Study Protocol

Efficacy of an online mindfulness-based cognitive skills program on depressive symptoms and quality of life in university student

Principal Investigator	Yun-Ling Chen, Doctor Study Director Chung Shan Medical University Taichung, Taiwan, 402

Protocol identification number	Online MBCT Program for University Students (dated 2023-04-07)
ClinicalTrials.gov Identifier:	NCT05804877

1. Introduction

The goal of this interventional study was to examine the efficacy of the online mindfulness-based cognitive therapy program(MBCT) in youth (18-25 years old) with depressive symptoms. The main questions it aimed to answer were:
Whether the program could reduce depressive symptoms in university students.
Whether the program could increase the quality of life in university students.
The effectiveness, acceptance, and practicability of the program for university students. Participants in the experimental group would be arranged to attend online mindfulness-based cognitive programs for eight weeks. The control group would be educated with the knowledge of mental health to manage their negative emotions.

2. Statistical Analysis Plan (SAP)

A randomized controlled trial (RCT) was conducted to examine the efficacy of the online mindfulness-based cognitive therapy program(MBCT) in youth (18-25 years old) with depressive symptoms. The investigators expected the online MBCT program could assist university students in reducing their depressive mood and facilitating quality of life. The investigators also discussed the effectiveness, acceptance, and practicability of the online MBCT program to the subjects.

2.1 Study design

Participants in the experimental group would be arranged to attend online mindfulness-based cognitive programs for eight weeks. Each week was divided into 3 parts: detailed skill training with pictures or short videos, techniques application in different scenarios, and concepts consolidation through a web-based assignment. Participants were requested to complete the 3 parts above, which would take approximately 15 minutes in total per week. The content of the online intervention includes 8 chapters reflecting multiple topics (e.g. explaining MBCT, automatic pilot, awareness of mood, accentedness, staying with the present experience, linking habitual reactions to the unpleasant event, using breathing and body as an anchor, and planning to continue mindfulness practice) which were delivered to subjects each week by the research team.
Participants in the control group would acquire knowledge of mental health to manage their negative emotions. There would be 2 times of mental health education and one web-based assignment including writing feedback to ensure learning effectiveness each week. The content for 8 weeks would include knowledge about depression, recognition of depression and depressive mood, symptom management, adaptation skills and coping skills, myths of depression, depression prevention, and referral information for mental health. The investigators would evaluate the effectiveness of the two groups using the outcome assessment of BDI-II, WHOQOL-BREF, BAI, OSA, and COPM 1 week before intervention (pre-test) and 1 week after intervention (post-test).

2.2 Populations and subgroups to be analysed

This study would use a Survey Cake form, announced through the university website or online platforms, to recruit participants, primarily targeting undergraduate students at a certain medical university in Taichung, Taiwan. Participants would be screened through the BDI-II and the basic information questionnaire. The inclusion criteria were as follows: (1) aged between 18 and 25 years; (2) scoring at least mild on the Beck Depression Inventory-II (BDI-II); (3) having the LINE messaging application; and (4) being literate and willing to participate in the study. Exclusion criteria were: (1) self-reported other mental illnesses such as schizophrenia or bipolar disorder; (2)

self-reported major physical illnesses such as cancer or stroke; and (3) unwillingness to accept random assignment. The sample size was estimated that a correlational study requires at least 30 participants. Considering potential dropouts or inability to complete the online study, a 35% attrition rate was applied, resulting in a minimum of 46 valid questionnaires being collected. Participants would then be randomly assigned, with 23 in the experimental group and 23 in the control group.

2.3 Outcomes

Baseline Characteristics

The contents included the subject's gender, age, grade, living situation, employment status, economic status, whether there was a diagnosis of mental or physical illness (if so, the subject was asked to provide the name of the diagnosing hospital and physician), whether there was any psychological treatment involving medication (if so, the subject was asked to provide the frequency and location of treatment), contact phone number, and LINE ID.

