Cover page

Effectiveness of a dementia anti-stigma intervention in rural Kenya

NCT number – Not yet assigned

16th October 2024

Effectiveness of a dementia anti-stigma intervention in rural Kenya

FUNDING AGENCY: Alzheimer's Association

INVESTIGATORS, QUALIFICATIONS AND INSTITUTIONAL AFFILIATIONS

Name	Qualification	Institution	Role
Dr. Christine Musyimi	*PhD*	*Africa Institute of Mental and Brain Health (AFRIMEB), Kenya*	*Principal Investigator*
Dr. Nicolas Farina	*PhD*	*University of Plymouth, UK*	*Co-Investigator/Mentor*

ROLE OF INVESTIGATORS AND COLLABORATORS

1. **Dr Christine Musyimi** will support research activities and will be responsible for project staff training, conduct workshops, preliminary data analysis, manuscript preparation, report writing and data presentation/dissemination meetings at local, national, and international meetings under the guidance of her mentor.
2. **Dr Nicolas Farina** will provide expert opinions into the evaluation of the implementation program. He is also a mixed methods researcher, understanding the value of both quantitative and qualitative data. He will also have bi-weekly meetings with Dr. Musyimi with a focus on achieving training and research objectives; developing collaborations and networks; discussing interpretation of findings; and checking-in about progress on publications, conference presentations, and future grant proposals.

Table of Contents

ABSTRACT

Stigma underlies many health disparities in Kenya, and dementia-related stigma is no different. Preliminary evidence highlights the short-term benefits of a dementia anti-stigma intervention in Kenya. We aim to ascertain the long-term effectiveness of a locally developed dementia anti-stigma intervention in order to establish a community resource that will improve dementia understanding, reduce stigma and improve health behaviours. In AIM 1, we will assess what public stigma towards people with dementia and their carers looks like in Kenya, through a survey (n=600). Individual interviews with 20 members of the general public who completed the survey will be conducted to explore what stigmatizing beliefs are held and why they form. Triangulation techniques will then be used to integrate quantitative and qualitative data. Reflecting on AIM 1 findings, we will engage 20 key stakeholders to refine an existing anti-stigma intervention, to better target culturally specific misconceptions and negative beliefs about dementia (AIM2). In AIM 3, we will determine the effectiveness of the intervention among members of the general public (n=184), through a stepped wedge cluster randomized trial (SWT). Given the expected increase in the number of people with dementia by 2050, approaches that raise awareness will provide a route to improve the lives of 100,000s of people with dementia in Kenya by tackling stigma. Ultimately, the findings will contribute to understanding dementia-related stigma in Kenya, how to reduce it, and ultimately provide mechanisms to minimize health inequality.

BACKGROUND

Public stigma is a type of stigma in which the general public are the perpetrators. This type of stigma manifests in various ways, including discrimination, prejudice, and social exclusion. When people with dementia are subjected to public stigma, it can lead to severe consequences such as isolation and neglect. Furthermore, public stigma can influence health-seeking behaviors, as people with dementia may delay or avoid seeking help due to fear of judgment or rejection by others. In addition to public stigma, people with dementia and their carers may also experience other types of stigma including stigma by association (e.g., stigma attached to those associated with the person with dementia such as a carer) and self-stigma (e.g., people with dementia internalising public stigma) (1). Dementia stigma negatively affects the health and quality of life of those living with the condition and their carers (2). The burden of stigma extends to caregivers, who may experience stress, anxiety, and a sense of isolation as a result of the negative attitudes and discrimination they encounter. The symptoms of dementia and the stigma associated with it

are perceived and understood differently across various cultures and regions of the world (3). These differences in understanding can influence how dementia is diagnosed, treated, and managed, as well as how those living with the condition and their caregivers are supported by their communities.

In Sub-Saharan Africa, limited research has revealed that different causal attributions for dementia are held by people including biological, psychological and spiritual (4). Among these, psychosocial explanations are the most commonly held while biological explanations are less frequently considered (4). In many communities within the Sub-Saharan Africa, dementia is considered normal part of ageing, which often leads to the underdiagnosis and undertreatment of dementia, as symptoms may be dismissed as merely signs of growing older. Additionally, dementia is sometimes linked to stigmatizing beliefs, including association with witchcraft (5). These stigmatizing beliefs were often used when knowledge about medical conditions were uncommon and strange behaviours associated with dementia were interpreted as dangerous and caused by evil spirits (4–6), resulting in inconsistent health seeking behaviour (7). Beliefs, knowledge and attitudes towards people living with dementia and their families are therefore important areas of investigation in understanding the manifestations of public stigma.

