TCTR ID : TCTR20211019003

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	16 October 2021
First Posted Date :	19 October 2021
Last Update Posted Date :	03 May 2022

Title

Public Title :	Effectiveness of Behavioral Activation on Depression among the Elderly
Acronym :	BADE
Scientific Title :	Effectiveness of Behavioral Activation on Depression among the Elderly
Sponsor ID/ IRB ID/ EC ID :	IRB No. 680/61
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20211019003
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	089/2019
Date of Approval :	24 January 2019
Board Name :	The Institutional Review Board of Faculty of Medicine, Chulalongkorn University
Board Affiliation :	Chulalongkorn University, Thailand
Board Contact :	Business Phone : 6622564493 Ext. No Data
	Business Email : medchulairb@chula.ac.th
	Business Address : The Institutional Review Board of Faculty of Medicine, Chulalongkorn University, 1873 Rama 4 Road, Patumwan, Bangkok 70330, Thailand,

Sponsor

Source(s) of Monetary or Material Supports :	Chulalongkorn University
Study Primary Sponsor :	Chulalongkorn University
Responsible Party :	Name/Official Title : Chulalongkorn University
	Organization : Faculty of Medicine, Chulalongkorn University 1st floor, Anantamahidol Building, 1873, Rama 4 Road, Pathumwan, Bangkok 10330
	Phone : 022564000 Ext. 3404
	Email : prmdcu@gmail.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	The effectiveness of Behavioral Activation (BA) on depression among the elderly in non-Western countries is currently limited. We will examine the effectiveness of BA in reducing depressive symptoms among Thai older adults with subthreshold depression residing in the community.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	An older adult with subthreshold depression (mild to moderate) depression
Keywords :	Behavioral Activation, Older Adults, Subthreshold Depression, cluster randomized controlled trial

Eligibility

Inclusion Criteria :	subthreshold depression (mild to moderate) depression (with the Thai Geriatric Depression Scale or TGDS of 13-24)
Gender :	Both
Age Limit :	Minimum : 60 Years Maximum : N/A (No limit)

Exclusion Criteria :	1) hearing impairment and/or dementia assessed by the Mini-Mental State Examination Thai version (MMSE-Thai 2002), 2) potentially life-threatening psychiatric and medical comorbidities or conditions that would limit study participation or adherence, and 3) currently undergoing any psychotherapy or taking antidepressants.
Accept Healthy Volunteers :	No

Status

Overall Recruitment Status :	Completed	
Key Trial Dates	Study Start Date (First enrollment) : 26 February 2019	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 23 December 2019	Indicate Type : Actual
	Study Completion Date : 08 January 2020	Indicate Type : Actual

Design

Study Type :	Interventional
Primary Purpose :	Prevention
Study Phase :	Phase 1
Intervention Model :	Parallel
Number of Arms :	2
Masking :	Masked Masked Role : Allocation concealment, Subject,
Allocation :	Randomized
Control :	No treatment / Standard of care
Study Endpoint Classification :	Efficacy Study
Sample size	
	Planned sample size : 82
	Actual sample size at study completion : 82
Intervantion Arm 1	
	Intervention name : Behavioral Activation with usual care group
	Intervention Type : Experimental
	Intervention Classification : Behavioral
	Intervention Description : This Behavioral Activation intervention contained 12 weeks and 2 hour weekly sessions composed of three main steps, activity monitoring, activity scheduling, and modification. It aimed to (a) increase engagement in rewarding activities, (b) decrease avoidance and isolation that maintain depression or increase the risk of depression, and (c) target factors that restrict access to reinforcement or maintain aversive control. A nurse working at the local Health Promoting Hospital and nine local village health volunteers (VHVs) who would serve as research assistants were recruited and provided one day of training on data collection and management of the participants during the BA intervention period. Groups of 3 VHVs were assigned to follow-up with and assist 13-14 participants in the residential community. The first week of BA intervention started with the instruction about the principles and process of BA, the concept of the depressive cycle and prevention of depression, the introduction to activity scheduling, and the recording of the activity schedule form. Homework was assigned to the participants to practice activity schedule recording. Participants were encouraged to seek assistance from family members and VHVs to complete this activity. Later, weekly BA sessions emphasized specific tasks, (1) activity monitoring examining the effect of specific activities on mood, (2) activity scheduling developing a plan to increase pleasant activities, and (3) modification utilizing problem-solving to alter contextual problems that may be eliciting or maintaining depressed mood.
Intervantion Arm 2	
	Intervention name : Usual care only group
	Intervention Type : Active Comparator
	Intervention Classification : Behavioral
	Intervention Description : Participants in the usual care group underwent regular physical examinations to review their current health symptoms and assess their individual health needs and psychoeducation (similar to the intervention group) delivered by the local mental health nurse every week for the twelve weeks. The investigator (WS) standardized usual care activities to ensure that the intervention (BA plus usual care) and the usual care-only groups followed the same procedure.

