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Rationale and design of Mind-HF: randomized trial of the original Mindfulness-Based Heart Training for patients with heart failure

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ABSTRACT

Introduction: There is evidence that mindfulness-based interventions can be effective in the treatment of patients with depression, anxiety, posttraumatic distress syndrome and many other disorders. Psychological disorders are common among heart failure patients. In the management of heart failure interventions based on mindfulness are used sporadically, and there is also a need for more evidence-based data to prove the efficacy of these methods.

Material, methods and results: Mind-HF is a pilot, single-centre, open-label study in which 30 adults hospitalized for heart failure (HF) are randomized to start Mindfulness-Based Heart Training (MBHT) or psychoeducational intervention. The efficacy and safety of MBHT training in comparison to psychoeducational intervention will be assessed over 3 months. Both interventions will be delivered online, therefore, additional feasibility of educational interventions through online tools will also be tested.

Conclusions: Mind-HF will provide evidence of the efficacy and safety of the original, HF-tailored mindfulness program delivered online. The results will thus be relevant for introducing MBHT to clinical practice for the management of HF. It will also check the feasibility of online tools in delivering education and psychological support for this group of patients.

Key words: heart failure, mindfulness, online, psychoeducation, Mindfulness-Based Heart Training

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Introduction

Heart failure (HF) is a clinical syndrome associated with poor prognosis. Recurrent rehospitalizations, progressive health deterioration, social isolation, and impaired quality of life (QoL) are common among HF patients. Individuals with HF often experience symptoms of chronic stress, depression, anxiety, hostility, chronic pain, insomnia, fatigue and dyspnoea [1, 2].

Depression and anxiety disorders, including generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD) and panic disorder, are the most com-

mon psychiatric conditions among HF patients and are associated with adverse outcomes, poor adherence to treatment recommendations, poor self-care management and increased risk of hospitalization and mortality [3, 4]. Mental disorders are linked to pathophysiologic mechanisms, such as dysregulation of the autonomic nervous system (ANS) resulting in sympathetic overactivation and parasympathetic downregulation, altered glucose and lipid metabolism, increased blood pressure and increased inflammation which promote the development of cardiovascular diseases (CVD), progression of HF, and sudden cardiac death (SCD)

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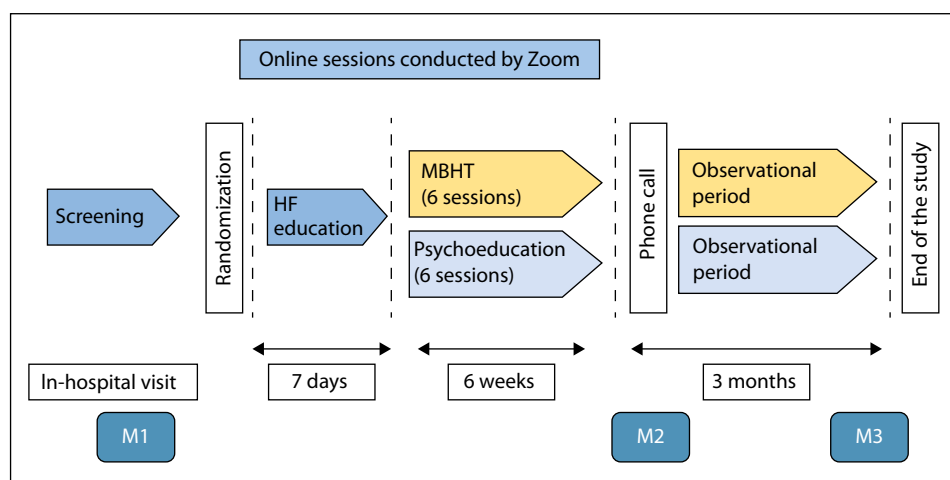


Figure 1. Study design

[5]. A meta-analysis of 36 studies found that clinically significant depressive symptoms affect 21.5% of HF patients [6]. More than 13% of HF patients fulfilling diagnostic requirements for a formal anxiety disorder [7].

The role of stress and pathological arousal of the sympathetic part of ANS in the development and progression of CVD, including HF, are well documented [8]. In addition, growing evidence exists on good mental health as a resilience factor and a contributor to adaptive functioning, which is associated with faster recovery, increased survival, and CVD risk reduction, despite physical illness [9]. Sound mental health and well-being protects against psychopathology. Thus, it makes interventions with a positive impact on mental health and stress levels highly relevant.

