

# Expert patients as a coach in a self-management program for newly diagnosed patients with diabetes type two: a randomised controlled trial

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| <b>Submission date</b><br>30/05/2007   | <b>Recruitment status</b><br>No longer recruiting              | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>30/05/2007 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                            |
| <b>Last Edited</b><br>06/08/2021       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan           |
|  |  | <input checked="" type="checkbox"/> Results                  |
|  |  | <input type="checkbox"/> Individual participant data         |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## **Secondary identifying numbers**

N/A

# **Study information**

## **Scientific Title**

Expert patients as a coach in a self-management program for newly diagnosed patients with diabetes type two: a randomised controlled trial

## **Acronym**

DIO

## **Study objectives**

1. Self-management coaching by an expert patient leads to more control and better quality of life in newly diagnosed patients with diabetes type two
2. Self-management coaching by an expert patient leads to better coping in newly diagnosed patients with diabetes type two
3. Self-management coaching by an expert patient leads to better quality of care in newly diagnosed patients with diabetes type two

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Not provided at time of registration

## **Study design**

Randomised, single blinded, active controlled, parallel group trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Not specified

## **Study type(s)**

Quality of life

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Diabetes Mellitus type 2

## **Interventions**

Self-management coaching by an expert patient:  
Patient-tailored information and counselling about diabetes and its consequences for functioning and lifestyle.

200 patients, included in the study within one year, will be randomised and stratified for sex. Patients in the experimental group (N = 100) are coached by an expert patient for three months. A self-management program is used with a focus on diet and physical activity. The coaching is given additional to the usual care by the general practitioner, dietician and diabetic nurse.

Before, three and six months after the intervention, all patients complete a questionnaire about quality of life, quality of care, self-efficacy, self-management behaviour and coping.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Self-efficacy.

**Secondary outcome measures**

1. Quality of life
2. Coping
3. Self-management behaviour
4. Quality of care

**Overall study start date**

15/09/2007

**Completion date**

01/04/2009

**Eligibility****Key inclusion criteria**

1. Patients with diabetes type two
2. Good understanding of Dutch language

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

200

**Total final enrolment**

133

**Key exclusion criteria**

1. Impaired cognitive function
2. Belonging to minority group for which separate intervention is needed (Turkish, Moroccan, etc.)

**Date of first enrolment**

15/09/2007

**Date of final enrolment**

01/04/2009

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Centre Utrecht (UMCU)

Utrecht

Netherlands

3508 TA

**Sponsor information****Organisation**

University Medical Centre Utrecht (UMCU) (The Netherlands)

**Sponsor details**

Julius Centre

Nursing Sciences

P.O. Box 85500

Utrecht

Netherlands

3508 GA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.juliuscentrum.nl/julius/>

**ROR**

<https://ror.org/04pp8hn57>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Diabetes Research Fund (The Netherlands)

# 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> |         | 01/10/2012   | 06/08/2021 | Yes            | No              |