ISRCTN11913581 https://doi.org/10.1186/ISRCTN11913581

A people-centred approach through Self-Management and Reciprocal learning for the prevention and management of Type 2 Diabetes

Submission date
16/12/2016

Recruitment status
No longer recruiting

Registration date
10/01/2017

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[X] Individual participant data

Plain English summary of protocol

Plain English summary as of 01/10/2018:
Background and study aims
Type 2 diabetes mellitus (T2DM) is a long-term condition where sufferers have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or the body's cells don't react to insulin as they should do (insulin resistance). Pre-diabetes is a condition where a person's blood sugar levels are higher than normal, but not high enough to be classified as T2DM. If left untreated, then pre-diabetes can turn into T2DM. T2DM and pre-diabetes are a growing problem worldwide, and healthcare systems in many countries are struggling to help patients effectively manage and control their conditions. This study is looking at a community component for helping prevent and manage T2DM. The aim of this study is to evaluate the added benefit of a community component for the prevention and management of type 2 diabetes in addition to standard care at health centres.

Who can participate?
Residents of participating communities aged between 30 and 75 years who have a high risk of diabetes or have pre-diabetes or T2DM.

What does the study involve?
Health centres and their catchment areas are randomly allocated to one of the two study groups. In the first group, participants receive standard facility-based care, which involves the usual care provided in each setting. Those in the second group receive a community component through a linked peer support system in addition to standard care. This involves the use of community health workers or community link teams where possible to link the facility and community components. In Uganda, because available diabetes care is not yet of the required standard, facility-based care is optimized to the level of the required standard of care, there is an additional study group, who receive the routine usual care that is currently available in Uganda. In Sweden, the peer support component will follow a peer mentoring format and consists of a care companion with whom the participant performs tasks to improve their skills to manage their diabetes or pre-diabetes by promoting a healthy diet and physical activity. At the start of the study and after 12 months, participants have blood tests in order to assess the blood

sugar control in each group. In addition, the costs and any negative effects of the programs are recorded.

What are the possible benefits and risks of participating?
Participating in this study will provide participants with the necessary skills to manage their diabetes or pre-diabetes through material and resources to help, understand and explore appropriate self-care strategies and lifestyle changes to control blood sugar or engage in the appropriate lifestyle activities. Through peer groups and healthy lifestyle buddies, they will get a forum to discuss difficult issues or challenges and support from others with similar experiences to find solutions that will work for them and their families. In addition, participants will also receive ongoing support from the health centres and the research team during the study period. There are very few risks involved with participating, although some participants may experience pain, swelling or bruising following blood sample collection.

Where is the study run from?
1. At 9 primary health centers in two rural districts of Iganga and Mayuge in Uganda
2. At 2 community health centers (CHCs) in the Khayelitsha township in Cape Town in the Western Cape, South Africa
3. At 2 urban districts within Stockholm municipality, Sweden

When is the study starting and how long is it expected to run for?
February 2017 to August 2018

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
1. Dr Meena Daivadanam (scientific)
2. Ms Linda Timm (public)
3. Dr Francis Kasujja (public)
4. Miss Kululwa Ndayi (public)
5. Professor David Guwatudde (scientific)

Previous plain English summary:
Background and study aims
Type 2 diabetes mellitus (T2DM) is a long-term condition where sufferers have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or the body's cells don't react to insulin as they should do (insulin resistance). Pre-diabetes is a condition where a person's blood sugar levels are higher than normal, but not high enough to be classified as T2DM. If left untreated, then pre-diabetes can turn into T2DM. T2DM and pre-diabetes are a growing problem worldwide, and healthcare systems in many countries are struggling to help patients effectively manage and control their conditions. This study is looking at a community component for helping prevent and manage T2DM. The aim of this study is to evaluate the added benefit of a community component for the prevention and management of type 2 diabetes in addition to standard care at health centres.

Who can participate?
Residents of participating communities aged between 30 and 75 years who have pre-diabetes or T2DM.

What does the study involve?
Health centres and their catchment areas are randomly allocated to one of two groups. In the

first group, participants receive minimal facility-based care, which involves the usual care provided in each setting. Those in the second group receive a community component through a linked peer support system in addition to standard care. This involves the use of community health workers or community link teams where possible to link the facility and community components. In Uganda, there is an additional study group, who receive the routine care that is currently available in Uganda. At the start of the study and after 12 months, participants have blood tests in order to assess the blood sugar control in each group. In addition, the costs and any negative effects of the programs are recorded.