The classical approaches such as disease education, lifestyle modification and physical training are effective in improving health-related quality of life (HRQoL) and reducing hospitalizations and mortality but they do not focus on psychological distress and mental health improvement [10]. One of the evidence-based interventions with a positive impact on mental health are mindfulness-based interventions (MBI) [11, 12]. Existing literature suggests that MBIs emerge as promising strategies for reducing the severity of depression, anxiety, chronic fatigue, pain, improving QoL, cognitive functions, attention, emotional regulation, and social functioning among HF patients [13–16].

This publication presents the design and methodology of the ongoing MIND-HF study in the population of HF patients. The objectives of the study are: (a) examining the feasibility and acceptability of online-delivered original Mindfulness Based Heart Training (MBHT) for patients with HF (primary outcome), (b) exploring possible effects of the MBHT on self-reported and objectively assessed selected parameters of the physical and mental state (secondary outcomes), (c) assessing the safety

of the MBHT, (d) assessing the clinical characteristics of the HF population participating in the MBHT training, (d) assessing the patients' adherence to the interventions.

Material and methods

Study design

The MIND-HF is a randomized, open-label, parallel-group, a single-centre study assessing the efficacy and safety of the original Mindfulness Based Heart Training (MBHT) in comparison to psychoeducational intervention for HF patients during the 3-month follow-up. The study is conducted in the Department of Invasive Cardiology at the Central Clinical Hospital of the Ministry of Interior in Warsaw, Poland. The recruitment of patients started in January 2022. The data collection period is planned from 01/2022 to 12/2023. The study design is presented in Figure 1.

Study population

Participants are recruited selectively during hospitalization. Inclusion criteria are: 1) willingness to provide informed consent, 2) being 18 years or older, 3) chronic HF proven by echocardiography (reduced left ventricular ejection fraction (LVEF), systolic dysfunction, diastolic dysfunction, ventricular hypertrophy, chambers enlargement) 4) high motivation for changing lifestyle and implementation of self-care declared by patient, 5) motivation to alleviate the stress symptoms through mindfulness techniques declared by patient, 6) access to electronic devices enabling participation in online sessions. Exclusion criteria are: 1) acute decompensation of HF requiring IV treatment (diuretics, catecholamines) at the time of randomization, 2) NYHA

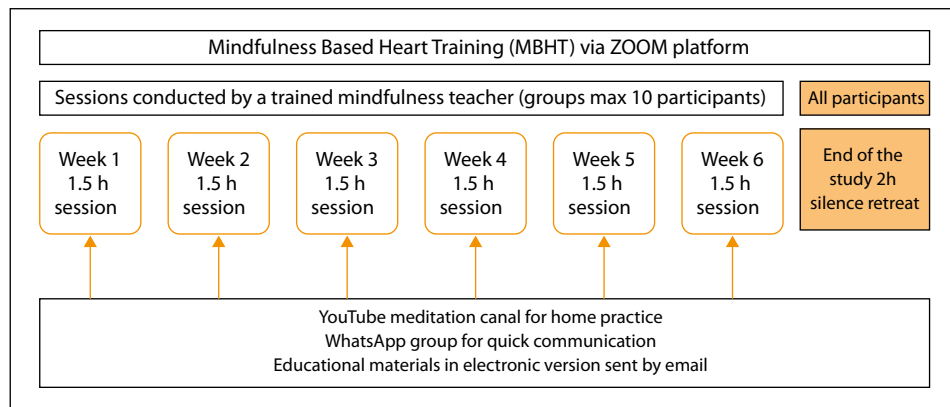


Figure 2. Mindfulness-Based Heart Training (MBHT) intervention scheme

IV (New York Heart Association class IV), 3) acute, unstable psychiatric problems requiring diagnosis and treatment, 4) acute, unstable CVD including unstable HF at the time of randomization, 5) medical invasive procedures during the last month before randomization or during the 3 months post randomization, 6) substance abuse, 7) cognitive impairment interfering with communication and adherence, 8) inability to cooperate and follow recommendations, 8) occurrence of highly stressful circumstances during the 3 months before randomization. No previous experience in mindfulness or meditation is required.

Before starting any trial procedures all participants are asked to sign informed consent (ICF). The study is conducted according to the Declaration of Helsinki. The study protocol was approved by the Bioethics Committee in the Central Clinical Hospital of the Ministry of Interior and Administration in Warsaw on May 9th, 2022 (No 30/2022).

