

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

Submission date

12/09/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

09/09/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ 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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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

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(s)

Weight gain

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2006

Eligibility

Key inclusion criteria

20 adults with cystic fibrosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Dietitians Department

Cambridge

United Kingdom

CB3 8RE

Sponsor information

Organisation

Department of Health (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

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