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A community based randomised controlled trial of a low calorie/low fat diet with a low glycaemic load diet in pre-diabetes mellitus: a feasibility study (The ISAIAH Project)

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
13/04/2010

Condition category
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

Protocol serial number
N0071154003

Study information

Scientific Title

Acronym
ISAIAH

Study objectives
Over a six month period people identified with pre-diabetes who are given intensive education, encouragement, support and exercise advice will lose more weight and take more exercise than those who are given brief advice and an information sheet only.

Over a six month period people with pre-diabetes who adopt a low glycaemic load diet will lose more weight and show greater improvements in blood sugar, insulin and cholesterol levels than those adopting a low fat/low calorie diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield Local Research Ethics Committee approved of this trial prior to participant recruitment.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes

Interventions
This is a two-phase pragmatic single centre, community based, un-blinded randomised controlled feasibility trial. It will compare two 'diet, exercise and motivation' programs with each other and with a 'brief advice' control group. All subjects will all have been identified as having pre-diabetes mellitus.

Phase two of the study starts after six months. Subjects randomised to the two Intensive Courses will finish their programs and will then simply be observed for a further six months. At the six month point the control group subjects will be randomised to one or other of the two diet /motivation courses. They are therefore a control group for six months and a wait-for-randomisation group until the second six months. In this way they too will have the benefits of the education, motivation and exercise programme. It is an 'all win' scenario.

The principal research question is whether over time encouraging subjects to adopt a low glycaemic load diet will have a significantly better effect on biophysical and biochemical features of pre-diabetes than either a low calorie/low fat diet or brief advice and provision of a leaflet.

Note: A low glycaemic load diet is one where blood sugar changes after the meal are minimised by making particular choices on the amount and type of carbohydrate in the meal

Definitions:
A subject is considered to have pre-diabetes mellitus if he or she has impaired fasting glucose and/or impaired glucose tolerance. The definitions of these are as follows:
Impaired fasting glucose: fasting blood glucose 6.1 - 7.0 mmol/l
Impaired glucose tolerance - two hour post load glucose 7.8 - 11.1 mmol/l
Levels falling higher than these ranges are diagnostic of diabetes. Levels below both ranges are normal.

The biophysical markers are weight, body mass index (BMI) (kg/m^2), abdominal girth and body fat percentage.

The biochemical markers are fasting and post load glucose levels, fasting insulin and insulin /glucose ratio, total cholesterol, high and low density lipoprotein cholesterol and serum triglyceride levels.

Identification of subjects:
Doctors and practice nurses at The Nethergreen Surgery will identify subjects as having pre-diabetes mellitus.

Enrolment:
Those who are eligible for enrolment and who give fully informed consent will be randomised to one of the two diets or to the control group.

Consent:
Consent to enrolment and randomisation will be obtained by the research nurse in a face to face meeting at which the subject will have ample and unrestricted opportunity to ask questions and discuss the trial. No coercion or inducement will be offered to subjects.

Randomisation:
A member of the Institute of General Practice Medical Statistics Department will perform Randomisation. Pre-prepared closed randomisation envelopes will be used. The only stratification will be to equalise the male/female numbers in each group.

Co-ordination:
The research nurse will co-ordinate the running of the programme including attendance for evening meetings and for collection of biochemical and biophysical data.

Statistical analysis:
Statistical analysis will be performed by Professor Campbell and will look at an analysis of variance between the groups as well as a narrative presentation of qualitative data.

Probity:
The trial proposal is being submitted to the Ethics committee for inspection and approval

Patient safety:
Patient safety is paramount. To achieve this care will be taken in applying the inclusion and exclusion criteria for the trial. No special foods or supplements are used in this trial nor are any drugs or medication being used as part of the trial. The trial does not require exposure of

subjects to any form of ionising radiation. Subjects may leave the trial at any stage without prejudice.

Planned Analysis:
Baseline demographic data will be presented with appropriate statistical analysis of difference between the two groups (analysis of variance). Changes in biophysical and biochemical variables will be presented as comparisons over the duration of the trial within groups. Differences in these variables will be compared between the groups. The analysis will also be on an 'intention to treat' basis. A full analysis will be performed after the conclusion of the trial. An interim analysis will be performed at the six month stage.