Randomization procedure and blinding

The process of randomization is performed via a randomization list carried out by phone. The researcher sends a text message (SMS) to the randomization centre and participants are randomly assigned to either the intervention (MBHT) or control (psychoeducation) arm according to the randomization list. Study staff and participants cannot be blinded due to their active role in the intervention.

Experimental procedure and intervention

After signing the informed consent, patients are randomized 1:1 to one of the two groups: 1) the MBHT (the investigational arm) or the psychoeducation (the control arm). Both interventions are conducted online in the form of group sessions with up to 10 participants for 6 consecutive weeks (Fig. 2). In the intervention

group subjects take part in 90-minute long MBHT sessions for six consecutive weeks. Additionally, they are encouraged to have a daily home practice for at least 20–30 minutes using audio meditations available on the dedicated YouTube channel “Mindfulness for Heart” [17]. After each session, digital training material will be shared via email. The Mindfulness sessions are conducted by certified mindfulness instructor. All sessions will be conducted according to the same schedule: 1) invitation, 2) meditation, 3) round of enquiry, 4) theory session, 5) meditation, 6) round of enquiry, 7) homework overview, 8) session closing.

MBHT is the original mindfulness intervention that integrates selected elements of cognitive behavioural therapy with the clinical application of mindfulness mediation and was created based on scientifically proven programs, such as Mindfulness-Based Stress Reduction (MBSR) [18, 19] and Mindfulness-Based Compassionate Living (MBCL) [20]. It is focused however on the specific needs of patients with HF. The MBHT combines mindfulness techniques (body scan, breathing meditation, visualization, mindful movement, self-compassion, gratitude) with cognitive-behavioural techniques (experimental and behavioural techniques) to develop self-awareness, concentration, acceptance of present experience as well as the modification of mental and physical reactions to these events. An overview of the contents of the training sessions in MBCT is presented in Table 1.

The control group takes part in one-hour long psychoeducation sessions. Psychoeducational meetings cover the following topics: 1) cognitive model of thoughts — emotions — behaviour, 2) psychological symptoms of emotions and strategies to deal with them, 3) negative thoughts, 4) patients’ rights and social network, 5) value system, setting life goals, strengthening social roles, 6) behavioural strategies to prevent disease recurrence. The psychoeducation sessions are conducted by an experienced clinical psychologist.

Table 1. MBHT session overview

Session	1	2	3	4	5	6
Themes	The structure of the human brain The concept of Mindfulness and Compassion	Stress theory and its impact on health The role of chronic stress in the development of CVD	Three emotion regulation systems Threat system Drive system Soothing system	Behavioural patterns Behavioural automatisms Inner critic	The role of the soothing system in the healing process Ways to strengthen the soothing system.	Theory of happiness The role of compassion and gratitude in reducing stress reaction
Formal practices	Body scan meditation	Breathing meditation	Mindful movement meditation	Self-acceptance meditation	Metta meditation	Gratitude meditation
Informal practices	Breaks in daily activities to calm down and observe body sensations	Breaks in daily activities to focus on breath	Breaks in daily activities to observe the sky	Caring out a chosen activity of daily living slowly and carefully	Making a pleasure list	Acts of kindness during the day
Attention diary	Focus on body sensations (with special attention to legs and breath)	Focus on unpleasant sensations/ resistance	Focus on pleasant sensations	Focus on inner patterns and reactivity	Focus on everyday activities	Focus on soothing/relaxing activities
Homework	Audio meditations from YouTube canal, diary, informal practice	Audio meditations from YouTube canal, diary, informal practice	Audio meditations from YouTube canal, diary, informal practice	Audio meditations from YouTube canal, diary, informal practice	Audio meditations from YouTube canal, diary, informal practice	Audio meditations from YouTube canal, diary, informal practice

Data collection

To collect the data three measurement points are planned during the study: before the interventions (M1), after the 6-week intervention (M2) and 3 months after the intervention (M3). During all three visits metrics such as clinical status, psychological status, session attendance, medical treatment adherence and safety will be collected according to the clinical research form (CRF). The following demographic data will be captured during M1: gender, age, education, living conditions, place of living, and working status. The data on the status of the illness: HF duration, previous hospitalizations, comorbidities, aetiology of HF and type of HF will be collected from medical records.

Primary outcomes

To assess the program’s feasibility following metrics will be collected on all visits: retention rates, session attendance and the amount of individual mindfulness practice. To measure acceptability, the 5-item satisfaction Likert scale will be used.

