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Evaluating the efficacy of a community participatory intervention to prevent suicide in Thailand: a randomised controlled trial protocol

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ABSTRACT

Introduction The age-standardised suicide mortality rate in Thailand has been stable at a high level in recent years, highlighting the need for suicide prevention interventions. In Thailand, community involvement plays a key role in health promotion. The aim of this ongoing trial is to evaluate the efficacy of a community participatory intervention in two subdistricts in Thailand for reducing suicidality symptoms among individuals considered at high risk for suicide and compare the outcomes to two control subdistricts.

Methods and analysis In this cluster (subdistrict) randomised controlled trial, we randomised two districts to either the community participatory intervention arm or the control arm. From each district, we selected one large and one small subdistricts. We estimated that we need 235 participants per study arm, who were recruited from subdistrict health centres. The primary outcome is suicidality symptoms. Secondary outcomes are depression symptoms, quality of life, stress level and health and community service accessibility.

Ethics and dissemination This trial has been approved by the Research Ethics Committee, Faculty of Nursing, Chiangmai University (number 050/2022). All participants were required to provide informed consent. The findings of the study will be disseminated in peer-reviewed journals and via conferences.

Trial registration number TCTR20220620003; the Thai Clinical Trials Registry.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The studied comprehensive interventions to prevent suicide employ culturally rooted, community-oriented suicide prevention activities in addition to the conventional healthcare-oriented suicide prevention services.
⇒ A cluster randomised controlled trial is applied to examine the efficacy of the studied intervention, for which the most notable strength is the control arm that will reflect the counterfactual scenario of doing nothing.
⇒ Two-year experimental design—with three time-point data collections at baseline, 1 year and 2 years after starting the studied intervention—could demonstrate the immediate effect at the end of the 1-year capacity-building interventions and at the end of the first year following implementation of the community participatory suicide-prevention activities.
⇒ Two major limitations are the small number of subdistricts with only two interventions and two control subdistricts and any potential spillover effects.

INTRODUCTION

With an age-standardised suicide mortality rate of 8.0 per 100 000 population in 2019, Thailand has the highest rate in the Association of Southeast Asian Nations Region's 10 countries.[1] Following a gradual decline in the early 2000s, the suicide mortality rate in Thailand has been stable since the mid-2000s, hovering between 7.5 and 8.9 per 100 000 population.[2] In light of the United Nations' Sustainable Development Goals (SDGs) target to reduce premature mortality from non-communicable diseases by one-third through prevention and intervention, under which reducing the suicide mortality rate falls (SDG V.3.4.2),[3] it is clear that action is needed to prevent suicide in Thailand.

Over the last several decades, Thailand has put much effort into strengthening its primary healthcare system to attain universal health coverage. During this time, the government recognised that community involvement is of paramount importance to public health in Thailand.[4] As a result, Thailand introduced community health volunteers in the 1960s[4] who not only assist health personnel in service provision but also serve as a link between clinical care and community resources.

In 2009, as part of a pilot project, the Thailand healthcare system developed and tested an evidence-based surveillance and

care system for depression and suicide, which has operated at all levels of healthcare provision throughout the country since 2010.[5] The six main components of this system include the following: (1) screening, (2) assessment, (3) diagnosis and treatment, (4) psychosocial care, (5) continuing care and (6) education and awareness. First, screening for depression in at-risk groups, using a two-question tool (the Patient Health Questionnaire-2, PHQ-2),[6] is carried out by community health volunteers in the community and by health personnel in district hospitals or at various clinics in the provincial hospitals (eg, diabetes clinics, non-communicable disease clinics, antenatal care clinics and psychiatric clinics). Most suicides are related to psychiatric diseases, particularly depression.[7] In fact, it has been recommended that the treatment of depression be one of the main components in a national suicide prevention strategy.[8] Second, for those who were screened as being positive by the PHQ-2, depression severity is assessed using a nine-question scale (the PHQ-9[6] and the suicidality severity is assessed using the Thai Department of Mental Health's 8-question Questionnaire Assessing Suicide Risk (8Q) (see online supplemental material 1) at the district hospital by either a nurse or general practitioner.

