Title

Implementation Science in Thailand: Design and Methods of a Geriatric Mental Health Cluster-Randomized Trial.

Journal

Psychiatric Services, 73(1)

Authors

Gallagher-Thompson, Dolores
Tongsiri, Sirinart
Wisetpholchai, Bussabong
et al.

Publication Date

2022

DOI

10.1176/appi.ps.202000028

Peer reviewed

HHS Public Access

Author manuscript

Psychiatr Serv. Author manuscript; available in PMC 2023 January 01.

Published in final edited form as:

Psychiatr Serv. 2022 January 01; 73(1): 83–91. doi:10.1176/appi.ps.202000028.

Implementation Science in the Thai Context: Design and Methods of a Geriatric Mental Health Cluster-randomized Trial

Hongtu Chen, PhD,
Dept. of Psychiatry, Dept. of Global Health and Social Medicine, Harvard Medical School, Boston, MA

Sue Levkoff, ScD, MSW,
College of Social Work, University of South Carolina, Columbia, SC; Dept. of Global Health and Social Medicine, Harvard Medical School, Boston, MA

Komatra Chuengsatiansup, MD. Ph.D.,
Thailand Research Fund Senior Research Scholar, Society and Health Foundation, Thailand.

Siranee Sihapark, PhD,
Boromarajonani College of Nursing, Khon Kaen, Thailand

Ladson Hinton, MD,
Department of Psychiatry and Behavioral Sciences, University of California Davis, Sacramento, CA

Dolores Gallagher-Thompson, PhD, ABPP,
Dept. of Psychiatry & Behavioral Sciences, Stanford University School of Medicine, Stanford, CA

Sirinart Tongsiri, MD, PhD,
Quality of Life Research Unit, Faculty of Medicine, Mahasarakham University, Mahasarakham, Thailand

Bussabong Wisetpholchai, PhD,
Society and Health Institute, Ministry of Public Health Thailand, Nonthaburi, Thailand

Stacy Fritz, PhD, PT,
Physical Therapy Program, Department of Exercise Science, Arnold School of Public Health, University of South Carolina, Columbia, SC

Andrea Lamont, PhD,
Dept. of Psychology, University of South Carolina and Wandersman Center, Columbia, SC

Ariel Domlyn, MA,
Clinical-Community Psychology, University of South Carolina, Columbia, SC

slevkoff@mailbox.sc.edu .

Trial Identifier: NCT03264378 (ClinicalTrials.gov; date registered 08-24-2017)

Editor's Note: In partnership with Milton L. Wainberg, M.D., *Psychiatric Services* is publishing protocols to address the gap between global mental health research and treatment. These protocols present large-scale, global mental health implementation studies soon to begin or under way. Taking an implementation science approach, the protocols describe key design and analytic choices for delivery of evidence-based practices to improve global mental health care. This series represents the best of our current science, and we hope these articles inform and inspire.

Abraham Wandersman, PhD,
Wandersman Center and University of South Carolina, Columbia, SC

Andrea Horvath Marques, M.D., Ph.D.
Center for Global Mental Health Research, National Institute of Mental Health, Bethesda, MD, U.S.

Abstract

Introduction: Thailand faces a rapidly aging population yet lacks evidence for effective and scalable evidence-based psychosocial interventions to support persons living with dementia and their family caregivers. In this study of a culturally-adapted and evidence-based clinical program designed to reduce behavioral and psychological symptoms of dementia (BPSD) in older adults [Reducing Disabilities in Alzheimer's Disease (RDAD)], we test the hypothesis that an implementation support strategy [Getting-To-Outcomes®" (GTO®)] would show better implementation and clinical outcomes compared to usual implementation of RDAD in the Thai context.

Methods: The study uses a hybrid type III cluster randomized design comparing 8 geographical districts (intervention arm) that receive training to implement both the RDAD clinical intervention and GTO implementation support strategies vs. 8 districts (control arm) that receive the same RDAD training without training in GTO implementation support strategies. GTO is an evidence-based intervention designed to provide implementation support for implementers to better plan, implement, and evaluate innovative intervention programs in a novel setting. Primary outcomes will be assessed at baseline, month 3 (post-treatment), and month 6 (3 month follow-up), including implementation outcomes and clinical outcomes.

Next Steps: If clinical trial findings are positive, we plan to replicate and scale up the proposed implementation science approach to enhance and expand mental health services for older adults with dementia across Thailand.

Keywords

Behavioral problem; dementia; elderly; implementation science; Thailand; exercise; behavioral management

Introduction

Background:

Like many other low and middle-income countries (LMICs) in Asia, Thailand is facing a dramatic increase in the number of older persons with dementia (PwD) in the coming decades (1), yet very little evidence exists to guide policy makers in developing programs and supports for older adults living with dementia and their family caregivers (2). This project represents Thailand's first effort to develop a scale-up implementation research study to close the mental health treatment gap for older adults with any mental health condition. The primary focus of this project is on the reduction of behavioral and psychological symptoms of dementia (referred to hereafter as BPSD), present in 50% to 100% of persons with dementia, and which are associated with many adverse outcomes, including increased

disability and reduced quality of life for the person with dementia, as well as more stress, burden, and reduced quality of life for family caregivers (3).

