1. Title: Integrating places of worship (PoW) into the primary care pathway to prevent and control non-communicable diseases (NCDs) in the Caribbean

In which countries will the project take place? Caribbean Commonwealth Countries (CARICOM countries), primary site Guyana, secondary sites Jamaica and Dominica

Duration: 36 months Total amount requested: £567K

**Principal health systems research question:** Can health advocates (HAs) in places of worship (PoWs) be successfully integrated into the primary care pathway to support the prevention and control of NCDs in low-income settings?

**Specific objectives:**

a) Describe the organisational, sociocultural and religious contexts of PoWs that influence the confidence, competence and commitment of health advocates (HAs) to promote NCD prevention and management activities.

b) Describe the impact of HAs and their activities on health systems (e.g. service delivery, health workforce, governance), and congregations.

c) Describe the plausible mechanisms that allow the linkage (or not) between (a) and (b) and how these vary within and between countries.

d) Identify solutions to implementation barriers in health systems and PoWs and construct a concept map to inform up-scaling, if results are positive.

2. Importance

**Burden of NCDs & implications for health systems:** The Caribbean epidemic of NCDs is the worst in the Americas, driven as elsewhere by ageing populations, urbanisation (with poor communities worst affected), globalisation of risk factors, and underlying social determinants. In response in 2007 CARICOM convened the first world summit of Heads of Government to address NCDs and issued the historic Port of Spain Declaration “Uniting to Stop the Epidemic of Chronic Non-Communicable Diseases” in which they called for the engagement of civil society in a multi-sectoral response. Regional health policy makers recognise the potential of PoWs in health promotion and the Healthy Caribbean Coalition (HCC), a recent alliance of >40 Caribbean NGOs and civil society organisations, including faith-based organisations, was set up to combat NCDs. While in the USA all-cause mortality 2000 – 2010 has declined by 30%, it has only declined by 14% in the Caribbean. In the USA, 85% of the decline is due to improvements in cardiovascular disease (CVD) and diabetes mellitus (DM) mortality, compared to 51% for the Caribbean, indicating a Caribbean deficit for improving CVD DM mortality. Within the Caribbean, there is notable variation in the change in CVD DM mortality, from a decline of 39% in Martinique, to an increase of 58% in Guyana. NCDs account for more than 60% of mortality in the Caribbean and this has continued to increase over the last two decades. The majority of cases are driven by the common risk factors of poor dietary practices, low levels of physical activity, and harmful use of tobacco and alcohol. While these drive the incidence of hypertension, DM and hyperlipidaemia, adverse outcomes like renal failure, retinopathy and limb loss are aggravated by poor adherence to lifestyle changes, medication and inadequate access to or uptake of health services.

The Caribbean is characterised by fragile health systems that are under-resourced and in need of structural and policy reform but there is insufficient evidence to guide best policy. The rapid transition in disease burden to NCDs is an enormous challenge for these weak systems. In Guyana for example the annual indirect cost of NCDs in 2010 was approximately US$207.5 million or 10% of the GDP. Interventions targeting reduction of risk factors and treatment adherence have been identified but progress is being stalled by shortfalls in the ability of health systems to ensure the effective and equitable delivery of these interventions. NCDs need early detection and monitoring of risk factors, increased integration, care provided over a longer period than is needed for acute conditions and that combines both drugs and psychosocial interventions which target behaviour change. The Caribbean has lower than average literacy rates for all LMICs, with functional literacy lowest in Guyana. Low literacy and health literacy are associated with poor engagement with health services, health knowledge, adherence to treatment and self-management, markers of disease progression, and higher rates of hospital admissions. Our approach of using PoWs to make NCD prevention accessible, regardless of literacy level, promotes a broader public health model by addressing the complex interplay between NCD understanding, attitudes and behaviours in communities, social determinants of health, and the delivery of services.

**Why a cross-country comparison?** The 3 countries were selected due to their differing geographical, economic, cultural and urban-rural contexts, extent of NCD burden, amid continuing
high levels of infectious diseases such as HIV, and variations in the extent of weak governance, low resources and inadequate information systems affecting health care. This diversity will yield important insights into the variation in implementation and experience of the intervention in different settings. Understanding variations in outcomes rather than the average effect will allow for richer discussion of replicability in other settings when up-scaled to other parts of the country or region. The commitment of the local researchers (see PIs/CIs) and of the Chief Medical Officers and the timeliness of the intervention with recent policy initiatives (e.g. Health Vision plans) also drove the selection of countries. Guyana was chosen as a primary site due to much greater ethnic and religious diversity and its economic disadvantage compared with Dominica and Jamaica.

**Variations in socio-economic and cultural context:** Guyana, the primary site, is the third poorest country in the Western hemisphere, following Haiti and Nicaragua, with 55% below the poverty line. There is low female labour force participation, high teenage pregnancy, and low functional literacy. Its population (~748,000) is diverse. The major ethnic groups are Indo-Guyanese, Afro-Guyanese, mixed ethnicity, and indigenous Amerindians, among whom poverty rates are highest, as across the whole Caribbean. The main religions are Christianity (mainly Pentecostal, Roman Catholic, Anglican), Hinduism (Sanatan, Arya Vedic) and Islam. Jamaica and Dominica follow closely behind Guyana in relation to Human Development Indices (education, health and GNI per capita). Jamaica’s population total is 2.8 million, mainly of African ancestry. Rural poverty and urban slums challenge equitable health care delivery despite a decentralised national health service. Dominica is a small island with a population of 72,000, 5% of whom are Carib (Kilinago) Indians. It has a French and Creole culture, and 30% live below the poverty line (50% for children).