Self-Assessment Questionnaire

This study used well-validated instruments with good reliability, including the Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), the Chinese version of the Occupational Self-Assessment (OSA), the Chinese version of the Canadian Occupational Performance Measure (COPM), and the Taiwan version of the World Health Organization Quality of Life-BREF (WHOQOL-BREF-TW) in both pre- and post-tests (with BDI-II used for case screening only). These tools assessed the level of depression, anxiety, self-efficacy, environmental support, occupational performance issues and changes, and quality of life.

Qualitative Feedback Information

One week after the intervention ends, the researcher would design a questionnaire for participants to evaluate the effectiveness and practicality of the online "Mindfulness Cognitive Skills" program. This would include qualitative interview questions and quantitative items for participants to rate. The purpose was to understand whether the eight-week online study meets the needs of the participants, assisted in learning and managing self-emotions, and to gather feedback on usage after the study and suggestions for the research.

2.4 Analyses

The study would use descriptive statistics to record and analyze the basic information and follow-up measurement data of the participants, described in terms of percentages, means, and standard deviations. Changed in depression levels and quality of life between the experimental and control groups would be analyzed using a mixed-effects model to verify the effectiveness of the "Online Mindfulness Cognitive Skills" program on depression and quality of life among students with depressive tendencies. The analysis would be conducted using SAS 9.4 statistical software, with a significance level set at $\alpha = 0.05$.

2.5 Aims and objectives

The purpose of this study was to explore the impact of the "Online Mindfulness Cognitive Skills" program on the depressive emotions and quality of life of university students. It was hoped that through the learning of mindfulness cognitive skills, participants would be guided to recognize their irrational thoughts, distinguish automatic thinking, and achieve significant counseling effects. Additionally, participants would be able to apply mindfulness techniques in daily life when experiencing negative emotions, improving self-acceptance, reducing depressive emotions, and enhancing quality of life. The researchers hoped that this study would

provide a deeper understanding of the challenges and living conditions of students with depressive tendencies, and identified which mindfulness techniques are more effective in reducing emotional distress among university students. The goal was to confirm the most suitable mindfulness techniques and behavioral programs for students with depressive tendencies and to explore the advantages of delivering counseling information online to this population. It was anticipated that, following the completion of the study, the promotion of mindfulness cognitive skills through the LINE platform would continue, allowing students at the university to access mindfulness information. The findings were also expected to be valuable for educators, healthcare professionals, and social welfare organizations.

3. Informed Consent Form (ICF)

This study design had been approved by the First Institutional Review Board (IRB) of *Chung Shan Medical University Hospital* (CSMUH No: CS1-22150). Additionally, a *Waiver of Documentation of Informed Consent or Written ICF* was applied for and granted by the *Research Proposal Committee at Chung Shan Medical University Hospital*. Approval details can be found in *Figure 1*. The following points outline the justification for this waiver:

Minimal Risk Design

The study is designed to pose minimal risk to participants, involving participatory mindfulness exercises and questionnaire surveys without any invasive procedures or treatments. The research activities are expected to cause no discomfort or adverse effects during the execution phase.

Approved Research Design

The research design has been reviewed and approved by the National Science Council (NSC). The study's feasibility and structure are appropriate for the research objectives. This study utilizes a "randomized controlled trial" design, where the experimental group will receive an eight-week "Online Mindfulness Cognitive Skills" program, delivered once a week via the LINE social platform, while the control group will be provided with information on depression and self-emotion management. To ensure the well-being of participants, the co-investigator will monitor and engage with participants weekly through messages on the online platform. The informed consent form clearly states that researchers will send information to participants via a social platform on mobile devices each week and invite them to complete questionnaires. Participants can freely choose the time and place to review the information and complete the questionnaires. The procedures and methods of this study are integrated into daily life activities.

