Intermittent rehabilitation in the therapy of type 2 diabetes

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

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

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 measure 1. Metabolic parameter HbA1c

Secondary outcome measures

- 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.

Overall study start date 01/10/2006

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

Age group Adult

Sex Both

Target number of participants 420 patients

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)

Sponsor details Burgweg 3 Bad Neuenahr Germany 53474 +49 (0)2641 90620 service@refonet.de

Sponsor type

Industry

Website http://www.refonet.de

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

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	
Results article	

Details Date created results 01/06/2009

06/01/2021 Yes

Peer reviewed?

Date added

Patient-facing?

No