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STUDY PROTOCOL

Health Coaching Intervention to Improve Self-Care Management of Hypertension Among Older People in Indonesia: A Randomized Controlled Study Protocol

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Purpose: One-third of the global population is predicted to be diagnosed with hypertension (HTN) in 2025, with the percentage highest among older people. Without proper self-care management, uncontrolled HTN causes negative health consequences and decreases the quality of life. The previous scoping review identified various challenges that older adults may face in dealing with HTN and that effective approaches should consider each individual's circumstances and attributes. This study aims to investigate the efficacy and sustainable impact of an Indonesian adaptation of an 8-week nurse health coaching intervention on self-care management and self-efficacy among older people with HTN.

Patients and Methods: The coaching sessions will last for 30 min weekly for 8 weeks. The data will be measured at three points: baseline (initial), 1 week after the eighth health coaching session, and 3 months after concluding the intervention.

Discussion: This study will be the first health coaching intervention research based on motivational interviewing and cognitive behavioral therapy approach with Indonesian background adjustment. The study result will help develop a guideline for nurses and other health workers providing health coaching for older people in Indonesia and other countries with similar characteristics in terms of sociodemographics or lifestyle.

Trial Registration: thaiclinicaltrials.org Identifier: TCTR20230410001 (Date of registration: April 9, 2023).

Keywords: self-care hypertension, health coaching, randomized controlled study

Introduction

One-third of the global community is predicted to be diagnosed with hypertension (HTN) by 2025,[1] with the percentage highest among the older people group. The American Heart Association defines HTN as systolic blood pressure readings of ≥130 mmHg and diastolic blood pressure readings of ≥80 mmHg.[2] Compared to young and middle-aged people, HTN is more prevalent among older people.[3] The highest group percentage of HTN was among the 65–74-year-olds (63.2%) in Indonesia.[4,5] These data indicate persistent findings that older people are at high risk of having HTN. Furthermore, uncontrolled HTN is a primary risk factor for heart disease, stroke, and kidney failure.[6,7] Risk factor reduction with HTN is emphasized in primary and secondary prevention and treatment.[1]

Nonpharmacologic lifestyle interventions should be encouraged in addition to medication to prevent HTN progression and as adjunctive therapy for existing HTN.[1] The eighth Joint National Commission recommends multiple self-care activities, including body weight management, tobacco cessation, specific types of dietary intake, reduced alcohol consumption, medication adherence, and physical exercise.[8] Lifestyle risk factor modifications through consistent healthy self-care activity adherence is now recognized as an essential treatment aspect, as patients with HTN who implement

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such self-care strategies have achieved reduced blood pressure, decreased complications associated with HTN, increased antihypertensive medication adherence, and lowered overall mortality rate related with HTN.[9]

Moreover, uncontrolled HTN causes negative health consequences and decreases the quality of life in the absence of proper self-care.[10] Furthermore, the aging process affects disease progression. Management strategies for older people with HTN should consider the frailty degree, increasingly complex medical comorbidities, and psychosocial factors that must be approached individually.[1]

Previous studies to enhance self-care among older people mainly focused on giving health education about diet, exercise, and medication adherence. Most of these HTN management approaches fail because they lack specific targets and plans for adjusted HTN management for patients based on their condition.[10] Additionally, our previous scoping review revealed various challenges in self-management among patients with HTN which were likely solved by multiple methods.[9] Therefore, individualized approaches that consider personal attributes and external circumstances are essential in assisting individuals in changing their behavior. Individual health coaching has successfully changed health behaviors.[11] Patient-determined goals and the active learning process combined with health education improve the achievement of health goals.[12,13]

The health condition of older people is prone to deteriorate due to the aging process, which leads them to suffer from chronic disease. One health coaching program for older people in the United States of America is Healthy Lifetime (HL). Flaherty-Robb et al[14] developed HL which combined cognitive behavioral therapy (CBT), motivational interviewing (MI), and other evidence-based concepts managed by trained nurse health coaches to motivate older adults to improve and maintain self-care management. HL is designed to intervene in health deterioration by engaging them in effective and immediately beneficial health-promoting behaviors. HL is focused on facilitating change at a point where the older person has the prime opportunity for longer-term benefits of improving their health behavior and preventing negative consequences of chronic conditions.[14] HL is provided in a series of eight weekly, 30-minute coaching sessions based on topics aligned with an evidence-based set of content modules. Eight weeks intervention period is chosen to ensure the sustainable health behavioral changes and impact. These series of studies have shown that HL for older people improved their health behaviors, cognitive–behavioral indicators, enhanced self-esteem, empowerment, and sustainable commitment to health behavior change. However, HL is targeted at older people in general and tested only in Western Countries.[11,15,16] Additionally, interventions designed to actively involve patients in its management are scarce while the number of older people with uncontrolled HTN in Indonesia is sharply increasing.[17] Indonesia's different lifestyles, cultures, characteristics, and food preferences may influence the use and success of HTN self-care management.[9]