What are the possible benefits and risks of participating?
Participating in this study will provide participants with the necessary skills to manage their diabetes or pre-diabetes through material and resources to help, understand and explore appropriate self-care strategies and lifestyle changes to control blood sugar or engage in the appropriate lifestyle activities. Through peer groups, they will get a forum to discuss difficult issues or challenges and support from others with similar experiences to find solutions that will work for them and their family. In addition, participants will also receive ongoing support from the health centres and the research team during the study period. There are very few risks involved with participating, although some participants may experience pain, swelling or bruising following blood sample collection.

Where is the study run from?
1. At 9 primary health centers in two rural districts of Iganga and Mayuge in Uganda
2. At 2 community health centers (CHCs) in the Khayelitsha township in Cape Town in the Western Cape, South Africa
3. At 2 urban districts within Stockholm municipality, Sweden

When is the study starting and how long is it expected to run for?
February 2017 to August 2018

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
1. Dr Meena Daivadanam (scientific)
2. Ms Linda Timm (public)
3. Dr Francis Kasujja (public)
4. Miss Kululwa Ndayi (public)
5. Professor David Guwatudde (scientific)

Study website
http://ki.se/en/phs/smart2d

Contact information

Type(s)
Scientific

Contact name
Dr Meena Daivadanam

Contact details

Widerströmska Huset
Plan 4, Tomtebodavägen 18a
Stockholm
Sweden
17177

Type(s)
Public

Contact name
Ms Linda Timm

Contact details
Widerströmska huset
Plan 4, Tomtebodavägen 18a
Stockholm
Sweden
17177

Type(s)
Public

Contact name
Dr Francis Kasujja

Contact details
Makerere University School of Public Health
Upper Mulago Hill Road
Kampala
Uganda
7072

Type(s)
Public

Contact name
Miss Kululwa Ndayi

Contact details
University of the Western Cape School of Public Health
Robert Sobukwe Road
Belville
South Africa
7535

Type(s)
Scientific

Contact name
Prof David Guwatudde

Contact details
Makerere University School of Public Health
New Mulago Hill Road
Kampala
Uganda
7072

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
643692

Study information

Scientific Title
Implementation of a contextualized self-management approach to prevent and manage type 2 diabetes

Acronym
SMART2D

Study objectives
Primary hypothesis:
Addition of a community component to existing and standardized facility care will lead to a reduction in blood glucose values as measured by HbA1c between baseline and after 12 months in individuals with type 2 diabetes or pre-diabetes.

Secondary hypothesis:
Addition of a community component to existing and standardized facility care will improve self-management outcomes related to self-care (such as medication and follow-up indicators) and lifestyle (such as healthy diet and increased physical activity) for type 2 diabetes and related to lifestyle for pre-diabetes between baseline and after 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approvals:
1. Higher Degrees, Research and Ethics Committee of Makerere University School of Public Health (426)
2. Uganda National Council for Science and Technology (HS 2118)
3. South Africa from the Biomedical Science Research Ethics Committee of the University of the Western Cape (BM/17/1/36)
4. Sweden from the Regional Ethical Board in Stockholm (2016/2521-31/1)

Previous information about ethics approval:
1. Higher Degrees,Research and Ethics Committee (HDREC) of Makerere University School of Public Health (Uganda)
2. Uganda National Council for Science and Technology (UNCST), 26/07/2016, ref: 426 (Uganda)
3. The Senate Research Committee of the University of the Western Cape, awaiting approval (South Africa)
4. Regional Ethical Board in Stockholm, awaiting approval (Sweden)

Study design
Study design as of 01/10/2018:
Pragmatic cluster randomized trial in South Africa, Uganda and Sweden. The Swedish component focuses on the feasibility of implementation.

Previous study design:
Pragmatic cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes and pre-diabetes

Interventions
Intervention as of 01/10/2018:
Health facilities and their catchment areas are designated as clusters. Clusters are randomized to either a facility-only intervention arm (defined as standard facility-based care, which is usually the routine care), or a facility + community intervention arm (standard facility-based care complemented by community components). Since routine care in Uganda is inadequate, they have a third comparison arm of routine care.

Control arm: Participants in the control arm receive standard facility-based care as represented by standardized routine facility care in each setting. This involves the:
1. Organization of care process to ensure the availability of functioning minimal infrastructure and equipment needed for diagnosis and treatment of type 2 diabetes and the use of appropriate diagnostic and treatment guidelines
2. Strengthening patient role in self-management through a behavioural coaching component

during baseline and follow-up visits, providing participants with an overview of their care process and their role and access to measuring devices to self-monitor weight, blood pressure or blood sugar as required.

