 145 participants starting in each arm. We target to complete the recruitment process within 20 weeks; therefore, an average rate of recruitment about 14 subjects per week is anticipated. It might be possible to shorten the recruitment period if the threat posed by the pandemic weakens.

Experimental group. The experimental group will receive the MB programme in 6 weekly sessions (each session lasts 2 hrs in a group of 6 participants) delivered in a confined and quiet room on the campus, plus a session of home practice on a weekly basis. The study intervention will be delivered by a certified music therapist who has been trained by the Co-I, Dag Körlin. At the beginning of the first session, information on the concept of mindfulness will be delivered. The MB will comprise three components, including therapist-guided meditative breathing, breathing with music listening, drawing a mental image of the breathing practice with a circle as a reference and sharing and processing of the experience (Körlin, 2019). The detail of the study intervention is presented in Table 1. **Home practice** will be carried out according to a weekly schedule during the 6-week intervention; the participants will record the frequency and duration of home practice: mindful breathing, music listening and drawing images. In the orientation during the first week, the participants will be asked to work out a plan for implementing home practice and to complete an online schedule during the subsequent weeks. To increase the compliance rate, they will also receive reminders to perform their home practice via WhatsApp messages or email. The research team will monitor the participants' progress, provide motivation and encouragement to continue the home practice.

Control group.

Participants (6-8 participants per group) will receive a 30-minute Mental Health Education Programme (MHE) in the first meeting (week 1) and second meeting (week 6). The content of the MHE is adopted from the Student Health Service, Department of Health, HKSAR. The MHE is comprised of the following topics:
What is Stress?
https://www.studenthealth.gov.hk/english/health/health_ph/health_ph_stress.html);
Tips on Being Joyful
(https://www.chp.gov.hk/archive/joyful/en/contentsab5e.html?id=40);
Breathing Exercise practice
(https://www.studenthealth.gov.hk/english/emotional_health_tips/eht_re/eht_re.html);
and
Music listening.
A take home kit which consists of the fact sheet information of the health talk and the video link of the breathing exercise and musical pieces will be provided to the participants after the first meeting. They are instructed to practice the breathing exercise and listening to the musical pieces at home. A weekly reminder via WhatsApp message and email will be sent to the participants to enhance their compliance. In the second meeting, participants will receive the revision talk about on the MHE and share their experience in stress management with the group members.

Treatment Fidelity. To ensure treatment fidelity, the certified music therapist will have at least 25 hours of MB programme training; the implementation of the intervention will be supervised by Dag Körlin, the Co-I. The group sessions will be audio-taped with the consent of the participants, and the recordings will be given to the supervisor for quality monitoring. Written session reports will be provided and regular meetings via Zoom (i.e., three supervisions in the first group, and then two supervisions in the subsequent groups) will be arranged for maintaining the quality of the intervention. The research team will discuss any issues that may arise regarding the study protocol to ensure the quality and consistency of study intervention via regular face-to-face or online meetings.

Measures. Primary and secondary measures will be collected at before-intervention (T0), after-intervention (week 6; T1) and 1-month follow-up (week 10, T2) via a self-administered questionnaire. The salivary cortisol levels will be collected at T1.

Primary outcome

Sense of coherence. The 13-item Chinese version of the Sense of Coherence Scale (C-SOC-13) (Ding et al., 2012) will be used to measure the comprehensibility, manageability and meaningfulness of the participants' lives (Antonovsky, 1993). This

scale is scored on a 7-point semantic scale with two anchoring phrases, ranging from 1 (very poor) to 7 (very strong). The higher mean score represents a greater sense of coherence. The original SOC-13 was shown to have high internal consistency (Cronbach's α = .74 – .91) (Antonovsky, 1993).

Secondary outcomes

Coping self-efficacy. The Coping Self-Efficacy Scale (CSES) is used to measure a person's confidence in their ability to cope effectively with stress (Chesney et al. 2006). It is a 13-item scale with three subscales: (1) use problem-focused coping, (2) stop unpleasant emotions, and (3) seek support from friends and family. The CSES has strong reliability (α = 0.79–0.92) and concurrent validity. It is rated on an 11-point scale on which the participant believes they could perform the behaviour. The anchor points range from 0 (cannot do at all), to 10 (certain can do). Higher scores indicate higher levels of coping self-efficacy.

