ISRCTN10291077 https://doi.org/10.1186/ISRCTN10291077

Self-Efficacy and Peer Support Enhance the Effectiveness of Disease Management in Diabetes Type 2 (SPEED)

Submission date
13/04/2010

Recruitment status
No longer recruiting

Registration date
17/11/2010

Overall study status
Completed

Last Edited
10/02/2016

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
Patient self-management and peer support are promising new approaches in diabetes care. This study will show whether peer support including occasional professional support can help people with type 2 diabetes improve their quality of life.

Who can participate?
A total of 77 GP surgeries and 1327 patients currently enrolled in the "Therapie aktiv" disease management programme in the province of Salzburg are invited to participate.

What does the study involve?
Participants will be randomly allocated into either the intervention group or the control group. Participants in the intervention group will take part in a peer support programme, which consists of regular group meetings of patients with type 2 diabetes run by trained peer supporters. They will exercise together, talk about medical, nutritional, personal, social and emotional issues regarding diabetes, and will receive occasional support from doctors, dieticians, diabetes nurses, clinical psychologists and physical education trainers. Those allocated to the control group will receive usual care within the disease management programme.

What are the possible benefits and risks of participating?
The possible benefits include higher quality of life, better control of blood pressure and weight loss.

Where is the study run from?
Paracelsus Medical University (Austria)

When is the study starting and how long is it expected to run for?
June 2010 to August 2013

Who is funding the study?
International Diabetes Federation (Belgium)

Who is the main contact?
Andreas Sönnichsen
Andreas.soennichsen@uni-wh.de

Study website
http://aktivtreff.com

Contact information

Type(s)
Scientific

Contact name
Prof Andreas Soennichsen

Contact details
Institute of General Practice and Family Medicine
University of Witten/Herdecke
Alfred-Herrhausen-Str. 50
Witten
Germany
58448

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LT09-261

Study information

Scientific Title
Effectiveness of a peer support program versus care as usual in disease management regarding improvement of metabolic control and diabetes management self-efficacy: a cluster-randomised controlled trial

Acronym
SPEED

Study objectives
As an additional component of disease management the peer support program Di-AKTIV improves metabolic control, patient self-management efficacy, risk profile and quality of life of patients with diabetes mellitus type 2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of the Province of Salzburg, Austria, 24/02/2010, ref: 415-E/1168/2-2010

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Diabetes mellitus type 2

Interventions
1. Intervention group:
Peer support group meetings and exercise modules (1h per week). Patients will be encouraged to further daily exercising. The aim is to achieve at least an exercise level of 1000 kcal/week. A handbook regarding the following topics will be given to the peer groups:
1.1. daily management and living with diabetes
1.2. basic understanding of diabetes and diabetes care
1.3. diabetic medication
1.4. nutrition and diabetes
1.5. physical exercise, specifically motivational problems that may lead to less exercising than recommended
1.6. cardiovascular risk management
1.7. diabetic foot care and prevention
1.8. prevention of diabetic complications
Peer groups will get professional guidance by nutritionists, doctors, sports instructors and psychologists twice a year by each

2. Control group:
Usual care within the Disease Management Programme "Therapie aktiv"

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 12/07/2013:
Decrease in HbA1c in the intervention group compared to controls, to be measured between 01/10/2010-31/07/2011 (baseline) and 01/10/2010-31/07/2013

Previous primary outcome measures:
Decrease in HbA1c in the intervention group compared to controls, to be measured between 01/10-31/12/2010 (baseline) and 01/10-31/12/2012 (end of intervention).

Secondary outcome measures
Current secondary outcome measures as of 12/07/2013:
1. Higher quality of life
2. Improved control of cardiovascular risk factors (hypertension, hyperlipidemia)
3. Lowering of global cardiovascular risk
4. Weight (body mass index [BMI]) reduction
5. Increased smoking cessation
The secondary outcomes will be measured between 01/10/2010-31/07/2011 (baseline) and 01/10/2010-31/07/2013 (end of intervention).

Previous secondary outcome measures:
1. Improved diabetes management self-efficacy
2. Higher quality of life
3. Improved control of cardiovascular risk factors (hypertension, hyperlipidemia)
4. Lowering of global cardiovascular risk
5. Weight (body mass index [BMI]) reduction
6. Increased smoking cessation
The secondary outcomes will be measured between 01/10-31/12/2010 (baseline) and 01/10-31/12/2012 (end of intervention).

Overall study start date
01/06/2010

Completion date
31/08/2013

Eligibility

Key inclusion criteria
1. Patients with diabetes mellitus type 2 (American Diabetes Association [ADA]/World Health Organization [WHO] criteria)
2. Currently enrolled in the disease management programme (DMP) called "Therapie aktiv"
3. Aged greater than 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Refusal or withdrawal of consent
2. Dementia or major psychiatric illness
3. Advanced neoplastic disease or other diseases with drastically reduced life expectancy

Date of first enrolment
01/06/2010

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
Austria

Germany

Study participating centre
University of Witten/Herdecke
Witten
Germany
58448

Sponsor information

Organisation
International Diabetes Federation (IDF) (Belgium)

Sponsor details
166 Chaussée de la Hulpe
Brussels
Belgium
1170
+32 (0)2 538 5511
info@idf.org

Sponsor type
Research organisation

Website
http://www.idf.org

ROR
https://ror.org/04t34tv83

Funder(s)

Funder type
Research organisation

Funder Name
International Diabetes Federation (IDF) (Belgium) - BRIDGES programme (grant ref: LT09-261)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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?
Results article	results	01/11/2016		Yes	No