**Health systems:** Substantial differences exist between countries in the type and scale of health system barriers to effective NCD prevention. However health systems in all countries are marked by workforce shortages, concentration of health services in urban areas, and inadequate integration between primary and secondary care. In Guyana, for example, over half of all nursing vacancies are unfilled, the highest in English-speaking CARICOM countries. Health care financing is fragile with less than 4% of GDP allocated to health. All three countries have decentralised, public-sector led health systems consisting of health regions (2, 10 and 4 in Dominica, Guyana and Jamaica respectively) and networks of primary care facilities, with care free at the point of access. Guyana faces the most geographical challenges in terms of universal access to care for all population groups spread over 21,500 sq. km. compared to Dominica on 790 sq. km., but resource limitations affect all three countries. Jamaica is most advanced with the provision of secondary and tertiary services at 24 hospitals island-wide including 6 specialist hospitals, while Guyana and Dominica each have one major hospital providing secondary care. In Dominica tertiary care is accessed at hospitals in neighbouring islands. None of the countries have well developed information systems. Jamaica has an embryonic electronic data gathering system in some sectors of the health service (injury surveillance and patient management systems in major hospitals) but in Guyana and Dominica these are even less developed.

**Religious capital and health:** The global development agenda recognises the need to promote public health policies that address underlying social determinants. The critical challenge is how to translate knowledge of social determinants into effective, large-scale, sustainable action to prevent and manage NCDs in poor communities. The underlying premise of our approach is that health systems need to shift from individually-focused interventions to work collaboratively with families and communities. The value of faith-based health interventions has been shown in several studies, but we are not aware of any that attempted to formally integrate this approach into the primary care pathway. Systematising the recruitment and training of lay HAs in PoWs and embedding them into the care pathway could improve quality, governance and sustainability and enhance linkages to continuing care. There is strong evidence for this leverage of investment to strengthen health systems via partnerships with PoWs, which are embedded in community networks. In the Caribbean, several initiatives demonstrate the potential of PoWs in health promotion but, as in other LMIC, have so far focused on infectious diseases (e.g. chikungunya in Guyana). Umbrella organisations (e.g. Inter-Religious Organization (IRO) in Guyana, Caribbean Council of Churches) have also conducted health advocacy activities e.g. suicide prevention in young people. Interventions for the prevention and treatment of NCD through PoWs have largely been limited to high-income countries using Christian churches and few studies have involved mosques or mandirs in programme design or delivery. Interventions using PoWs are generally informed by a socio-ecological approach addressing social and community influences on health.
However, reviews highlight a lack of explicit theory in many studies making it difficult to identify the precise mechanisms of change. Sociological theories support a functionalist view of religion as shared beliefs and practices which bind people into ‘moral communities’. Drawing on social capital theory, the concept of ‘religious social capital’ suggests that social resources available to individuals and groups through connections with a religious community, including shared values and norms, high levels of trust, and social support may facilitate behaviour change and adaptive coping. In disadvantaged neighbourhoods with high levels of religious participation, religion may be a primary source of social capital.

The moral and ethical status of PoWs within communities can enhance acceptability, reach and sustainability. They target families and deprived and vulnerable members of their communities through an ethos of altruism and social justice. They are located in communities across all sectors of society, including remote rural locations which are often medically underserved, and provide well-established social networks and resources including physical infrastructure and committed congregations who may be a potential source of volunteers. Interventions can be ‘faith-placed’ in which they are adapted to the religious setting or ‘faith-based’ i.e. developed collaboratively with PoWs to draw on religious social structures, norms and values in implementing the intervention. Collaborative, faith-based approaches may increase the salience of health interventions through targeting the ‘deep structure’ i.e. the cultural, social, historical, environmental and psychological factors influencing health behaviours, as well as the ‘surface structure’ of observable social and behavioural characteristics such as food preferences.

**Asset-based approaches and task-shifting to strengthen health systems:** Collaborative partnerships with PoWs in design, delivery and evaluation of health interventions are underpinned by the principles of community-based participatory methods. This assets-based approach draws on ‘salutogenic’ theories of community capacity for ‘health creation’ as opposed to deficit models of health risk. Health assets are the resources individuals and communities have at their disposal to maintain health and wellbeing. Asset-based approaches work with local communities to identify problems and create solutions building on the existing capabilities and capacities of individuals and communities. PoWs are community assets and the proposed engagement of HAs in public health programmes is steeped in asset-based thinking. CHWs and HAs act as a bridge between communities and public services and have been successfully trained to deliver interventions for HIV/AIDS and maternal and child health in LMIC. The training of HAs is well established in the Caribbean (e.g. ‘Wellness Warriors’ in Guyana, child health interventions in Jamaica) and there are policy commitments to diversify their role into NCD management. Use of HAs in PoWs, not previously used to address NCDs, is a potentially powerful strategy to increase the reach of primary care, particularly among those with distrust of health services, difficulties with access, or low motivation to engage with self-care, and facilitate better uptake and outcomes. HAs will be drawn from local congregations and embedded in local communities. They may therefore be better placed than clinical staff to disseminate health promotion messages, deliver community-based interventions and support adherence, particularly for vulnerable/low-income groups. They can adapt interventions to meet local needs and preferences, address barriers to participation, and draw on established community networks to influence health behaviours. However, there has been a lack of attention to integrating the role of HAs into the wider health system. Unexplored issues relate to those of governance, adequate and sustainable training and supervision, and system-wide effects such as increased burden on PHC workers from increased uptake of services.