Third, diagnosis and treatment, including the prescribing of antidepressant medications or the hospitalisation of the patient, are performed by general practitioners for patients with moderate and severe depression. For those who require more intensive treatment, the general practitioner refers the patient to a psychiatric hospital to receive advanced psychiatric care. Fourth, psychosocial care is provided by psychiatric nurses for patients with mild depression. Fifth, continuing care for relapse and suicide prevention, including monthly home visits and monitoring of depressive symptoms and suicidality, using the PHQ-9 and the 8Q, for 6 months is conducted by subdistrict health centre personnel. Finally, national-level education and awareness campaigns for promotion of mental well-being and prevention of depression in at-risk populations are executed by the Department of Mental Health, Ministry of Public Health.

From 2009 to 2012, more than 137 000 community health volunteers were trained to use the PHQ-2 questionnaire for screening people who were at risk for depression, 21 000 primary healthcare personnel were trained to assess and provide basic interventions, and 1900 general practitioners received training to recognise, diagnose and treat major depressive disorder. This comprehensive hospital-oriented system increased the accessibility of care for patients with depressive disorders from 5.1% in 2009 to 48.5% in 2016.[5] However, the suicide mortality rate did not decrease during this time.[2] This finding suggests that there is something missing in the Thai surveillance and care system for depression and suicide, which could potentially be related to community involvement.

Therefore, we aim to conduct a cluster randomised controlled trial to evaluate the efficacy of a suicide prevention community participatory intervention for reducing suicidality symptoms among individuals considered to be at high risk for suicide. Our study objectives will be to develop community participatory suicide prevention interventions and to examine the efficacy of these interventions by comparing their impacts on reducing suicidality symptoms among people at high risk of suicide in the intervention subdistricts with those in the control subdistricts. If successful, a larger randomised trial with multiple subdistricts is planned to prepare for national implementation.

METHODS AND ANALYSIS

Design

This study is a cluster (subdistrict) randomised controlled trial. Two districts within Chiangmai Province, Thailand, were randomly assigned to either the community participatory intervention arm or the control arm. From each district, one large and one small subdistricts were sampled (see details below). See figure 1 for the study flowchart. This study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials guideline.[9]

Population

Participant recruitment was conducted at health centres in each of the selected subdistricts. Participants who fulfilled the inclusion criteria and who signed informed consent forms were enrolled in the study. The recruitment duration lasted for approximately 2 months, from August to September of 2022.

Inclusion criteria

Patients were eligible for the trial if they are 18 years old and above and had a history of one of the followings: (1) a past suicide attempt, (2) a chronic mental illness (defined as schizophrenia, bipolar disorder, depressive disorder, alcohol and substance use disorders), (3) a chronic non-communicable disease (including cancer, cardiovascular disease, diabetes, hypertension and chronic respiratory diseases) and/or (4) a life crisis experience such as the loss of a significant other, the loss of employment or high debt.[10]

Exclusion criteria

Participants were excluded if they fulfilled any of the following exclusion criteria:

- Active psychotic symptoms.
- Unable to participate in data collection activities due to physical or mental illness.
- Planned migration out of the studied subdistrict.
- Patients who cannot communicate in the Thai language.