In Kenya, where cultural beliefs and misconceptions significantly shape public perceptions of the dementia, there is limited scientific evidence on the perceptions of the disease including stigma. However, much of the evidence is derived from small sample qualitative research (8,9). Additionally, there is lack of contextually appropriate interventions that address the unique socio-cultural dynamics at play in Kenya, such as beliefs in witchcraft, which are often linked to dementia symptoms. To develop effective, tailored interventions, it is important for us to understand "who" and "what" we should target (10). For this to happen, we need to generate representative data about what dementia stigma looks like in Kenya, and to understand who is likely to hold these beliefs (**AIM 1)**. These findings will be fed into the existing dementia anti-stigma intervention, to better tailor it to the needs of the Kenyan people (**AIM 2).** Most anti-stigma interventions have been developed and tested in high income countries (10). We have preliminary evidence demonstrating the short-term effects of a culture-specific dementia anti-stigma intervention developed from the ground up in Kenya by the investigators. We will use a longer follow-up that will allow confirmation of continuity of initial gains from the intervention (11,12) and to better establish whether behavioral changes occur (**AIM 3).**

AIMS

Overall aim

The overarching aim of this research is to refine and evaluate a dementia stigma reduction intervention tailored to meet the needs of people in Kenya, in preparation for future implementation and adoption within existing policies.

Specific objectives

We will achieve this through the following three specific aims.

i) **AIM 1**: To adapt dementia-related knowledge and attitudes tools and develop a representative dementia stigma profile of the general public in Kenya.
ii) **AIM 2**: To refine an existing anti-stigma intervention to better target culturally specific misconceptions and negative beliefs about dementia.
iii) **AIM 3**: To determine the effectiveness of the anti-stigma intervention through a stepped wedge cluster randomized trial (SWT) among members of the general public.

METHODS

Study site: Makueni County in rural Kenya

AIM 1: Adapting a dementia-related knowledge and attitudes tools and developing a representative dementia stigma profile of the general public in Kenya

We will conduct a survey of 600 adults (18 years and older) in Makueni County, a rural setting in Kenya. Individuals in rural communities have higher rates of dementia, experience more health disparities and additional challenges with cultural belief systems, and utilization of care compared to their urban counterparts (13). Participants will be recruited from three geographically defined areas served by six Community Health Workers (CHWs), and ensure a diverse demographic profile based on age, sex and socio-economic status. The three geographically selected rural areas are representative of other rural regions in Kenya due to their similar settings. Participants will complete measures of knowledge (Dementia Knowledge Assessment Scale (DKAS)) (12) and attitudes (Dementia Attitudes Scale (DAS)) (14). DKAS is a reliable and valid tool for assessing dementia knowledge across a range of participants including members of the general public (15)(16). It has been used among older adults in Africa (17). DAS is based on the tripartite model of attitude (18), has been validated for members of the general public and has a high Cronbach's alpha coefficient ranging from 0.83 to 0.85 (19). To ensure that the measures are suitable for use

within Kenya, they will undergo cross-cultural adaptation (forward and backward translations will be conducted, inconsistencies checked, and then pilot tested (n=24 general public members). Up to twenty individual interviews will also be held with a convenient sample of members of the general public who completed the survey to better explore what stigmatizing beliefs are held in the communities and why they form.

Recruitment and approach: Members of the general public (n=24 for piloting the study tools and procedures) and (n=600 participants who will be recruited for the main study)**,** aged 18 years and above will be recruited by the CHWs. All participants will need to speak the local language (Kamba) and have capacity to consent. There are no other exclusion criteria. Households will be approached (i.e., door knocking) upon a convenience basis in the first instance, within geographic regions that the CHWs serve. CHWs will ensure that there is equal representation based on age, sex and socioeconomic status. CHWs will be familiar with the demographics of participants that reside in the local community. All participants will provide either written/thumb print informed consent. We will liaise with the CHWs on a weekly basis to reflect on the recruitment progress, but also to identify underrepresented groups. Door knocking benefits from minimizing sources of bias that might occur through other channels (e.g., social media), who reflect certain demographics. We will however be vigilant that door knocking during the day may lead to an under-representation of working population (e.g., younger, males). In instances within a household where an underrepresented group resides but not present during the initial visit, CHWs will reorganize the visit for a time and date convenient for the potential participant. Guided by the need to achieve thematic saturation, up to 20 members of the general public who completed the survey will also be identified by CHWs through convenience sampling based on their availability, to better explore what stigmatizing beliefs are held in the communities and why they form.

Analysis plan and sample size: Descriptive data will be reported to identify misconceptions and common beliefs within the sample. Regression models will be developed to identify what factors are associated with stigma. To detect a small effect size (f2=0.04) and enter 20 predictors in the model (Power =0.8, alpha = 0.05), accounting for 10% missing data, a sample size of 600 is required. Inductive thematic analysis will be used for the qualitative interviews. We will recruit participants until thematic saturation is achieved (i.e., until no new themes are inductively identified). Thematic saturation typically occurs between 9 and 17 participants (20). Triangulation techniques will be used to integrate quantitative and qualitative data.