**3. Scientific potential**

**3.1 People and track record:** Our proposal is underpinned by active collaborations between Caribbean and UK research groups, and effective partnerships between the local academic teams and WHO/Pan American Health Organization (PAHO) and the MoHs (see partner letters). The team reflects disciplinary breadth. The local PIs are Dr Rambaran (Director, School of Medicine, University of Guyana (UG), Prof Wilks (cardiovascular epidemiologist, Tropical Medicine Research Institute, University of the West Indies (UWI), Jamaica) and Dr Ricketts (behaviour change scientist, Ross University, Dominica). All have extensive experience in primary health care and research management.

In Guyana, the primary site, Dr Gobin (public health scientist), Director of the recently started MPH, Principal Tutor of Community Field Assignments, UG will be the project manager, overseeing the evaluation. The project will provide excellent on-the-ground training for a new cadre.
of public health scientists in the evaluation of complex interventions with communities and PHC, a rare skill-set in LMICs. 5 research assistants (RAs) drawn from the MPH/MBBS programme will be appointed. They will be involved in the entire research process – co-design with stakeholders, observation and qualitative interviews, surveys of congregations, analysis of data, writing up findings and engagement with policymakers and practitioners. The team of field assessors on short term contracts to conduct the surveys will include students who work part time (e.g. undergraduates in social sciences). Dr Thomas (statistician, UG) will be responsible for the methodology for surveys of congregations and analysis of quantitative data, and will work closely with Dr Abdulkadi (health economist UWI, Jamaica) on the economic evaluation. Dr Martin (social scientist, UG) will oversee the public engagement strategies and also work closely with the rest of the team in the iterative mixed method approach to data analysis. The core team will be completed by a researcher to be appointed with mixed method skills. Dr Samuels (chronic disease epidemiologist, UWI, Barbados) is currently an advisor for CARICOM and will be instrumental in ensuring up-scaling if the results are favourable. Dr Read (anthropologist, MRC Career Development Fellow, KCL) has led qualitative investigations of health care experiences and health behaviours in Ghana and with ethnic minorities, including Black Caribbeans, in London. She will support the local teams on all aspects of qualitative research. Prof Harding (social epidemiologist, KCL) has extensive research experience in international comparative studies of the health of ethnic minorities and behaviour change with deprived communities. She will support the local teams in issues of overall governance and will advise on effective community-based engagement strategies to enhance equitable access to health interventions. She led an MRC funded programme for 10y. Prof Cruickshank (cardiovascular medicine/diabetes/clinical epidemiology, KCL) has collaborated with the local Caribbean teams for over 20 years on management of cardiovascular disease. He is Co-PI on the recently funded MRC Stratified Medicine awards ‘AIM-HY’ for Hypertension and on T2 Diabetes (‘Mastermind’). Profs Poston & Sandall (KCL), experienced in implementation science in low resource settings, will provide methodological review and advice throughout the project. Prof Ogedegbe (New York University), a longstanding collaborator on studies in West Africa and with African Americans in poor US neighbourhoods, will also provide (at no salary cost) methodological support and opportunities for comparative research.

3.2 Environment: This project will be part of a programme of work that seeks to establish a long-lasting partnership and scientific link between the research groups in the UK with the research group in the Caribbean, and to develop trained researchers in the Caribbean who can continue working in the field of translational research after the project concludes. UoG was established in 1963 and has ~ 5000 students in 60 under-graduate and post-graduate programmes. In addition to the Master of Public Health, it offers postgraduate degree programmes in major clinical specialties via its affiliate, the Institute for Health Sciences Education (IHSE), established in collaboration with universities in North America, including Vanderbilt University (USA), University of California, San Francisco (USA), and University of Calgary (Canada). In 2015, a historic memorandum of understanding covering all aspects of teaching and research activity was signed by the UoG, Ministry of Health, and Georgetown Public Hospital Corporation (Guyana's largest tertiary care institution, its only approved teaching hospital and home of the IHSE). Students in the MBBS and all postgraduate programmes are required to conduct research, and mentors are drawn from faculty based in Guyana, North America and the Caribbean. UWI faculty often serve as external examiners for the UoG programmes. The proposed project will, therefore, not only provide the UoG with much needed opportunities for undergraduate and graduate research and capacity building, but also enable it to extend its existing network of academic, research and healthcare collaboration to the UK. TMRI_UWI has a regional remit via University Units in Jamaica and Barbados and collaboration with 14 UWI contributing territories including St Vincent and the Grenadines and St. Lucia. Dr Samuels’ letter emphasises how the inter-campus collaboration will support potential upscaling activities. TMRI has a historic collaboration with the Jamaica MoH’s Health Promotion & Protection Division to support best available evidence to plan and implement national health strategies and programmes. Ross University School of Medicine (RUSM) has a close working relationship with the Dominican MoH, especially in supporting the country’s efforts at strengthening Primary Health Care and addressing NCDs. KCL is a premier UK university with long collaborations with the Caribbean. KCL and its affiliated health services are located in South London which has a large Caribbean ethnic minority population. The new Centre for
Implementation Science promotes the value of implementation science to healthcare organisations across the world. The King’s Centre for Global Health promotes collaborations in global health education and research with a strong focus on capacity building of health professionals and communities. NYU’s Global Institute of Public Health has a distinguished research record in evaluating public health interventions in under-served communities in the US and worldwide. Capacity building through collaboration, mentoring and supervision is central to our project. UG is planning to have its first intake of PhD students 2016, one to be proposed from this project. Local teams will be supported to deliver high quality research and publications, and to seek further developmental opportunities (e.g. fellowship applications). The project also builds capacity of health practitioners in PHCs to work towards greater involvement of communities.