Based on the observation that many government-promoted prior initiatives have failed to be fully accepted, implemented, and sustained by local practitioners, this study focuses on testing whether an evidence-based implementation support strategy, Getting To Outcomes (GTO) (4) leads to both better implementation outcomes and clinical outcomes for the Reducing Disabilities in Alzheimer's Disease (RDAD) intervention (see Hypotheses below). GTO, an intervention protocol designed to provide implementation support for implementers to better plan, implement, and evaluate evidence-based intervention programs, has been found to increase the capacity of organizations to implement a variety of evidence-based programs, particularly in improving fidelity and performance of implementation (4, 5). Given RDAD has been found to reduce BPSD in both experimental settings (6) and community-based residential settings (7), we rely on a stage III hybrid study design, which primarily tests implementation support strategies, with a secondary aim evaluating clinical effectiveness (8, 9).

Given the shortages of mental health specialists, insufficient financing for mental health services, and accumulating evidence for using trained non-specialists to deliver mental health care (i.e., the "task-sharing" approach) (10), we plan to implement RDAD, a culturally adapted version of an evidence-based intervention model (11) in both study arms. RDAD combines physical exercise and behavioral management for older adults with dementia and BPSD, relying on community-based health workers with additional training in elder care, i.e., Care Managers (CMs) and Community Caregivers (CCGs), for program delivery in the Thai setting.

Methods

Study design:

The study will be implemented in 16 geographical districts (i.e., clusters), and all districts will be randomly assigned to either the intervention arm or the control arm. Both intervention and control arms will receive the same RDAD clinical intervention protocol. The intervention arm will receive the RDAD intervention plus the GTO implementation support protocol (RDAD+GTO), while the control arm will receive the RDAD only.

The intervention study period lasts for 6 months, providing adequate time to observe effects. Patient and caregiver data will be collected at baseline, month 3 (post-treatment), and month 6 (3 month follow-up).

Study sites:

This study will be conducted in Khon Kaen province, Thailand, which has 26 districts, with each district including up to 3–18 subdistricts. Each subdistrict has one long-term care program, led by a Care Manager (CM), typically a trained nurse, along with several Community Caregivers (CCGs), typically a community health worker with additional training in elder care, who provide health and social care to community residing elders. Ten of the 26 districts were excluded for the following reasons: already participating in another

dementia-related project (2); health care systems too new to be fully functioning (4); and too few active long-term care (LTC) programs to support feasibility of the intervention within the LTC system (4). This leaves 16 districts (including 147 subdistricts, with over 267,000 older adults) in the study, with 8 districts being randomly selected for the experimental arm; the other 8 districts, for the control arm.

Inclusion and exclusion criteria:

Patients are included in the study *is they are* aged 60 and above; have probable dementia; have 1 or more behavioral and psychological symptoms; ambulatory; and have an adult (age 18+) family caregiver who lives with or spends a minimum of 4 hours every day with the patient. Measures used to determine the eligibility include: (a) Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), a locally validated short questionnaire to assess cognitive impairment in older adults that is completed by a family relative or friend familiar with the person (score of ≥ 3.47 indicates probable dementia) (13); (b) Neuropsychiatric Inventory (NPI-Q): a well validated instrument translated into Thai that relies on caregiver self-report to assess the presence and severity of BPSD (14); (c) Ambulatory test: a validated test that assesses a person's ability to walk independently or with assistive device (such as canes or walkers), but without physical assistance for support from another person (5); and (d) Medical History: Questions asked to family caregivers on presence of chronic diseases, with any positive response being further evaluated by the Study Physician to determine those persons with medical contradictions to physical exercise who should be excluded from study participation.

Patients are excluded from the study if they or their family caregivers (a) do not provide assent to study participation; or (b) their CM and/or primary care providers do not recommend the patient to participate in the intervention due to concerns about medical condition (e.g., severe/unstable cardiovascular disease) and/or frailty based on medical record.

Recruitment procedures:

Patients are primarily recruited from referrals from Thailand's LTC system, where participating CMs identify candidate study participants based on their Mini-Mental State Examination (MMSE) scores, which are routinely collected and included in the patients' LTC plans. Those LTC patients who have been identified as having cognitive impairment based on the MMSE will be screened using the IQCODE to identify cases/persons "at high risk" for dementia, referred to hereafter as "probable dementia." Participants with an IQCODE mean score above the 3.47 threshold for probable dementia, and who present with at least one significant BPSD symptom as measured by the Neuropsychiatric Inventory will be eligible for participation in the trial. Based on the high sensitivity (90%) and specificity (95%) of the IQCODE (15), we anticipate that the positive predictive value of the IQCODE will be >90%, thus ensuring the likelihood of our successfully recruiting the required sample in the proposed study period.

Case confirmation:

Because many persons with dementia in Thailand will not have received a formal diagnosis, we will rely on an adjudication process to identify persons with probable dementia, as project resources do not allow for obtaining a clinical diagnosis. After the initial screening based on IQCODE is completed, a team consisting of the Research Assistant, Research Director, CM, and Study Physician will review the results of the IQCODE, along with other medical conditions (e.g., cardiac disease, hypertension), to 1) determine if the person meets clinical criteria for dementia (according to DSM-5), and 2) identify any medical contraindications to the exercise intervention.