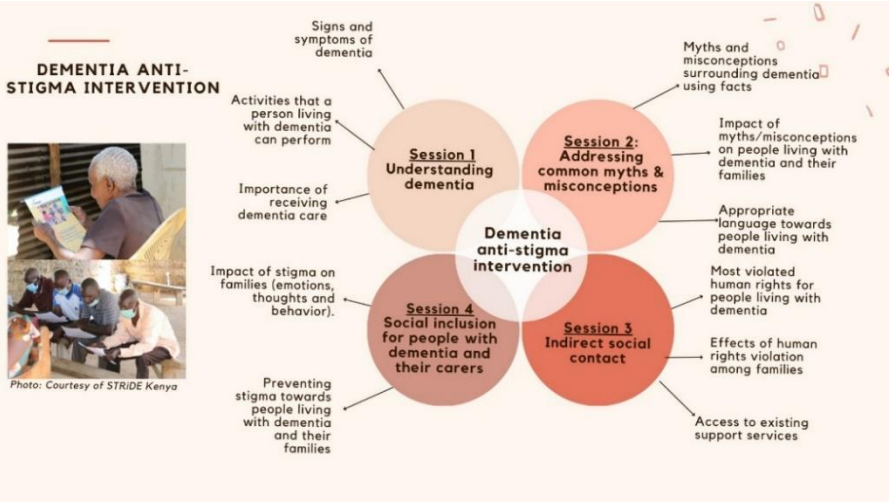
Outcomes:

1) Cross-culturally adapt the questionnaires for use in Kenya, 2) generate summary report of findings, and 3) academic publication.

AIM 2: Refining an existing anti-stigma intervention to better target culturally-specific misconceptions and negative beliefs about dementia- (AIM 2).

A consortium of the 20 key stakeholders (people with dementia, carers, clinicians, policy makers, academicians and researchers) will be gathered to review the summary report comprising of AIM 1 findings, which will help to identify stigma drivers and target common culturally specific misconceptions and negative beliefs about dementia. Their distribution will be purposive, based on the relevance of stakeholders to the research objectives. This will be discussed alongside the existing intervention to identify any gaps, or whether further refinement of the content is required. The existing intervention is a train-a-trainer programme (21) contextually developed, for delivery (via demonstrations and role-plays) by lay providers such as community health workers (22). It is delivered bi-weekly in a group setting and each session ranges between 1.5 to 2 hours. The co-development of the intervention followed the Medical Research Council framework for development of complex interventions comprising of four phases (23). In each phase, key considerations were made such as relevant stakeholder engagement throughout the development process and dynamic iterative processes to intervention development (24). Co-development stakeholders included carers of persons with dementia, members of the general public, clinicians, community health workers, community leaders, researchers and academicians.

Intervention content (figure on the right): This includes four sessions that promote: (i) understanding of dementia, (ii) demystifying myths and misconceptions, (iii) empathetic connections using videos of people with dementia and carers (virtual social contact) and (iv) social inclusion through a case vignette and discussions. The intervention was well received amongst 59 participants, with positive feedback particularly in terms of its format and accessibility. There were no dropouts. At one month post intervention delivery, positive effects among members of the general public



were reported with modest effects in reducing negative beliefs related to treatment ($\eta 2 = 0.34$), living well with dementia ($\eta 2 = 0.98$) and care ($\eta 2 = 0.56$). Knowledge surrounding causal attribution did not significantly change following the intervention and lack of family support was still considered a cause of dementia. The small sample size, lack of a control arm and very short follow-up (one month) in the initial testing of the intervention restricts our ability to conclude effectiveness and our ability to report on the continuity of any initial gains from the intervention. Therefore, the proposed research will allow for effectiveness testing in a suitably designed and powered study.

Recruitment: From the list of 20 stakeholders, persons with lived experience will be recruited from Alzheimer's Dementia Organization, Kenya. We will draw on our established networks of collaborators to identify the other stakeholders for the refinement process.

Analysis plan: No defined analysis plan. Instead, the refinement process will be described through detailing the context of the meeting, meeting minutes, and action points. A full list of refinement recommendations alongside a rationale about why they were/were not adopted will be described.

AIM 2 outcomes

1) Deliver a consensus workshop to reflect on the findings from AIM 1 and existing content within the anti-stigma intervention, and 2) Publish a summary of the consortium and actions taken.

