

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

<b>Submission date</b> 13/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/02/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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?
<a href="#">Results article</a>	results	01/11/2016		Yes	No