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Eat well, feel well, stay well (the STREAM Trial)

Submission date
02/09/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Ongoing

Last Edited
29/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
About 10-15% of people over the age of 65 living at home are at risk of malnutrition. In particular poor appetite is an important risk factor for malnutrition and for weight loss, and a risk factor for the development of infections, hospital admissions and even longer-term mortality. This may be because they are not getting enough to eat, or because they are not eating enough of the right food.
We have developed an approach ('intervention') 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. Our intervention, called 'Eat well, feel well, stay well', includes booklets and other materials for older adults, and support for health professionals. The support for health professionals includes guidance about when to see patients, and for those more severely at risk when to use oral nutritional supplements. 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. In the study, we aim to assess the effectiveness of the intervention.

Who can participate?
Patients aged 75 or older who are either living alone or have one or more major medical or social problem(s) known to increase nutritional risk.

What does the study involve?
All patients get a brief intervention with patient booklets and follow-up, but individuals who are at much greater risk will have the brief intervention plus oral nutritional supplements (ONS) for short spells when they are unwell. For comparison we will follow a group of patients who have the usual care that is provided by their doctors' surgery. We will assess outcomes including the number of infections people get, change in eating patterns, weight and quality of life. We will also compare patients and health professionals' experiences of being in these different groups.

What are the possible benefits and risks of participating?
Possible benefits are helping to reduce any worries about eating patterns and helping participants to eat well even when appetite is low. We tested the study tasks with 350 participants in the STREAM Feasibility study, so are confident that there are no risks in taking part.

Where is the study run from?
The University of Southampton, UK

When is the study starting and how long is it expected to run for?
October 2019 to October 2025

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

Who is the main contact?
Miss Natalie Thompson (STREAM Programme Manager)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263245

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42564, IRAS 263245

Study information

Scientific Title
Eat well, feel well, stay well: the Screen and TREAt for Malnutrition (STREAM) trial

Acronym
STREAM

Study objectives
Screening for and treating people at risk of malnutrition improves quality of life and/or the number and duration of infections

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/08/2019, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ; +44 207 104 8009; nrescommittee.northwest-gmeast@nhs.net), ref: 19/NW/0415 IRAS project ID: 263245

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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 people aged 75 years or older

Interventions
Current interventions as of 08/01/2024 to 30/01/2020:
We aim to recruit approximately 7200 participants by a predominantly postal questionnaire from 250 general practices in order to identify at 1153 patients at nutritional risk. This will include those with a BMI <25 and with either a SNAQ score of ≤13 or who report losing 5 kg of weight unintentionally identified in the baseline questionnaire.

Screening and Baseline Measures:
1. General practices will do a database search and mail out to eligible patients.
2. Interested patients will send back a reply slip to the research team in either Southampton, Warwick or Oxford.
3. The research team as above will send interested patients a consent form and baseline questionnaire. Participants return these in Freepost envelopes.
4. Practices randomised to intervention or usual care group. Practices and patients are informed of what group they have been randomised to.
5. Participants that have consented to do a urine collection (three samples, self-collected in the mornings over a 10 day period) and blood spots are sent the kits. These are posted back to the lab on completion.
6. Those patients randomised to intervention practice who are at nutritional risk are invited by their practice for baseline appointment with practice nurse/HCA. Those from a practice in the usual care group do not attend a baseline appointment.
7. At the baseline appointment, the participant will be weighed and have their height measured (as part of MST screening) and will have a grip strength test and will do a Timed Up and Go Test (TUGT). They will be given the main booklet and goal booklet and will be offered printed booklets addressing their needs, a brief phone follow-up, and brief face-to-face appointments with a practice nurse at intervals. Those scoring above two could also be offered Oral Nutritional Supplements (ONS) for 2 weeks also ill or losing weight.
8. Participants in the usual care group will continue to have the normal existing medical support provided by their GP surgery. Usual care practices will be provided with a link to the online version of NICE guideline 32, 'Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition'.

Follow-up measures:
All participants at nutritional risk will:
1. Receive follow up postal questionnaires at 6, 12 and 18 months.
2. Attend a face to face appointment with practice nurse - weight, height, grip strength test, and TUGT.
3. Complete optional urine and blood tests.

A sample of participants "not at nutritional risk":
Will be sent the follow-up questionnaires at 18 months. This group will also be asked to provide urine and blood (optional) for testing at baseline and 18 months. This group will be a random sample of 325 usual care and 325 intervention participants that are not identified as at nutritional risk from the baseline questionnaire.