Partnership support is a critical aspect of this project to optimise successful implementation. The Pan American Health Organization (PAHO) provides technical cooperation and direction and mobilizes partnerships to improve health and quality of life in the region. In 2013, PAHO produced a Plan of Action for the Prevention and Control of NCD which pledges technical cooperation to assist member states to implement and evaluate cost-effective, innovative NCD interventions in primary care. PAHO is also working with the Caribbean Community (CARICOM) to evaluate the Port-of-Spain Declaration, which pledged to support initiatives aimed at strengthening regional health institutions to reduce the burden of NCDs. The Caribbean Public Health Agency (CARPHA) provides regional strategic direction to public health priorities. CARPHA’s objectives include conducting research on the causes of NCDs and preventive strategies, and developing evidence-based options for health promotion and preventive action.

3.3 Research plans

3.3.1 Theory-driven evaluation: The method focuses on evaluation of the contexts, processes and experiences of delivering the intervention and implications for health systems and PoW. We propose a mixed method approach which does not focus exclusively on downstream disease and mortality impacts and ensures methodological and theoretical integrity. It is informed by realist evaluation and the recent MRC guidance for process evaluation of complex interventions to advance the theoretical understanding of the best conditions to increase the impact of integrating HAs in PoWs into the primary care pathway. There is a growing consensus that research on interventions that occur in complex social systems presents significant methodological challenges. The contexts of PHCs and PoWs are multi-faceted and dynamic, and arguably the same intervention might not work in the same way in different contexts. A key focus of realist evaluation and the new guidance is to understand “what works in which conditions for whom?”, rather than “does it work?”, and to identify the underlying mechanisms of change that explain how the intervention reaches its outcomes in different contexts. Programmes have good outcomes only if they introduce the appropriate ideas and opportunities (mechanisms) to actors in the appropriate social and cultural conditions (context). Central to this approach is to identify these context-mechanism-outcome configurations and to explain variability in intervention outcomes. Realist evaluation recognises that the subjects of interventions are active participants, rather than passive recipients, that responses change over time, and that intervention is an event in a system producing feedback loops, emergent effects, adaptations and unintended consequences. The intervention proposed here, the integration of HAs into the care pathway, has the features of a complex intervention (e.g. multiple stakeholders, complex tasks to be delivered by HAs, multiple and variable outcomes), suitable for realist evaluation (e.g. interaction with health system and PoW context leading to emergent behaviour and outcomes as the intervention is implemented). The Figure shows the logic model with the key intervention components, how they may interact to produce change, likely short-, medium- and long-term outcomes, and resources required for implementation. Our hybrid approach aligns well with the WHO recommendations for systems thinking in the strengthening of health systems as the method of evaluation explores wider health system synergies and behaviour and ‘loop-thinking’ that might achieve the health goals.

3.3.2 The settings

Sampling in Guyana, the primary site, is more extensive and captures its greater religious and ethnic diversity compared to Jamaica and Dominica. We included intervention and comparator sites in each country so that the potential intervention effect can be gauged, adjusted for confounding factors, and contextual factors which are critical to the intervention’s success (or
failure) can be identified (see section 3.3.4). However, given that this is not a randomised control trial, the counterfactual cannot be ruled out.

In Guyana, we selected 2 administrative regions for intervention (Region 5, Mahaica-Berbice - population 50,000; Region 3, West Demerara - 107,000) based on need (relatively high prevalence of obesity, diabetes, deprivation) and a lack of public health programmes targeting NCDs, which – had they existed – could have made it difficult to assess the specific impact of the proposed intervention. The PHCs were selected on the following criteria: 1) easily accessible (i.e. located on the coast, not the interior), 2) located at a distance from a hospital, and 3) at least one state registered nurse on staff. These criteria identified 14 major PHCs in Region 3, and 8 in Region 5, as eligible for inclusion. We then used information provided by the Regional Health Officers to allocate PHCs to intervention and comparator groups, attempting to ensure that the 2 groups were comparable in terms of healthcare resources, accessibility, and demographics (religion, ethnicity) and socioeconomic status of the catchment populations. National religious organisations (e.g. Guyana Inter-religious Organisation [IRO]) and Regional Executive Offices helped to build a sampling frame of PoWs, and we mapped each church, mandir, and mosque to the nearest PHC. With the help of the IRO, we identified PoWs with appropriate infrastructural capacity (e.g. a room that can be used for clinics) and with congregational size of ≥70. One PoW for each major religion (Christianity, Hinduism, Islam) was selected for each intervention PHC. The final selection of 1PHC-3PoW clusters attempted to minimise likely contamination between intervention and control clusters by making sure that each cluster covered a different clinic catchment area (villages served). This resulted in 16 PHC-PoW clusters, 8 in the intervention and 8 in the comparator group. The 24 PoWs should yield a congregational population size of ~3000, 1500 in the intervention and 1500 in the comparators areas, allowing for an 80% response rate.