Intervention arm: Participants will receive a community component through a linked peer support system in addition to the standard facility-based care. The community component includes:
1. Community mobilization through messages on lifestyle and diabetes for community member and key stakeholders
2. Strengthening support from the environment for diabetes prevention and management through a participant peer group programme and care companions or healthy lifestyle buddies and the promotion of a supportive physical environment
3. Use of community extension such as community health workers or community link teams where possible to link the facility and community components.

Standard care arm (Uganda only): Participants receive routine care as is currently available in the Ugandan setting.

The details of the site-specific adaptations of the intervention framework and its implementation are outlined in the SMART2D intervention protocol.

Data will be collected at baseline and end-line at months 0 and 12 respectively in all study arms in the three sites. Process and quality checks to track the progress and participation in the interventions will be carried out from months 1-11.

Previous intervention:
Health facilities and their catchment areas are designated as clusters. Clusters are randomized to either a facility-only intervention arm (defined as minimal facility-based standardized care, which is usually the routine care), or a facility + community intervention arm (minimal facility-based standardized care complemented by community components). Since routine care in Uganda is inadequate, they have a third comparison arm of routine care.

Control arm: Participants in the control arm receive minimal facility-based care as represented by standardized routine facility care in each setting. This involves the:
1. Organization of care process to ensure the availability of functioning minimal infrastructure and equipment needed for diagnosis and treatment of type 2 diabetes and the use of appropriate diagnostic and treatment guidelines
2. Strengthening patient role in self-management through a behavioural coaching component during baseline and follow-up visits, providing participants with an overview of their care process and their role and access to measuring devices to self-monitor weight, blood pressure or blood sugar as required.

Intervention arm: Participants will receive a community component through a linked peer support system in addition to the minimal facility-based standardized care. The community component includes:
1. Community mobilization through messages on lifestyle and diabetes for community member and key stakeholders
2. Strengthening support from the environment for diabetes prevention and management through a participant peer group programme and care companions or healthy lifestyle buddies and the promotion of a supportive physical environment
3. Use of community extension such as community health workers or community link teams where possible to link the facility and community components.

Standard care arm (Uganda only): Participants receive routine care as is currently available in the Ugandan setting.

The details of the site-specific adaptations of the intervention framework and its implementation are outlined in the SMART2D intervention protocol.

Data will be collected at baseline and end-line at months 0 and 12 respectively in all study arms in the three sites. Process and quality checks to track the progress and participation in the interventions will be carried out from months 1-11.

Intervention Type
Mixed

Primary outcome measure
Plasma glucose, as measured by HbA1c levels between baseline and 12 months

Secondary outcome measures
1. Incidence of diabetes as measured by HbA1c levels between baseline and 12 months
2. Incidence of conversion from pre-diabetes state to normal plasma glucose level state as measured by HbA1c levels between baseline and 12 months
3. Adverse events, including hospitalizations due to hypo- or hyperglycemia, morbidity, as measured by self-reported data using interview schedules at month 12
4. Incremental costs to the system related to implementation of the intervention as estimated through costing questionnaire for facility and community components between months 3-10
5. Out-of-pocket expenditure for diabetes – comparison between country sites and change in cost to the individual – through self-reported out-of-pocket expenditure using interview schedules at baseline and 12 months
6. Evaluation of the intervention process through Likert-scaled questionnaires, focusing on treatment satisfaction, knowledge about diabetes, autonomy support, self-efficacy, social support and sources of support, measured at baseline and 12 months
7. Differences between the country sites, in regard to baseline contextual factors relating to infrastructure, guidelines and personnel for prevention and management of diabetes as measured by facility checklist questionnaires between months 3-10
8. Degree of implementation of the intervention elements in each country, and differences between the country sites, through a process evaluation at each site using tracking forms, checklists and qualitative methods between months 2-11
9. Differences between the country sites, and changes within these contexts, as a result of implementing the intervention elements such as stigma towards overweight or obese individuals, security concerns in public spaces, and collaboration between primary care, municipalities and local networks through qualitative methods after 10 months
10. Assessment of the food environment in each site and comparison between the three country sites using a modified EPOCH (Environmental Profile of a Country's Health) questionnaire between months 6-10

Overall study start date
30/01/2017

Completion date
31/03/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 01/10/2018:
1. Currently residing in, and have resided in their respective communities for at least 6 months prior to enrolment
2. Aged between 30 – 75 years
3. Have no plans of migrating out of the study area over the next 12 months from the date of enrolment
4. Able to provide written informed consent
5. Agree to home visits and follow-up contacts as part of study participation
6. Have not been previously diagnosed with diabetes for longer than 12 months
7. Have a positive confirmatory test of pre-diabetes or diabetes

Previous inclusion criteria:
1. Current residents who have resided in their respective communities for at least 6 months prior to enrolment into the study
2. Aged 30 – 75 years
3. Able to provide written informed consent
4. Agree to allow home visits or follow-up contacts as part of participating in the trial
5. Have a positive confirmatory test of pre-diabetes or diabetes following screening or within past 12 months of trial start. In Sweden, this includes high risk of diabetes based on FINDRISC scores.

