**Health through Faith: can faith-based organisations support weight management and reduce the risk of NCDs in South Africa? An exploratory feasibility study**

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# Rationale

In 2013, 63% of South African (SA) women and 31% of SA men aged over 15 were overweight or obese1. Overweight and obesity are established risk factors for non-communicable diseases (NCDs). The 2008/9 Cardiovascular Risk in Black South Africans Study demonstrated diabetes prevalence of 13.1%; impaired glucose tolerance 11.2%2; and hypertension 38.9%3. NCDs4,5 and obesity6 bring staggering costs to the health system as well as low levels of quality of life4,7 and economic productivity4,6,8 for people who experience them. In LMICs, where resources are already limited, the financial burden of NCDs on households is acute9,10 through direct costs of accessing health care and indirect costs of the inability to work and resulting absenteeism10. In SA, increasing levels of NCDs are placing substantial demand on the already over-burdened public health system11. Community level approaches to improve diet and physical activity are advocated to reduce NCD prevalence12.

# Proposed study

We will develop a weight management and healthy living programme for obese adults delivered through churches in two settings in South Africa.

Our team has considerable experience of developing group-based weight management and healthy living programmes which are effective in the long-term, have good reach and continue to engage those who are most at risk in both SA and UK13-17. For example, Football Fans in Training (FFIT) is a highly effective programme for men aged 35-65 years set in professional football clubs16. The football club context had both social and symbolic meaning for participants18. FFIT ‘hooked’ men at high risk of ill health as their desire to do something for their health combined with the chance for an ‘insider view’ of their club19. They continued with the programme because of the enjoyment of being with ‘people like me’ and a sense of team-spirit when successfully changing lifestyles in a valued, masculinised, context18; their weight loss was maintained to 12 months16. Thus, as others have argued20, the interaction between the content of the intervention (evidence-based behaviour change techniques and simple information) and the context in which it was delivered (the football club) were both critical to its success. The programme has been adapted successfully to be delivered to women21 and implemented more widely across the UK. We have adapted the programme for delivery in other professional sports club settings and as the basis for a new health promotion programme in the prison setting.

In this research we will use the lessons we have learnt from FFIT and other programmes to develop a weight management programme that is attractive to, engages and enables low income, South Africans to reduce their weight and risk of ill health.

The ‘hook’ to the programme will be its setting in the churches attended by our target population and opportunities to engage with other members of the congregation in similar positions. Faith-based organisations have an important role in delivering health care to some of the poorest people in Sub-Saharan Africa22 but their potential to support NCD risk reduction is unexplored. A scoping review identified 32 lifestyle interventions delivered through churches in North America; programmes were small-scale and variably evaluated23 but demonstrate the potential of the concept. South Africa is a deeply religious society: 83% of women and 63% of men responding to the demographic surveillance study conducted by the Africa Centre for Population Health report spending at least 1 hour a week in religious practice.

The content of the programme will build on existing evidence for successful weight management24-27, will include opportunities for interaction18 and social support28 but adapted to local circumstances. If the results of this study suggest that it is possible to deliver a programme in SA churches that is likely to reach people at risk and to be effective we will propose a formal pilot RCT. Since the evidence on which most weight management programmes are based has been developed in high-income countries. It is important to consider how programme components may need to be adapted to other settings without losing effectiveness. A brief scoping review demonstrated that only two interventions have been shown to be effective for adults in South Africa29,30. Others had no effect31 or are yet to report32. None have been subject to large-scale evaluation or shown to be attractive to large numbers of people.

This study will allow essential research to develop a weight management and healthy living programme that is likely to be attractive to, and effective for, low income black South Africans in rural and urban settings.

# Aim and objectives

The overall aim is to develop a weight management and healthy living programme that is likely to be attractive to, and effective for, low income South Africans in rural and urban settings.

Our specific research objectives are to establish:

1. what adaptations are necessary to components of existing evidence-based programmes to be appropriate to the target population;
2. the target group of the programme in terms of age and gender, and whether mixed or single sex groups are likely to be of most appeal;
3. the feasibility of delivery of the programme;
4. the acceptability of the programme to the target population and feasibility of collecting outcome and process data in a subsequent pilot RCT.