Power analysis:

To achieve 80% power for a medium effect (.4) at an alpha level of .05 and 16 districts/clusters will require 288 dyads for the whole study. We plan to recruit a total of 340 (170 per group) dyads allowing for 15% attrition.

Consent procedures:

Two separate consents will be obtained, one for participation in screening and one for participation in the intervention study. Those elderly who screen positive on the screening assessments (i.e., IQCODE and NPI) are eligible for participation in the RCT. Per Thai Internal Review Board (IRB) laws, both the Family Caregiver (FCG) and the patient with dementia (PwD) are required to provide consent for the participation of the PwD in the trial. The FCG, or someone who has the right to act as the PwD's legally authorized representative (e.g., legal guardian or family member), will provide a signature to indicate his/her permission for their relative's study participation. If the FCG is not able to read and write, a thumb fingerprint from the FCG is required to indicate his/her permission for the PwD to participate.

The PwD will be read a consent form that uses simple language to explain the study. We follow recommendations of Black and colleagues (2010) for assisting those persons whose capacity for "consent" might be diminished. Thus, study staff are trained to observe verbal willingness to participate (e.g., saying yes, or willing to go along with whatever their family caregiver consents to), behavioral indications (e.g., acting agreeably; cooperation), and emotional indications (e.g., having a positive facial expression) (16). They will also observe indications of "dissent" to participate, as expressed verbally (e.g., saying no), behaviorally (e.g., not cooperating, being agitated), or emotionally (e.g., showing distress, unhappiness) (16).

Those PwD who do not provide verbal, behavioral, or emotional dissent, will be consented through providing either a signature or a thumb fingerprint to confirm their agreement for study participation. If PwD are not able to provide consent by either signature or thumb fingerprint, they will be approached up to 2 additional times. The reason for this is that PwD have fluctuating behavioral and psychological problems (e.g., agitation, apathy, paranoia) that might interfere with their ability to engage in the consent process at any one time. If they are not able to consent after three attempts, they will not be eligible for study participation. While different from U.S. IRB study procedures, which rely on an 'assent

process' for those with diminished capacity to consent, facilitated by an expert assessing the PwD's capacity for assent, the proposed procedure is compliant with Thai IRB laws as well as the applicant institution's IRB.

In addition, consent will be obtained from the FCG for their own participation in the RCT intervention study. Although the FCG is not required to participate in the intervention's physical exercise activities, they will be actively engaged in helping ensure the safety of the PwD throughout the physical activity intervention. The FCG will also be engaged in the behavioral aspects of the intervention study, learning how to better manage BPSD. Similar to prior interventions showing reductions in stress and burden and increased quality of life for involved caregivers, we also plan to document and analyze changes in family caregiver outcomes.

Randomization Procedure:

Cluster randomization will occur at the district level. To maximize the even distribution of factors that may affect outcomes (17), we employed the following three steps to implement the cluster randomization procedure: First, we conducted a formative evaluation of geographical variation among districts in Khon Kaen province and identified two covariates that might affect implementation outcomes: number of sub-districts (range: 4 to 18); and the ratio of active LTC systems to number of LTC systems, as discussed above. Second, we stratified all participating sites/districts by these two covariates for a 2×2 distribution of districts, resulting in an even distribution across the four conditions. We next conducted stratified randomization, using a computer-generated randomization program to randomize the sites in sequence to ensure equal distribution within each block.

Intervention Protocols:

Both intervention and control arms will receive the exact same culturally adapted and evidence based RDAD clinical intervention with its standard implementation guidelines, as well as "usual practices" of program implementation in Thailand. Usual implementation practice consists of a top-down centralized program announcement, with a printed description of the program and its administrative requirements (e.g., schedule for submission of "care plans" and other performance indicators), as well as basic consultation support from district LTC management offices.

The intervention arm will receive the additional GTO intervention to support implementation of the RDAD protocol (see Table 1).

RDAD Intervention: The RDAD protocol was part of the Seattle Protocols originated by Teri (study consultant) and colleagues (8, 9,18) in a series of clinical trials. The RDAD protocol includes two main components. The ***behavioral management component*** involves: teaching family caregivers how to identify and modify patient behavioral problems that impair day-to-day function and adversely affect patient-caregiver interactions; providing information about dementia, nutrition support, support with home environment adaptation, and support for enhancing FCG coping skills; and identifying pleasant activities in which family caregivers can engage (8, 9). The ***physical exercise component*** includes: aerobic/

endurance activities, strength training, balance, and flexibility training, with the goal of engaging patients in a minimum of 30 minutes a day of physical exercise (19).

GTO Intervention: GTO is an evidence-based intervention to support the systematic planning, implementation, and evaluation of innovative interventions (defined as new practices, policies, or procedures), such as RDAD, in novel settings (20). The core components of GTO include (1) training GTO technical assistance specialists (TAS) to provide implementation support to CMs, and (2) training CMs to execute quality implementation by following the GTO protocol. Through a ten-step process (i.e., assessing needs, developing goals and desired outcomes, selecting a best practice, ensuring program fit, ensuring sufficient capacity, planning, process evaluation, outcome evaluation, continuous quality improvement, and sustainability), GTO provides a detailed roadmap for those seeking to implement evidence-based interventions customized to their communities.