Secondary outcomes

To assess the clinical impact of the interventions routine diagnostics tests will be performed according to the hospital protocol. Clinical measurements, which include medical history, physical examination (dyspnoea, NYHA class, oedema, SBP, DBP, signs of HF), biochemical parameters (Na+, K+, Cr, eGFR, glucose, hsCRP, NT-proBNP, serum cortisol, FE, TSAT, TSH), exercise capacity (6-MWT), Holter ECG (heart rate ventricular rate, ventricular arrhythmia patterns), echocardiography parameters (EF, GLS, LVEDd, LAVI, RVSP, E’, E/E’), self-care behaviours (9-EHFScBS), intensity of chronic pain (VAS), sleep quality (PSQI), cognitive functions (MMSE), adherence to the therapy (based on patient’s declaration) will be taken during on-site visits M1 and M3.

To assess the impact of the interventions on psychological parameters, patients will complete self-reported questionnaires on visits M1 and M3. All psychological measurements and related instruments used in the study are presented in Table 2.

Safety outcomes

Spontaneous adverse events reported by patients during the study will be recorded. The frequency of adverse events of special interest will also be assessed and includes worsening emotional symptoms, emotional instability, changes in the intensity of positive and negative emotions, and relapses of traumatic experiences.

Table 2. Instruments used in the study to assess clinical and psychological outcomes

Outcomes	Abbreviation for questionnaire	Full name of questionnaire
Self-care	9-EHFScBS	The nine-item European Heart Failure Self-care Behaviour Scale
Mindfulness	FFMQ	The Five Facet Mindfulness Questionnaire
Mental health	GHQ-30	The 30-item General Health Questionnaire
Coping	Brief-COPE	The Brief version of the Coping Orientation to Problems Experienced Inventory
Cognitive impairment	MMSE	The Mini-Mental State Examination
Stress	PPS-10	The Perceived Stress Scale
Sleep quality	PSQI	The Pittsburgh Sleep Quality Index
Pain	VAS	The Visual Analogue Scale

Statistical analysis

To calculate the sample size, the statistical program G*Power v3.1 was used. A standard common alpha value of 0.05 and a sufficient test power of at least 0.8 have been adopted in this study. The sample size was estimated for a medium effect, based on the following two statistical analyses:

- a multivariate regression and a fixed model with a total number of predictors equal to 15 yielding a minimum required sample size of 139 patients (i.e., the effect size is set at medium ($f^2 = 0.15$; where: $f^2 \geq 0.02$ — small effects; $f^2 \geq 0.15$ — medium effects; $f^2 \geq 0.35$ — large effects);
- a mixed ANOVA analysis with a medium effect ($f = 0.25$; where: 0.10 — small effect; 0.25 — medium effect; 0.40 — large effect), resulting in a minimum required sample size of 28 patients. To deal with potential violation of assumptions for parametric analysis and small sample size, as implied by a mixed ANOVA analysis, a relevant statistical technique has been applied (e.g., cleaning of the data, bootstrapping procedure, restriction of the number of explanatory variables).

Clinical impact

The results of the MIND-HF study will assess the usefulness of the first MBI tailored to the needs of HF patients. MBHT is a simple and cost-effective intervention delivered online which may help to manage psychological aspects of HF and enhance patients' self-care ability leading to improvement of disease prognosis. Obtaining positive results would form the basis for implementing MBHT into the holistic management of HF.

Discussion

To the best of the authors' knowledge, the MIND-HF program is the first MBI adapted for HF patients. In con-

trast to traditional, 8 weeks long, cognitive-behavioural programs, MBHT has been shortened to 6 sessions. Key concepts of the session are short and presented mainly through enactments, while the number of written materials is limited. During the week, participants are asked to meditate at home choosing a short or long version of audio meditations.

Meditation has a history that goes back thousands of years, and many meditative techniques are rooted in Eastern traditions. The term "meditation" refers to a variety of practices that focus on mind and body integration to harmonize the nervous system, calm the mind, and enhance overall well-being. Some types of meditation involve a mental focus on a particular sensation or object as breathing, a visual image, or body sensations. Meditation is the main component of mindfulness training and is based on a special type of kind awareness focused on the present moment in a nonjudgmental way [21]. Another important component of mindfulness, which is a relatively new concept in Western psychology, is self-compassion. This is a self-directed, warmhearted, caring, empathic and non-judgmental orientation towards the self during times of suffering and failure, accompanied by a gentle motivation to alleviate this suffering [22–25]. Existing literature suggests self-compassion serves as an adaptive emotion regulation strategy which helps restore positive cognitive reappraisal and acceptance of negative situations [26, 27]. The present program is based on both abovementioned techniques. Mental focus techniques aim to establish basic awareness to stabilize the mind. The compassionate acceptance helps to reduce disease-related stress and enables participants to refocus attention towards developing more supportive coping behaviours including self-care (noticing HF symptoms, conscious breathing, spending time in nature, mindful movement, mindful eating and fluid consumption, compliance with recommendations, managing pain and anxiety, dealing with charged thoughts).

