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Does social capital affect mental health, quality of life and disease control in diabetes patients from Côte d'Ivoire?

Submission date
29/04/2022

Recruitment status
No longer recruiting

Registration date
09/05/2022

Overall study status
Completed

Last Edited
11/01/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes mellitus (DM) and its severe complications contribute significantly to disability. Social capital is defined as the resources that individuals and groups access through their social connections. In low- and middle-income countries (LMICs) like Côte d'Ivoire, studies are generally lacking on social capital and diabetes. This study should allow us to know to what extent a diabetic who benefits, in addition to the usual diabetic care, from a family care partner has better mental and physical health and better well-being than a diabetic without a family partner.

Who can participate?
Participants in this study will be recruited from individuals of both sex, aged 18 years or older, living in the city of Abidjan (Côte d'Ivoire) and newly diagnosed with type 2 diabetes, for which initial care is provided by INSP

What does the study involve?
This is a single-center, interventional study. It assesses the benefit (or not) of adding a family member (as an intervention) to the usual care for diabetes patients at INSP. The nature of the intervention is social and family-based. That is a family caregiver from the patient's family will be designated to act as the patient's care partner. The effects of this intervention on the glucose level, mental health and well-being of the patients, will be checked over a one-year period from when the patient joins the study.

What are the possible benefits and risks of participating?
Your participation in this study will only provide you with the benefit of a reduced cost of blood glucose control. The results of the study may necessitate the adaptation of the usual diabetes care at INSP to include a compulsory support partner if they show significant improvements in diabetes control and quality of life in patients with diabetes or similar chronic disease condition.

Where is the study run from?
The study will be run at INSP which is an institution positioned centrally in the provision of diabetes care in Côte d'Ivoire. It is located in the capital city of Abidjan.

When is the study starting and how long is it expected to run for?
January 2020 to October 2024

Who is funding the study?
The project is funded by the Swiss TPH Directorate and INSP

Who is the main contact?
Prof. Dr. Nicole Probst-Hensch
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
HSR 2021-17

Study information

Scientific Title
The relationship of social capital with disease control, mental health and quality of life in diabetes patients from Côte d'Ivoire: the SoDDiCo randomized control trial

Acronym
SoDDiCo

Study objectives
Including a family member in the training for diabetes self-care does not improve the effectiveness of care provided to adult type 2 diabetes patients at INSP, for diabetes control, over the course of 12 months, irrespective of social capital and depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/07/2021, Ethikkommission Nordwest- und Zentralschweiz, Switzerland (Hebelstrasse 53, 4056 Basel, Switzerland; +41 061 268 1351; eknz@bs.ch), ref: AO_2021-00041
2. Approved 20/04/2022, National Ethics Committee for Sciences of Life and Health (CNESVS), Côte d'Ivoire (Institut Pasteur de Côte d'Ivoire, CHU de Cocody, BP 490 Abidjan 01, Ivory Coast; no telephone number provided; marilyne.koko@gmail.com), ref: 049-22/MSHPCMU/CNESVS-kp

Primary study design
Interventional

Study design
This study is a single-center interventional randomized controlled trial.
During a period of 1 year ((October 2022 to October 2023) we expect to recruit 1000 diabetes patients newly diagnosed and received for treatment at INSP into a randomized controlled trial. All diabetes patients newly diagnosed at INSP at the beginning of the trial will be invited to participate.
Patients will be randomized to two parallel arms (intervention and control arms) using blocked randomization in a gender-stratified manner.

The randomization sequence will be generated separately for each gender with a 1:1 allocation ratio using random block sizes of 10, 16, 20 and 24 on the Randomization Website (https://www.sealedenvelope.com/simple-randomiser/v1/lists). Generated sequences will be managed by an independent computer scientist uninvolved with clinic activities and trials at INSP.
The intervention allocation will be concealed until the completion of the eligible patient's first visit. And thus, before leaving the diabetic clinic, they will be allocated either to the intervention group or to the control.
This allocation will be done by using 2 separate stacks of 1009 consecutively ordered, opaque, colored and sealed envelopes. We will have one stack of blue envelopes for males and another one of red envelopes for females. Each envelope will have the order number on the outside and the corresponding randomization number on the inside.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improving glycemic control and quality of life in patients with type 2 diabetes (T2D)

Interventions
Patients will be randomized to two parallel arms (intervention and control arms) using blocked randomization in a gender-stratified manner.

1. Intervention arm: Addition of a social supporter to the routine care provided at INSP. The diabetes patients will nominate one family member as a social supporter to accompany them to all care and educational sessions as prescribed by the patient's treating physician at INSP

2. Control arm: Routine care provided at INSP

Participants are followed up for 12 months

Intervention Type
Behavioural

Primary outcome(s)
HbA1c measured using blood test 3 and 12 months

Key secondary outcome(s)
1. HbA1c at baseline, 3 and 12 months
2. Hypoglycemia event profile measured using patient (self-tests) and hospital records after 3 and 12 months
3. Quality of life measured using Depression, Anxiety and Stress Scale-21 (DASS-21) at baseline, 3 and 12 months
4. Mental health status (depression, anxiety and stress) measured using WHO Quality of Life (WHOQOL-BREF) Questionnaire at baseline, 3 and 12 months

Completion date
01/10/2024

Eligibility

Key inclusion criteria

1. Having a T2D diagnosed within the 3 months period prior INSP first visit
2. Receiving first prescription of antidiabetic drug from INSP
3. Aged 18 years or older and living in the city of Abidjan
4. Having no plan to move from home for the following 12 months
5. Living with family member or someone in the household
6. Access to a telephone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severely ill patients requiring hospitalization at first visit
2. Diagnoses of other illnesses not suitable with the study (cancer, severe psychiatric disease /dementia, asthma, spinal cord injury, congestive heart failure)
3. Pregnant or preparing for pregnancy (women only)
4. Unwilling to provide informed consent

Date of first enrolment
01/10/2022

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Côte d'Ivoire

Study participating centre
Institut National de Sante Publique
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
Directorate, Swiss Tropical and Public Health Institute, Switzerland

Funder Name
National Institute of Public Health, Côte d'Ivoire

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Nicole Probst-Hensch, nicole.probst@swisstph.ch and Franck Ekou, franck.ekou@swisstph.ch. These data will be shared with researchers who provide a methodologically sound proposal – and if needed an ethics approval for the project. To gain access, data requestors will need to sign a data-access agreement. Data will be made available directly to the person requesting the data.

Individual participant data that underlie the results reported in the article after deidentification (text, tables, figures, and appendices) will be shared and the study protocol and questionnaires. Data will be available beginning 15 months and ending 48 months after the publication of the article. The types of analyses shared will achieve the aims in the approved proposal at the level of individual data including meta-analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/01/2024	11/01/2024	Yes	No