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

| Recruitment status No longer recruiting | Prospectively registered | | |
|---|---|--|--|
| | ☐ Protocol | | |
| Overall study status Completed | Statistical analysis plan | | |
| | [X] Results | | |
| Condition category | [] Individual participant data | | |
| | No longer recruiting Overall study status Completed | | |

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 f.rossiter@soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Helen Roberts

Contact details

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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 |