Notes reviews:
The participants' medical records will be reviewed to assess: demographic information; medical problem(s), increasing nutritional risk; frailty; health service use. These will be completed once the participant has completed the follow-up.

Qualitative data collection:
16-20 participants and 12-20 health care professionals will be interviewed during the study.

Previous interventions as of 30/01/2020:
We aim to recruit approximately 7400 participants by a predominantly postal questionnaire from 110 general practices in order to identify at 1100 patients at nutritional risk. This will include those with a BMI <25 and with either a SNAQ score of ≤13 or who report losing 5 kg of weight unintentionally identified in the baseline questionnaire.

Screening and Baseline Measures:
1. General practices will do a database search and mail out to eligible patients.
2. Interested patients will send back a reply slip to the research team in either Southampton, Warwick or Oxford.
3. The research team as above will send interested patients a consent form and baseline questionnaire. Participants return these in Freepost envelopes.
4. Practices randomised to intervention or usual care group. Practices and patients are informed of what group they have been randomised to.
5. Participants that have consented to do a urine collection (three samples, self-collected in the mornings over a 10 day period) and blood spots are sent the kits. These are posted back to the lab on completion.
6. Those patients randomised to intervention practice who are at nutritional risk are invited by their practice for baseline appointment with practice nurse/HCA. Those from a practice in the usual care group do not attend a baseline appointment.
7. At the baseline appointment, the participant will be weighed and have their height measured (as part of MST screening) and will have a grip strength test and will do a Timed Up and Go Test (TUGT). They will be given the main booklet and goal booklet and will be offered printed booklets addressing their needs, a brief phone follow-up, and brief face-to-face appointments with a practice nurse at intervals. Those scoring above two could also be offered Oral Nutritional Supplements (ONS) for 2 weeks also ill or losing weight.
8. Participants in the usual care group will continue to have the normal existing medical support provided by their GP surgery. Usual care practices will be provided with a link to the online version of NICE guideline 32, 'Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition'.

Follow-up measures:
All participants at nutritional risk will:
1. Receive follow up postal questionnaires at 6, 12 and 18 months.
2. Attend a face to face appointment with practice nurse - weight, height, grip strength test, and TUGT.
3. Complete optional urine and blood tests.

A sample of participants "not at nutritional risk":
Will be sent the follow-up questionnaires at 18 months. This group will also be asked to provide urine and blood (optional) for testing at baseline and 18 months. This group will be a random sample of 225 usual care and 225 intervention participants that are not identified as at nutritional risk from the baseline questionnaire.

Notes reviews:
The participants' medical records will be reviewed to assess: demographic information; medical problem(s), increasing nutritional risk; frailty; health service use. These will be completed once the participant has completed the follow-up.

Qualitative data collection:
16-20 participants and 12-20 health care professionals will be interviewed during the study.

Previous interventions:
We aim to recruit approximately 7400 participants by predominantly postal questionnaire from 110 general practices in order to identify at 1100 patients at nutritional risk i.e. with a SNAQ score of 14 or less or who report losing 5kg of weight unintentionally; with BMI <25 (all based on responses in baseline questionnaire).
Screening and Baseline Measures:
- General practices will do a database search and mail out to eligible patients.
- Interested patients will send back a reply slip to the research team in either Southampton, Warwick or Oxford.
- The research team as above will send interested patients a consent from and baseline questionnaire. Participants return these in Freepost envelopes.
- Practices randomised to intervention or usual care group. Practices and patients are informed of what group randomised to.
- Participants that have consented to do a urine collection (three morning samples self-collected over 10 days, and blood spots are sent the kit. These are posted back to the lab on completion.
- Those patients randomised to intervention practice who are at nutritional risk are invited by their practice for baseline appointment with practice nurse/HCA. Those from a practice in the usual care group do not attend a baseline appointment.
- At the baseline appointment, the participant will be weighed and have height measured (as part of MST screening) and will have a grip strength test and will do a Timed up and go test (TUGT). Those scoring 1-4 in the MUST will be given the main booklet and goal booklet. These same participants will be offered printed booklets addressing their needs, a brief phone follow-up, and brief face-to-face appointments with a practice nurse at intervals. Those scoring above two could also be offered Oral Nutritional Supplements (ONS) for 2 weeks also ill or losing weight.
- Participants in the usual care group will continue to have the normal existing medical support provided by their GP surgery. Usual Care
practices will be provided with a link to the online version of NICE guideline 32, 'Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition'.