Informed Consent Procedure

The informed consent process will be conducted by the co-investigator through an online document, explaining the study details to the participants or their legal representatives and obtaining their consent. This process is estimated to take about 5-10 minutes to ensure participants fully understand the study. Participants will be asked to complete an online informed consent feedback form to confirm their comprehension of the study. Detailed information about the informed consent process is provided in the attached *"005-1 Informed Consent Form for Participants"* (see *Figure 2*). This informed consent form will also be emailed to participants for their reference and records.

Figure 1 Permission of Research Proposal Committee at Chung Shan Medical University Hospital

Permission of Research Proposal
Chung Shan Medical University Hospital

Date: Jan 18, 2023

Protocol Title: Efficacy of an online mindfulness-based cognitive skills program on depressive symptoms and quality of life in university students

Protocol No: NA

Principal Investigator & Affiliated Institution: Yun-Ling Chen／Chung Shan Medical University

Date of meeting: 2022/11/24

Version: 【see above】

Effective duration approved: 2023/01/18 to 2024/01/17

Frequency of Interim Report: every 12 months. Please file an extension before the expiry date, if you need.

Above study has been approved with the full-board review by Institutional Review Board of the Chung Shan Medical University Hospital on Jan 18, 2023. About the essential duties, obligations and responsibilities of the principal investigator please refer to the back page.

Thomas Chang-Yao TSAO, MD/PhD.
Chairman
The Institutional Review Board

本委員會組織與執行皆符合 ICH-GCP 規範及赫爾辛基宣言之精神

This Committee has been organized and operated in conformance with ICH-GCP requirements and the essence of Declaration of Helsinki.

Figure 2 "005-1 Informed Consent Form for Participants"

Informed Consent Form for Participants

Project Title: Efficacy of an online mindfulness-based cognitive skills program on depressive symptoms and quality of life in university student

Research Institution: Department of Occupational Therapy, Chung Shan Medical University
Collaborating/Sponsoring Organization: National Science Council

Principal Investigator: Chen Yun-Ling, Assistant Professor, Phone: 04-24730022 #12394
Responsibilities: Execution of the Project and Informed Consent Procedures
Co-Principal Investigator: Lin Ting-Hui, Undergraduate Student, Phone: 0975-756893
Researcher: Lin Ting- Hui, Undergraduate Student, Phone: 0975-756893, E-mail: whitney1119@gmail.com
24-Hour Emergency Contact: Lin Ting- Hui, Phone: 0975-756893

Introduction

To gain a deeper understanding of the challenges and living conditions of university students with depressive tendencies, and to enhance and provide new knowledge for educators, healthcare professionals, and social welfare institutions, thereby serving the younger population, **Principal Investigator Chen Yun-Ling** is conducting a study targeting university students. We invite you to agree (or decide to have a proxy agree) to participate as the primary subject of this research project. This is a participatory mindfulness practice and questionnaire study. Only those who agree to participate will need to complete the questionnaire. Please take some time to read the following information before deciding whether to participate. If you have any questions after reading the purpose, methods, procedures, and rights of this study, we are willing to provide further explanations to ensure you fully understand.

1. Research Background and Motivation

University is a crucial stage in personal development, and individual stress and emotions can affect interpersonal relationships and life adaptation during this period. Mindfulness-Based Cognitive Therapy (MBCT), which combines cognitive behavioral therapy and mindfulness-based stress reduction, has been proven to improve anxiety and depressive symptoms in patients with depression. Therefore, this study aims to develop an "Online Mindfulness-Based Cognitive Skills" program for university students, making mindfulness-based cognitive therapy more accessible, convenient, and unrestricted. We hope to improve the depressive symptoms of university students with depressive tendencies and enhance their quality of life.

2. Research Objectives

To explore the effectiveness of the "Online Mindfulness-Based Cognitive Skills" program in improving the depressive symptoms and quality of life of participants, as well as the acceptability and practicality of the program among university students.