Randomisation

We purposely selected the Chiangmai Province as the study site given that the suicide mortality rate is considerably higher in upper northern Thailand compared with the national average[11]; Chiangmai Province=14.61 deaths by suicide per 100 000 population in 2020.[12] Within

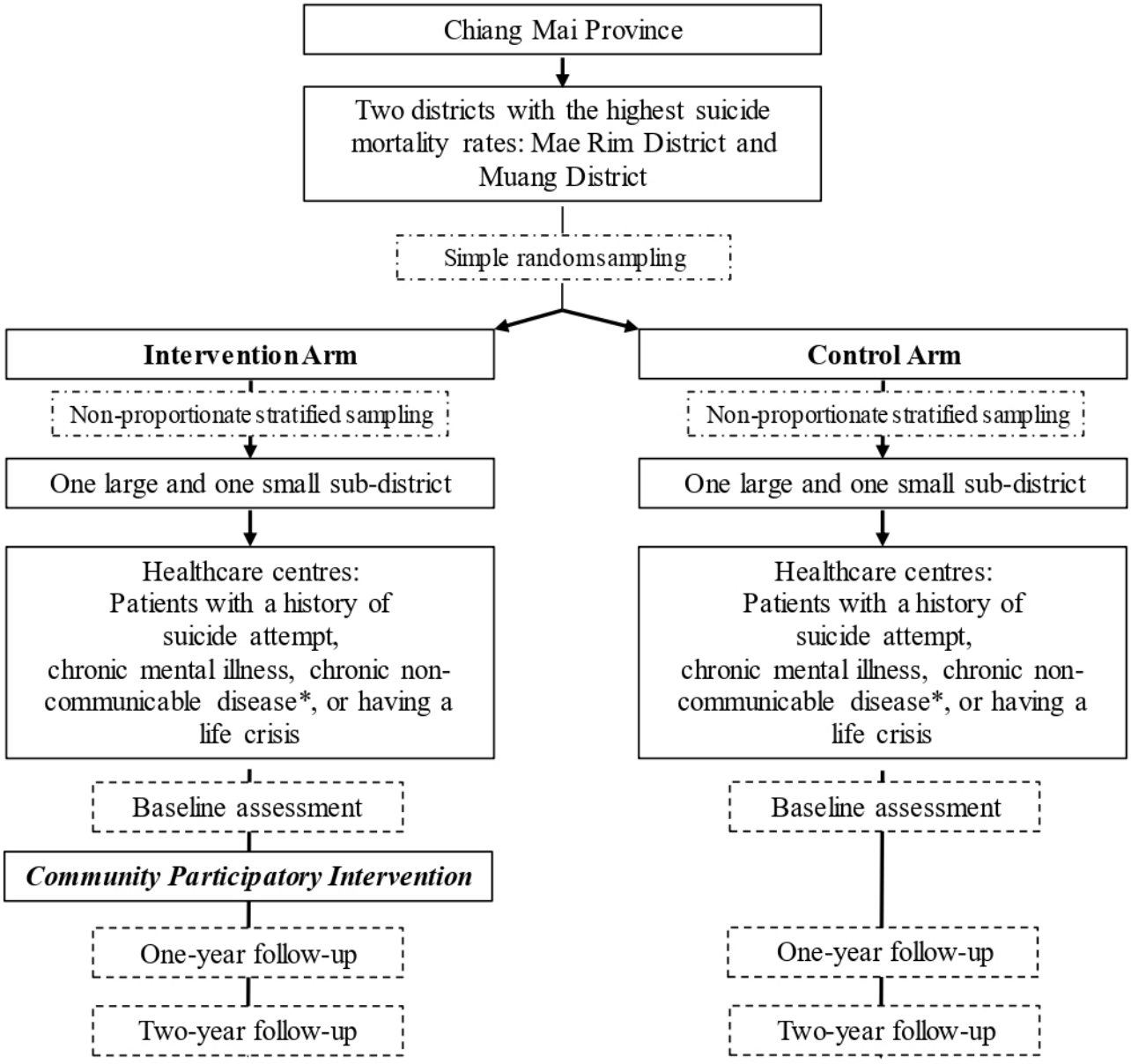

Figure 1 A community randomised controlled trial design to examine the efficacy of community interventions to prevent suicide.

Chiangmai Province, we chose two districts with high suicide mortality rates: Mae Rim district (26 deaths by suicide per 100 000 population) and Muang District (21 deaths by suicide per 100 000 population).[13] We randomly allocated one of these two districts to the community participatory intervention arm and the other to the control arm. We then selected one large and one small subdistrict from each of the two districts.

