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Chin tuck against resistance with feedback: swallowing rehabilitation in frail older people admitted to hospital with pneumonia. A feasibility randomised controlled study of two types of rehabilitation exercise using chin tuck against resistance to improve swallowing, eating and drinking

Submission date 20/01/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/02/2020	**Overall study status** Completed	
Last Edited 23/06/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Pneumonia is a common reason why older people are admitted to hospital. The cause is frequently blamed on the entry of infected saliva into the lungs. As they get older, some people develop weakness of their muscles, including those involved in swallowing. Research evidence shows that the ability to eat and drink (swallow) safely may be affected. For many this may only result in then eating and drinking slower than when they were younger. These muscles help to stop food and drink going down 'the wrong way'. This is done by pulling the voice box up and forward helping to close the airway. At the same time the valve between the throat and gullet opens up to allow food through. When you are well, the weakness of the muscles involved in swallowing may not cause much in the way of problems but over time the weakness in these muscles may get worse, particularly when you are unwell. This may result in eating and drinking may become more difficult, with small amounts of food and/or saliva entering the lungs and may be associated with the development of a chest infection (often called pneumonia). Whilst you are unwell a speech and language therapist may recommend that your diet is changed. This may mean eating softer food and drinking thicker drinks. Often, little else is offered to assist your ability to swallow to improve. Research has shown that by exercising the muscles involved in swallowing, people are more likely to be eating more and to be eating a normal diet.

Who can participate?

Frail older people (usually >75 years of age) admitted to hospital with pneumonia

What does the study involve?
All people taking part will be assessed by a speech and language therapist. Two-thirds of the group will be allocated to a set of exercises using a device called the ExerPhager. This, essentially, is an American football with a pressure device. The pressure device is linked via blue-tooth to a mobile phone or tablet. The group allocated to the exercise programme will be divided into two groups. One group undertakes the exercises daily, the other group, twice a day. This will continue for three months. People will be contacted monthly for an assessment. Each person will be followed up for a further three months. At the final assessment, some people will be asked about their experience in the study.

What are the possible benefits and risks of participating?
Benefits for taking part include testing the feasibility of the protocol and use of the ExerPhager. Participants will be taking part in a study to develop a device that has the potential to assist in the rehabilitation of some one's ability to swallow. This in turn will improve the type and amount of food eaten. The aim is to improve nutrition, hence improve immunity and reduce admission to hospital.

Where is the study run from?
Queen Elizabeth Hospital, Lewisham and Greenwich NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2018 to May 2023 (updated 07/06/2021, previously: April 2022)

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
273240

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44366, IRAS 273240

Study information

Scientific Title
Chin tuck against resistance with feedback: swallowing rehabilitation in frail older people admitted to hospital with pneumonia. A feasibility randomised controlled study of two types of rehabilitation exercise using chin tuck against resistance to improve swallowing, eating and drinking

Acronym
CTAR-SwiFt

Study objectives
Many older people are admitted to hospital with a chest infection. This is frequently attributed to aspiration (entry of food, liquid or saliva into the airway. Aspiration is may be associated with swallowing problems. When admitted to hospital people may be denied food and water for a period of time and also lose muscle strength. Research has suggested that if older people

undergo a period of rehabilitation for their swallow, there are more likely to eat more, swallow safely and less likely to be readmitted to hospital. Many exercises have been suggested to improve swallowing including those that strengthen neck muscles and the ability to protect the airway reducing aspiration. These exercises can be difficult to do, when old and frail and lack consistency of effort. We propose to undertake a randomised study to see whether neck exercises associated with visual feedback via a tablet/ mobile phone in a structured exercise programme can improve the ability to swallow and eat in frail older adults. We have developed a ball with a pressure sensor that links to a mobile phone or tablet. This will set the level of exercise and provide visual feedback to encourage consistency of effort. The tablet/phone will also record how often the exercises are undertaken compared to what is expected. The exercises will continue for 12 weeks. People will be followed up monthly if in the exercise arms or 3 monthly if in the group that doe snot get the exercises. Follow up will continue for a further 12 weeks.
This is a feasibility study to see whether such a research study is able to recruit people, whether the device works and is usable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2020, North West – Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester M1 3DZ. UK; +44 (0)207 104 8012; Rachel.katzenellenbogen@nhs.net), ref: 20/NW/0009

Study design
Randomised; Interventional; Design type: Treatment, Device, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Swallowing problems in frail older people

Interventions
People will be recruited when they are medically safe to be so, from Acute Frailty wards/Units at Queen Elizabeth Hospital and Southmead Hospital. When they agree to take part, consent will be sought. Following consent all people will have their general condition assessed and their ability to swallow using a series of standard assessments. The study will be seeking 60 participants, 30 from each hospital site. 10 will act as controls and receive the usual follow-up and 20 on each site will be divided between undertaking a series of chin tuck exercises for several minutes either once or twice a day. Allocation to the three groups will be done randomly by the clinical trials unit (King's College) via the telephone.