Furthermore, the interaction between health workers and patients in Indonesia is mainly a one-way discussion where patients tend to be passive. Therefore, we plan to adopt the program for older people with HTN in Indonesia. We expect that Indonesian older people could be actively involved in setting behavioral targets by coaching interventions and implementing them based on their condition. This study will be the first health coaching intervention based on MI and CBT approaches with Indonesian background adjustment.

Materials and Methods

Objective and Purpose

This study aims to (1) determine the efficacy of an Indonesian adaptation of an 8-week nurse health coaching intervention on self-care management and self-efficacy in older people with HTN and (2) identify the sustainable impact of health coaching on self-care management in older people with HTN after a 3-month no-treatment follow-up phase. We hypothesize that an 8-week nurse health coaching intervention will positively affect the self-care score, reduce blood pressure, decrease body weight, diminish urine salt, and lower high-sodium food consumption.

Study Design and Registration

This is a randomized 2×3 repeated measure experimental design. These 2 groups, namely the intervention and control groups, will be measured thrice: baseline, 1 week after health coaching intervention ends, and 3 months after no intervention. A randomized control trial design is selected because it provides the highest level of evidence due to its

potential to minimize all kinds of bias. The participants, considering a small-to-moderate effect, will not be blinded because the trial compared nonpharmacological interventions that could not be masked.However, we will recruit participants based on the different Public Health Center service days to prevent bias, as one of many in-person recruitment techniques in a randomized controlled trial.[18] Participants who made contact on Monday, Wednesday, and Friday will be allocated as the participant candidates for the intervention group. Those who made contact on Tuesday, Thursday, and Saturday will be the control group. There will be no contamination because the intervention will be conducted at the intervention group member's house.

The intervention groups will be given an 8-week health coaching program. The usual care or control group will receive an explanation of the meaning of blood pressure, blood glucose level, urine salt, and another measurement without any coaching session. Additionally, control group members will continue to receive care from the public health center.

Setting

The study will be completed at Rappokalling Public Health Center, Makassar, Indonesia. Rappokalling area is located in the heart of Makassar city, a metropolitan city in the eastern part of Indonesia. HTN is the second most prevalent disease among older people in Rappokalling.[19]

Sampling Method

We plan to recruit 140 older people with HTN living in Makassar, South Sulawesi, Indonesia, as the study participants based on the Slovin formula for 5% significance error and 95% power to detect effect size.[20] Therefore, each group will include 70 participants.

Inclusion/Exclusion Criteria

Inclusion criteria are individuals aged ≥60, diagnosed with HTN by a medical doctor, medically stable, and have no cognitive issues based on screening using the Integrated Care for Older People form.[21] This study will exclude those who have unstable health conditions requiring visits to a physician or hospital stays or a scheduled impending surgery, are terminally ill, have severe visual and/or hearing deficits that are not corrected by devices, such as a hearing aid or eyeglasses, and require assistance from other people. Participants who could not finish the 8-week coaching program will be considered drop-outs.

Recruitment

A flyer that describes the study will be posted at Public Health Centers. Permission to post the flyers will be requested from the head of the Public Health Center. The flyer will provide a contact phone number, and those who use the contact number to inquire will be categorized as the interested group. Interested individuals will be screened by phone following our inclusion and exclusion criteria. If they are deemed eligible, we will request their agreement to an appointment for a home visit to verify their condition and appropriateness based on the criteria. Suppose they are determined to be eligible for the study during the home visit. In that case, the researcher will provide a complete description of the informed consent and protections of research participants, review all study procedures, answer any questions, and then give the consent form for their review. Once the potential subject has answered all questions, and the person is unable or unwilling to consent, the researcher will terminate the home visit and not pursue their study participation. If a potential subject meets the study criteria, indicates willingness, and signs the consent form, the person will be considered "enrolled" in the study. Participants will be recruited and enrolled over a 2-month time frame.