With respect to participants, our sample included all patients meeting our inclusion criteria specified above, except for patients with diabetes and hypertension since there were so many patients in these two disease categories. In addition, we conducted simple random samplings from the lists of patients with diabetes and hypertension and recruited patients until we reached 150 participants per subdistrict for all four sampled sub-districts.

Intervention

The intervention consists of two parts (see figure 2). Part 1 of the intervention includes a series of capacity-building workshops for relevant key stakeholders at the subdistrict level and the community level, delivered by the study team. The key stakeholders at the subdistrict level include officials from the subdistrict health centre and the subdistrict municipality. The key stakeholders at the community level include community health volunteers, community caregivers and community leaders, who were identified by the subdistrict health centre personnel as proactive individuals. Stakeholders from each of these groups have been participating in a five-step capacity-building process. This 1-year process involves (1) introductory workshops, (2) community participatory data collection and planning workshops, (3) key competency training series

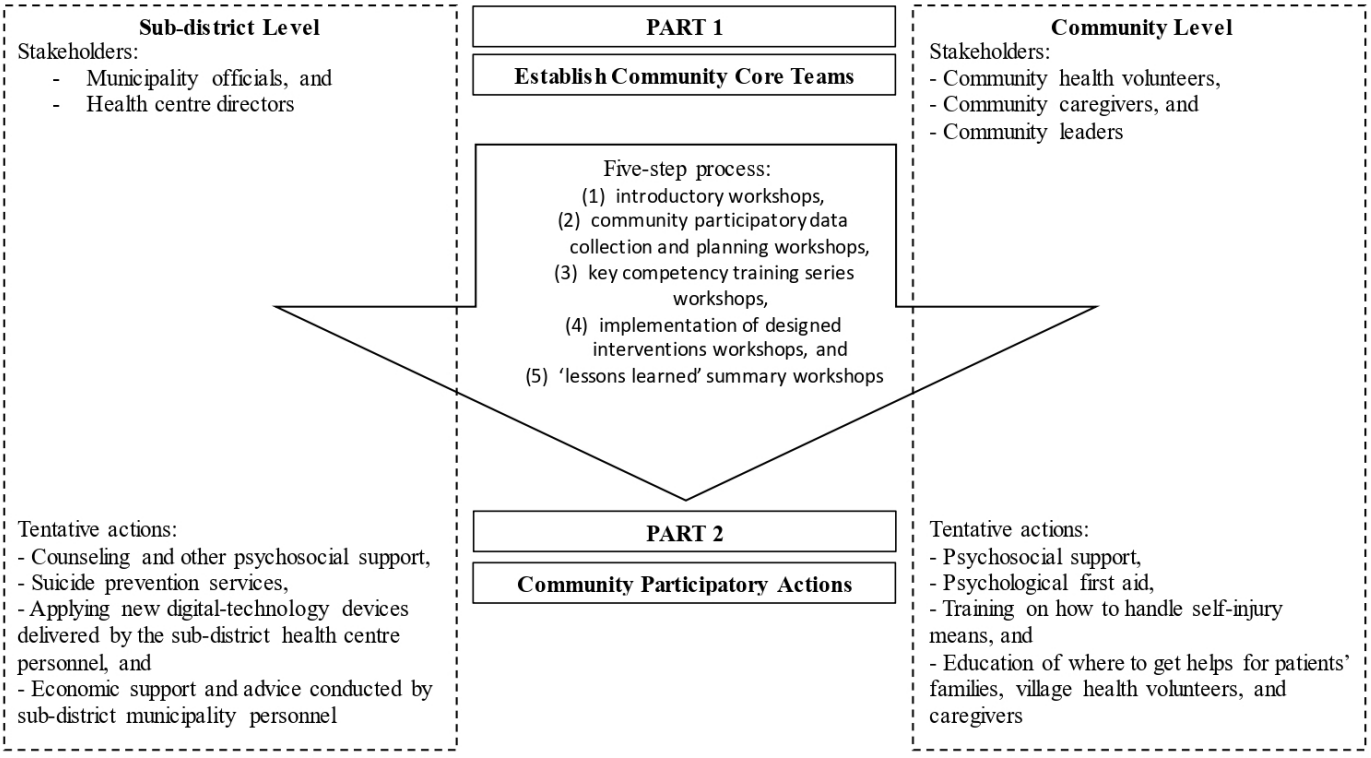

Figure 2 A two-part intervention: capacity-building plus community participatory action.

workshops, (4) implementation of designed intervention workshops and (5) 'lessons learnt' summary workshops. The first three activities were conducted until May 2023 and the last two activities will be conducted in June and July 2023.

We first approached the directors of the intervention-arm subdistrict health centres to invite them to join the study. We then asked them to recommend key individuals from the above-specified groups, with the aim of amassing a group of 30–40 people per subdistrict. These groups are called the 'subdistrict core teams'. All capacity-building activities were and will be delivered to these core teams in the subdistricts. After training, these key people will go back to their subdistricts to run the same capacity-building series for their colleagues at both the subdistrict and community levels.

The introductory workshop aimed to inform members of the overall rationale for the study and study design. The community participatory data collection and planning step involved two substeps: a community participatory data collection workshop and a data interpretation and planning workshop. The former workshop trained the participants on what data to collect and how to collect them. The latter workshop trained them to analyse and interpret the collected data and then guided them to design and plan suicide