AIM 3: Determining the effectiveness of the anti-stigma intervention through a stepped wedge cluster randomized trial (SWT) among members of the general public

This will involve sequential delivery of the intervention to six community-level groups from one site at a time, until all the three sites are exposed to the intervention (n=184). Using participants surveyed in AIM 1, six randomly selected community- level groups consisting of 10-12 members from each of the three geographically defined areas (sites) will be randomly allocated to start on one of three dates (three months apart). Randomization to receive the intervention will be conducted by a blinded independent researcher. Participants will be blinded to allocation while the research assistant will be blinded to the schedule of intervention delivery. Following the listing of the 600 assessed participants, sites will be block randomized into six community-level groups (clusters), then randomly ordered to receive the intervention. Cluster randomization will reduce contamination before the intervention phase, expected to be seen at an individual level. Although all groups will start with a three-month "control condition", six groups from each site will receive the intervention after every three months. With the three-month interval, the rollout program is

expected to take about 12 months. The SWT design ensures that all clusters receive the intervention rather than entirely denying benefits to control groups, since there is evidence that the proposed intervention has a short-term positive effect in a context that lacks implementation of evidence-based dementia anti-stigma interventions. Stigma-related outcome data will therefore be collected at baseline (three months before being exposed to the four-session group awareness program), switch points (rollout period during which the clusters will cross over from the control phase), 6- and 12-months post two-week intervention. The primary outcomes will be the dementia attitudes (DAS)[8] and dementia knowledge (DKAS)[6]. Secondary outcomes will include intervention acceptability, dementia engagement (behaviour).

Recruitment and retention: Members of the general public (n=184) will be selected from the participants identified in AIM 1. As such, all participants will be aged 18 years and older, able to speak Kamba and have capacity to consent. All participants will have been given the option to participate in the anti-stigma intervention in AIM 1. If there are more than 184 participants (from AIM 1) who have consented to be contacted about the anti-stigma intervention, all potential participants will be randomly listed within each village site. Then from this list, six sets of 10-12 members will be randomly selected and randomly allocated to start on one of three dates (three months apart). Similar to the previous testing phase of the intervention, CHWs who are proximal will be paired to facilitate sessions. Separate informed consent will be obtained from participants for this AIM. For individuals who refuse to participate, the next person from the randomized list will be selected. Using AIM 1 as a means to list for AIM 3 will help identify potential sources of recruitment bias in the sample. Retention: We acknowledge that retaining participants throughout the study duration is important. This can be particularly challenging with: (i) people with dementia and carers because of emotional changes due to the condition or caring role, and (ii) Other members of the general public due to busy schedules. Nevertheless, CHWs will be trained to assess willingness to participate, address any challenges and describe the importance and purpose of the study. The six CHWs will also be available to ensure assessments are conducted at a day and time convenient to the participants.

Leveraging existing resources, Community Health Workers (CHWs): CHWs are county employed volunteers who are funded through hybrid public/private reward scheme. They deliver services such as making home visits, providing health promotion messages, treating common ailments and illnesses, within a defined geographical area. CHWs are typically given monetary

incentives by the public sector based on commitment while private institutions are encouraged to support existing committed CHWs with transport reimbursements while conducting household visits to improve motivation and performance. Within Kenya, the adoption of CHWs to facilitate health related research and outreach is commonplace and is of great success (e.g., recruiting more than 500 participants/month). As part of the Strengthening Responses to Dementia in Developing Countries (STRiDE) project, six CHWs have already received training about dementia as part of the initial anti- stigma intervention testing. As such, the CHWs will receive refresher training to enable them to deliver the intervention to newer groups other than those in the initial phase of testing the intervention. The aim is to better establish whether behavioral changes occur in the long-term and establish continuity of initial gains for participants receiving the intervention at different times. *Retention:* To enhance recruitment, retention and performance, CHWs will receive branded uniforms (thus increasing project visibility, supported by word of mouth), and transport reimbursement based on the number of participants assessed.

Sample size: The sample size was estimated using the stepped wedge cluster randomized design package (swCRTdesign) in RShiny app, under a linear mixed-effects model (25). Assuming an alpha error of 0.05 and a power of 0.9, it was estimated that a four-step design, using a maximum of 12 subjects per cluster and with 6 clusters per sequence, a total of 154 participants will be required to detect a significant mean difference of 0.3. While accounting for 20% loss to follow-up, we expect a final sample of 184 participants.

AIM 3 outcomes: 1) report the change in dementia-related knowledge and attitudes at 6-and 12 months after receiving the intervention. 2) report the behavioural changes that occurred at 6- and 12 months after receiving the intervention.

Analysis plan: Statistical analyses will be performed using R v4.2.2 based on participant level data, clustered within sites. Descriptive analyses of the socio demographic characteristics and dementia-related knowledge and attitudes of the groups will be performed at baseline to assess cluster variation. A generalized linear mixed model will be used to adjust for time-specific confounding and intra-cluster correlations, and model time and intervention effects as fixed effects. An intention to treat approach will ensure that all participants randomized and receiving baseline assessments are included in the analysis.