2021 European Society of Cardiology (ESC) guidelines for HF recommend Cognitive Behavioural Therapies (CBT) as supportive, nonpharmacological strategies to help manage HF patients [28]. Also, the 2017 American Heart Association experts' opinion pointed to the limitations of the effectiveness of HF pharmacotherapy and recommended including diverse forms of cognitive therapies, including MBI in the management of HF patients [29]. CBT is a group psychological intervention focused on psychoeducation intending to modify the influence of mindset, attitude, emotions, and behaviours on the subjective experience of disease [12]. Clinical programs which leverage mindfulness meditation and self-compassion may combine various approaches and activities and are classified as the third wave of CBT [12].

Abbot et al. conducted a meta-analysis of 9 randomized clinical trials (RCT) to determine the effectiveness of MBSR and MBCT programs on psychological and physical outcomes for people with cardiovascular diseases. The results showed evidence of reductions in stress (-0.36 ; 95% CI -0.67 to -0.09 ; $p = 0.01$), depression (-0.35 ; 95% CI -0.53 to -0.16 ; $p = 0.003$), and anxiety (-0.50 ; 95% CI -0.70 to -0.29 ; $p = 0.001$). effects on physical outcomes (blood pressure, albuminuria, and stress hormones) were mixed [13]. In another meta-analysis, conducted by Scott-Sheldon et al. including 16 studies, compared to controls, participants who received MBI reported greater improvements in psychological outcomes i.e., anxiety, depression, distress, and perceived stress. MBI recipients also reduced their systolic but not diastolic BP relative to controls [30]. In the review conducted by Zou et al. involving 5 studies (467 patients with HF), there was a consistent finding that mindfulness-based interventions could significantly reduce depression and anxiety and improve HRQoL. However, the effect on physical symptoms of HF was inconsistent [16]. Large data analysis of 61 267 National Health Interview Survey participants revealed that meditation was independently associated with a lower prevalence of hypercholesterolemia (OR 0.65; 95% CI 0.54–0.79; $p = 0.001$), systemic hypertension (OR 0.86; 95% CI 0.75–0.99; $p = 0.04$), diabetes (OR 0.70; 95% CI 0.59–0.84; $p = 0.0001$), stroke (OR 0.76; 95% CI 0.58–0.99; $p = 0.04$), or coronary artery disease (OR 0.51; 95% CI 0.39–0.66; $p < 0.001$). Till now there is a small number of RCTs confirming the effectiveness of MBI in the population of patients with HF. Existing research focuses primarily on classic mental aspects of HF such as anxiety and depression symptoms. MIND-HF is aimed to assess the impact of MBHT and psychoeducation on coping skills and resilience to promote self-care behaviours and compliance which are the key drivers of lifestyle changes which are needed to improve HF prognosis. The authors also focus on a broad range of clinical symptoms of the disease including echocar-

diography measures, which brings an aspect of novelty to the present trial.

Although a high heterogeneity was observed in the methodological approaches, scientific literature confirmed that MBI can now be translated into a first-line intervention for improving physical and psychological well-being in CVD patients. It should be emphasized that currently available Mindfulness interventions do not consider the specific needs of HF patients and are practically overlooked in clinical practice. Due to its simplicity, ease of implementation, cost-effectiveness and good safety profile, there is a need for a Mindfulness program tailored for HF patients.

Given the limitations that HF imposes on patients (i.e., advanced age, dyspnoea, physical inactivity, uncertainty caused by instability of the disease, limitations in everyday functioning, etc.) and the limited availability of medical educators, the online version of the program was proposed. As the readily accessible Internet has become the most popular educational resource for the general population it is not entirely clear whether online tools such as communication platforms would also be suitable for health education and cognitive behavioural therapy for HF patients. Therefore, the authors are interested in measuring the adoption of online solutions among HF patients.

Conclusions

The Mind-HF study will provide evidence for the efficacy and safety of the original Mindful-Based Heart Training delivered online. The results will thus be relevant for introducing Mindfulness-Based Interventions in clinical practice to support the conventional treatment of patients with HF. It will also check the feasibility of online tools in delivering education and psychological support to this group of patients.

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