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Oral nutritional supplements and dietary advice versus dietary advice alone on clinical outcomes in malnourished community dwelling individuals

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
05/10/2012

Overall study status
Completed

Last Edited
20/02/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sometimes the effect of disease means people become malnourished (under-nutrition) and this affects 5% of the UK population, with the majority of people affected living in the community. Malnutrition has adverse consequences including poorer clinical outcomes. Effective management can improve nutritional status and outcomes. UK guidelines recommend that individuals are screened to detect malnutrition and where risk is identified, action is taken to tackle this. Commonly used nutrition strategies for malnourished people who can eat and drink include dietary advice (modifications to the diet to increase nutrient intake) and oral nutritional supplements (nutrient-enriched drinks). There is a lack of evidence to support oral nutrition support strategies for people living in their own homes in the community. The aim of this study is to determine which of these two methods (dietary advice, or advice with oral nutritional supplements) is most effective in individuals identified as being at risk of malnutrition in the community.

Who can participate?
Men and women aged over 50 with disease-related malnutrition.

What does the study involve?
After giving consent to take part in the study, the participants will be randomly allocated to a nutritional treatment. They will receive either nutritional drinks and a simple diet information leaflet or just receive the simple diet information leaflet for a period of 3 months. After this the treatment will then stop but they will be followed up by the researchers for a further 3 months. They will be involved in the research for a total of 6 months (with an optional follow-up at 12 months). Each participant will see the researcher five times over the 6-month period, with additional phone contact between visits. Each visit will last about 30 minutes. The researcher will visit them in their own home.

What are the possible benefits and risks of participating?
The nutritional treatments used in this study may help to improve the participants' nutritional status and help them to feel better. The study will help health professionals decide the best

type of nutritional treatment to use in people with malnutrition living in the community in the future. The treatments used are nutritional treatments (not medicines) that are already widely used in clinical practice for people with poor nutrition and are very unlikely to cause side effects. These treatments are not associated with any risk or disadvantage to health.

Where is the study run from?
Southampton General Hospital (UK).

When is the study starting and how long is it expected to run for?
The study started in October 2012 and will finish in October 2015.

Who is funding the study?
Nutricia Ltd (UK).

Who is the main contact?
Dr Abbie Cawood
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Contact information

Type(s)
Scientific

Contact name
Dr Abbie Cawood

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13116

Study information

Scientific Title
A randomised trial of oral nutritional supplements and dietary advice versus dietary advice alone on clinical outcomes in malnourished community dwelling individuals

Study objectives
This randomised trial will investigate the efficacy of oral nutritional supplements and dietary advice (information on food fortification, snacks, food choice) as first-line treatments for disease-related malnutrition in non-institutionalised free living older people.

This trial in free living older people, aims to investigate whether oral nutritional supplements and dietary advice as a first line treatment for malnutrition are more clinically and cost effective than giving dietary advice alone.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13116

On 31/10/2014 the overall trial end date was changed from 15/10/2015 to 01/09/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Southampton A, First MREC approval date: 10/09/2012, ref: 12 /SC/0423

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Malnutrition in the elderly

Interventions
1. Dietary Advice: Dietary Advice written information
2. Oral Nutritional Supplements + Dietary Advice

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of Life (QOL) at baseline (BL), wk 4,8,12, 6 months and optional 12 months

Secondary outcome measures
1. Acceptability and complicance at BL, weeks 4, 8, 12
2. Clinical / Functional at BL, weeks 4, 8, 12, 6 months and optional 12 months
3. Intake at BL, weeks 4,8,12, 6 months and optional 12 months
4. Resource Use at BL, weeks 4, 8, 12, 6 months, optional 12 months
5. Weight at BL, weeks 4, 8, 12, 6 months and optional 12 months

Overall study start date
15/10/2012

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Male or female
2. Age > 50 years
3. Disease-related malnutrition using Malnutrition Universal Screening Tool (MUST)
4. Malnutrition caused by disease/clinical condition
5. Competent to provide written informed consent and able to answer questions
6. Able to eat and drink
7. Willingness to take part in the trial and to follow the trial protocol

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. Galactosemia or known lactose intolerance
2. Currently receiving (or likely to receive in next 12 weeks) nutritional support including dietary advice, oral nutritional supplements, tube or parenteral nutrition

3. Chronic renal disease requiring dialysis
4. Dysphagia
5. Poorly controlled diabetes
6. Liver failure
7. Cancer
8. Palliative / end of life care
9. Active malignancy / active cancer treatment / palliative care
10. Malnutrition as a result of social factors e.g. unable to purchase food
11. Currently residing in an institution to receive care e.g. care home
12. Participation in other clinical trials

Date of first enrolment
14/12/2012

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
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Sponsor type
University/education

ROR

https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Nutricia Ltd (UK) - educational grant

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?
Abstract results	results presented at ESPEN :	01/09/2017		No	No
Abstract results	results presented at ESPEN :	01/09/2017		No	No
Abstract results	results presented at ESPEN :	01/04/2018		No	No
Abstract results	results presented at ESPEN :	01/09/2018		No	No