# Methods

The study will take place in two settings: the Hlabisa sub-district, KwaZulu-Natal (KZN), specifically the Africa Centre’s Population Intervention Platform Survey Area, and Guguletu ‘township’ in Cape Town, Western Cape.

In each setting, churches have already expressed interest in participating in the research. From these two will be chosen based on convenience for local travel, having stable congregations, regular church services and likely to have a large enough congregation to recruit up to 15 programme participants when the programme is delivered. Thus faith leaders and congregation members/participants will come from 4 churches.

The research will be undertaken in two phases.

## Phase 1. Adaptation of components of existing, evidence-based, group weight management programmes to the SA setting – co-development groups (objectives i and ii, months 1-9):

We will develop the programme iteratively with the support of two co-development groups, one in each of Hlabisa and Gugulethu.

*Co-development groups, members and workshops*

Each co-development group will be made up of up to14 congregation members and faith leaders who volunteer from the 2 participating churches. They will be offered reimbursement of travel to the workshops which will be held in locally accessible venues, refreshments will be provided, and they will be offered reimbursement in thanks for the time to spend on co-development.

Each co-development group will meet in three half- or full-day workshops.

Each workshop will be convened by one of the research team and an experienced member of local fieldwork teams. At workshop 1, the researcher or local fieldworker in each site will verbally explain the study process to the group present in their home language, to ensure that they fully understand what the process will entail and what will be required of them. Information and consent forms will be available in home languages. They will be asked to sign a consent form agreeing to their participation.

All workshops will be experiential and participative.

In *workshop 1*, we will seek views and experiences on:

* the problem of NCDs from the perspective of participants;
* the best ‘hook’ to attract people to lifestyle change;
* programme leadership;
* target age group;
* acceptability of inclusion BMI >30;
* adaptation of behaviour change techniques;
* relevant physical activity;
* gender-sensitisation and single sex deliveries;
* sensitisation for Christian ethos and whether sensitisation should vary by denomination.

We will also provide an overview of the sort of materials and activities that could be provided in the programme and specifically investigate the problems of accessing healthy diets in the context of poverty and food insecurity. Based on these findings the initial draft of the programme will be further developed and adapted.

In *workshop 2*, approximately 2 months later, the revised programme will be presented and elements of it tried out (e.g. physical activity and dietary elements of the programme will be delivered, including self-monitoring, goal setting, social interaction and experiential learning) to gain views on how they can be adapted.

*Workshop 3*, approximately 2 month later, will deliver elements of a leaders’ training programme. We will explicitly seek views on: format and length of training; leaders’ qualifications or experience; and whether high quality delivery will require payment.

*Data processing and analysis*

Detailed notes will be taken at workshops, discussions tape-recorded and, as necessary, selectively transcribed. Key points for re-development will be identified between workshops and a programme, including target population, developed prior to formative evaluation delivery.

*Outputs*

Decisions on target population and recruitment processes, delivery protocol for leaders, participant information booklet, training protocol. Where necessary these materials will be translated into isiXhosa and isiZulu. There is capacity for this (and other) translation in both research sites.

The likely components of the programme will include training in the use of behaviour change techniques such as goal setting, self-monitoring and ‘if-then’ plans for relapse prevention, growing social support for change within the church community, support on healthy eating and on safe increases to physical activity.

The programme is likely to be delivered in church associated venues and delivered by a trained lay member of the congregation

## Formative evaluation of the delivery of the programme (objectives iii and iv, months 10-18):

We will: a) recruit and train programme leaders to deliver the programme in four churches (two in Hlabisa, two in Gugulethu); b) invite congregation members to participate in delivery of the programme to groups of 15 people.

*Participants*

Inclusion criteria will be decided during the phase 1 research. However, because increasing physical activity and losing weight if overweight is beneficial for everyone, including those with long term conditions, we will seek to be inclusive and to include all participants whose blood pressure does not put them at risk from physical activity.

Inclusion criteria are likely to be:

* Adult, aged between 30 and 65;
* Want to lose weight and get fit;
* Have no contraindications to physical activity, assessed by blood pressure;
* Who consent to measurement before and after the programme.