prevention interventions at the community levels. The key competency training series covered several needed key competencies desired by the subdistrict core teams. These key competencies included effective counselling skills for suicide prevention and how to apply digital knowledge for better counselling for subdistrict health personnel; psychosocial support and psychological first aid for patients' families, village health volunteers, and caregivers; how to conduct community activities for psychosocial supports and economic counselling for people at high risk for suicide. The implementation of designed interventions will be piloted by the responsible key stakeholders at the community level. The last step will aim to summarise what can be learnt from the pilot. The last two activities will be conducted in June and July 2023.

Part 2 of the intervention covers 1-year (expected to be from August 2023 to July 2024) community participatory actions to prevent suicide and will be conducted at both the subdistrict and community levels by the community core team. These actions will cover both individual and organisational interventions. The tentative actions at the subdistrict level may be counselling and other psychosocial support, and suicide prevention services, applying new digital-technology devices delivered by the subdistrict health centre personnel and economic support and advice conducted by subdistrict municipality personnel. The tentative actions at the community level may include psychosocial support, psychological first aid, how to handle self-injury means and how to get helps for patients' families, village health volunteers and caregivers. However, the final detailed actions will be designed by the subdistrict core teams, with involvement with relevant key players at both levels, during the capacity-building process (ie, part 1 of the intervention). The individuals at high risk for suicide (eg, past suicide attempt) and their family members will be involved in these community participatory actions.

Outcomes

There are two levels of outcomes in our study: ultimate and immediate outcomes. The primary ultimate outcome is suicidality symptoms among individuals considered at high risk for suicide, as measured by the 8Q screening tool (see online supplemental material 1).[5] The 8Q is the Thai version of the Mini International Neuropsychiatric Interview using to assess the suicidality with its sensitivity of 0.96 and specificity of 0.91.[14] The secondary ultimate outcomes will include depression symptoms, screened by the PHQ-2[6] and subsequently assessed by the PHQ-9,[6] if applicable, quality of life, measured by the EuroQol 5-dimension 5-level,[15] and stress level, measured the 5-item stress test[16] (see online supplemental material 2).

