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Improving Self-management of Diabetes in Persons Living with HIV

Submission date
19/03/2019

Recruitment status
No longer recruiting

Registration date
21/03/2019

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Persons living with HIV have an increased risk of developing diabetes which has been attributed to factors including advancing age, abnormal immune function, minority race/ethnicity, and the use of HIV medication. Concomitant self-management of HIV and diabetes can be difficult because of the complexity of these two different medical regimens, sometimes conflicting input from multiple health care providers, and overlapping treatment side effects and symptoms. This study aims to address the unique challenges of the dual diagnosis of HIV and diabetes. We will (1) adapt an evidence-based type 2 diabetes mellitus (T2DM) intervention (content and format) and study protocol based on a focus group of persons with HIV-T2DM and (2) test the feasibility of the HIV-T2DM intervention.

Who can participate?
Adults diagnosed with HIV+T2DM

What does the study involve?
The intervention is a small group intervention for a total of 6 hours of educational instructions, then six follow up phone calls. Data collection was done at baseline and after completion of the phone calls, estimated to be 4 months from baseline to follow up.

What are the possible benefits and risks of participating?
Participants in the feasibility may not receive direct benefit from participating in this study; however, the possible benefits of participation are helping to contribute to the understanding of self-management of diabetes for persons with HIV. They may improve health information on HIV and diabetes, as well as improve self-management skills. There are no foreseeable risks for participating in the educational sessions of the intervention. Participants will be providing a blood sample as part of data collection. There is a small risk that the patients would develop a hematoma at the blood draw site.

Where is the study run from?
The University of Texas at Austin

When is the study starting and how long is it expected to run for?
January 2015 to January 2016

Who is funding the study?
The University of Texas at Austin Office of Research Support and Compliance

Who is the main contact?
Julie Zuniga, jzuniga@nursing.utexas.edu

Contact information

Type(s)
Public

Contact name
Dr Julie Zuniga

ORCID ID
http://orcid.org/0000-0003-3778-8148

Contact details
1710 Red River
School of Nursing
Austin
United States of America
78712
+15124714696
jzuniga@nursing.utexas.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
100

Study information

Scientific Title
A Pilot Study to improve Self-management of Diabetes in Persons Living with HIV

Study objectives
A six hour group intervention will improve diabetes self-management in persons living with HIV

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2015, The University of Texas at Austin (Office of Research Support and Compliance, P.O. Box 7426, Austin, TX; 78713512-232-1543; irb@austin.utexas.edu), ref: 2015-05-0104

Study design
One group pre-post-test

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
HIV and diabetes

Interventions
The intervention provided 6 hours of educational sessions for groups of approximately six to eight participants followed by six follow-up telephone calls. The topics included pathophysiology of HIV and T2DM; medications; diet; depression; and relevant lab tests for HIV+T2DM. Each topic was introduced interactively using case studies, role-play, games, and group discussions. The intervention sessions concluded with an unfolding case study that contained information about all the topics covered. A registered nurse or licensed social worker led the groups and made six follow-up telephone calls to participants, in which they solicited participants' questions about each of the intervention topics and re-explained or reinforced the intervention content. Telephone calls lasted about 10 minutes each.

Intervention Type
Behavioural

Primary outcome measure
All measures were taken twice: baseline and 4 months.
1. Blood draws to measure HgA1c
2. Summary of Diabetes Self-Care Activities (SDSCA)
3. Diabetes Knowledge Test (DKT)
4. HIV Knowledge Questionnaire (HIV-KQ-18)

Secondary outcome measures
All measures were taken twice: baseline and 4 months.
1. Blood draws to measure CD4 count, and viral load.
2. NIH Toolbox Instrumental Support Survey
3. NIH Toolbox Neuro-QOL Depression
4. Adherence Visual Analog Scale
5. Drug and Alcohol Involvement Scale

Overall study start date
08/01/2015

Completion date
12/01/2016

Eligibility

Key inclusion criteria
1. Adult aged > 18 years
2. Diagnosed with HIV and diabetes for over 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Diagnosis of gestational diabetes

Date of first enrolment
10/01/2015

Date of final enrolment
06/01/2016

Locations

Countries of recruitment
United States of America

Study participating centre
The University of Texas at Austin
1710 Red River
Austin
United States of America
78712

Sponsor information

Organisation
The University of Texas at Austin

Sponsor details
1710 Red River
School of Nursing
Austin
United States of America
78712
5124714696
jzuniga@nursing.utexas.edu

Sponsor type
University/education

ROR
https://ror.org/00hj54h04

Funder(s)

Funder type
University/education

Funder Name
The Center for Transdisciplinary Collaborative Research in Self-Management Science, University of Austin, Texas

Results and Publications

Publication and dissemination plan
We will present at conferences then write a paper to be published in a high-impact peer-reviewed journal

Intention to publish date
15/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/11/2019	02/03/2022	Yes	No