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The Southampton Mealtime Assistance Roll-out Trial (SMART) V1

Submission date
28/10/2014

Recruitment status
No longer recruiting

Registration date
30/12/2014

Overall study status
Completed

Last Edited
18/02/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Malnutrition is a common problem in older hospital patients. In 2011, a national survey found that 28% of patients over the age of 65 admitted to hospital were at risk of malnutrition. Malnutrition is known to be associated with increased problems in hospital (such as pressure ulcers and infections), slower recovery from illnesses and longer hospital stays. Nutrition is an important part of a patient's treatment during their stay in hospital. We know from research here in the UK (and internationally) that nursing staff sometimes feel they are not able to offer as much help as they would like to for older patients at mealtimes. The Southampton Mealtime Assistance Study (SMAS) took place in our hospital in 2011 and looked at introducing volunteers trained as mealtime assistants to help older patients during mealtimes. These volunteers worked on one ward in the Medicine for Older People department. The study showed that introducing volunteers led to an improvement in the mealtime care of the patients they helped. Patients, staff and relatives all appreciated the help from the volunteers. Following on from this study, the Southampton Mealtime Assistance Roll-out Trial (SMART) is looking at whether it is feasible and acceptable to introduce volunteer mealtime assistants in five different departments of the hospital. The whole study will be happening in Southampton General Hospital. The five different departments will be Medicine for Older People, the Acute Medical Unit, Adult Medicine, Trauma and Orthopaedics and General Surgery. We will be looking at whether we can recruit, train and maintain the number of volunteers required to assist patients in these departments. We will be assessing whether staff and patients find the volunteers helpful, and the volunteers' experience of their role. We will assess the food choices and dietary intake of patients both before and after the introduction of the volunteers. We will compare the hospital departments to identify similarities and differences.

Who can participate?
Participants aged 70 or older in each hospital department in order to be able to compare the patients between departments.

What does the study involve?
Each participant goes through an assessment which takes about an hour. It involves some general questions about their home circumstances and lifestyle, followed by some questionnaires about appetite, memory, mood and physical activity. The participant is then

asked to walk a short distance (4 metres) and the strength of their grip is measured. The composition of their body, that is how much of the body is muscle, water or fat, is measured using a machine and sticky electrodes placed on their hands and feet. Following this assessment, each participant is asked to wear an activity monitor, similar to a wristwatch, for up to 48 hours. 5-10 participants per department are asked to take part in a short interview (around half an hour) to discuss their views and experiences of nutrition, hospital food and volunteer mealtime assistants. Additionally, 5-10 relatives of patients who are unable to consent are asked to take part in a similar interview in each department. Volunteers and staff are also invited to take part in focus groups to discuss their views and experiences of mealtimes in hospital and volunteer mealtime assistants.

What are the possible benefits and risks of participating?
The benefit of being involved in this study is that by performing a detailed assessment, information about each participants health and body composition will be made available that would not be part of your usual care. This information will help in deciding whether there is any benefit to mealtime assistance and then make recommendations to improve future patient care. There are no risks associated with being involved in this study.

Where is the study run from?
Southampton University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2014 to December 2015

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

Who is the main contact?
Dr Fiona Rossiter
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Contact information

Type(s)
Scientific

Contact name
Dr Helen Roberts

Contact details
University Geriatric Medicine
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SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02229019

Secondary identifying numbers
17531, MED1203

Study information

Scientific Title
The Southampton Mealtime Assistance Roll-out Trial (SMART)

Acronym
SMART

Study objectives
The principal question of the study is to establish whether it is feasible and acceptable to introduce trained volunteers to act as mealtime assistants across five different departments of a large hospital trust. The secondary aims of the study are to assess changes in food choice and dietary intake in patients in different departments before and after the introduction of volunteers and to assess the costs associated with the introduction of the volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/1363; First MREC approval date 31/07/2014

Study design
Non-randomised; Observational; Design type: Cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Ageing; Subtopic: Ageing; Disease: All Ageing

Interventions
Trained volunteers offer mealtime assistance on weekdays on intervention wards in five departments of one acute hospital

Intervention Type
Not Specified

Primary outcome measure
Feasibility and acceptability of involving trained volunteers; Timepoint(s): end of study

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/08/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Inpatients aged 70 years and over admitted to study wards
Target Gender: Male & Female ; Lower Age Limit 70 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Patients who have active bowel pathology
2. Patients who have undergone bowel surgery during their admission
3. Patients whose primary reason for admission is related to bowel pathology
4. Patients who are being artificially fed (either enterally or parenterally)
5. Patients in the terminal phase of illness

Date of first enrolment
22/08/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Geriatric Medicine
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Resarch and Development Office
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	15/02/2019		Yes	No
HRA research summary			26/07/2023	No	No