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Trial of lifestyle intervention by group care in the management of type 2 diabetes (ROMEO Trial)

Submission date
28/01/2009

Recruitment status
No longer recruiting

Registration date
10/02/2009

Overall study status
Completed

Last Edited
26/08/2014

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] 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
N/A

Study information

Scientific Title
ROMEO: Rethink Organisation to iMprove Education and Outcomes. A randomised controlled multi-centre trial of lifestyle intervention by group care in the management of type 2 diabetes

Acronym
ROMEO

Study objectives
Scarcity of resources, expertise and evidence-based models have so far limited delivery of patient-centred therapeutic education in clinical routine. We have developed and validated a Group Care approach that is applicable to everyday practice and cost-effective in improving metabolic control, knowledge of diabetes, health behaviours and quality of life in type 2 diabetes. A clinical trial (Rethink Organisation to iMprove Education and Outcomes [ROMEO]) was planned to evaluate the applicability and reproducibility of Group Care in other centres and in a larger patient population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Molinette san Giovanni Battista University Hospital and Maria Adelaide Hospital, Torino (Comitato Etico Interaziendale AOU San Giovanni Battista di Torino e AO CTO Maria Adelaide di Torino), approved on 27/01/2009 (ref: 0006703).

Study design
Randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Type 2 diabetes

Interventions
Participants were randomly allocated to the following two groups:

Intervention group: Group Care, consisting of a clinical approach in which diabetes care is routinely delivered as group sessions built upon a systemic education programme whereas individual care is dedicated to emerging clinical problems, yearly checks for complications or patients' explicit requests. Each group session lasted on average 50 min.

Control group: Traditional one-to-one visits delivered by the same physicians/ nurses/ dieticians/ educators involved in Group Care. Each control individual visit lasted on average 15 min.

Visits took place every 3 months for 4 years. Total duration of follow-up: 4 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Clinical outcomes
1.1.Glycated haemoglobin, measured every 3 months for 4 years
1.2. Low-density lipoprotein (LDL) cholesterol, assessed yearly for 4 years
1.3. Systolic and diastolic blood pressure, measured every 3 months for 4 years
2. Cognitive and psychological outcomes
2.1. Quality of life, assessed yearly for 4 years
2.2. Knowledge of diabetes, assessed every 2 years for 4 years
2.3. Health behaviours, assessed yearly for 4 years

Secondary outcome measures
1. Cardiovascular events, followed up for 4 years
2. Cost-effectiveness analysis at 4 years

Overall study start date
09/05/2000

Completion date
14/07/2007

Eligibility

Key inclusion criteria
1. Outpatients with non insulin-treated type 2 diabetes millitus (T2DM) of at least 1 year known duration
2. Both males and females, aged <80
3. Normally followed in a diabetes centre

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
532

Key exclusion criteria
1. New diagnosis of diabetes
2. Age <40 or >80
3. Insulin treatment
4. Established psychiatric problems
5. Presence of terminal illness

Date of first enrolment
09/05/2000

Date of final enrolment
14/07/2007

Locations

Countries of recruitment
Italy

Study participating centre
Laboratory of Clinical Pedagogy
Torino
Italy
I-10126

Sponsor information

Organisation
University of Turin (Italy)

Sponsor details
c/o Prof Massimo Porta
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Sponsor type
University/education

Website
http://www.unito.it

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Industry

Funder Name
European Foundation for the Study of Diabetes/Juvenile Diabetes Research Foundation (EFSD /JDRF)/Novo Nordisk Type 2 Diabetes Research Grant (Denmark)

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?
Protocol article	protocol in:	01/06/2004		Yes	No
Results article	results	01/04/2010		Yes	No
Results article	results	01/09/2014		Yes	No