Follow Up Measures:
All participants at nutritional risk will:
- Receive follow up postal questionnaires at 6, 12 and 18mths.
- Attend a face to face appointment with practice nurse - weight, height, grip strength test and TUGT.
- Complete optional urine and bloods.

Sample of "not at nutritional risk":
A random sample of 225 usual care and 225 intervention pts that are not identified as at nutritional risk from the baseline questionnaire will be sent the 18 month follow up questionnaires. This group will also be asked to provide baseline and 18mth urine and bloods (optional).

Notes reviews:
The participants' medical records will be reviewed to assess: demographic information; medical problem(s), increasing nutritional risk; Frailty; Health service use. These will be completed once the participant has completed follow up.

Qualitative data collection:
16-20 participants and 12-20 health care professionals will be interviewed during the study.

Intervention Type
Other

Primary outcome measure
1.Quality of Life using the SF-36
2. Infections - proportion experiencing an infection during the follow-up period

Secondary outcome measures
1. Timed up and go test – baseline (for intervention pts) and 18 months all pts
2. Grip strength using a handgrip dynamometer (3 measurements from both hands)- baseline (for intervention pts) and 18 months all pts

Baseline and 18 months for:
3. Current actual and/or estimated height and weight for BMI calculation,
4. Weight change (eg. Looser or tighter clothing/rings/belts)
5. Current / recent acute illness
6. Falls
7. Number of regular medications
8. SNAQ appetite questionnaire
9. Food frequency questionnaire
10. Geriatric Depression Scale (GDS4)
11. Wellbeing – WEMWBS
12. Psychological measures, informed by the logic model from the development phase of the study (self-efficacy, risk awareness, outcome expectancy)
13. Frailty (EFI) score
14. Optional urine samples and optional blood spot samples –the samples will be analysed to structurally annotate biomarkers of nutrient intake and frailty risk
15. Demographic questionnaire, including: Health service use and drugs, including taking ONS (prescribed or over the counter over the last year), taking multivitamins, details about recent hospitalisation, current drugs

Overall study start date
01/02/2019

Completion date
30/10/2025

Eligibility

Key inclusion criteria
1. Patients aged > = 75 who are either living alone or have one or more major medical or social problem(s) known to increase nutritional risk. These are:
1.1 Chronic Obstructive Pulmonary Disease (COPD)
1.2 Cerebrovascular disease, including stroke
1.3 Cardiac failure
1.4 Chronic Kidney Disease (stage IIIb/IV/V)
1.5 Chronic gastrointestinal problems or chronic liver disease, including inflammatory bowel diseases and constipation (but excluding functional conditions e.g. IBS)
1.6 Recent hospital discharge in the last 3 months
1.7 Parkinson's disease; current depression (in the last 12 months)
1.8 Excessive polypharmacy (10 or more medications)
2. A proportion of participants (n=1110) will be identified as being at high risk of malnutrition, based on their questionnaire answers (with a SNAQ score of less than 14 or who report losing at least 5Kg of weight in the previous 6 months, and whose estimated BMI is less than < 25), and in the intervention group only these individuals will be invited to screening and assessment
3. English needs to be good enough to understand the study materials, as funding for the trial does not allow for translation.

Participant type(s)
Patient

Age group
Adult

Lower age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 1,153; UK Sample Size: 1,153

Key exclusion criteria
1. Used ONS in the last 6 months
2. Terminal disease
3. Ongoing primary treatment for cancer
4. Diabetes
5. Established dementia (this group would be substantially different mandating involvement of the carers, and different outcomes)
6. Receiving established nutritional support
7. Unable to consent
8. Institutionalised patients

Date of first enrolment
01/10/2019

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care, Population Sciences and Medical Education, University of Southampton
Aldermoor Health Centre
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SO16 5ST

Study participating centre
Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences
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Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0614-20004

Results and Publications

Publication and dissemination plan
We intend to publish the results of the trial and economic analysis

Intention to publish date
30/10/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1	30/01/2020	30/01/2020	No	No
HRA research summary			26/07/2023	No	No

Protocol file	version 10	18/07/2023	29/01/2025	No		No