Exclusion criteria are likely to be:

*Participants*

Inclusion criteria will be decided during the phase 1 research. However, because increasing physical activity and losing weight if overweight is beneficial for everyone, including those with long term conditions, we will seek to be inclusive and to include all participants whose blood pressure does not put them at risk from physical activity.

Inclusion criteria are likely to be:

* Adult, aged between 30 and 65;
* Want to lose weight and get fit;
* Have no contraindications to physical activity, assessed by blood pressure;
* Who consent to measurement before and after the programme.

Exclusion criteria are likely to be:

* Participants found to have elevated blood pressure at pre-programme measurement sessions (systolic ≥ 160mmHg and/or diastolic ≥ 100mmHg, (assessed according to a protocol using 3 readings and an appropriate sized cuff), which is classified as ‘moderate’ hypertension in 2014 Standard Treatment Guidelines and Essential Medicines List for South Africa33) will be NOT be allowed to participate in physical activity elements of the programme until they have provided evidence to the programme leader that their blood pressure is lower. They will, however, be encouraged to take part in other aspects of the programme and to undertake moderate intensity walking activities.

As described under data collection below, those classified as having any hypertension will be managed according to a clinical SOP to identify exclusions, and also to define when there is a need for urgent care.

*Data collection*

We will use four methods of data collection:

*Observation of delivery of the programme*: Half of the sessions in each delivery will be observed and detailed field notes taken with a proforma structured around fidelity to the programme protocol and participants’ response to the programme.

*Focus group discussions*: A sub-sample of participants (n=6) in each programme will be invited to discuss: acceptability of the programme, components found effective or ineffective, unexpected outcomes, experiences of measurements and whether follow-up will be possible.

The focus groups will be facilitated by the postdoctoral researchers in Cape Town and Hlabisa, with the assistance of a fieldworker to translate into isiXhosa and isiZulu (where appropriate) so that participants are free to express themselves in their home language.

They will be convened in a locally accessible venue (preferably church premises) and participants offered refreshments and reimbursement for their travel costs.

*Individual interviews:* Up to 8 church leaders will be interviewed about barriers and facilitators to programme delivery and fit in the flow of church activities.

They will be conducted by the postdoctoral researchers in Cape Town and Hlabisa, with the assistance of a fieldworker to translate into Xhosa and Zulu (where appropriate) so that participants are free to express themselves in their home language. They will be conducted in locally accessible venues, and participants will be offered reimbursement of the time they spend in helping us.

*Collection of anthropometric, physical and questionnaire measures*: Programme participants will be asked to consent to baseline and post-programme measurements including: objectively measured weight, height, waist circumference, resting blood pressure, self-reported physical activity and sedentary behaviour (Global Physical Activity Questionnaire), eating habits, as well as willingness to be followed up face-to-face and through data linkage (e.g. text messages).

Resting blood pressure will be taken after 5 minutes sitting rather than supine. It will be taken by a study nurse in Hlabisa and by a postdoctoral biokineticist in Gugulethu. If the first test is recorded as within normal limits (<140 (systolic) and <90 (diastolic), the actual measures will be recorded and no additional measures taken. If measured BP was systolic ≥140 and/ or the diastolic ≥90, then 2 further measures will be taken and recorded. The mean will be calculated from the latter two measures.

Participants found to have elevated blood pressure at pre-programme measurement sessions will be managed according to a clinical SOP to identify exclusions, and also to define when there is a need for urgent care. The SOP is likely to include that participants with elevated blood pressure at pre-programme measurement sessions (systolic ≥ 140mmHg and/or diastolic ≥ 90mmHg) will be given a letter and encouraged to attend their local health clinic for further checks. In Hlabisa an Africa Centre nurse will be available for them to see in 10 local clinics. It will also include what to do if hypertension measures indicate that urgent care is needed.

The letters will be written in English and isiZulu/isiXhosa and will be designed to encourage further checks but avoid anxiety. Records will be kept of all letters issued.

Measurement sessions will be overseen by the Research Fellows on the project in Gugulethu and Hlabisa, both of whom are post-doctoral or have equivalent experience. Questionnaire measures will be translated and back-translated into isiXhosa and isiZulu. In Hlabisa all data collection will take place using tablet computers, pre-programmed using Africa Centre’s standard operating procedures.

They will be convened in a locally accessible venue (preferably church premises) and participants offered refreshments and reimbursement for their travel costs.

