Intermittent rehabilitation in the therapy of type 2 diabetes

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/08/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/12/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
06/01/2021	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 05008

Study information

Scientific Title

Intermittent rehabilitation in the therapy of type 2 diabetes

Study objectives

An intermittent rehabilitation consisting of 3 weeks in-patient treatment, a follow up week after 6 months and frequent telephone calls leads to higher efficacy than standard rehabilitation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Applied to the ethics committee of the Medical School Hanover, awaiting approval as of 10/08/06.

Study design

Randomised controlled trial with one intervention and one control group.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type two diabetes

Interventions

The intervention for both groups consists of a 3-week in-patient treatment. The goal is to improve diabetes specific knowledge and skills like balanced diet, physical exercise, foot care etc. Additionally the intervention group receives a follow-up week after 6 months to refresh the knowledge and gets expert advice every 6 weeks on the phone. This intensive care has the aim to remind and motivate the patients.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Metabolic parameter HbA1c

Key secondary outcome(s))

- 1. Cardiovascular Risk-Score PROCAM
- 2. Body Mass Index (BMI)
- 3. Diabetes related quality of life and coping skills
- 4. Satisfaction with therapy
- 5. Diabetes related costs

The data will be collected in the beginning, after the rehabilitation and one year later.

Completion date

30/09/2009

Eligibility

Key inclusion criteria

- 1. Covered by Deutsche Rentenversicherung (social pension fund)
- 2. Type 2 diabetes
- 3. Employable

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

420

Key exclusion criteria

- 1. Inadequate knowledge of the German language
- 2. Inadequate writing and literacy
- 3. Phone calls are impossible
- 4. Follow-up is impossible
- 5. Serious secondary disease
- 6. Not employable in the next 12 months

Date of first enrolment

01/10/2006

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Germany

Study participating centre Hochstrasse 13-19

Bad Neuenahr Germany 53474

Sponsor information

Organisation

Refonet (Germany)

ROR

https://ror.org/04yeh2x21

Funder(s)

Funder type

Industry

Funder Name

Refonet - Rehabilitations-Forschungsnetzwerk der Deutschen Rentenversicherung Rheinland (No. 05008) (Germany)

Results and Publications

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	01/06/2009	06/01/2021	Yes	No