Emotion regulation. The Difficulties in Emotion Regulation Scale (DERS) is used to assess the ability to regulate emotions (Gratz & Roemer, 2004). It contains a total scale score (36 items) and six factors including nonacceptance of emotional response, difficulties in engaging in goal-directed activity, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity. Items are measured on a 5-point Likert-type scale from 1 (almost never) to 5 (almost always), with higher values indicating difficulty in emotion regulation.

Mindfulness. The 15-item Mindful Attention Awareness Scale (MAAS) (Chinese version) will be used to assess attentiveness to and awareness of experiences in the present moment (Deng et al., 2012). This scale is scored from 0 (almost always) to 6 (almost never); a higher mean score reflects a higher level of mindfulness. The internal consistency of the scale is good (coefficient of reliability > .82).

Depression, anxiety and stress. The 21-item Depression Anxiety Stress Scales (DASS-21) (Chinese version) comprise 21 statements on three components: (a) depression, (b) anxiety and (c) stress (Lovibond & Lovibond, 1995). The scales are scored using a 4-point Likert scale with response options from 0 (does not apply to me at all) to 3 (applies to me very much, or most of the time). The internal consistency has been demonstrated to be good (Cronbach's α values: Depression = .88, Anxiety = .75, and Stress = .81).

Subjective general well-being. The 24-item BBC Subjective Well-being Scale (BBC-SWB) will be used to measure the participants' subjective experiences of general well-being (Pontin et al., 2013). It measures three components: psychological well-being, physical health and well-being and relationships with good internal consistency (Cronbach's α = .94) and concurrent validity (r = .640 - .80) (Pontin et al., 2013). The scale is scored using a 5-point Likert-scale.

Salivary cortisol: Salivary cortisol levels (sCort) will be used as a biomarker of psychological stress. sCort is considered a reliable measure of hypothalamus pituitary adrenal axis (HPAA) adaptation to stress and correlates well with plasma cortisol (Nater et al., 2013). Average sCort levels in healthy subjects are 5.52 - 28.92 nM/l in the morning; 1.10 - 11.32 nM/l in the afternoon (Bozovic et al., 2013). sCort is stable for several days, non-invasive and easily obtained without adding stress to subjects (Bozovic et al., 2013), and so is suitable for this study in which the participants are required to provide multiple samples at home. Samples will be collected from saliva using Cortisol Salivary Test kits and analysed using a commercially available enzyme-linked immunoassay (eNano Health). Participants will be asked to provide 2 samples: 0700–0800 h and 1600–1700 h to avoid meals within 60 min of providing each sample and to avoid caffeine-containing food and drink during the two days of sampling. Participants will be instructed to keep the samples in an envelope and send to the laboratory for analysis.

Demographic information. A self-developed questionnaire will be used to collect demographic information about the participants, including age, gender, educational level, religious beliefs and practices, socioeconomic status and coping behaviour. The latter will be assessed using the Brief Cope Inventory (COPE) (Carver, 1997).

Statistical analysis. The statistical analysis will be performed in accordance with the study design, RCT with an intention-to-treat analysis using SPSS, Version 26. The baseline characteristics of the participants in the two arms will be compared to identify any clinically meaningful differences at baseline and at each time point using Chi-square test (for nominal data), Mann-Witney U test (for ordinal or non-normality data) or t-test (for normality data). Any variables considered to be significantly different will be further evaluated (e.g., included as covariates in the statistical analyses) and adjusted to account for their potential confounding effects on the outcomes. To measure both the primary and secondary outcomes, we will obtain repeated measures of multiple outcomes in the two groups, and the data will be analysed using a multivariate approach, such as a MANCOVA or Generalized Estimating Equation (GEE), with adjustment of the baseline outcome variables to test for between-group differences. Correlation analyses will be performed to determine the relationships among the dependent variables. Regression analyses and ANOVA will be conducted to assess significant differences in the effects of the demographic variables on each outcome variable. Repeated measures of ANOVA will be performed to explore the levels of sCort differing within subjects and between groups; between the two sampling days (day) and across the five sampling times (time). Path analyses will be conducted to test the mediating effects between stress-related symptoms and personal strength and emotional regulation. Sub-group analyses will be conducted according to categorisations such as

gender, coping style and religion.