Version:v1.0 Date:2022.10.05

3. Inclusion and Exclusion Criteria for Research Participants

The principal investigator or researchers will assess your eligibility and discuss the necessary conditions for participation in this study. If you meet the inclusion criteria and are willing to participate, you must sign this consent form before entering the study.

Inclusion Criteria (You must meet the following conditions)

1. Aged between 18 and 25 years old
2. Beck Depression Inventory-II (BDI-II) score indicating mild or higher depression
3. Possession of the LINE communication app
4. Literate and willing to participate in the study

Exclusion Criteria (If any of the following apply, you cannot participate in this study)

1. Diagnosed with major physical or mental illnesses (e.g., cancer, stroke, sensory processing disorder, bipolar disorder, etc.)
2. Unwilling to participate in the study

4. Research Methods and Questionnaire Overview

First, the researchers will explain the purpose of the study and invite you to participate. After you agree, you will be asked to complete six questionnaires, including:

1. The Taiwanese Brief Version of the World Health Organization Quality of Life Questionnaire, to assess your health-related quality of life;
2. The Beck Depression Inventory-II, to assess your level of depression;
3. The Canadian Occupational Performance Measure, to understand your occupational performance;
4. The Chinese Version of the Occupational Self-Assessment, to evaluate your self-competence and environmental support;
5. The Beck Anxiety Inventory, to measure your level of anxiety;
6. Short-answer questions on the acceptability and practicality of the "Online Mindfulness-Based Cognitive Skills" program. The detailed content of the questionnaires is provided in the appendix, and it will take approximately 40 minutes to complete.

You can participate in this study using your own mobile device through an online platform. After completing the questionnaires, the researchers will randomly assign you to one of two groups: the "Online Mindfulness-Based Cognitive Skills" group or the "Depression and Self-Emotion Management" group. You will then be invited to join the official LINE community platform for the assigned group, where you will receive weekly information for eight weeks. All exercises are friendly invitations, and you can adjust your participation based on your physical and mental condition. You may choose not to do certain exercises or participate to a limited extent.

One week after the program ends, the researchers will invite you to complete the six questionnaires again. This survey aims to understand your physical and mental health status, quality of life, occupational

performance, and sense of competence. There are no right or wrong answers; please select the most appropriate answers for you.

This study aims to recruit 46 participants. Through this research, we hope to gain a better understanding of the physical and mental conditions of university students with depressive tendencies. The information you provide will help us improve the quality of life and emotional management skills of university students in the future.

5. Storage Duration and Usage Plan for Research Materials

1. Storage Duration of Research Materials

The personal data and questionnaire responses collected in this study will be stored by the principal investigator, Chen Yun-Ling, in the computer storage system of the Department of Occupational Therapy, Chung Shan Medical University, located at No. 110, Sec. 1, Jianguo N. Rd., Taichung City. The collected data will only be used for data analysis and publication of research results. After 10 years, the principal investigator will be responsible for destroying the data. If the data is used for future analysis, it will be de-identified and will not be linked to your personal information, and will only be used for academic research purposes.

2. Usage Plan for Research Materials

The personal data and information collected, including questionnaire responses and interview records, will be used appropriately according to the research objectives. If the data is planned to be used in other research projects in the future, it will comply with relevant national regulations, and you can rest assured.

6. Potential Risks, Side Effects, Incidence, and Handling Methods

This study involves participatory mindfulness exercises and questionnaire surveys, with no invasive procedures. Participation in the study is not expected to cause any discomfort or side effects. However, if you experience any physical or mental discomfort during the study, please contact the principal investigator or researchers immediately for clarification or assistance. You may take appropriate breaks or limit your participation. You are also free to withdraw from the study at any time, and we will respect your decision.

7. Restrictions, Limitations, and Required Cooperation During the Study

You can participate in this study using your own mobile device through an online platform. Please pay attention to the messages in the official research community and follow the instructions provided by the principal investigator or researchers. Your responses will not affect your rights, and no special preparation or additional cooperation is required. Please relax and take care of your physical and mental well-being during the study, without any pressure.