It is hypothesized that the implementation support provided through GTO will increase capacity for all key programming activities, including goal setting, strategic planning, monitoring, continuous quality improvement, and sustainability. As a result, better performance of programming activities will improve program delivery, which in turn, will lead to better individual outcomes (20). The delivery of GTO training and GTO-based implementation support will be performed throughout the entire 3-month intervention period (see Table 1 below) to support implementation of the RDAD clinical intervention.

Feasibility and Cultural Adaptation:

To assess the feasibility of conducting the proposed intervention study in the Thai context, we conducted five formal meetings with over 30 key stakeholders (including health policymakers, different types of health service providers, researchers, and care receivers), in-depth qualitative interviews with 8 health professionals, and made site visits to community-based primary care settings and residential homes (12). The focus of these meetings was on determining the most appropriate service delivery system in which to implement the study.

Themes and key messages that emerged from these meetings were examined, and follow-up conversations held to clarify issues that were raised. A consensus among the research team was gradually achieved regarding the following: (a) there is an increased recognition of burden of care for older adults with BPSD; (b) given the system-wide shortages of mental health specialists in the long-term care (LTC) system, and the availability of trained community-based health professionals in the LTC system to deliver in-home support services to persons with dementia (see Box 1); (c) we should develop an intervention program that would be delivered by community-based health professionals in the existing service platform of the Thai LTC system.

Through the formative research, the original RDAD protocol was modified for local cultural, clinical, and service systems in a two-step process. First, possible modifications were explored in collaboration with RDAD's developer, during her consultation with the study team in Thailand. The research team then held a series of workshops with CMs and CCGs to obtain their feedback about the acceptability of the recommended cultural adaptations, the feasibility of implementing them for Thai culture, and also, any additional changes

that they recommended to ensure cultural and clinically appropriate communication of key concepts. The following adaptations to the original protocol were agreed upon: (1) using local devices (e.g., drums) and activities (e.g., walking to a Buddhist temple; local folk dance) to illustrate acceptable physical activities; (2) using storytelling to elicit CMs and CCGs clinical experiences to increase their appreciation of the relevance of the intervention programs to their clinical practice; and (3) shortening intervals between follow-up sessions (the original five-month RDAD intervention was changed to 12 weeks, which matches the reporting and monitoring cycle of the local LTC service system. All these adaptations were approved by the RDAD developer, who confirmed that all critical elements of the intervention were preserved.

The proposed protocol will be implemented over a 12-week period, for a total of 13 sessions. Each dyad, i.e., PwD and FCG will be seen in the patient's home for all 13 sessions, with each session lasting from approximately 30 minutes to 1 hour. Besides in-person discussion at each session, a brochure showing physical activity procedures, together with a set of forms (e.g., appointment schedule; RDAD; and procedures check list) will also be given to the family caregivers. The schedule of home visits is as follows: 8 sessions (2 sessions per week) for the first 4 weeks (Weeks 1–4), followed by 4 sessions (1 session per week) for 4 weeks (Weeks 5–8), and 1 last session on Week 12. After the first 9 home visit sessions primarily for teaching, coaching and reviewing, there are 4 additional follow-up home visit sessions to review status of behavioral management practice and physical exercise, answer questions, consolidate treatment gains, and encourage long-term retention in the program.

Training for Intervention Delivery:

To ensure CMs' and CCGs' adequate understanding of key concepts in both GTO and RDAD intervention protocols and that these intervention protocols fit the clinical workflow in the Thai context, we conducted workshops to teach CMs and CCGs about these two interventions, which were followed by qualitative interviews with trainees, and consensus meetings in which the research team, including clinicians, medical anthropologists, and public health officials, who worked closely with participating CMs and CCGs to determine the fit of the interventions within the existing clinical flow of the Thai LTC system.

Hypotheses:

Given that GTO has shown to increase implementers' overall capacity to implement evidence-based intervention programs, our primary hypothesis is that the intervention arm, which employs the GTO implementation support intervention, will result in significantly better **implementation outcomes**. Based on the prior literature (see below), we selected following five implementation outcome indicators: (a) *higher fidelity* in implementing the RDAD clinical intervention, (b) *higher dosage* of RDAD received by the participants, (c) *better reach* of participants in the community, (d) *better acceptability* as perceived by the RDAD program implementers, and (e) *higher satisfaction* of the participants (i.e., family caregivers and persons with BPSD) with the RDAD clinical intervention, as compared with the control arm.

Assuming that the improved implementation of the RDAD clinical intervention will lead to better outcomes of the intervention, our secondary hypothesis is that the intervention arm will lead to better **clinical outcomes** for persons with BPSD, including (a) more reduction in BPSD, (b) better physical health, and (c) improved overall quality of life, compared to persons with BPSD in the control arm. In addition, since the family caregiver is also a key receiver of the RDAD intervention while assisting persons with BPSD in the intervention, our tertiary hypothesis is that the intervention arm will also lead to better family caregiver outcomes including (a) reduced burden, (b) lower psychological distress, and c) improved quality of life, compared to caregivers in the control arm.

