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The Eat Well, Feel Well, Stay Well feasibility study

Submission date
31/08/2017

Recruitment status
No longer recruiting

Registration date
25/09/2017

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Other

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

Plain English summary of protocol
Background and study aims
About 13% of older people living at home are at risk of malnutrition. This may be because they are not getting enough to eat, or because they are not eating enough of the right food. A programme has been developed to help doctors and nurses in general practice to check if older adults who live at home are at risk of malnutrition. They can then offer support to those who need it. This is called 'Eat well, feel well, stay well', includes MUST (the Malnutrition Universal Screening Tool), booklets and other materials for older adults, and a support tool for health professionals. The support tool includes guidance about when to see patients and when to use oral nutritional supplements. MUST was developed by experts at BAPEN http://www.bapen.org.uk/. The rest of the intervention was developed by experts who looked at previous literature to find what helps or hinders older adults eating well, and what is likely to work best in general practice. The intervention was improved after feedback from people aged over 65 years, patients and healthcare professionals. This study aims to assess the feasibility and acceptability of the intervention by comparing two versions of the intervention. One is a brief intervention with MUST screening, patient booklets and follow-up; the other is a stepped care intervention. This means that patients will have the brief intervention plus oral nutritional supplements (ONS) for short spells when they are unwell. a group of patients who have the usual care that is provided by their doctors' surgery are also followed to assess outcomes including change in eating patterns, weight and quality of life. The results of the feasibility study will help us to design a full trial.

Who can participate?
Adults aged 65 and older who have one more major medical or social problems.

What does the study involve?
Practices are randomly allocated to one of three groups. Those in the first group receive the nurse care where they attend a screening appointment to check their health and calculate their MUST score. Participants are offered booklets with lifestyle advice and have a follow up phone call to see how things are going. They are invited to have more appointments and answer a questionnaire after six months. Those in the second group receive the nurse case and are also prescribed oral nutritional supplements. Those in the last group receive the standard care. Participants are followed up at six to nine months.

What are the possible benefits and risks of participating?
For participants who struggle to gain weight, taking part in the study may be beneficial. There are no anticipated risks with participation.

Where is the study run from?
This study is being run by the University of Southampton (UK) and takes place in practices in the UK.

When is the study starting and how long is it expected to run for?
January 2017 to October 2019

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Jackie Seely, J.Seely@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35533

Study information

Scientific Title

Screen and TREAt for Malnutrition (STREAM) Programme Workstream 1: Feasibility study

Acronym
STREAM

Study objectives
The aim of this study is to assess the feasibility of an intervention in primary care to encourage the use of malnutrition screen and treat (MST) policies for older people living in their own homes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 14/08/2017, ref: 224100

Study design
Randomised; Interventional; Design type: Treatment, Screening, Education or Self-Management, Dietary, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
This is a cluster randomised study. The practices are randomised to one of three study arms:
1. Nurse Care- Participants attend a screening appointment where Grip strength and Timed Up and Go Test (TUGT) are tested. Participants are screened using Malnutrition Universal Screening Tool (MUST). Participants with a MUST score of 1-4 are assessed for underlying problems using a nutritional assessment proforma. They are offered printed booklets addressing their needs, a brief phone follow-up, and brief face-to-face appointments with a practice nurse at intervals, depending on their MUST score. Participants may be referred to a dietitian for further assessment, depending on their MUST score, health and eating status.

2. Nurse Care with stepped approach to prescribing oral nutritional supplements. Participants have their nurse care intervention (as above) and are also be prescribed ONS if needed, initially in short courses during intercurrent illness, and longer courses as necessary.

3. Usual care: Participants continue to have the normal existing medical support provided by their GP surgery.

The total duration of screening and treatment for patients will be 6 months. A nested qualitative study will follow, at six to nine months, with a patients and healthcare professionals who opt to do this.

Intervention Type
Other

Primary outcome measure
Health outcomes are measured using SF36 physical outcome at baseline and six months.

Secondary outcome measures
1. Weight/Height/Weight loss is measured at baseline (for intervention groups) and six month (for all groups)
2. Current/recent acute illness/Vitamin/supplement are measured using questionnaires at baseline and six months
3. Appetite is measured using SNAQ appetite questionnaire at baseline and six months
4. Health status is measured using EQ5D5L at baseline and six months
5. Food Frequency is measured using the food frequency questionnaire at baseline and six months
6. Psychological measures (e.g. self-efficacy, outcome expectancy, perceptions of supporter, self-regulation) are measured using questionnaire at baseline and six months
7. Episodes of infection are measured using note review post six month follow up
8. Grip strength - which is a useful marker of malnutrition, and the prognosis of malnutrition is measured using a Jamar Hydraulic Hand Dynamometer at baseline (for intervention groups) and six months (all groups)
9. NHS resource usage (consultations, new conditions identified, or new drugs prescribed, antibiotic use, hospital admissions, care home admissions) and mortality is measured using note reviews post at six month follow up
10. Dietary markers are measured using urine and or blood samples at baseline and six months (optional)

Overall study start date
01/01/2017

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Be aged ≥65 years
2. Have one or more of these major medical or social problem(s) increasing nutritional risk: COPD, cerebrovascular disease, cardiac failure, CKD (stage IIIb/IV/V), chronic liver disease, Crohn’s disease, hospital discharge in previous 2-3 months, Parkinson’s disease, current depression, living alone

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria
1. Terminal disease
2. Ongoing primary treatment for cancer
3. Diabetes
4. Established dementia
5. Using oral nutritional supplements (ONS)
6. Established nutritional support
7. Unable to consent

Date of first enrolment
01/10/2017

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury Medical Practice
Fisherton House
Fountain Way
Wiltshire
Salisbury
United Kingdom
SP2 7FD

Study participating centre
Cowplain Family Practice
26-30 London Road

Cowplain
United Kingdom
PO8 8DL

Sponsor information

Organisation
University of Southampton

Sponsor details
Research Integrity and Governance Manager
Building 37, Room 4079
University Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 18/01/2022:
Planned publication of qualitative data from the feasibility study in a peer reviewed journal. The data has been presented at relevant conferences. Findings and a progress report were made available to the NIHR programme grants committee.

Previous publication and dissemination plan:
Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

Anonymised data will be released upon a suitable request for the proposed use of the data. Contact Prof Paul Little, p.little@soton.ac.uk or Prof Mike Stroud, M.A.Stroud@soton.ac.uk. In the unlikely event that we decline to release the data we propose that the funder would arbitrate the decision. The detail of what we release we will be guided by ethics.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	04/08/2017	26/10/2017	No	Yes
Other unpublished results			18/01/2022	No	No
Protocol file	version 6	14/11/2018	18/08/2022	No	No
Other publications	Qualitative study	11/11/2021	11/10/2023	Yes	No