ETHICAL CONSIDERATIONS

Ethical approval will be obtained from the Maseno University Ethics Review Committee (MUERC) and a research permit sought from the National Commission for Science, Technology, and Innovation (NACOSTI). We will seek informed consent from all participants recruited in the study. Participant information sheets and informed consent forms will be written in the local language, enabling potential participants to understand the aims, procedures and implications of the study, and the nature of participation. Participants will be given a copy of the participant information sheet to keep. Only those who consent voluntarily will be invited to proceed with the study but with a provision of them to withdraw anytime without any loss of benefits. Confidentiality and anonymity of data will be ensured throughout the research process, from data collection to data storage, analysis and publication.

All data collected will be stored in well-organised folders and file names using password-protected access at Africa Institute of Mental and Brain Health offices. Audio recordings will be downloaded onto password-protected computers. The code sheet to identify participants will be stored separately from the data to protect privacy. The data will be cleaned, and all identifiable information anonymised before analysis. In the publication or presentation of study results, information will never be presented such that a participant could be identified.

Although the study targets the general public, provisions to protect the rights and welfare of individuals with dementia encountered during data collection will be put in place. These include training data collectors to recognize and respect the vulnerabilities of individuals with dementia, employing appropriate communication techniques to minimize distress, identifying signs of discomfort or distress and responding in a sensitive and supportive manner as well as ensuring confidentiality through anonymization.

ANTICIPATED CHALLENGES AND SOLUTIONS

Sequential timeline (All AIMs)

The AIMs are sequential by design. Delays in ethical approvals or recruitment (etc.) within AIM 1, will result in delays in the AIMs 2 and 3. Realistic timeframes have been put together, with contingency time embedded.

Recruitment (AIMs 1 and 3)

There may be difficulties reaching recruitment targets. However, the CHWs have previously demonstrated the capacity to achieve these figures (3,500 participants in 6 months in an earlier household survey). Additional efforts may be needed to be more selective in recruitment strategies to ensure that we do have heterogeneity in our sample

Drop-out (AIM 3)

The long-term nature of follow-ups are susceptible to drop-out, which could bias our findings. We have previous evidence that retention on similar studies is good (3% after one month). We will also adopt appropriate analyses and imputation depending on data missingness (e.g., last observation carried forward).

TIMELINE

Table 1: Timeline illustrating the 3-year project milestones

Milestone	Description	Timeline		
Study Preparation		**Year 1**	**Year 2**	**Year 3**
Approvals and permitting	Receive ethical approval and amendments (Month 11 (M11)) from the Kenya Medical Research Institute, a research permit from the Kenya National Commission on Science, Technology and Innovation (NACOSTI)	M1-3		
Community entry	Community entry will be performed and approvals from County and sub-county governments sought	M4		
AIM 1: Adapt and develop a representative profile of public stigma				
Adaptation of data collection tools	Forward and backward translation of tools, synthesizing process and discussion of the discrepancies	M5-6		
	Pilot testing the instruments with 24 individuals	M7		
Qualitative interviews	20 key informant interviews to explore stigmatizing beliefs among members of the general public	M8-9		
Conduct a household survey	Administer measures of knowledge and attitudes to 600 adults (18 years and older)			
AIM 2: Refinement of existing anti-stigma intervention				
Consensus workshop	20 key stakeholders to review the summary report from AIM 1 above	M10		
AIM 3: Stepped wedge cluster randomized trial (SWT)				
Community Health Workers' training	CHWs will receive training on the program and re-training on intervention delivery	M11		
Outcome assessor training	A research assistant will be trained to conduct assessments	M11		
Randomization process	Sites block randomized into six community-level groups, then randomly ordered to receive the intervention	M12		
Roll-out sequence (interventions) with outcome assessments conducted at switch points, 6- and 12-months following intervention.	Site 1 (6 groups) (control condition)		M1-3	
	Site 1 (6 groups) (intervention (Year 2-M4) and assessments)		M1,4,10	M4
	Site 2 (6 groups) (intervention (Year 2-M7) and assessments)		M4,7	M1,7
	Site 3 (6 groups) (intervention (Year 2-M10) and assessments)		M7,10	M4,10
International travel (conference presentations)				
Conference presentations	These will be conferences with a focus on dementia e.g., Alzheimer's Association International Conference	M7	M7	M7
Report writing	This will take place at the end of each year	M12	M12	M12
Data analysis and dissemination				
Final dissemination	Dissemination of findings to local stakeholders via workshops			M11
Data analysis	Data entry, analysis and manuscript writing	M5-7	M8-12	M1-12

BUDGET

Activity	**Cost (USD)**
Personnel Cost	96,000
Travel Cost	7,500
Other Costs	96,483.40
Total	**199,983.40**