Outcome Measures:

Three sets of measures will be used for outcome evaluation (see Table 2). Implementation outcomes (primary objective) include: **Fidelity** (the extent to which the content of the intervention is delivered as intended) assessed by percentage of scheduled sessions being completed, based on a study log documented by the FCG after each session and confirmed by CCG weekly (10); **Dosage** (the actual amount of intervention received by the participants) assessed by CCG and documented in study log (8); **Reach** assessment based on records from interventionists (i.e., CM and CCG) and administrators and documented in study log (21); **Acceptability** assessed by CCG and CM responses to a brief questionnaire at month 3 and month 6 (22); **Satisfaction** assessed by FCG and PwD (if possible) in response to questionnaire administered at month 3 and month 6 (23); and **Readiness for change** assessed by Activity-Based Readiness Tool, a self-report questionnaire to be completed by CCGs and CMs at baseline, month 3, and month 6 (24).

Patient clinical outcomes (secondary objective), collected at baseline, 3 months (post-treatment), and 6-month follow-up, include **behavioral and psychological symptoms** assessed by NPI-Q (14); **depressive symptoms** assessed by the Geriatric Depression Scale (GDS) (25); **cognitive impairment** assessed by the Thai Mental State Examination (TMSE) (26); **physical functioning** assessed by the Short Form-36 (27) and the Sickness Impact Profile (SIP; mobility subscale) (28)**; activities of daily living** assessed by the Barthel ADL Index (29); and **quality of life** assessed by QoL-AD (30). All above scales, except for the TMSE, are based on caregiver report.

Caregiver clinical outcomes (tertiary objective), collected at baseline, month 3, and month 6, include **caregiver burden** assessed by the Zarit Burden Interview (ZBI) (31); **depressive symptoms** assessed by the Patient Health Questionnaire (PHQ-8) (32) (i.e., PHQ-9 without the suicidality item); **caregiver distress** by symptom related distress on the NPI-Q (14); and **Quality of life** assessed by QoL-AD for Caregivers (30).

Data Analysis:

In addition to descriptive analyses and univariate comparisons of the experimental and control intervention group conditions at baseline, we will use repeated measure mixed models to analyze each of the implementation as well as clinical outcome measures. We will also use intra-class coefficient (ICC) to reflect the expected positive within-group correlation. The outcomes will be nested within each participant, which will be nested

in within each district. Using an intention-to-treat approach, we will conduct analysis of covariance by using a multivariate linear regression modeling to test effects of the intervention at month 3 and month 6. Intercepts and treatment effect will be modeled as random effects at the participant's level and as fixed effects at the district level, while patient characteristics (e.g., levels of dementia severity and mobility) as well as length of time of caregiver involvement (i.e., average hours spent per day) will be control variables. Results of statistical procedures will be presented using adjusting means (Least-squares means) with 95% confidence intervals for intervention and control groups respectively.

Anticipated Results

We anticipate that over the 3 to 6 months intervention period, there will be significantly more improvements in the delivery of the RDAD intervention program as indexed by implementation outcome measures (i.e., fidelity, dosage, acceptability, satisfaction) in the experimental than control group. Further we anticipate that patients in the experimental arm will demonstrate significantly better improvement in their mental and physical health, and that caregivers will report more reduction in both caregiver burden and stress than those in the control arm. These findings, together with other published studies using a similar approach, will form a convincing empirical foundation for policymakers and clinical leaders in Thailand to consider not only utilizing an evidence-based intervention to improve care for older adults with BPSD, but also utilizing the GTO implementation support strategy to ensure success of intervention program delivery.

This clinical trial is the first large-scale implementation intervention study in Thailand with a primary focus on evaluating the benefit of utilizing implementation science methodology for successful implementation of clinical programs. In LMICs such as Thailand, where mental health professional resources are limited, it is crucial to identify evidence-based intervention programs that can be culturally adapted and implemented relying on the available workforce in the existing service system, and that can be scaled up with the support necessary for expanding service capacity. Our approach, delivering an intervention to address a mental health challenge by relying primarily on existing community-based health care resources (e.g., CMs, CCGs, and FCGs) with minimal support of participating medical professionals (e.g., physicians and psychiatrists), provides a promising message about how to deliver a feasible mental health treatment solution in a LMIC country. The implementation support strategies, through GTO protocol-based interactive training and use of trained TA specialists for support, may inform the current practice and add new knowledge to the research of implementation science.

Next Steps

If successful, findings from this study can be used to further the agenda of expanding mental health care for older adults in Thailand. We will first provide the eight control districts with the combined RDAD and GTO programs, a requirement of our Thai collaborators, to ensure control district participants felt they were being treated equally. Second, we will introduce the GTO-based implementation support model to other regional or national policymakers, employing the technical assistance specialists trained for this research project

as peer trainers to build a similar implementation support capacity in other regions to enhance further scaling up of the RDAD program. And third, we will work with interested investigators and policymakers to assist them in building capacity to implement other types of evidence-based mental health clinical intervention programs, with GTO implementation support.