The immediate outcomes will cover an ability to access needed subdistrict's health and welfare services and relevant community support activities as well as an ability to access potential self-harm instruments. Accessing the needed health and welfare services delivered by the subdistrict health centre and municipality includes meeting health personnel as scheduled, taking medication as prescribed and getting counselling, psychosocial care, or psychotherapy as scheduled and welfare support services. These indicators are measured by assessing patients' health-service utilisation behaviours. See online supplemental material 3 for the health service accessibility assessment questionnaire. Accessing the relevant community support activities covers getting relevant health and psychosocial supports from patients' family members, community health volunteers, caregivers and getting relevant community support activities, such as volunteer activities, leisure activities and economic problem consultations. See online supplemental material 4 for the questionnaire assessing the accessibility to these community activities. See online supplemental material 5 for the questionnaire assessing patient's ability to access potential self-harm instruments.

Sample size calculation

Based on effect size definitions of Cohen,[17] we applied the sample size calculation method for studies with no prior study available to estimate the effect size of the intervention of interest. Using a power of 0.9, alpha of 0.05, and a small to medium effect size, which is the effect size of 0.3. We estimated that we need 235 participants per study arm. Assuming a dropout rate of 20%, we aimed to recruit 294 patients for each arm (ie, 147 patients per subdistrict), for a total of 588 participants.

Data collection

Our study employs mixed quantitative and qualitative methods. For the quantitative part of the study (figure 2), our trained field researchers (university nursing students) collected data by interviewing all target study samples using all outcome measure tools mentioned above at baseline (ie, prior to the intervention), and then we will collect data two more times at 1 year and 2 years after starting the intervention. We have been interviewing a close relative of each patient to assess two important variables: the patients' accessibility to any tool that can be used for injuring oneself and compliance with prescribed medications and psychosocial services.

For the qualitative component of the study, the research team conducted at baseline (in August and September 2022), 10 in-depth interviews with subdistrict health personnel and municipality personnel, community leaders, community health volunteers and caregivers per subdistrict, for a total of 40 interviews. These qualitative data will also be collected at the same time intervals as the quantitative data collection at 1 year and 2 years postintervention started. Patients are able to stop their research participation anytime if they feel uncomfortable to continue or they are unable to participate in data collection activities due to physical or mental illness.

Data analysis

Mean and percentage will be used to describe the distribution of continuous and discrete variables, respectively. The primary outcome is defined as the mean score of the 8Q tool for assessing suicidality symptoms 2 years of postintervention. Analysis of covariance will be used for examining the difference between 8Q scores of the intervention group and the control group, taking differences between conditions on the initial assessment into consideration. The qualitative data will be analysed using thematic analysis to explore pathways for suicide prevention activities at the community and the subdistrict levels[18] as it will be able to deal with the abundance of written data in this trial.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The trial protocol (amendment number 1, on 5 June 2022) has been approved by the Research Ethics Committee, Faculty of Nursing, Chiangmai University (#050/2022). Patients' written informed consent is required at all participating health centres (see online supplemental material 6). Research assistants are responsible for obtaining informed consent from study participants or legal representatives. Research assistants will contact the target samples, explain them the study protocol and get their signed informed consents if they are agreed to join the study. All target samples will be informed that the study participation was not a requirement for getting treatment or other health interventions. Confidentiality is assured through data anonymisations and controlled access to care report forms and the electronic data capture system. Any violations of confidentiality or study protocol will be reported to the research ethics committees.

We intend to publish the results of this randomised controlled trial in peer-reviewed journals as they become available. The data will also be presented at scientific conferences. Consent for publication will be obtained

directly from patients as part of the informed consent process. Individual clinical trial participant-level data (IPD) that underlies the results reported after deidentification and documents (study protocol, statistical analysis plan, analytic code, tables, figures and appendices) will be available for sharing 1 year after publication for a period of 2 years. Access to the IPD and documents will be open to investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. The information will be available for achieving aims in the approved proposal. Proposals should be directed to the corresponding author.

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Contributors BS, JR, DT, KTo, DH conceptualised the study design. BS, JR, DT, AW, KTh, KTo, VR, AS developed the detailed operationalisations of the interventions. BS, JR, SL drafted the study protocol. All authors improved and approved the study protocol.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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