REFERENCES

1. Corrigan PW, Watson AC. Understanding the impact of stigma on people with mental illness. World psychiatry. 2002;1(1):16.
2. Batsch NL, Mittelman MS. World alzheimer report 2012. Overcoming Stigma Dementia Alzheimer's Dis Int (ADI), London; 2012 Accessed May. 2015;5.
3. Alzheimer's Association. Dementia | Symptoms, Diagnosis, Causes, Treatments. [Internet]. 2019. Available from: https://www.alz.org/alzheimers-dementia/what-is-dementia
4. Spittel S, Maier A, Kraus E. Awareness challenges of mental health disorder and dementia facing stigmatisation and discrimination: a systematic literature review from Sub-Sahara Africa. J Glob Health. 2019;9(2).
5. Brooke J, Ojo O. Contemporary views on dementia as witchcraft in sub-Saharan Africa: A systematic literature review. J Clin Nurs. 2020;29(1–2):20–30.
6. Mavundla TR, Toth F, Mphelane ML. Caregiver experience in mental illness: A perspective from a rural community in South Africa. Int J Ment Health Nurs. 2009;18(5):357–67.
7. Musyimi C, Mutunga E, Ndetei D. Stigma and dementia care in Kenya: strengthening responses to dementia in developing countries (STRiDE) project. World Alzheimer Rep 2019 Attitudes to Dement. 2019;121–2.
8. Jacobs R, Schneider M, Farina N, Du Toit P, Evans-Lacko S. Stigma and its implications for dementia in South Africa: A multi-stakeholder exploratory study. Ageing Soc. 2024;44(4):867–97.
9. Musyimi CW, Ndetei DM, Evans-Lacko S, Oliveira D, Mutunga E, Farina N. Perceptions and experiences of dementia and its care in rural Kenya. Dementia. 2021;20(8):2802–19.
10. Corrigan PW. Best practices: Strategic stigma change (SSC): Five principles for social marketing campaigns to reduce stigma. Psychiatr Serv. 2011;62(8):824–6.
11. Herrmann LK, Welter E, Leverenz J, Lerner AJ, Udelson N, Kanetsky C, et al. A systematic review of dementia-related stigma research: Can we move the stigma dial? Am J Geriatr Psychiatry. 2018;26(3):316–31.
12. Annear MJ, Toye CM, Eccleston CE, McInerney FJ, Elliott KJ, Tranter BK, et al. Dementia knowledge assessment scale: development and preliminary psychometric properties. J Am Geriatr Soc. 2015;63(11):2375–81.
13. Wiese LAK, Gibson A, Guest MA, Nelson AR, Weaver R, Gupta A, et al. Global rural health disparities in Alzheimer's disease and related dementias: State of the science. Alzheimer's Dement. 2023;19(9):4204–25.
14. O′ Connor ML, McFadden SH. Development and psychometric validation of the dementia attitudes scale. Int J Alzheimer's Dis. 2010;2010(1):454218.
15. Annear MJ, Toye C, Elliott KEJ, McInerney F, Eccleston C, Robinson A. Dementia knowledge assessment scale (DKAS): confirmatory factor analysis and comparative subscale scores among an international cohort. BMC Geriatr. 2017;17:1–11.
16. Zhang Q, Deng J, Luo H, Wang L. Senile dementia and psychiatric stigma among community health service providers and relatives of diagnosed and suspected dementia

patients: a cross-sectional study. PeerJ. 2023;11:e14613.
17. Awuol MDA, Innocent BK, Winfred A. Prevalence, factors associated and knowledge of probable dementia among adults 50 years and over attending a faith-based geriatric center in Uganda. Sci Rep. 2023;13(1):6737.
18. Teichmann B, Gkioka M, Kruse A, Tsolaki M. Informal caregivers' attitude toward dementia: The impact of dementia knowledge, confidence in dementia care, and the behavioral and psychological symptoms of the person with dementia. A cross-sectional study. J Alzheimer's Dis. 2022;88(3):971–84.
19. Abdalrahim A, Alamoush KM, ALBashtawy M, Hamaideh SH, Mohammad KI, Alkhawaldeh A, et al. Jordanian community people's knowledge of and attitudes toward dementia. SAGE Open Nurs. 2023;9:23779608231201052.
20. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. Soc Sci Med. 2022;292:114523.
21. Pearce J, Mann MK, Jones C, Van Buschbach S, Olff M, Bisson JI. The most effective way of delivering a Train-the-Trainers program: a systematic review. J Contin Educ Health Prof. 2012;32(3):215–26.
22. Musyimi C, Farina N, Evans-Lacko S, Muyela L, Mutunga E, Mutiso V, et al. Dementia anti-stigma intervention. Africa Ment Heal Res Train Found Kenya. 2022;
23. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008 Sep 29;a1655.
24. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.
25. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the Shiny CRT Calculator. Int J Epidemiol. 2020;49(3):979–95.