In Jamaica, we have selected 4 PHCs in poor areas, 2 urban (Olympic Gardens and Norman Gardens) and 2 rural (Riversdale and Yallahs), with a total catchment population of 20,000-40,000. We have mapped 4 Christian churches to each intervention PHC, representing a variety of denominations, with an estimated total 1200 congregants. In Dominica we have identified 2 PHCs in the Kalinago Territory (Atkinson and Gaulette River), with a catchment population of 400-600 persons (up 20% of the whole population). 6 churches will be mapped to the intervention PHC, with an estimated total of 300 congregants. Churches will not be mapped to comparator clinics in Jamaica or Dominica (see section 3.3.4).

3.3.3. The intervention (Guyana months 7 to 26; Jamaica/Dominica months 17 to 26): Based on a ratio of 1HA to 35 congregational members ~50 HAs will be recruited in Guyana, and 20 in Jamaica. In Dominica congregational sizes for the Kalinago are smaller and 10 HAs will be recruited (at least 1 per PoW). In the development of this proposal the CMOs and IRO suggested that the selection of HAs should be guided by the administrative bodies of the PoWs, with the minimum requirements of completion of high school education and a general aptitude for health promotion. The CMOs agreed that HAs will be supervised by nurses at the local PHC with at least weekly contact, and receive a stipend, at a level agreed with the local MoHs in line with their payments to lay workers on other programmes. Regular performance assessments of nurses and HAs will enable reflective practice, address unrealistic expectations, identify additional training requirements, and agree on achievable goals. PoWs will be given a nominal contribution of $US75 for use of space for ‘open clinics’ run by HAs and a memorandum of understanding between the administrative headquarters of each religion and the MoH will be proposed.

HAs will be trained by local MoH/PAHO to promote physical activity (e.g. group exercise in PoW), healthy food choices (e.g. portion size control, salt reduction), early detection (e.g. high blood pressure), patient support (e.g. diabetic foot care, treatment adherence), and facilitate uptake of welfare services (e.g. completing housing benefit applications). HAs will train congregation members, promoting diffusion of health literacy across the congregation and congregants’ families. HAs will receive 4 days of training plus half day refresher training at 6 monthly intervals. Training will cover teaching and demonstration, interactive exercises (e.g. group dance exercise, tasting healthy food alternatives) and knowledge testing. The following draws on an existing programme for youth ‘Wellness Warriors’ in Guyana, adapted to focus on NCDs: Day 1) Introduction to care protocols, good clinical practice, data collection forms, introduction to NCDs (heart disease, hypertension, diabetes, obesity) - symptoms, risk factors, co-morbidities; Day 2) Management of NCDs, diet and physical activity, motivating behaviour change; Day 3) Practical - blood pressure,
use of BMI wheel calculators and home measurement kits for blood sugar testing, foot care; Day 4) Practical – shadowing PHC nurses assigned to the programme.

Printed and digital material on NCD prevention (diet, physical activity, smoking, alcohol, foot and eye care) and welfare, national health insurance, and disability entitlements will be provided by PAHO, MoHs and other Ministries (e.g. Education and Employment, Agriculture, Social Welfare). Civil society groups (e.g. Ptolemy Reid Rehabilitation Centre, Diabetes Associations) will provide information through talks/printed material on self-management and peer support/advocacy. HAs will use a combination of individual and group-based methods to deliver these messages tailored to the needs of their congregations. For example individual sessions could be a bi-weekly drop-in clinic for an hour at the PoW before or after worship. Commonly used evidence-based motivational techniques for behaviour change will be used to encourage goal setting and problem-solving and gradual sustainable behavioural change. Regular events at PoWs such as fairs, activity camps, youth/women’s groups, religious sermons, will provide opportunities for a mixture of interactive (e.g. cookery classes, exercise groups) and educational sessions. Illustrated printed material and digital displays in PoWs will reinforce key messages. The aim is ensure adaptability in delivery to best suit the needs of local congregations (e.g. faith-based messages, cricket or football matches for example), but all HAs in all settings will have the same roles and responsibilities to promote NCD prevention and use evidence-based materials. HAs will keep a record of the nature, delivery and number of activities facilitated, numbers enrolled or attending individual or group sessions, and numbers referred to PHC.