The exercise involves tucking one's chin into a ball tucked under the neck. The ExerPhager ball can measure pressure exerted on it and communicate with a mobile app. Each participant will be shown what to do by a member of the research team. The exercise will be standardised using an app on a mobile phone or tablet. To set this up, participants will exert maximum pressure on the ball. The app will set the amount of effort needed to 30% and a green light appears when this

has been reached during the exercises. The app will also record whether someone is undertaking the exercises at the right time, rather than just before review. The participants will be expected to undertake the exercises daily for 12 weeks, followed by a further 12 weeks follow-up. For those in the exercise arms, they will be reviewed monthly. At 12 weeks/3 months the exercises will stop and participants will be reviewed for a further 3 months to assess whether any improvement has remained. Those in the control group will be reviewed at baseline, 12 weeks and 24 weeks (6 months). Reviews, where possible, will occur at the hospital site.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ExerPhager

Primary outcome(s)
1. Recruitment rates across two NHS hospital sites assessed using the number recruited per month and the total in the study period recorded using REDcap trial management software
2. Willingness to be recruited to the study assessed using the number of people who refuse and their reasons for refusing recorded using REDcap trial management software
3. Study retention (<30% drop out) assessed using number not completing the study relative to the number agreeing to participate recorded using REDcap trial management software
4. Compliance: 80% of exercises undertaken daily assessed using the Exerphager app, which will show the exercise data for all sessions completed
5. The absence of adverse incidents assessed using the number of reports using REDcap trial management software
6. Acceptability of intervention assessed using a 5-point questionnaire
7. Mechanics of swallowing assessed using videofluoroscopy (reduced PTT; reduced residue post swallow)
8. Aspiration prevention assessed by analysing laryngeal movement, UES opening and tongue base retraction visualised using videofluoroscopy
9. Swallow speed assessed using TWST (time taken to drink 90 ml of water)
10. Ease of use of the CTAR-SwiFt feedback system assessed using using verbal feedback and the Swift-ball usability questionnaire
11. Swallowing ability assessed using FOIS (food oral intake score). It is scored between 1 and 7. 0 refers to being unable to eat or drink. 7 is normal diet. This is completed by medical staff.
12. Dysphagia-related quality of life assessed using the Swal-Qol questionnaire
13. Health status assessed using the EQ-5D questionnaire
14. Strength and mobility assessed using Timed Up and Go test. Participants must stand from sitting, walk 3 m, then turn around, walk back to the chair and sit down again.

All measures are assessed at baseline, 12 weeks and 24 weeks.

Key secondary outcome(s))
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Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Medically stable (systolic BP > 110; Heart rate > 60 bpm, MEWS < = 1)
2. Over the age of 75 years (though someone fulfilling the frailty criteria who is slightly below this age will be considered)
3. Clinical Frailty Score of > = 4 < 8
4. MoCA > 14
5. Able to provide consent (Different media will be provided to patients to enable consent to occur e.g. pictures; Speech Therapy support)
6. No significant breathlessness (St Georges COPD Score)
7. Not requiring oxygen
8. No past history of stroke or neurological disease
9. No evidence of severe rheumatoid arthritis (risk of neck instability)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Failure to provide consent to take part in the study
2. Progressive medical conditions (some malignancy, neurological disease)
3. MoCA < 14
4. Dysphagia requiring active intervention at the time of assessment
5. Dysphagia secondary to surgical treatment of head and neck cancer

Date of first enrolment
08/06/2021

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Lewisham and Greenwich NHS Trust
Stadium Road
Woolwich
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SE18 4QH

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Rd
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Sponsor information

Organisation
Lewisham and Greenwich NHS Trust

ROR
https://ror.org/05tn2bq24

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

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/05/2022	23/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	Abstract P-651 preliminary data	30/09/2022	19/05/2023	Yes	No
Other publications	Preprint deep learning framework for medical video segmentation	22/02/2023	19/05/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		16/06/2025	23/06/2025	No	No
Protocol file	version V1	28/01/2020	06/02/2020	No	No