Ethical considerations. Ethical clearance will be sought prior to the study from the study institution. Consent will be obtained and anonymity ensured to protect privacy. Participants will receive study information and have autonomy to withdraw from the study at any time.

Significance of the study. The call to investigate effective strategies for stress management and improved mental well-being among young people has been prominent in this decade, particularly during the global pandemic period. The findings from the proposed study are expected to provide support for the potential benefits of a therapy option that integrates mindful breathing and music therapy with the intent to engender SOC in coping with stress in young people. The results will add knowledge of SOC to the stress and coping process and support the advancement of stress reduction-related knowledge. The findings will advance the level of professional knowledge, thus supporting researchers, health care professionals and policymakers who plan, implement and evaluate public health services and improve teaching and learning. While the MB programme requires professionally trained music therapists for delivery, the skills can be learned and practised by the participants. This therapy option provides an opportunity for young people to learn the techniques and benefit from the long-term effect of this intervention. In the long run, young people will have improved ability to cope with stressors in their everyday lives and will experience fewer psychological burdens and better health. Furthermore, in an era where the headlines seem dominated by war, plague and global warming, acquiring a coping skill that can be self-practised echoes the social distancing and reduce the demand for healthcare services. For young people, improved mental well-being can facilitate a healthy transition into adulthood and should yield promising results throughout their lives. These individuals are key contributors to the workforce and will contribute to economic growth and a positive societal environment.

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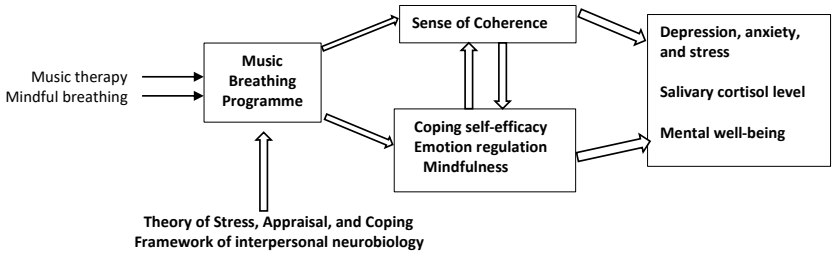