3.3.4. Data collection
(a) Stakeholder consultations (Guyana months 4-5; Jamaica /Dominica months 14-15): Aims: (i) to understand and develop a model of factors affecting implementation using PHCs, PoWs and HAs; (ii) to increase stakeholder communication and collaboration; (iii) to assess implementation readiness, including areas that may need to be addressed before and during implementation (e.g. training, physical infrastructure of PoWs); (iv) to identify inputs, processes and outputs needed to measure progress for PHCs and PoWs, and more generally (v) to identify possible system-wide ramifications of the intervention, potential positive and negative effects of implementation, and intended and unintended consequences (e.g. overburdening PHC). Methods: We will use concept mapping, a structured participatory methodology which provides a framework to gather information on factors influencing implementation, prioritise areas for health system improvement, develop conceptual models of implementation, and foster communication and collaboration across stakeholder groups. A multi-disciplinary stakeholder group will have representation from congregations (Muslims, Christians, Hindus), the IRO, PHC practitioners, administrative support staff at PHCs, regional health directors, and MOH officials. A research facilitator will guide 4 concept mapping workshops using the following format: a) Generation: Groups will brainstorm on focused questions related to the intervention aims; b) Structuring: Participants will sort the statements into categories based on similarity and rate each statement on importance and changeability; c) Representation: Statements will be used to construct a “concept map” showing potential positive and negative effect pathways and interactions. The output will be an interim ‘road map’ with country specific differences in line with the different socio-cultural, religious and health system contexts. The group will serve as a reference group and will be consulted at key stages of the study to help interpret the findings, suggest how best to maximise potential synergies between PHCs and PoWs and minimise negative effects. Potential members of this stakeholder group have already been consulted and the issues raised will help to frame focused questions for the concept mapping workshops. In Guyana we consulted the Chief Medical Officer (CMO), practitioners in Regional Health Centres and PHCs, and religious leaders (Imams, Christian pastors, Rastafarians, Sanatan/Aryan Hindu Pandits). Key constraints were identified (e.g. limited capabilities and capacity, inadequate information systems/metrics) as well as enablers (readily understood cultural mechanism using PoW and their benefits – reach to the poor across generations, generating local solutions sensitive to community needs). The CMOs and regional directors of health suggested a tentative framework for governance (e.g. supervision of HAs by assigned nurse at PHC, reviewing processes to monitor performance and competencies) and financing (MoH direct financing of HAs via government and donor funds) if results are positive. In Jamaica a consultation with 14 faith-based organisations recognised their potential value in the prevention and control of NCDs and identified challenges for sustainability.
without integration into PHC related to lack of technical, financial and human resources. Support from the MoH to guide standards and assist sustainability was seen as vital.

(b) Document review (Guyana months 0 to 4; Jamaica/Dominica months 12 to 14) of relevant policies and protocols that could affect implementation and of information systems. For example, care protocols for foot care of diabetics will be amended for use by HAs, existing training modules for CHWs will be amended to suit the needs of HAs in the different PoWs, simple amendments of PHC information systems will allow care/referral experiences of patients seen by HAs to be tracked. With the help of the CMOs a review of their Health Action Plans has already begun.

(c) Longitudinal tracking of the experiences of congregants, HAs and PHC practitioners (Guyana, N=58, months 8-10, 14-16, 25-26; Jamaica N=38, Dominica, N=20 months 18 and 26). Longitudinal qualitative interviews repeated throughout the intervention will be essential to capture context-mechanism-outcome interactions over time and allow modifications to maximise likely positive impacts. The baseline survey (see below) will provide a sampling frame of congregants. We will use stratified purposive sampling for congregants by gender, location (urban/rural), age (under 35y/35y or older) and religion, and for PHC workers by rural/urban location.

Guyana: 36 congregants (12 Muslims, 12 Hindus, 12 Christians), 12 HAs (4 from each religious group) and 10 PHC workers (2 physicians, 6 nurses, 2 administrators). Within each religious group 4 congregants from each of the following categories will give a spread of exposure to health services and of health status prior to the study: a) no contact with health services over the last 6 months, b) currently an NCD patient at the PHC but not an inpatient in secondary services over last 6 months, or c) was an in-patient in the last 6 months due to NCD regardless of PHC contact.

Jamaica: 24 congregants (6 from each of 4 Christian denominations, 2 from each care pathway), 8 HAs, and 6 PHC workers (1 physician and 2 nurses from 1 rural and 1 urban clinic).

Dominica: 12 congregants (8 Roman Catholic, 4 Protestants, 4 from each care pathway), 4 HAs and 4 PHC workers (2 physician and 2 nurses).

Interviews will examine perceived enabling and constraining factors that affect fidelity to protocols and processes, satisfaction with and equity in reach of intervention, and emergent behaviour and outcomes (adaptation, unintended consequences). Interviews with congregants will also aim to give detailed insight into their interactions with HAs, experiences of referral to and care at PHC, understanding of health needs, motivations to engage with health promoting behaviours/adherence to treatment protocols, and the role of religion. Interviews with HAs and PHC practitioners will also cover perceptions of competencies and skills, understanding of health needs, risk behaviours (diet/physical activity etc.), communication, planning and monitoring of service, and motivations for and barriers to volunteering. All interviews will be digitally recorded and transcribed verbatim.