Procedures and Measures

An 8-week health coaching is designed engage patients actively. The coaching sessions will last for 30 min weekly. Figure 1 illustrates the framework of the coaching concept. The session will be conducted in a closed room at the participant's house to prevent disturbance.

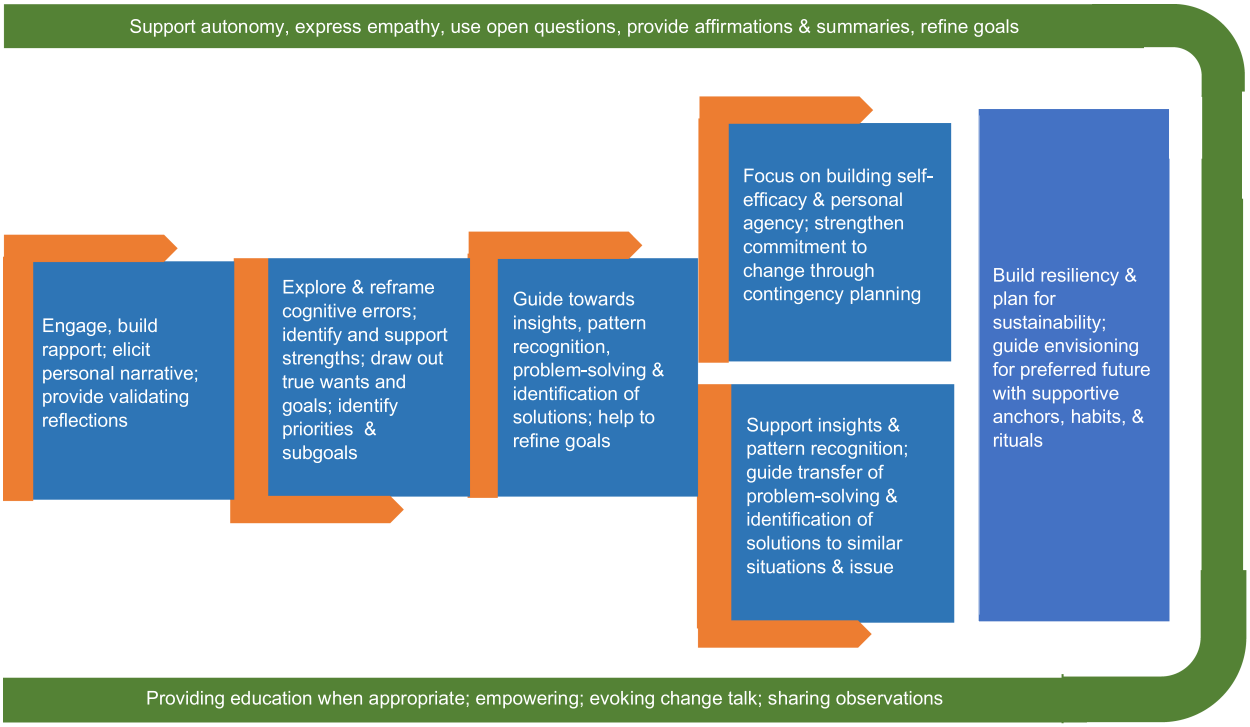

Figure 1 Process of health coaching weeks one through eight.
Notes: Reproduced with permission from Flaherty-Robb M, Calarco M, Butterworth S, et al. Healthy Lifetime (HL): An Internet-Based Behavioral Health Coaching Protocol for Older Adults. *Front Digit Health*. 2022;4; Article 795,827.[14.]

The researcher and participants will review the baseline measurement result in the first week of the intervention. They will identify the ultimate goals and simple-step plans and explore barriers and facilitators for achieving them in the second to fifth weeks. Further, the researcher will notice and stimulate change talk by providing supportive statements as the participant shares barriers, facilitators, and willingness to take steps toward their goals. With their permission and using cognitive behavioral methods, the researcher will guide the participants on detailed techniques to improve self-care skills and provide supportive coaching as they modify their behavior toward achieving their goals.