8. Source of Research Funding, Expected Benefits, and Potential Commercial Interests

This study is funded by the National Science Council. If you agree to participate, the principal investigator will have your authorization to store and use the data you provide for research purposes. This

study is not expected to generate commercial benefits. Through this research, we hope to understand the physical and mental conditions of university students with similar conditions, which will help educators, healthcare professionals, and social welfare institutions provide better assistance in the future.

9. Confidentiality and Protection of Participants' Personal Data

1. The use or publication of data obtained from the study will ensure absolute confidentiality of participants' privacy (e.g., names, identifiable photos, etc.).
2. The raw data you provide will only be stored and used in the principal investigator Chen Yun-Ling's database and will not be linked to other institutions. If other units or research projects related to public welfare need to use your data, we will seek your consent again. Otherwise, we will not provide it to them. Your personal data and privacy will be protected in accordance with relevant national laws.

10. Remedies or Compensation for Damages and Insurance

1. This is an observational study involving questionnaire completion and data collection. Principal Investigator Chen Yun-Ling and Co-Principal Investigator Lin Ting-Cheng will not perform any interventions or procedures on you. It is not expected that you will face any additional physiological risks by participating in this study.
2. Principal Investigator Chen Yun-Ling and the research team will make every effort to prevent and avoid any leakage of your personal data or other adverse effects during the research process. The responsibility will be determined by applicable national laws.
3. Signing this consent form does not waive any of your legal rights.
4. This clinical study does not have liability insurance.

11. Rights of Research Participants

1. You will not incur any additional costs during the study.
2. Participants who complete the full 8-week online learning program and complete the pre- and post-test questionnaires will receive a NT$200 gift voucher or equivalent as a token of appreciation for your participation.
3. Any significant findings related to your health or illness that may affect your continued participation in the study will be promptly provided to you or your legal representative.
4. If you have any questions about the study or concerns about your rights as a research participant, or if you suspect that you have suffered due to participation in the study, you can contact the Secretariat of the Institutional Review Board (IRB) for consultation. The contact information is as follows: Phone: 04-24739595 ext. 21735-21737; Fax: 04-35073516; E-mail: irb@csh.org.tw/ irb_2nd@csh.org.tw.
5. If you have any questions or issues now or during the study, or if you wish to withdraw your consent, you can contact Co-Principal Investigator Lin Ting-Cheng (24-hour contact number: 0975-756893).

6. This consent form has fully explained the nature and purpose of the study. You may keep a copy for reference. The principal investigator or research team members will answer any questions you have about the study.

12. Withdrawal and Termination from the Study

Your participation in this study is entirely voluntary, and you have ample time to decide whether you wish to participate. You are free to withdraw from the study at any time without providing a reason. Withdrawing from the study will not affect your medical care or any normal medical rights. Principal Investigator Chen Yun-Ling (Phone: 04-24730022 #12394) is willing to provide appropriate and necessary assistance during the research process.

If you wish to withdraw your consent before the data analysis, please contact Principal Investigator Chen Yun-Ling (Phone: 04-24730022 #12394). We will still ensure your privacy.

If you decide to withdraw from the study, please contact Principal Investigator Chen Yun-Ling immediately (Phone: 04-24730022 #12394). We will immediately destroy or delete your data. However, if the data has already been analyzed, it cannot be deleted. In future publications, your data will be de-identified, ensuring your privacy is not affected.

13. Execution Record

Please take your time to consider the above information. If anything is unclear, do not hesitate to ask Principal Investigator Chen Yun-Ling or Co-Principal Investigator Lin Ting-Hui for further clarification. If you have fully understood the research methods, potential risks, and benefits, and agree to participate as a voluntary research subject in this clinical study, please fill out the "Informed Consent Feedback Evaluation Form" attached to this email and return it to the researcher's email address (whitney1119@gmail.com).