(d) Ethnographic observation (Guyana months 3, 9, 15, 26; Jamaica/Dominica months 16, 20, 26): Ethnography uses immersion in a social context to produce naturalistic data based on observations of real world interactions and practices and enable a critical interpretation of underlying social processes. Ethnography will examine the mutual influence of the context and intervention during implementation. Aim: To map the social and cultural context impacting on implementation and outcomes including organisational structure and culture of PHC/PoWs and influence on behaviour; interactions and networks between health workers/congregants/community members; possible consequences of change in the health system, potential points of resistance and leverage. Researchers will conduct a series of non-participant/participant observations at 4 clinics and 6 PoWs (2 from each religious group) in Guyana and 2 clinics (1 urban/1 rural) and 4 churches (2 rural/2 urban) in Jamaica and in Dominica. Observations in PHC will include patient consultations, staff meetings, administrative practices and in POWs will include religious services and rituals, meetings, social gatherings. During observations researchers will engage in informal, unstructured conversation with PHC staff, congregants, and other community members to explore responses to and perceptions of the intervention during implementation. Subject to informed consent, photographs/video recordings will be taken which illustrate the PHC/PoW context e.g. ritual events, physical environment. Fieldnotes will record details of observations and conversations as well as preliminary reflections and analysis.
Baseline and endline assessments of likely influence of integration on health of communities and health systems (Guyana months 5-6 and 26-27): Questionnaire surveys of congregations in intervention and comparator PoWs will be used to collect data to be used in conjunction with the qualitative data to examine the influence of HAs on NCDs and well-being. These will include key outcome measures such as General Health Questionnaire measure of mental health, doctor diagnosed hypertension and diabetes, current smoking & alcohol consumption, International Physical Activity Questionnaire measure of physical activity, fruit and vegetable consumption, overweight), health literacy (using the Health Literacy Questionnaire), satisfaction with services (access to and quality of services provided by HAs, and PHC nurses and doctors) and quality of life (WHOQOL-BREF). It will also include measures of key structural factors (e.g. own education, family assets, area deprivation) and psycho-social influences (e.g. religious capital, social support) that could influence social inequality in outcomes. All congregants of the PoWs included in the study (intervention and comparator areas) will be invited to take part. Coverage of the entire congregations rather than just of those who had contact with the HAs will enable an exploration of the diffusion of benefits via support networks. Information will be collected about contact with the HAs and attendance to health promotion sessions. In addition data from the PHC information systems in both the intervention and comparator areas will be used to examine differences in level and nature of uptake of PHC services (e.g. referrals, attendance to clinic appointments, number of prescriptions issued, co-morbidities). In Jamaica and Dominica we will conduct only the audit of PHC records of the participating PHCs.

The table shows power calculations using STEPS 2011 (Trinidad & Tobago). A 10% change in behaviour is very likely to be detected with our sample size for the congregational survey in Guyana, allowing for 80% response rates. The sample size calculations focus on comparing the intervention and comparator groups before and after the intervention. For sample sizes, power is set to 0.80 and the probability of Type I error to 0.05. For power for a given effect, a total sample size is 2000 is assumed. When the variable is reported as a proportion, the percentage change is computed as the actual change in the proportion. When the variable is reported as an average (for example average number of days), the percentage change is computed as (value after value before)/value before. The assignment to intervention and comparator is not randomized and the pre- and post-intervention measures will not necessarily be repeated measurement on the same individuals. Where possible, repeated measurements on the same individuals will be adjusted for dependence by taking the difference between the two scores.

### Table

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean/ Proportion</th>
<th>SD</th>
<th>Intervention group Proportion 10% change</th>
<th>Total Sample Size for 80% Power (both groups) 10% change</th>
<th>Power with total Sample of 2000 10% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently smoking</td>
<td>0.21</td>
<td>0.41</td>
<td>0.11</td>
<td>330</td>
<td>0.98</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0.40</td>
<td>0.49</td>
<td>0.30</td>
<td>565</td>
<td>1.00</td>
</tr>
<tr>
<td>Mean no of days fruits eaten/week</td>
<td>3.40</td>
<td>2.63</td>
<td>3.74</td>
<td>1486</td>
<td>0.89</td>
</tr>
<tr>
<td>Mean no of days vegetables/week</td>
<td>4.50</td>
<td>2.64</td>
<td>4.95</td>
<td>650</td>
<td>0.99</td>
</tr>
<tr>
<td>Low Physical Activity according to GPAQ</td>
<td>0.45</td>
<td>0.50</td>
<td>0.65</td>
<td>596</td>
<td>1.00</td>
</tr>
<tr>
<td>Eye Exam last 2y among those with diabetes</td>
<td>0.47</td>
<td>0.50</td>
<td>0.57</td>
<td>600</td>
<td>1.00</td>
</tr>
<tr>
<td>Foot Exam last 2y among those with diabetes</td>
<td>0.20</td>
<td>0.40</td>
<td>0.30</td>
<td>306</td>
<td>1.00</td>
</tr>
</tbody>
</table>