Previous inclusion criteria as of 16/10/2017:
1. Currently residing in, and have resided in their respective communities for at least 6 months prior to enrollment
2. Aged between 30 – 75 years
3. Have no plans of migrating out of the study area over the next 12 months from the date of enrollment
4. Able to provide written informed consent
5. Agree to home visits and follow-up contacts as part of study participation
6. Have not been previously diagnosed with diabetes for longer than 12 months
7. Have a positive confirmatory test of pre-diabetes or diabetes

Previous inclusion criteria:
1. Current residents who have resided in their respective communities for at least 6 months prior to enrollment into the study
2. Aged 30 – 75 years
3. Able to provide written informed consent
4. Agree to allow home visits or follow-up contacts as part of participating in the trial
5. Have a positive confirmatory test of pre-diabetes or diabetes following screening or within past 12 months of trial start

Participant type(s)
Mixed

Age group
Adult

Lower age limit

30 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
The total number of clusters across all three study sites will be 13, with 1,869 expected participants. Minimum numbers for each site are as follows: 1) South Africa: 2 clusters, 292 participants per arm (142 with pre-diabetes, 150 with diabetes); 2) Sweden: 2 clusters, 58 participants per arm (With high risk of diabetes or have pre-diabetes or diabetes) - total of at least 118 participants; and 3) 3) Uganda: 9 clusters, 265 participants per arm (124 with pre-diabetes, 141 with diabetes) - total of at least 795 participants. Sample size in Sweden has been modified due to the change in focus to feasibility of implementation.

Total final enrolment
712

Key exclusion criteria
Current exclusion criteria as of 16/10/2017:
1. Pregnancy
2. Serious mental disability

Previous exclusion criteria:
1. Currently known to be pregnant
2. Plans of migrating out of the study area over the next 12 months from the date of enrollment into the study
3. Previous diagnosis of diabetes, 12 months prior to enrollment into the study

Date of first enrolment
30/01/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
South Africa

Sweden

Uganda

Study participating centre
Karolinska Institutet
Widerströmska huset, Tomtebodavägen 18a

Stockholm
Sweden
17177

Study participating centre
Maker ere University School of Public Health
New Mulago Hill Road
Kampala
Uganda
7072

Study participating centre
University of the Western Cape School of Public Health
Robert Sobukwe Road
Cape Town
South Africa
7535

Sponsor information

Organisation
European Commission

Sponsor details
DG Research & Innovation
Brussels
Belgium
B-1049

Sponsor type
Government

Website
http://ec.europa.eu/research/index.cfm?lg=en

ROR
https://ror.org/00k4n6c32

Organisation
Swedish International Development Agency

Sponsor details
Valhallavägen 199
Stockholm
Sweden
115 53

Sponsor type
Government

Organisation
Karolinska Institutet Research Foundation Grants for young scientists

Sponsor details
Department of Public Health Sciences,
Karolinska Institutet
Widerströmska Huset, Floor 4
Tomtebodavägen 18A,
Stockholm
Sweden
171 77

Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 16/10/2017:
1. Site-specific papers on formative research leading up to the intervention development in various stages of drafting to submissions from June 2016
2. Cross site papers on SMART2D concept, trial protocol, intervention development and cross-lessons planned for 2017
3. Cross site papers on baseline data planned for 2018
4. Disseminated through peer-reviewed publications and through local and international scientific meetings.

Previous publication and dissemination plan:
1. Cross site papers on SMART2D concept, protocol, intervention development and cross-lessons planned for 2017
2. Site-specific papers on formative research leading up to the intervention development in various stages of drafting to submissions from June 2016
3. Cross site papers on baseline data planned for 2018

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/03/2018		Yes	No
Results article	results	24/03/2020	09/04/2020	Yes	No
Results article	Process evaluation	01/09/2022	27/09/2022	Yes	No
Dataset		02/05/2022	27/03/2023	No	No
Protocol (other)		02/05/2022	27/03/2023	No	No
Results article		02/05/2022	27/03/2023	Yes	No
Other publications		03/02/2020	05/02/2025	Yes	No
Other publications	Nested study	28/10/2021	05/02/2025	Yes	No