

# 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

<b>Submission date</b> 08/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/06/2024	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> 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'Keefe

**ORCID ID**  
<http://orcid.org/0000-0002-7682-5004>

**Contact details**  
Unit 4, Merlin Park Hospital  
Galway  
Ireland  
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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 health 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?
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[Results article](#)

06/01/2016

03/06/2024

Yes

No