Fig. 1 Conceptual Framework of the study

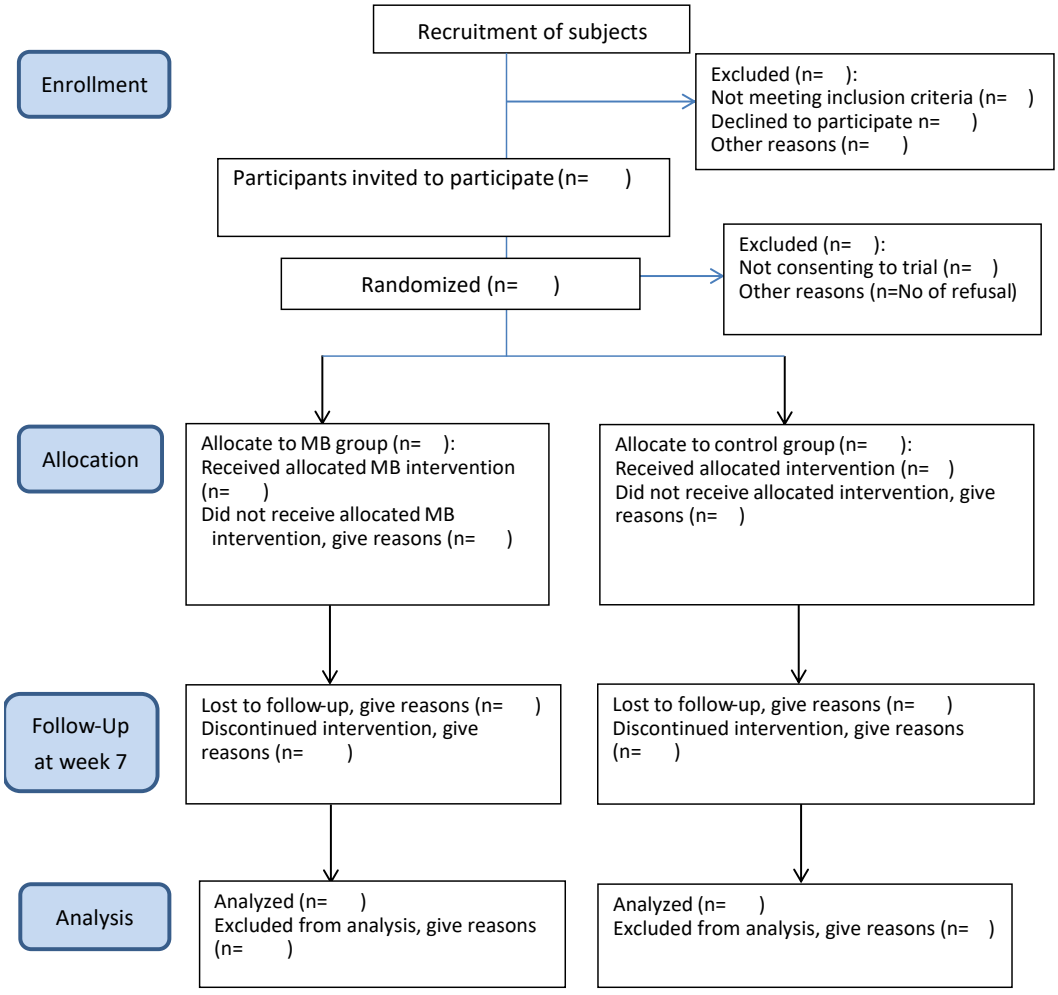

Figure 2. Study flow diagram

Table 1. Study intervention

Session	Activities (2 hours)	Weekly home exercise
1	a) Concept of mindfulness b) Discovery breathing c) Draw the mental image of the practice of discovery breathing d) Triangular breathing e) Silent Breathing (SB) f) Draw the mental image of the practice of SB g) Debriefing - Share and process the experience	- 5-min practice - Practise triangular breathing and SB and draw the mental image of the practice of SB.
2	a) Sharing and debriefing of the mental image drawn at home b) SB practice and drawing to the mental image of SB practice & debriefing c) Music Breathing (MB) d) Draw the mental image of MB with debriefing e) Debriefing - Share and process the experience	- 8-min practice - Practise SB, MB (Use music in the 2nd session) and the mental image of the practice of MB
3	a) Sharing and debriefing of the mental image drawn at home b) SB practice and drawing to the mental image of SB practice & debriefing c) Music Breathing (MB) d) Draw the mental image of MB with debriefing e) Debriefing - Share and process the experience	- 11-min practice - Practise SB, MB (Use music in present and previous sessions), and draw the mental image of the practice of MB
4	a) Sharing and debriefing of the mental image drawn at home b) Music Breathing (MB) c) Draw the mental image of MB with debriefing d) 30-second Music listening with breathing e) Discourse on the effects of each piece of music on self f) Debriefing - Share and process the experience	- 14-min practice - Practise SB, MB (Use music in present and previous sessions), and draw the mental image of the practice of MB
5	a) Sharing and debriefing of the mental image drawn at home b) Music Breathing (MB) - Perform breathing with listening to music pieces selected by therapist from the pre-arranged list c) Draw the mental image of MB with debriefing d) 30-second Music listening e) Debriefing - Share and process the experience	- 17-min practice - Practise SB, MB (Use music in present and previous sessions), and draw the mental image of the practice of MB
6	a) Sharing and debriefing of the mental image drawn at home b) Music Breathing (MB) c) Draw the mental image of MB with debriefing d) Movement to the music e) Debriefing - Share and process the experience f) Closing activities/ritual	- 20-min practice - Practise SB, MB (Use music in present and previous sessions), and draw the mental image of the practice of MB