How will this feasibility study contribute to the design of a subsequent larger trial?
1. Subject numbers: One of the principal aims of the pilot study is to enable the medical statistician to calculate how many subjects would need to be recruited for the subsequent trial. It is anticipated that trends will be revealed by this pilot study which will allow a calculation of sample size for the main trial.
2. Duration of evening meetings: The pragmatic question 'what will work in practice?' is a core principal of the ISAIAH project. A questionnaire will be used to collect this data.
3. Content of evening meetings: An outline of the framework for the evening meetings is reproduced below. The usefulness and acceptability of our arrangement will be surveyed using the questionnaire, which is in preparation.
4. Number of evening meetings: Are six sessions too few or two many? Data analysis will help determine this using biochemical and biophysical endpoints. However the experience and opinion of the subjects using a questionnaire will also be useful. 'Duration, Content and Meeting Number' information will be used in planning the precise intervention to be used in the cluster randomised trial.
5. Appropriateness and utility of written support materials: Opinion will be sought on the usefulness of the books and carb/calorie counters given out during the course using a questionnaire. This will enable choices to be supported or revised for the main trial.
6. Subjective experience of waist and hip measurement: There is anecdotal evidence that overweight people might find measuring girth slightly distasteful. This will be enquired about sensitively. This data and an analysis of its utility in predicting or tracking change will be used to decide whether to include as a required biophysical item in the main trial.
7. Is a 2-hour post-load blood glucose level measurement necessary?. Is it an end point measurement that is useful? Is any use it may have outweighed by the inherent nuisance value it poses to subjects and trial staff alike? This will be answered by the questionnaire and by analysing and collating results from the biochemical and biophysical data analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Quantitative data:
Biochemical parameters will be measured at baseline, at the end of the 12 month trial and at predetermined times in between. The biochemical variables to be measured are fasting blood sugar, fasting blood insulin, fasting insulin/glucose ratio and fasting lipid profile. Samples will be collected at baseline and at four, twelve, twenty-four weeks and at seven, nine and twelve months.

Biophysical parameters will be measured at baseline, at the end of the 12 month trial and at predetermined times in between. The biophysical parameters are weight, height, body mass index (BMI), waist and hip circumference, hip/waist circumference ratio and body fat percentage measured by electrical impedance.

Qualitative data:
Subjective comment and observation will be solicited from both the trial staff and the trial subjects. This will be presented in a narrative fashion.

Narrative data will be collected from a questionnaire. The questionnaire is in preparation presently. Narrative data is being collected principally to inform the ISAIAH team about the subject's experiences of being on the programme with a view to refining the protocol of the anticipated subsequent large cluster randomised trial. Questionnaires will be collected, but not looked at, by the evening meeting team. They will be regarded as confidential and will be forwarded to Dr Barclay assessment and for analysis at the end of the trial. The qualitative data will address several areas of interest:
1. The conduct, content and arrangements of the evening meeting programme
2. The educational content of the programme
3. Experience with measures of 'adherence' (diet and exercise diaries)
4. Controls experience of waiting to begin the programme
5. 'Other' comments: Every questionnaire will have a section left available for observations and comments by the subjects. These will be collected and surveyed to inform the team as part of the planning for the next trial.

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/11/2005

Eligibility

Key inclusion criteria
Forty consecutive patients identified with pre-diabetes at 'The Nethergreen Surgery', Sheffield, will be given verbal and written information about the proposed study by the NHS practice nurse or GP who initially gives the diagnosis of pre-diabetes to the patient.

Those who consent and enrol into the study will be randomised to one of two groups, the study group and the control group. These two groups will be further randomised to one diet of the other. The Study groups will commence their programme at week one. The Controls will wait to enter the programme until week 26 when they cease to be controls for the study group and become a study group themselves. The whole study finishes after 52 weeks

Power calculations have not been performed for this study as it is a feasibility project. It is anticipated that the results of this study will be used to calculate power for a larger subsequent study.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Participants known to be related or living under the same roof of a subject already recruited; the first subject seen and consented will be allowed to proceed with the trial. Second and subsequent subjects will be ineligible to avoid being randomised to the contrary group and contaminating the trial protocol.
2. Use of medication: patients on oral costicosteroids, oral or injected contraceptives, oral or transdermal hormone replacement therapy (HRT) products or other medications that may interfere with gastrointestinal function, glucose/insulin or lipid metabolism
3. Alcohol and drug abuse: absolute exclusions
4. Medical conditions: conditions which can affect weight, fat or glucose metabolism. These include diabetes mellitus, unstable thyroid disease, malignancy disease, malabsorptive syndromes, known cholelithiasis, hepatic and renal disease.
5. Pregnancy and lactation: absolute exclusions
6. Psychiatric conditions: absolute exclusions

Date of first enrolment
18/08/2004

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Nethergreen Surgery
Sheffield
United Kingdom
S11 7EJ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

Funder Name
Sheffield Health and Social Research Consortium (UK)

Funder Name
NHS R&D Support Funding (UK)

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	01/08/2008		Yes	No