In the sixth week of the pilot study, the researcher will remind the participant that the study will end in two weeks. The participants are expected to disengage from their participation smoothly, and they will be assisted by providing them with anticipatory guidance at the edge of the study program. The researcher will determine the participant's progress and readiness to disengage from the intervention. The researcher will prepare the participants for dis-engagement by co-creating with them the loose end they want to address by the end of the final session. We will focus on these issues in weeks seven and eight and review the procedure for accomplishing the post-study measures. Figure 2 displays details of the coaching intervention, and Figure 3 describes the study flow diagram. The researcher will visit the participants at their houses once again when the study is completed to share the study results.

Three nurses who have attended and passed the Healthy Lifetime training course from the University of Michigan School of Nursing will conduct the coaching session.[22] These nurses will perform trials to coach two individuals for 8 weeks to ensure their coaching ability before data collection.

Table 1 shows the details of the measurement. We aimed to collect data after 3 months of follow-up with no intervention because habit formation interventions, such as health coaching, change the behavior. Drawing any maintenance changes is important compared to baseline health behaviors to predict the program's success.[23] Therefore, longer follow-ups are also required to determine and achieve the sustainability of behavioral changes.[10]

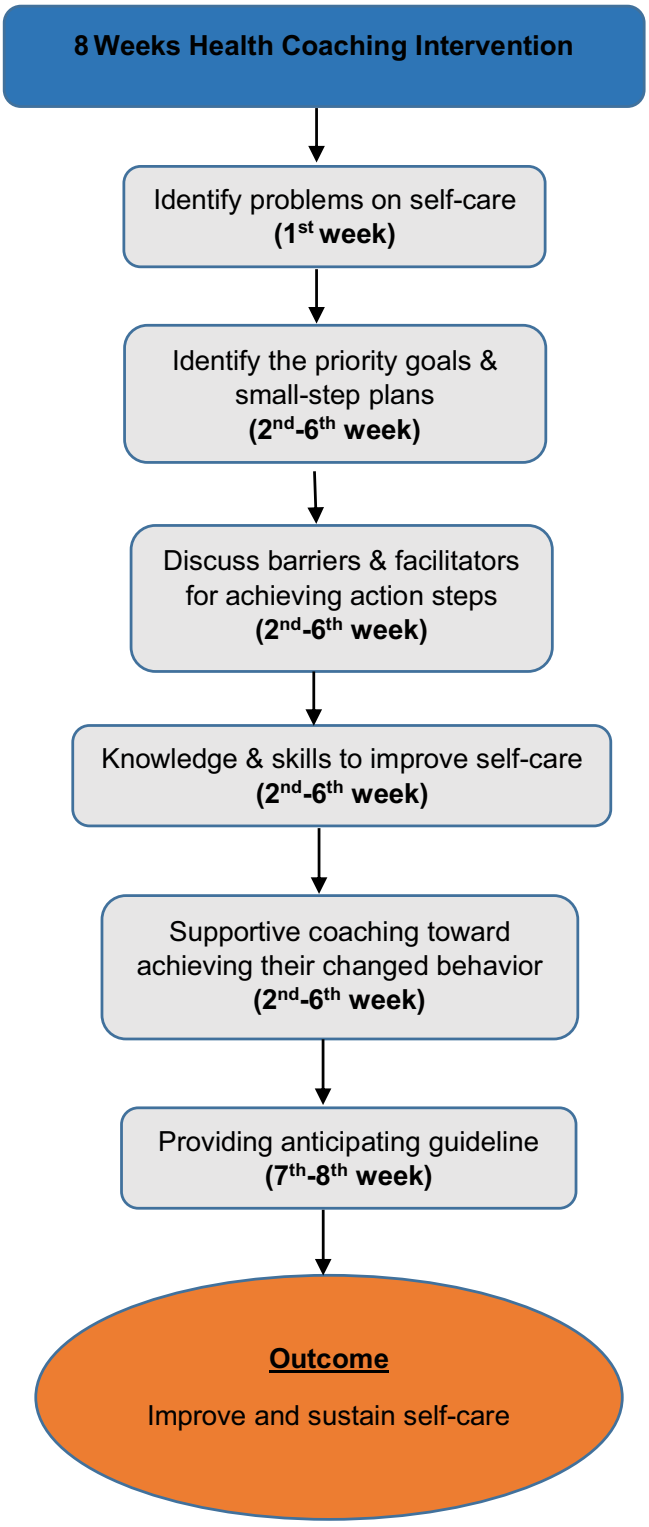

Figure 2 Coaching intervention map.