The fieldwork team in both settings will be experienced fieldworkers who have worked on our projects in the recent past. They will be fully trained in all measurement and consent procedures.

*Data processing and analysis*

Observation field notes will be written electronically in English. Focus group discussions and interviews will be audio-recorded, transcribed and translated into English, in Hlabisa by members of the trained qualitative research team.

A thematic analytical framework, developed by the full project team, will be used to construct a detailed description of: feasibility and acceptability of programme delivery, any unexpected outcomes or processes and what aspects would require further adaptation prior to more formal delivery and evaluation.

Pre and post programme measurements will be analysed descriptively, to describe the study population and changes between baseline and post programme measurements. The ease with which data were collected will be used to assess data collection feasibility.

*Outputs*

Description of the delivery of a weight management and healthy living programme through four SA churches in rural and urban settings and assessment of what would need to change to a) improve the programme and b) conduct a more formal, pilot, outcome evaluation.

# Research team and institutional support

The project will be led by an experienced multi-disciplinary team from the UK and SA. Programme development will be led by PI Wyke. The UK and SA teams have considerable experience of combining research evidence, interdisciplinary theory and person-centred approaches for programme development. Hunt has particular expertise in gender-sensitisation of programmes. Qualitative methods will be led by Co-I Draper with input from the GU researchers. All UK team members and Draper have considerable expertise in the application of qualitative methods to formative evaluation. Quantitative methods will be led by Co-I Micklesfield with input from Co-I Barnighausen and PI Wyke as well as the wider team. Co-I Micklesfield has extensive experience of anthropometric measurement and analysis. Co-I Tomaz, the postdoctoral researcher working on the project, is a registered biokineticist, and has a significant amount of experience in community health promotion, including the collection of anthropometric, physical and questionnaire measures. Co-I Tomaz will also provide input on the physical activity components of the intervention, as she also has worked extensively with adults with non-communicable diseases, which involves appropriate exercise prescription.

In KZN, the research will be conducted through the Africa Centre for Population Health; PI Wyke is a collaborating scientist and Co-I Barnighausen is senior faculty. The Africa Centre is funded by the Wellcome Trust and has high quality infrastructure for population research. In Cape Town, the research will be conducted through the Division of Exercise Science and Sports Medicine, University of Cape Town. Both research centres have access to the necessary facilities and fieldworkers (fluent in the local languages). At the Africa Centre we organised a meeting with 33 local faith leaders to investigate views on the usefulness of an NCD prevention programme. Participants were overwhelmingly positive and 13 signed up to support the work further. Two churches in Gugulethu have also agreed to be involved should we be funded. Funding has subsequently been obtained from the UK MRC.

# Ethical considerations

This study adheres to the guidelines described in the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. Participation in the study is entirely voluntary. Written consent will be obtained from all participants who meet the inclusion criteria. Informed consent documents will be translated (and back-translated into English) into Xhosa and Zulu. For those who have difficulty reading, or who are illiterate, the fieldworker in each site will assist participants to complete the consent forms, and will verbally explain the information sheet to ensure that they fully understand the nature of the study and what their participation in the study entails. The fieldworkers will also be available to answer any other questions about the study during the consenting process. Furthermore, the fieldworkers will be involved in the study (in their respective sites) in an on-going basis, so they will also be able to respond to any questions that arise during the course of the research process.

All consent forms will outline the research being done (including the purpose and benefits of the research), and explain that participants may withdraw from the study at any time, without prejudice. Furthermore, it will be highlighted that the research results will be treated anonymously, without revealing the identity of participants or church name. Participants will be informed of the study’s findings by the research team. The direct benefit of this study to participants is the information they will obtain about their physical health and non-communicable disease risk.

# Data management

All data will be stored in password-protected files. The data will be available to the members of the research team only, and will be used for publication in peer-reviewed scientific journals and submitted for presentation at scientific conferences.

# Plans for dissemination

We will work with the Africa Centre’s community engagement and communications team we will draw up dissemination plans relevant to this study. As appropriate, we will provide information on the study at regular roadshows and a summary will be provided to all who request it and available on our website. We have also budgeted for an end of project meeting and small conference to inform all stakeholder and co-development workshop member of the outcomes and next steps.

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