Outcome

Primary Outcome

1. Outcome Name : Depressive symptoms scores

Metric / Method of measurement : Participates reported outcome using a questionnaire (Thai Geriatric Depression Scal: TGDS)

Time point : 0, 3, 6 and 9 months

Secondary Outcome

1. Outcome Name : 1. Depressive symptoms, stress, and anxiety Score, 2. Heart Rate Variability (HRV), and 3. Daily step count

Metric / Method of measurement : 1. Participates reported outcome using a questionnaire, 2. Evaluate using a HRV cardiogram (ECG) recordings, 3. Evaluate by pedometer

Time point : 0, 3, 6 and 9 months

Location

Section A : Central Contact

Central Contact	First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
	Degree : Ph.D.	Phone : 0939516154 Ext. : No Data	Email : sahviwan@hotmail.com
Central Contact Backup	First Name : Wiroj	Middle Name :	Lastname : Jiamjarasrangsi
	Degree : Ph.D.	Phone : 0878020764 Ext. : No Data	Email : wjiamja@gmail.com

Section B Facility Information and Contact

1. Site Name : Department of Preventive and Social Medicine, Faculty of Medicine, Chulalongkorn University

	City : Pathumwan	State/Province : Bangkok	Postal Code : 10330
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Wiroj	Middle Name :	Last Name : Jiamjarasrangsi
	Degree : Ph.D.	Phone : 0878020764 Ext. : No Data	Email : wjiamja@gmail.com
Facility Contact Backup	First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
	Degree : Ph.D.	Phone : 0939516154 Ext. : No Data	Email : sahviwan@hotmail.com
Investigator Name	First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
	Degree : Ph.D.	Role : Principal Investigator	

2. Site Name : Department of Community Public Health, School of Public Health, Walailak University

	City : Thaiburi	State/Province : Nakhon Si Thammarat	Postal Code : 80160
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
	Degree : Ph.D.	Phone : 0939516154 Ext. : No Data	Email : sahviwan@hotmail.com
Facility Contact Backup	First Name : Wiroj	Middle Name :	Last Name : Jiamjarasrangsi
	Degree : Ph.D.	Phone : 0878020764 Ext. : No Data	Email : wjiamja@gmail.com
Investigator Name	First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
	Degree : Ph.D.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
Degree : Ph.D.	Phone : 0939516154 Ext. : No Data	Email : sahviwan@hotmail.com
Postal Address : Department of Community Public Health, School of Public Health, Walailak University		
State/Province : Nakhon Si Thammarat	Postal Code : 80160	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Chulalongkorn University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Wanvisa	Middle Name :	Last Name : Saisanan Na Ayudhaya
Degree : Ph.D.	Phone : 0939516154 Ext. : No Data	Email : sahviwan@hotmail.com
Postal Address : Department of Community Public Health, School of Public Health, Walailak University		
State/Province : Nakhon Si Thammarat	Postal Code : 80160	
Country : Thailand	Official Role : Study Principal Investigator	

Organization Affiliation : Walailak University

Summary Results

Date of posting of results summaries :	24 September 2020
Date of first journal publication of results :	14 December 2020
URL Link to Results :	https://doi.org/10.2147/CIA.S274262
Baseline Characteristics :	The participant's age, gender, marital status, monthly income, living status, personal disease history, baseline MMSE, TGDS, and DASS scores were similar between groups. However, in the BA with the usual care group, a greater number of participants had no education, and unemployment was higher compared to the usual care-only group.
Participant Flow :	A sample size of 41 in each group, four participants in the experimental group dropped out (due to time constraint), while one participant in the control group dropped out for an unspecified reason, and one died (unrelated to depression) during the follow-up period. Hence, 37 participants in the experimental and 39 participants in the control group completed the study. The drop-out rates were 9.76% and 4.88% in the control and experimental groups, respectively.
Adverse events :	-
Outcome Measures :	A clustered randomized controlled trial was conducted in two health-promoting hospitals in the Samut Songkhram province of Thailand. One hospital was used for the intervention (BA with usual care group) and the other for the control (usual care-only group). Each HPH randomly selected 41 eligible older adults residing in their jurisdictions to take part in the study. Mental health outcomes were assessed using the Thai Geriatric Depression Scale and Depression Anxiety Stress Scales. The BA effectiveness was evaluated using generalized estimating equations (GEE) at a group level and the reliable change index (RCI) at the individual level.
Brief Summary of Results :	Over nine months, in the BA with usual care group, the mean in depression scores 13.66, mental health status, specifically depression, anxiety, and stress score 6.83, 6.93, and 7.24, respectively, In the usual care-only group, the mean in depression scores 16.02, mental health status, specifically depression, anxiety and stress score 8.24, 7.00, and 9.14, respectively.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	No
Reason :	Personal reasons

Publication from this study

MEDLINE Identifier :	33363364
URL link to full text publication :	https://doi.org/10.2147/CIA.S274262