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Intermittent rehabilitation in the therapy of type 2 diabetes

Submission date	Recruitment status
10/08/2006	No longer recruiting
Registration date	**Overall study status**
04/12/2006	Completed
Last Edited	**Condition category**
06/01/2021	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009	06/01/2021	Yes	No