Acknowledgments:

This article is part of a series of protocols of NIMH funded U19 focused on Global Mental Health Implementation Science. Getting To Outcomes and GTO are trademarks registered by the U. of South Carolina and RAND.

Grant info and disclosures: The grant, titled “Partnership in Implementation Science for Geriatric Mental Health (PRISM)”, is currently funded by the NIMH (5U19MH113201; Cinicaltrial.gov: NCT03264378).

References:

1. Prince M, Wimo AGM, Ali GC, Wu YT, Prina M: World Alzheimer Report 2015: the global impact of dementia: an analysis of prevalence, incidence, cost and trends. London: Alzheimer’s Disease International, 2015.
2. Hinton L, Tran D, Nguyen T, Ho J, & Gitlin L: Interventions to support family caregivers of people living with dementia in high, middle and low-income countries in Asia: A scoping review. BMJ Global Health 2019; 4(6): 1–12.
3. Charernboon T, Phanasathit M: Prevalence of neuropsychiatric symptoms in Alzheimer’s disease: a cross-sectional descriptive study in Thailand. J Med Assoc Thai. 2014; 97(5):560–565. [PubMed: 25065098]
4. Chinman M, Acosta J, Ebener P, Burkhart Q, et al. : Intervening with practitioners to improve the quality of prevention: One-year findings from a randomized trial of assets-getting to outcomes. TJ Prim Prev 2013; 34(3): 173–191.
5. Acosta J, Chinman M, Ebener P, Malone PS, Paddock S, Phillips A, Scales P, & Slaughter ME: An intervention to improve program implementation: findings from a two-year cluster randomized trial of Assets--Getting To Outcomes. Implement Sci 2013; 8:87. [PubMed: 23924279]
6. Teri L, Gibbons LE, & McCurry SM et al. : Exercise plus behavior management in patients with Alzheimer disease: A randomized controlled trial. JAMA 2003; 290(15): 2015–2022. [PubMed: 14559955]
7. Teri L, Logsdon RG, McCurry SM, Pike KC, McGough EL: Translating an Evidence-based Multicomponent Intervention for Older Adults With Dementia and Caregivers, The Gerontologist 2020; 60(3):548–557.
8. Benet AC, Willlens DE, & Bauer MA: Effectiveness -implementation hybrid designs: Implications for quality improvement science. Implementation Sci 2013; 8(1):S2.
9. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M: Reenvisioning clinical science: Unifying the discipline to improve the public health. Clin Psychol Sci 2014; 2(1):22–34. [PubMed: 25821658]
10. Padmanathan P, & De Silva M: The acceptability and feasibility of task-sharing for mental healthcare in low- and middle-income countries: A systematic review. Soc. Sci. Med. 2013; 97:82–86. [PubMed: 24161092]
11. McCurry SM, Logsdon RG, Pike KC, LaFazia DM, Teri L: Training area agencies on aging case managers to improve physical function, mood, and behavior in persons with dementia and caregivers: Examples from the RDAD-Northwest Study. J Gerontol Soc Work 2018; 61(1):45–60. [PubMed: 29135358]
12. Chuengsatiansup K, Wisetpholchai B, Sihapark S, Tongsiri S. Chen H. Levkoff S: The problem, context, and approach of the PRISM project. (unpublished manuscript, September 22, 2020).
13. Senanarong V, Assavisaraporn S, Sivasiriyanonds N, Printarakul T, Jamjumrus S, Udompunthurunk S, & Poungvarin N: The IQCODE an alternative screening test for dementia

for low educated Thai elderly. Journal of the Medical Association of Thailand 2001; 84, 648–55. [PubMed: 11560213]

14. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, & Gornbein J: The neuropsychiatric inventory: Comprehensive assessment of psychopathology in dementia. Neurology 1994; 44(12): 2308–2314. [PubMed: 7991117]
15. Siri S, Okanurak K, Chansirikanjana S, Kitayaporn D, Jorm AF. Modified Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) as a screening test for dementia for Thai elderly. Southeast Asian J Trop Med Public Health 2006; 37(3): 587–94. [PubMed: 17120985]
16. Black BS, Rabins PV, Sugarman J, & Karlawish JH: Seeking assent and respecting dissent in dementia research. Am J Geriatr Psychiatry 2010; 18(1): 77–85. [PubMed: 20094021]
17. Esserman D, Allore HG, & Travison TG: The method of randomization for cluster-randomized trials: Challenges of including patients with multiple chronic conditions. Int J Stat Med Res 2016; 5(1): 2–7. [PubMed: 27478520]
18. Teri L, Logsdon RG, & McCurry SM: Exercise interventions for dementia and cognitive impairment: the Seattle protocols. J Nutr Health Aging 2008; 12(6): 391–394. [PubMed: 18548177]
19. Teri L, McCurry SM, Logsdon RG, Gibbons LE, Buchner DM, Larson EB: A randomized controlled clinical trial of the Seattle protocol for activity in older adults. J Am Geriatr Soc 2011; 59(7):1188–1196 [PubMed: 21718259]
20. Chinman M, McCarthy S, Mitchell-Miland C, Daniels K, Youk A, & Edelen M: Early stages of development of a peer specialist fidelity measure. Psychiatric Rehabil J 2016; 39(3): 256–265.
21. Proctor E, Silmere H, Raghavan R, et al. : Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011; 38(2): 65–76. [PubMed: 20957426]
22. Weiner BJ, Lewis CC, Stanick C, et al. : Psychometric assessment of three newly developed implementation outcome measures. Implementation Sci 2017; 12(1):108.
23. Meyers DC, Durlak JA, & Wandersman A: The quality implementation framework: A synthesis of critical steps in the implementation process. Am J Community Psychol 2012; 50(3–4): 462–480. [PubMed: 22644083]
24. Wandersman A, Scaccia JP, et al.: Readiness Briefing Paper: FY 2017–2018. Wandersman Center, Columbia SC, 2018.
25. Yesavage JA, Brink TL, Rose TL, Lum O, Huang V, Adey M, Leirer VO: Development and validation of a geriatric depression screening scale: A preliminary report. Journal of Psychiatric Research 1983; 17: 37–49.
26. Train the brain forum committee. Thai Mental State Examination (TMSE) Siriraj Hosp Gaz. 1993; 45: 359–374.
27. Ware JE Jr, & Sherbourne CD: The MOS 36-item short-form health survey (SF-36). I. conceptual framework and item selection. Med Care 1992; 30(6): 473–83. [PubMed: 1593914]
28. Bergner M, Bobbitt RA, Carter WB, Gilson BS: The sickness impact profile: Development and final revision of a health status measure. Med Care 2018;19(8):787–805.
29. Collin C, Wade DT, Davies S, Horne V: The Barthel ADL index: A reliability study. Int Disabil Stud 1988; 10(2): 61–63.21. [PubMed: 3403500]
30. Logsdon RG, Teri L, Weiner MF, et al. : Assessment of agitation in Alzheimer's disease: The agitated behavior in dementia scale. Alzheimer's disease cooperative study. J Am Geriatr Soc 1999; 47(11) 1354–1358. [PubMed: 10573447]
31. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, & O'Donnell M: The Zarit Burden interview: A new short version and screening version. Gerontologist 2001; 41(5): 652–657. [PubMed: 11574710]
32. Kroenke K, Spitzer RL, & Williams JBW: The PHQ-9. J Gen Intern Med 2017; 16 (9): 606–613.

Box 1.

Formative Exploration of Key Challenges, Advantages and Design Solutions

Key Challenges
• Shortages of mental health specialists in general, and geriatric mental health specialists in particular • Insufficient financing for mental health services • Lack of infrastructure to support scaling-up of successful or promising programs
Key Advantages
• Increased recognition of population aging and its associated burden of care for **older adults with BPSD** • Availability of newly organized LTC system with trained CMs and CCGs providing in home support for **persons with dementia (PwD)** • Availability of evidence-based clinical intervention programs and implementation programs
Design Solutions
• Develop an intervention program to be delivered by community-based care providers (i.e., CMs and CCGs in the existing service platform of the Thai LTC system) who are familiar with the target population and have adequate readiness for implementing the program; • Develop an implementation support mechanism by training implementation technical assistance specialists in each participating district to support care providers in implementing RDAD • Use a stage III hybrid design to *primarily test the GTO implementation support strategy*, with a secondary aim to evaluate clinical outcomes of the RDAD intervention on persons with **BPSD** and their caregivers.

Highlights:

- This study is the first large-scale research in Thailand with a primary focus on examining the benefit of utilizing implementation science methodology for successful implementation of evidence-based clinical programs.
- The clinical trial evaluates both implementation and clinical outcomes of implementation strategies to support the delivery of a clinical program designed to reduce behavioral and psychological symptoms of dementia (BPSD) in older adults.
- Findings from this study can be used to further the agenda of expanding mental health care for older adults in Thailand.

