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A Randomised Trial of How Hospital Patients and Health Care Professionals Judge that Being Restricted to Taking Fluids of Different Consistencies Would Affect Their Quality of Life

Submission date
08/08/2015

Recruitment status
No longer recruiting

Registration date
16/08/2015

Overall study status
Completed

Last Edited
03/06/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Swallowing problems (dysphagia) are common especially in older people, and are associated with numerous medical conditions including stroke, dementia and head and neck cancers. A common complication of dysphagia is inhaling fluid into the lungs, causing an infection. Thin consistency liquids, such as water, are the most likely consistency to be inhaled so the thickening of fluids with commercial thickeners is commonly advised to minimise this risk. However patients often dislike thickened fluids because of the unpleasant taste, the greater effort required to drink these fluids and poor thirst-quenching ability. This means that patients prescribed thickened fluids consume less fluid than patients who are able to drink thin fluids.
The aim of the study is to find out whether people who drink X would be prepared to live less in exchange for a better quality of life compared to people who drink Y.

Who can participate?
A mix of medically stable adults admitted to hospital and fit for interview and of healthcare professionals.

What does the study involve?
Participants will be randomly allocated to one of two groups: one group will be required to drink 250ml of a mildly thickened solution, and the other will be asked to drink 250ml of a moderately thickened solution. All participants will then be asked to imagine themselves having ten years to live, only being able to consume fluid in the form their group was given and whether they would be prepared to give up any years from the rest of their lives if it meant being able to live in full health.

What are the possible benefits and risks of participating?
There are no notable benefits or risks of participating.

Where is the study run from?
Galway University Hospital (Ireland)

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

Who is funding the study?
Health Research Board Student Summer Scholarship and Galway University Hospitals (Ireland)

Who is the main contact?
Professor Shaun O'Keefe

Contact information

Type(s)
Scientific

Contact name
Prof Shaun O'Keeffe

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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Randomised Trial of the Effect of Different Fluid Consistencies on Quality of Life Estimates Using a Time Trade Off Approach By Hospital Patients and Health Care Professionals

Study objectives
The primary hypothesis was that heath care utilities would be lower for those randomised to receive a sample of a more viscous fluid (moderately rather than mildly thick consistency).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Galway University Hospital Clinical Research Ethics Committee, 20/05/2015, ref: CA 245

Study design
Single-site randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Dysphagia

Interventions
Subjects will be allocated, based on odd and even numbers in a list of random numbers, to drink 250 ml of either mildly (nectar-like) or moderately thick (honey-like) water. Time trade utilities will be elicited using a time trade-off approach using a 10 year life expectancy.

Intervention Type
Supplement

Primary outcome measure
Individual subject utilities will be elicited in face to face interviews. The average (median as non-parametric analysis planned) utility in each of the randomised groups will be compared.

Secondary outcome measures
1. Average utilities will be compared between patient and professional groups
2. The effect if any of age and gender on subject utilities will be examined
3. The amount of the sample of thickened fluid that each subject drank will be recorded as less than a third, between one and two thirds and more than two thirds
4. The relationship between the volume consumed and the subsequent utility rating of subjects will be analysed

Overall study start date
01/07/2015

Completion date

30/08/2015

Eligibility

Key inclusion criteria
Group 1: Consecutive patients admitted to the medical wards of a 600-bed university teaching hospital, who were judged by medical and nursing staff to be clinically stable and fit to be interviewed.
Group 2: A convenience sample of doctors, nurses and allied health professionals working on the medical wards of the hospital or on an associated rehabilitation unit.

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants
75 patients; 75 healthcare professionals

Key exclusion criteria
1. Patients with any of the following diagnoses present: dementia or delirium; stroke, Parkinson’s disease or parkinsonism, multiple sclerosis, dysphagia from any other condition, or receiving a texture modified diet for any reason
2. Those with limited command of English or with other major communication problems

Date of first enrolment
01/08/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Galway University Hospitals
Newcastle Rd
Galway
Ireland
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Sponsor information

Organisation
Galway University Hospitals

Sponsor details
Newcastle Rd
Galway
Ireland
Galway

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04scgfz75

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Health Research Board Student Summer Scholarship and Galway University Hospitals

Results and Publications

Publication and dissemination plan
We intend to submit for presentation in relevant conferences (such as those relating to geriatric medicine, nutrition or speech and language therapy) and for publication in a peer-reviewed journal.

Intention to publish date
01/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	06/01/2016	03/06/2024	Yes	No