Outcomes

An 8-week nurse health coaching intervention influenced the increased self-care score, decreased blood pressure, reduced body weight, diminished urine salt, and lowered salt concentration on food.

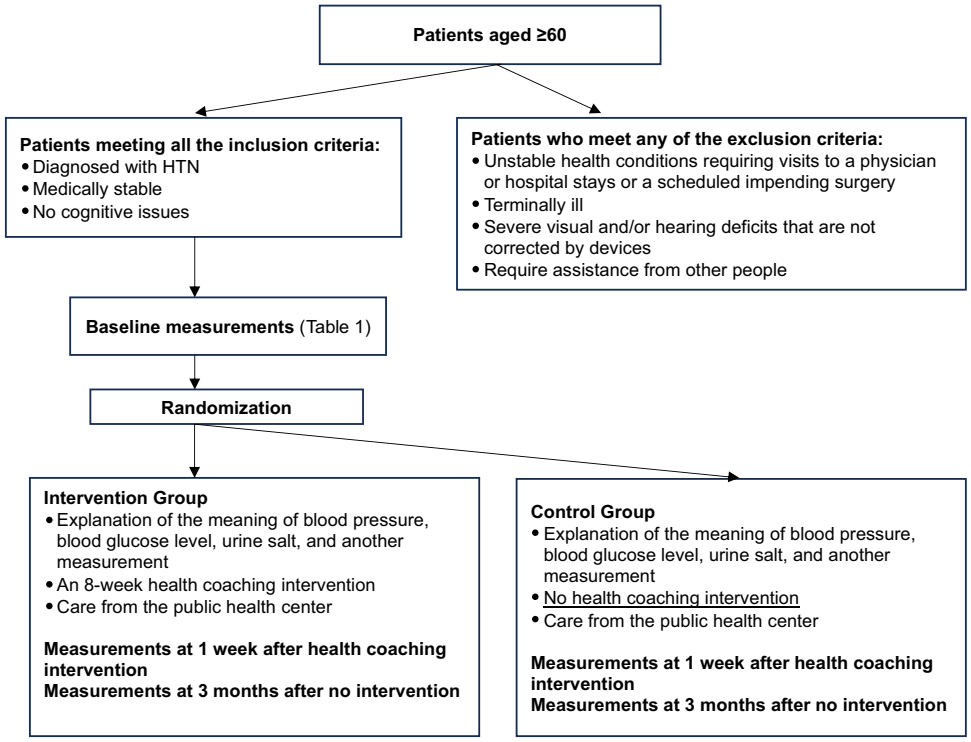

Figure 3 Study flow diagram.

Data Management

Data collected from participants during recruitment and enrolment will include identifying information, such as name, telephone number, and address, which will be kept in secure participant files accessible only by the Principal Investigator (PI). The nurse coach assigned to each participant will identify information to contact them for appointments. The PI will assign each participant a unique ID number that will be used for all the surveys, forms, audio recordings, and other information collected from participants. Names assigned to the numbers will be kept in a separate file used only by the PI and the nurse coach (for their specific clients). These files will be destroyed at the end of the study after all participant data is entered and double-checked. Nurse coaches will have access to identifiable information (name, phone number, and Email address) of all participants to whom they are assigned to conduct the initial screening, coaching sessions, and coaching appointment rescheduling.

Data Analysis

We will compute the participant attrition rate if any, and document reasons for not finishing the program. The data from participants who did not finish eight individual coaching sessions in the intervention group and those who did not return surveys in the control or intervention groups will still be analyzed and treated as missing data.

We will document the number of coaching sessions completed, the average minutes of sessions, and the total number of minutes engaged in coaching sessions. We will record a conversation by audio recording during each session upon participants' approval and informed consent. We will compute the average time participants consumed to complete the post-program questionnaires.