INFORMATION SHEET AND CONSENT FOR HOUSEHOLD SURVEYS

Title: Effectiveness of a dementia anti-stigma intervention in rural Kenya

Principal Investigator: Dr Christine Musyimi, Ph.D, Africa Institute of Mental and Brain Health (AFRIMEB)

Co-Investigator: Dr Nicolas Farina, Ph.D, University of Plymouth, UK

Sponsor: Alzheimer's Association

Study Invitation, Purpose and Location

You are invited to participate in a research study about dementia related knowledge and attitudes. It is up to you to decide if you would like to take part in this study. The purpose of the study is to ascertain the long-term effectiveness of a locally developed dementia anti-stigma intervention in order to establish a community resource that will improve dementia understanding, reduce stigma and improve health behaviours. The study takes place in Makueni County.

Participant Characteristics and Exclusionary Criteria

You are invited to take part in this study because you are aged 18 years and reside in Makueni County. You must be able to participate in the local language (Kamba) and have the capacity to consent.

Study Procedures

If you decide to take part, you will be required to complete a survey lasting between 60-90 minutes to obtain information about dementia stigma in Kenya. The survey questions will include questions about dementia knowledge and attitudes. This will aid in identifying the stigmatizing beliefs held in the communities and why they form. The survey will be facilitated by a staff from Africa Institute of Mental and Brain Health.

Study Benefits to the Participants

This study is not designed to benefit you personally. Completing the survey may give you a platform to share your perspective regarding dementia knowledge and attitudes held in your community. The information you provide will aid us in shedding more light on how to refine the existing dementia anti-stigma intervention, to better tailor it to the needs of the Kenyan people.

Anticipated Risks:

There is a possibility that participating in this study may make you feel uncomfortable. The responses you provide may bring to light dementia knowledge and attitudes within the community

and will be used to refine existing dementia anti-stigma intervention. There are no unknown risks for participation that would occur in typical day-to-day living.

Voluntary Participation and Withdrawal

Your participation in this study is completely voluntary. However, you do not have to take part in this research if you do not wish to do so. If you choose to participate, you are free to withdraw your consent and discontinue your participation at any time without your relationship with us being affected and without incurring any penalty.

Confidentiality

We will keep your records private to the extent allowed by law. We will use a study number rather than your name on study records. The information you provide will be stored at Africa Institute of Mental and Brain Health offices in locked cabinets and on password-protected computers. Audio recording will be downloaded onto password-protected computers. The code sheet to identify participants will be stored separately from the data to protect privacy. When we present or publish the results of this study, we will not use your name or other information that may identify you. However, we may share some photos on reports, media, posters and workshops to illustrate the activities/work of this project.

Compensation

You will not be paid to participate in this study. However, your travel costs will be reimbursed.

Contact Information

If you have any questions, concerns, or complaints about the study please contact me or the PI - Dr Christine Musyimi at Africa Institute of Mental and Brain Health on **(+254724572202)** or the **Secretary of Maseno University Ethics Review Committee** (MUERC) for any questions regarding human research rights on **Private Bag 40105, Maseno, Kenya,** or call on Tel**: +254-057 351 221,** or email: **muerc-secretariate@maseno.ac.ke**

Statement of Consent

I have read this consent form and have been given a chance to ask questions. I voluntarily agree to participate in this study.

I will receive a signed copy of form for my records.

_____ _____

Signature of Participant Date

Name of Participant_____

Researcher Obtaining Consent _____

Signature of Researcher _____ Date _____

INFORMED CONSENT FOR KEY INFORMANT INTERVIEWS

Title: Effectiveness of a dementia anti-stigma intervention in rural Kenya

Principal Investigator: Dr Christine Musyimi, Ph.D, Africa Institute of Mental and Brain Health (AFRIMEB)

Co-Investigator: Dr Nicolas Farina, Ph.D, University of Plymouth, UK

Sponsor: Alzheimer's Association

Purpose: The purpose of the study is to ascertain the long-term effectiveness of a locally developed dementia anti-stigma intervention in order to establish a community resource that will improve dementia understanding, reduce stigma and improve health behaviours. You are invited to take part in this interview because you participated in the survey. During this activity we aim to better explore your view concerning stigmatizing beliefs that are held in the communities and why they form.

Procedures: If you decide to take part, you will be required to actively participate in a discussion lasting between 60-90 minutes. This will aid in identifying the stigmatizing beliefs held in the communities and why they form. We will audiotape the interviews to learn as much as we can from these discussions. The sessions will be facilitated by staff from Africa Institute of Mental and Brain Health.

Benefits: These discussions are not designed to benefit you personally. Talking through the interview may give you a platform to share more of your perspective regarding stigmatizing beliefs that are held in the communities and why they form. The information provided will also aid in shedding more light on how to refine the existing dementia anti-stigma intervention, to better tailor it to the needs of the Kenyan people.

