

The POSEIDON trial: Promoting cOllaborative Support and Education in Diabetes for minOrity ethNic groups

Submission date

03/07/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

17/01/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/07/2018

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.newhamuniversityhospital.nhs.uk/poseidon>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SDO/111/2005

Study information

Scientific Title

The POSEIDON trial: Promoting cOllaborative Support and Education in Diabetes for minOrity ethNc groups

Acronym

POSEIDON

Study objectives

Informal story-sharing groups led by bilingual health advocates in the patient's own language will be no less effective than standard nurse led diabetes education through an interpreter, on clinical, biochemical and psychometric outcomes in minority ethnic groups with diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Research Ethics Committee (LREC) approval from East London and City on the 9th Nov 2005 (ref: LREC 05/Q0604/142).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Patient information can be found at: <http://www.newhamuniversityhospital.co.uk/poseidon/page1/assets/Patient%20Leaflet%202%20English.pdf>

Health condition(s) or problem(s) studied

Diabetes mellitus

Interventions

The intervention will have three components:

1. Professional development groups for Bilingual Health Advocates (BHAs) using a validated learning set model (in which stories about clients with diabetes form the basis of facilitated group discussion).
2. Story-sharing groups led by a BHA with support from a Diabetes Specialist Nurse (DSN). Stories about living with diabetes will form the basis of group discussions.
3. Organisational support for establishing these groups, including development and mainstreaming of patient pathways, data management, and information systems.

The comparison will be referral to traditional NHS education sessions (e.g. routine nurse led education groups in either primary or secondary care, or one to one education via General Practitioner [GP] or in hospital clinic) with an interpreter if needed.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

United Kingdom Prospective Diabetes Study (UKPDS-2) cardiovascular risk score (a composite of blood pressure, smoking status, lipid ratio, presence of atrial fibrillation, and HbA1c)

Secondary outcome measures

1. HbA1c
2. Well-being
3. Self-management skills
4. Diabetes-related actions
5. Cardiovascular events

Overall study start date

01/09/2006

Completion date

31/01/2007

Eligibility

Key inclusion criteria

1. 240 people with diabetes mellitus (either form) aged over 18
2. Referred (or self-referred) for diabetes education
3. Speak one of the languages in which story-sharing groups are offered that is, Urdu, Sylheti, Tamil, Somali, or English (for African-Caribbeans)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

240

Key exclusion criteria

1. Inability to give informed consent
2. Inability of unwillingness to do group work

Date of first enrolment

01/09/2006

Date of final enrolment

31/01/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

N19 5LW

Sponsor information**Organisation**

NHS Service Delivery and Organisation (NHS SDO) Programme (UK)

Sponsor details

London School of Hygiene & Tropical Medicine

99 Gower Street

London

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WC1E 6AZ

+44 (0)20 7612 7958

Phillip.Restarick@lshtm.ac.uk

Sponsor type

Government

Website

<http://www.sdo.lshtm.ac.uk/>

ROR

<https://ror.org/02wnqcb97>

Funder(s)

Funder type

Government

Funder Name

NHS Service Delivery and Organisation (NHS SDO) Programme (UK)

Results and Publications

Publication and dissemination plan

2009 results in http://www.net SCC.ac.uk/hsdr/files/project/SDO_FR_08-1504-111_V01.pdf

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/03/2005		Yes	No
Results article	results	01/01/2011		Yes	No