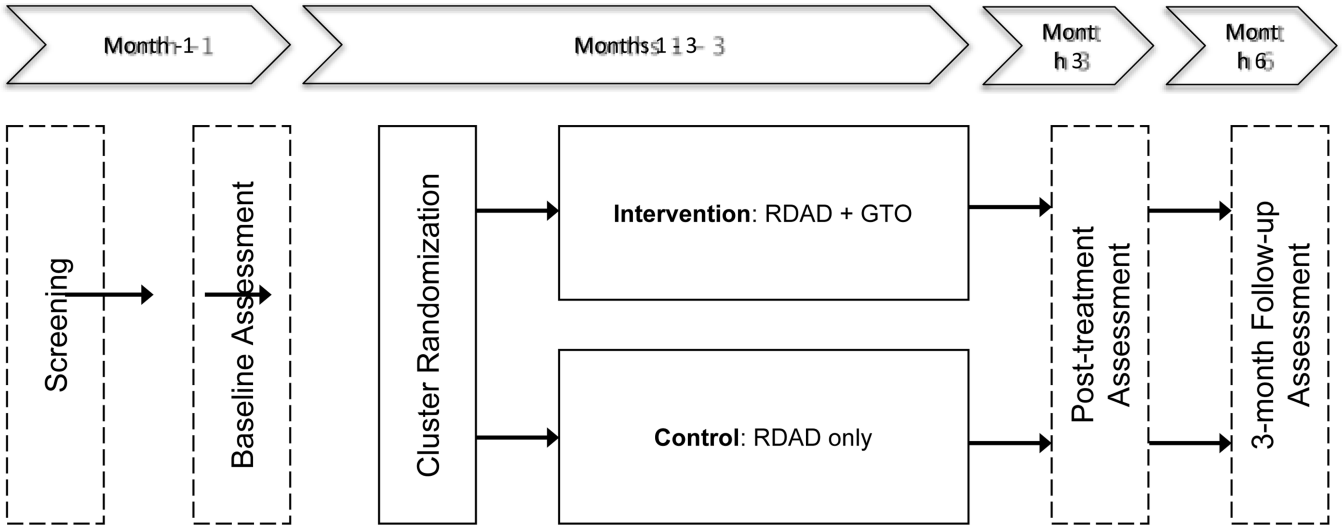

Figure 1.
Basic Design of the RCT Study

Table 1.

Summary of Intervention Activities

Time	RDAD Intervention Activities (both arms)	GTO Intervention Activities (experimental arm only)
Week −1	No activity	Session 1: TA skills (group) training to TA specialists: Overview of GTO steps 1–10 (3-day workshop)
Week 0	Session 2.2: CM in control arm (group) training on RDAD (2-day workshop)	Session 2.1: CM (group) training on RDAD and GTO steps 1–6. TA help sites complete tools for step 1–6 (3-day workshop)
Week 1	Session 1: Home visit * Session 2: Home visit	Session 3: On-site TA supporting CM on quality implementation.
Week 2	Session 3: Home visit Session 4: Home visit	Session 4: On-site TA supporting CM on quality implementation.
Week 3	Session 5: Home visit Session 6: Home visit	Session 5: On-site TA supporting CM on quality implementation.
Week 4	Session 7: Home visit Session 8: Home visit	Session 6: On-site TA supporting CM on quality implementation.
Week 5	Session 9: Home visit	Session 7: TA skills (group) training to TA specialists: Intensive training of GTO steps 7–9 and Lessons Learned in 5 weeks of TA. (2-day workshop)
Week 6	Session 10: Home visit	Session 8: CM (group) Training on GTO steps 7–9. TA help sites complete tools for step 7–9 (2-day workshop)
Week 7	Session 11: Home visit	Session 9: On-site TA supporting CM on quality implementation.
Week 8	Session 12: Home visit	Session 9: On-site TA supporting CM on quality implementation.
Week 9	No activity	No activity
Week 10	No activity	No activity
Week 11	No activity	Session 10: TA skills (group) training to TA specialists: Intensive training of GTO steps 10 and Lessons Learned in 11 weeks of TA. (2-day workshop)
Week 12	Session 13: Home visit (this should be something different that happens at this last session/ maybe need to specify	Session 11: CM (group) Training on GTO steps 10. TA help sites complete tools for step 10 (2-day workshop)

* All home visit sessions involve teaching, coaching, and reviewing activities.

Table 2.

Summary of Key Measures

Instruments	Authors, years (reference)	Respondent	Testing Occasion
Implementation Outcomes			
Fidelity	Teri et al, 2003 (6)	CCG	Intervention
Dosage	Teri et al., 2003 (6)	CCG or CM	Intervention
Reach	Proctor et al., 2011 (21)	CCG & CM	T2, T3 *
Acceptability	Weiner, 2017 (22)	CCG or CM	T2, T3
Satisfaction	Meyers et al, 2012 (23)	CCG	T2, T3
Activity-based Readiness Tool	Wandersman et al., 2018 (24)	CCG or CM	T1, T2, T3
PwD Clinical Outcomes			
IQCODE	Senanarong et al, 2001 (13)	Caregiver	Screening
Neuropsychiatric Inventory (NPI-Q) – Symptom	Cummings et al, 1994 (14)	Caregiver	Screening T1, T2, T3
Ambulatory Walk Test	McCurry et al., 2018 (11)	PwD	Screening
NPI-Q Symptom & Severity	Cummings et al, 1994 (14)	Caregiver	T1, T2, T3
Geriatric Depression Scale	Yesavage et al., 1982 (25)	Caregiver	T1, T2, T3
SF-36 (2 domains: physical functioning and role physical	Ware JE, et al, 1993 (27)	Caregiver	T1, T2, T3
Sickness Impact Profile - mobility subscale	Bergner et al., 1981 (28)	Caregiver	T1, T2, T3
Barthel ADL Index	Collin et al, 1988 (29)	PwD	T1, T2, T3
Quality of Life – PwD (QOL-AD)	Logsdon RG, et al (1999) (30)	PwD	T1, T2, T3
TMSE	Sirirach (1993) (26)	PwD	T1
Caregiver Clinical Outcomes			
Zarit Burden Interview	Bédard et al, 2001 (31)	Caregiver	T1, T2, T3
PHQ-8	Kroenke et al, 2017 (32)	Caregiver	T1, T2, T3
NPI –caregiver distress	Cummings et al, 1994 (14)	Caregiver	T1, T2, T3
Quality of Life – Caregiver	Logsdon RG, et al (1999) (30)	Caregiver	T1, T2, T3

* T1: Baseline; T2: Month 3; T3: Month 6.