Data analysis will consist of descriptive statistic means and standard deviations for continuous variables and frequencies for categorical variables. We will apply regression modeling with fixed-effect repeated measures to account for the longitudinal data collection at baseline, 8 weeks, and 3 months after the coaching session ended to determine the impact of the health coaching intervention on participant outcomes. We will use logistic regression for dichotomous outcomes and linear models with transformations for continuous outcomes, as needed. Independent

Table 1 Measurements

No	Variable	Instrument	Procedure
1	Demographic	The questionnaire consists of age, sex, marital status, educational level, living arrangement, and hypertension history.	Read the questionnaire to the participants.
2	Blood Pressure	Omron HEM-6323T automatic blood pressure monitor (Omron Corporation; Kyoto, Japan).	
3	Anthropometric	Weight will be measured using a digital weighing scale (HBF-251 Omron; Omron Manufacturing of Indonesia, Bekasi, Indonesia). Height will be measured by requesting the participants to stand in front of the wall at their houses, and we will measure their height by microtoise (Gea Medical; Tangerang, Indonesia). Waist circumference will be measured by placing a tape measure around the participant's middle waist, just above their hipbones.	Body mass index was calculated from weight and height (kg/m^2) and waist circumference.
4	Cholesterol and blood glucose levels	A portable device to check cholesterol and blood glucose levels (Accupro; Guilin Royalyze Medical Instrument Co.Ltd, Guilin, China).	We need to take a drop of blood from the participant's fingertip, swab it on the measurement stick each for cholesterol and glucose levels, and insert the sticks into the Accupro. The results will come out within 5 minutes.
5	Salt concentration	The percentage of salt in food was measured with a compact salt meter (LAQUAtwin; Horiba Scientific, Kyoto, Japan), and the concentration of salt in urine was measured using a KME-03 salinity checker (Kawano Me Lab, Yokohama, Japan), which has been validated and recommended by the Japanese Society of Hypertension for decreasing salt intake.[24]	We will request the participants to show their food in fluid forms, such as soup or cooked fish. We will then take a drop of fluid and place it at the center of the salt meter to measure the salt percentage in food. As for salt concentration in urine, we will give participants a special container for participants to collect their first/morning urine on the following day. The minimum urine volume is 200 mL. The next day, in the morning, we will come to insert a stick of salinity checker into the urine in the container to check the salt concentration.
6	Self-care	The Hypertension Self-Care Profile (HBP SCP) is a questionnaire consisting of 60 items grouped into three sections: motivation, behavior, and self-efficacy. Each section has 20 items that can be used together or independently. The HBP SCP was developed based on Orem's self-care model and motivational interviewing. It used the Likert Scale with four scales, namely very confident (4), confident (3), less confident (2), and not confident (1), with the highest score of 80 and the lowest score of 20. Concurrent and construct validities of the HBP SCP were achieved by significant correlations between HBP SCP scales and theoretically selected study instruments ($P < 0.05$ for all correlation coefficients). The original version is in English.[25] This tool has been validated. It is a reliable tool and has been translated into the Indonesian version.[26,27] The validity test results of the research instrument range from 0.391 to 0.806, and the r table was 0.361. These results indicated the instrument was valid for the research.[27]	Read the questionnaire to participants.

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covariates will include sex, marital status, age, education level, living arrangement, blood pressure, body mass index, and HTN history.

The primary variable of interest is the interaction between group and time. This interaction indicates a change in trajectory over time between the intervention and the control group. We will use a stepwise selection technique at an alpha level of 0.05 to prevent overfitting. This method will enable us to independently identify a parsimonious set of variables associated with the outcome variables. We will determine residual and quantile plots to test the model's fit. Trajectories over time and interaction plots will be reported.

Discussion and Conclusion

Effective self-care management has decreased blood pressure, complications, morbidity, and mortality.[28,29] Lifestyle modification, including nutrition and physical activity through behavioral counseling in health coaching, are crucial components of self-care management.[30] This study will benefit the outcome of improving self-care management for older people with HTN. This long-term risk reduction could improve HTN outcomes and life expectancy, and the study result will produce a guideline for nurses and other health workers on providing health coaching for older people in Indonesia and other countries with similar characteristics. This study protocol has some limitations. First, the data collection and intervention will only be conducted in a single public health center; thus, the population needs to be expanded and further generalization for the results is required. Second, the study was designed for a long-term intervention, and some participants may drop out.

Ethics Approval

The Institutional Review Board of the University of Michigan and Hasanuddin University have approved our preliminary pilot study. We will obtain Institutional Review Board approval of the RCT after incorporating lessons learned from the pilot study. Throughout the study, the ethical principles of written informed consent, participant privacy and confidentiality, voluntarily based, and anonymity will be ensured and comply with the Declaration of Helsinki standards. This study protocol has been listed on the Thai Clinical Trials Registry (Identifier TCTR20230410001).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

This paper was presented at the International Scientific Conference on Nursing in Manila, Philippines as a conference talk. The abstract was published in the abstract book of the conference.

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