Risks: There is the possibility that participation in this study may make you feel uncomfortable. The discussions may bring to light stigmatizing beliefs within the community, and why they form. However, the responses you give will be used to refine existing dementia anti-stigma intervention.

Voluntary Participation and Withdrawal: Your participation in this study is completely voluntary. However, you do not have to take part in this research if you do not wish to do so. If you choose to participate, you are free to withdraw your consent and discontinue your participation at any time without your relationship with us being affected and without incurring any penalty.

Confidentiality: We will keep your records private to the extent allowed by law. We will use a study number rather than your name on study records. The information you provide will be stored at Africa Institute of Mental and Brain Health offices in locked cabinets and on password-protected

computers. Audio recordings will be downloaded onto password-protected computers. The code sheet to identify participants will be stored separately from the data to protect privacy. When we present or publish the results of this study, we will not use your name or other information that may identify you. However, we may share some photos on reports, media, posters and workshops to illustrate the activities/work of this project.

Compensation: You will not be paid to participate in this study. However, your travel costs will be reimbursed.

Contact Information: If you have any questions, concerns, or complaints about the study please contact me or the PI - Dr Christine Musyimi at Africa Institute of Mental and Brain Health on **(+254724572202)** or the **Secretary of Maseno University Ethics Review Committee** (MUERC) for any questions regarding human research rights on **Private Bag 40105, Maseno, Kenya,** or call on Tel**: +254-057 351 221,** or email: **muerc-secretariate@maseno.ac.ke**

Consent form

If you are willing to volunteer for this research, please sign below.

Name of Participant _____

Signature of Participant _____ Date _____

Researcher Obtaining Consent _____

Signature of Researcher _____ Date _____

INFORMATION SHEET AND CONSENT FOR ANTI-STIGMA INTERVENTION

Title: Effectiveness of a dementia anti-stigma intervention in rural Kenya

Principal Investigator: Dr Christine Musyimi, Ph.D, Africa Institute of Mental and Brain Health (AFRIMEB)

Co-Investigator: Dr Nicolas Farina, Ph.D, University of Plymouth, UK

Sponsor: Alzheimer's Association

Purpose: The purpose of the study is to ascertain the long-term effectiveness of a locally developed dementia anti-stigma intervention in order to establish a community resource that will improve dementia understanding, reduce stigma and improve health behaviours. You are invited to take part in this study because you are aged 18 years, able to speak Kamba and reside in Makueni County.

Procedures: If you decide to take part, you will be required to actively participate in four psycho-education group sessions lasting about 60 to 90 minutes and will be taking place once or twice in a week. These will aid in improving our understanding about dementia, reduce stigma and improve health behaviours. We will audiotape the groups and interviews to learn as much as we can from these discussions. The sessions will be facilitated by two Community Health Workers from your area. There will also be assessments which shall be done by a member from the research team belonging to Africa Institute of Mental and Brain Health. These assessments shall take place three months before and at the beginning of the group sessions and again at 6 and 12 months. Groups will be composed of about 10 to 12 people.

Benefits: This study is not designed to benefit you personally. Talking in the group may aid in shedding more light on how to refine the existing dementia anti-stigma intervention, to better tailor it to the needs of the Kenyan people.

Risks: There is the possibility that participation in this study may make you feel uncomfortable. In case you may have concerns during the study, please feel free to talk to any of our research members using the contacts provided.

Voluntary Participation and Withdrawal: Your participation in this study is completely voluntary. However, you do not have to take part in this research if you do not wish to do so. If you choose to participate, you are free to withdraw your consent and discontinue your participation at any time without your relationship with us being affected and without incurring any penalty.

Confidentiality: We will keep your records private to the extent allowed by law. We will use a study number rather than your name on study records. The information you provide will be stored at Africa Institute of Mental and Brain Health offices in locked cabinets and on password-protected

computers. Audio recordings will be downloaded onto password-protected computers. The code sheet to identify participants will be stored separately from the data to protect privacy. If you are a group participant, we will ask all group members to keep information private. When we present or publish the results of this study, we will not use your name or other information that may identify you. However, we may share some photos on reports, media, posters and workshops to illustrate the activities/work of this project.

Compensation: You will not be paid to participate in this study. However, your travel costs will be reimbursed.

Contact Information: If you have any questions, concerns, or complaints about the study please contact me or the PI - Dr Christine Musyimi at Africa Institute of Mental and Brain Health on (+254724572202) or the **Secretary of Maseno University Ethics Review Committee** (MUERC) for any questions regarding human research rights on **Private Bag 40105, Maseno, Kenya,** or call on Tel**: +254-057 351 221,** or email: **muerc-secretariate@maseno.ac.ke**

Consent form

If you are willing to volunteer for this research, please sign below.

Name of Participant _____

Signature of Participant _____ Date _____

Researcher Obtaining Consent _____

Signature of Researcher _____ Date _____