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Randomised controlled trial to evaluate a behavioural educational strategy for adults with cystic fibrosis (Phase II)

Submission date	Recruitment status
12/09/2003	No longer recruiting
Registration date	**Overall study status**
12/09/2003	Completed
Last Edited	**Condition category**
09/09/2009	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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0542102367

Study information

Scientific Title

Study objectives
To see if adults with cystic fibrosis (CF), completing a home based nutrition education programme, will have an improved nutritional status, an improvement in nutrition knowledge and self efficacy regarding their ability to cope with a special diet, compared with those receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
Pilot study of 20 patients, randomly assigned to behavioural the intervention group or control. Patients randomised to the intervention group will be given a behavioural nutrition education programme, which is completed at home. It consists of 10, weekly structured sessions which cover the major nutrition topics, ie energy and fat, enzymes, malabsorption, vitamins and minerals and snacks. Intervention group patients will also attend four group workshops, to prompt interest and motivation. Control group patients will receive standard dietetic advice, from a single dietitian. All patients will be seen at the routine CF clinics at 3-monthly intervals, for 12 months. Outcome measures at 3, 6, 9 and 12 months: Nutritional status (Body Mass Index [BMI]), pulmonary status (forced expiratory volume in one second [FEV1]), general and specific Nutrition Knowledge questionnaires, dietary intake questionnaires, health related quality of life (HRQoL).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Weight gain

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/02/2003

Completion date
01/01/2006

Eligibility

Key inclusion criteria
20 adults with cystic fibrosis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
19/02/2003

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dietitians Department
Cambridge
United Kingdom
CB3 8RE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Papworth Hospital NHS Trust (UK) - NHS R&D Support Funding + Papworth Hospital Charitable Funds

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	01/05/2008		Yes	No