3.3.5 Analysis: Triangulation of findings from qualitative and quantitative results will be used to explore how the intervention led to observed outcomes and to identify enabling and constraining factors. Analysis will focus on the interaction of context, mechanism and outcomes – which mechanisms work in which context for which outcomes? Analysis will be repeated at 6 monthly intervals. After the first round of data collection, quantitative and qualitative data will be collated and subjected to preliminary analysis. Interpretation of emergent findings will be negotiated in discussion with stakeholders and researchers. These interpretations will be tested against findings from the next wave of data collection, looking explicitly for disconfirming or contradictory data. Data will be compared across religious groups, rural/urban locations, PHC clinics, within and across...
countries etc. to determine how mechanisms play out in different contexts. Analysis of qualitative data will take an iterative interpretivist approach using the constant comparative method\textsuperscript{28}. Analysis of the data from the PHC monitoring systems (all 3 countries) and quantitative surveys of congregations (Guyana), informed by the qualitative findings, will explore the influence of the intervention on differences in process and impact outcomes (see Figure) between intervention and comparator areas. In Guyana these analyses will be more extensive given the congregational surveys. Multilevel generalised linear regression models, with congregants nested within PoWs, and PoWs nested within PHCs, will explore potential effects at all levels. We will adjust for countries (as fixed effects for analyses with the PHC monitoring data) and confounders (age, gender, co-morbidities, socio-economic composition of areas). This is not an RCT it is unlikely that we will be able to account for all confounders. Baseline values in outcomes will be adjusted for. Exemplar questions to drive analyses will be (a) Mechanisms: What motivated congregational members to become HAs?; How do congregations respond to activities delivered by HAs and does it vary across religion, gender, age, education & ethnicity?; Does religion shape the delivery and reception of the intervention?; What hinders or enables positive PHC-HAs relationships? (b) Context: Which contexts facilitated positive outcomes for whom? What conditions are essential in health systems and PoWs?; Are there alternative explanations (i.e. other interventions that took place)?; Were there unanticipated impacts on the health systems and why?; Did the intervention impact diffuse beyond congregations into communities and if so how?; (c) Outcomes: Are the outcomes in the intervention areas different than those in the comparator areas? Outcomes are indicated in sections\textsuperscript{3.3.4 e} and in the logic model, includes process (e.g. number of HAs recruited, trained, retained, adherent to practice protocols; numbers attending HA sessions, referred to PHC, attending foot and eye care clinics, adhering to treatments satisfaction of PHC staff with new service model) as well as impact outcomes (reduction in co-morbidities, improved dietary and reduced low physical activity behaviours, increased satisfaction with services, improved NCD literacy, increased screening & lower admissions/emergency care for NCDs).

4. Ethics and research governance
The conduct of the study will be guided by MRC guidelines for good research practice including full disclosure of research goals and methodology, access to PHC monitoring records and strict quality assurance controls at every level of data collection, management and analysis. Informed consent will be obtained from all participants. Those with low levels of literacy will have information sheets/consent forms read to them, and if necessary proxy signatures will be obtained from a witness e.g. family member. Congregants who are patients and participate in HA sessions but refuse access to their PHC records will not be disadvantaged in any way. All clinical and research staff participating in the study will receive training in GCP and research ethics. Risks to participants from the intervention are low. Approval will be sought from the MoHs and University ethics committees in participating countries. All staff, collaborators and contractors will sign a confidentiality agreement and abide by the MRC and local University guidelines on the use of personal data.

5. Data preservation for sharing
Data will be stored securely on encrypted computers or in locked storage locally (UG, UWI, Ross). Participant research data will be stored with an ID number and personal details will be held separately in a secure unit. All identifying details will be removed from interview transcripts, clinical data retrieved from clinical records and quantitative data. The interviews and assessments will be conducted by trained RAs who are responsible to the investigators. Access to the datasets will be possible for the research team through password-protected entry. Our data sharing/access procedure will be guided by the following principles: the need to ensure that the data sets are first used to address the primary aims of the project (which will be done within two years of data collection); every effort will be made to offer unrestricted access thereafter, with the only proviso being the continued protection of the anonymity of participants and due acknowledgment given by subsequent users to the original source of the data. These conditions are in line with the MRC Policy on Data Management and Sharing. We will work to ensure that the data, whenever it is to become available to the public, is in a form that can be understood and used by the research community. (See Data Management Plan for details)
6. Exploitation and dissemination

Please see Pathways to Impact and communications plan for further details. We are committed to fully and interactively engaging with the public, voluntary sector organisations e.g., IRO, HCC, and the end-users of this research. Co-designing with stakeholders (health service providers and congregants) will provide ready routes for dissemination. We plan to work with the MoH staff in the training, co-ordination, professional registration and development of PHC staff. The MoHs plan to use the training materials as part of curriculum development for future training of HAs in NCD management. They will also be incorporated into the curricula of the MPH and MBBS programmes at the various Caribbean universities involved. Our tracking of users’ and practitioners’ experiences throughout the intervention phase will inform acceptability and applicability of the intervention. We will use digital dashboards in PoWs and advocacy activities of the IRO, Caribbean Council of Churches and the HCC, including music, film and drama (Co-I PM). CARPHA and PAHO will facilitate regional workshops with MoHs to synthesise findings across the sites and develop a toolkit to guide implementation in CARICOM states. In collaboration with CARPHA, a symposium will be held at its annual scientific meeting where the critical mass of attendees are early and mid-career social and health scientists, and students from all over the Caribbean. We will use an array of strategies including policy briefing papers, social media, and joint papers with MoH and scientists for scientific journals. This project has the potential to strengthen collaboration between RUSM and TMRI, UWI and other stakeholders in NCDs in the region.

Logic model for integrating Places of Worship into the Primary Care Pathway
References