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Swallow screening in care homes (SSinCH)

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
12/02/2020

Overall study status
Completed

Last Edited
19/07/2021

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
A problem swallowing (dysphagia) is relatively common in older people and a major source of referrals to Speech and Language Therapy (SLT) services. Such problems can be very distressing and become more common with common age-related conditions, such as stroke and Parkinson's disease. Unsurprisingly, such problems are particularly common in care home residents, resulting in high numbers of referrals, and in many cases attendances at emergency departments. However, data suggest that many problems could be dealt with by care home staff without the need for specialist input. The aim of this study is to evaluate the effectiveness of a new dysphagia screening tool, designed for use by staff in nursing homes, to identify those who do not need referrals to specialist SLT services and those who do.

Who can participate?
New nursing admissions in participating care homes

What does the study involve?
Participating homes identify staff (nurses or CHAPs (Care Home Advanced Practitioner)) who are trained by the research SLT in carrying out the NDAT assessments. Consenting participants have the NDAT assessment carried out by the trained nurse or CHAP within the first week of admission to the home. The NDAT is an observational tool and does not require any other than normal contact between the nurse or CHAP and the participant. The NDAT is completed by using knowledge of the participant's condition, direct observation as to how they are eating and drinking during normal meal-times and snacks, and reports by other carers and family members. This would form part of the admission process and does not require any participation from the participant. The research SLT is informed that there is a new participant and aims to visit the home to carry out a full SLT assessment as soon as is feasible after the NDAT is completed, and at least within 2 weeks. The SLT assessment requires a face-to-face meeting between the SLT and the participant which lasts no longer than half an hour. During this time there is a physical examination of the mouth and throat areas, if possible, and the participant is observed eating and drinking.

What are the possible benefits and risks of participating?
The possible benefit of participating is that a previously undiagnosed swallowing problem could be identified and appropriately managed. The risk of participating is that they will have one observational swallow assessment completed and one clinical swallowing assessment which may

be unnecessary, therefore the burden could be inconvenience for the participant and use of their time.

Where is the study run from?
Northumbria Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2018 to July 2021

Who is funding the study?
Nestle Healthcare Nutrition Gmbh

Who is the main contact?
Mrs Patricia Heaney
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Contact information

Type(s)
Scientific

Contact name
Mrs Patricia Heaney

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
238191

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 37798, IRAS 238191

Study information

Scientific Title
Dysphagia screening in nursing homes: validation of a novel screening tool

Acronym
SSinCH

Study objectives
Introduction: A problem swallowing (dysphagia) is relatively common in older people, and a major source of referrals to Speech and Language Therapy (SLT) services. Such problems can be very distressing and become more common with common age-related conditions, such as stroke and Parkinson's disease. Unsurprisingly, such problems are particularly common in care home residents, resulting in high numbers of referrals, and in many cases attendances at emergency departments. However, data suggest that many problems could be dealt with by care home staff without the need for specialist input.

Aims: The aim of this study is to evaluate the effectiveness of a new dysphagia screening tool designed for use in nursing homes by staff. The researchers' theory is that the tool can efficiently identify those who do not need referrals to specialist SLT services and those who do. In the long term they envisage that the tool can and improve outcome both for those with low-level dysphagia and those with more severe problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/08/2018, North East - Newcastle & North Tyneside 1 Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; Tel: +44 (0)207 1048 088; Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), REC ref: 18/NE/0105

Study design
Non-randomised; Interventional; Design type: Screening, Management of Care

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Screening

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
Dysphagia

Interventions
This is a validation study. The study will assess the ability of the NDAT screening assessment to identify dysphagia correctly compared to current best practice. The overall objective is to assess the usefulness of the screening tool by determining the ability to detect high-risk dysphagia (sensitivity) and absence of disease (specificity). It is anticipated that a sensitivity of 90% and specificity of 80% will be obtained.

Participants will be recruited from participating nursing homes within North Tyneside local government areas. The researchers will approach managers of nursing homes in the catchment and those that agree to participate will be included in the study. North Tyneside has a census population of around 200,000 people, with a slightly older demographic profile than the UK as a whole and includes 14 care homes. Prior to recruitment of clients, participating homes will be asked to identify staff (nurses or CHAPs (Care Home Advanced Practitioner)) who will be trained by the research SLT in carrying out the NDAT assessments. All new nursing home admissions during the study period will be approached for inclusion in the study, although they will only be included if consent to participate is given.

Consenting participants will have the NDAT assessment carried out by the trained nurse or CHAP within the first week of admission to the home. The NDAT is an observational tool and does not require any other than normal contact between the nurse or CHAP and the participant. The NDAT is completed by using knowledge of the participant's condition, direct observation as to how they are eating and drinking during normal meal-times and snacks, and reports by other carers and family members. This would form part of the admission process and does not require any participation from the participant.

The research SLT will be informed that there is a new participant and will aim to visit the home to carry out a full SLT assessment as soon as is feasible after the NDAT is completed, and at least within 2 weeks. The SLT assessment requires a face to face meeting between the SLT and the participant which will last no longer than half an hour. During this time there will be a physical examination of the mouth and throat areas, if possible, and the participant will be observed eating and drinking.

Intervention Type
Other

Primary outcome measure
The validity of the NDAT as a means of identifying those in need of specialist assessment by SLT services: specificity and sensitivity are used as standard summary measures of criterion validity with area under the receiver operating characteristic (AUROC) curve used as an overall measure of criterion validity. Measured at a single timepoint.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
07/08/2018

Completion date
30/07/2021

Eligibility

Key inclusion criteria
1. All new nursing admissions in participating care homes
2. Consent given from the care home resident to be included in the study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 182; UK Sample Size: 182

Key exclusion criteria
1. individuals who have PEG (percutaneous endoscopic gastrostomy) feeding and are NBM (Nil By Mouth) due to severe dysphagia
2. Individuals who arrive at the home with SLT dysphagia care plans already in place

Date of first enrolment
04/02/2019

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
c/o Caroline Potts
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Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
Nestle Healthcare Nutrition Gmbh

Results and Publications

Publication and dissemination plan
1. Protocol and participant information sheets are available from the study contact if required
2. Peer-reviewed scientific journals
3. Internal report
4. Conference presentation

Intention to publish date
30/07/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No