

# Making drinking fun

|                                        |                                                                |                                                              |
|----------------------------------------|----------------------------------------------------------------|--------------------------------------------------------------|
| <b>Submission date</b><br>14/12/2015   | <b>Recruitment status</b><br>No longer recruiting              | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>17/12/2015 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                            |
| <b>Last Edited</b><br>11/05/2016       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan           |
|                                        |                                                                | <input type="checkbox"/> Results                             |
|                                        |                                                                | <input type="checkbox"/> Individual participant data         |
|                                        |                                                                | <input type="checkbox"/> Record updated in last year         |

## Plain English summary of protocol

### Background and study aims

International and UK evidence suggests that 20% of older care-home residents are dehydrated (not drinking enough to maintain hydration and health) and more are verging on dehydration. Dehydration increases risks of mortality (death) and disability. As people we get older they are less likely to feel thirsty, so they lose their internal signal that they need to drink more. This means that conscious decisions to drink plenty, environmental reminders and finding ways around barriers to drinking, are key to ensuring that they drink enough fluids. Finding enjoyable ways to encourage this is the focus of this study. Care-home residents say that it needs to be explained to both residents and staff why drinking is crucial, and provide clear, consistent prompts – a “pro-drinking” environment. The researchers running this study will work with care-home residents, activity co-ordinators and care-staff to make drinking fun, and to create a varied, interesting, potentially low-cost, intervention (treatment) package to support “pro-drinking” environments in residential and nursing care-homes. This intervention will be an enjoyable drinking-focussed activities programme (the pro-drinking activities toolkit) supporting engagement, activity and mental health which can make drinking fun for residents and staff. Once developed, the intervention will be tried out in three care-homes, to find out if it is acceptable and practical. Potential effects on resident engagement, cognition, mood, drinking and hydration will also be investigated.

### Who can participate?

Residents of one of the three care homes taking part in the study.

### What does the study involve?

Initially, the researchers and care staff from the care homes participating in the study brainstorm drinking-related activities. East Anglian Film Footage around drinking is also collated and added to a DVD to be used as a basis for reminiscence, discussion and tastings around drinks. This DVD is included as part of the pro-drinking activities toolkit. Other potential activities to be included in the toolkit may, for example, include setting up a tea club, discussions around drinking, quizzes and games, keeping a drinks diary and talking to residents about the importance of drinking well and how it can help with any health problems. Meetings are also set up with the residents of the care homes, their relatives and the staff to discuss the importance of hydration and making drinking fun and developing the toolkit. Once the toolkit is developed,

it is tried out in the three care homes to find out whether it's acceptable, practical and to assess any potential effects on the residents. A blood sample are also taken from each resident to assess health.

What are the possible benefits and risks of participating?

Potential benefits include an improved assessment and development of care home activities, involvement in a home-wide push to make drinking more pleasant and support socialising around drinking, improving drinking and the ability to work together and feel part of a community, the positive feeling of contributing to research likely to benefit others, better staff and resident knowledge of the need to drink well, and individual drinks intakes and assessment of own hydration status and risk of depression, shared with care home manager and resident's general practitioner. Potential risks include being bothered by additional activities (though areas of each home will be maintained where activities do not take place) and assessment of cognitive function and mood causing some embarrassment and/or distress (this will be minimised by establishing a relaxed, friendly and accepting atmosphere in a private area for the interview). The blood test might cause some pain, bruising, infection and excessive blood loss, but this will be minimised by following correct technique and using appropriately trained and equipped staff.

Where is the study run from?

Three care homes for the elderly in the UK and the University of East Anglia (UK)

When is the study starting and how long is it expected to run for?

January 2016 to July 2017

Who is funding the study?

The Dunhill Medical Trust (UK)

Who is the main contact?

Dr Lee Hooper

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## Contact information

### Type(s)

Scientific

### Contact name

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

Making drinking fun - creating a pro-drinking environment: developing and testing an innovative low-cost activity-based intervention (pro-drinking toolkit) to support care home residents in keeping hydrated

## Study objectives

The aim of this study is to assess the feasibility, acceptability and potential effects on drinking, hydration, engagement, cognition and mood of a low-cost activity-based intervention aimed at creating a consistent “pro-drinking” environment, the pro-drinking activities toolkit, in care-homes over 12 weeks.

## Hypothesis:

Making drinking fun and creating a pro-drinking environment in care homes will help older adults drink well and prevent dehydration.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South Central - Hampshire A Research Ethics Committee, 17/02/2016, ref: 16/SC/0017

## Study design

Non-randomised interventional study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Other

## Study type(s)

Prevention

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet.

## **Health condition(s) or problem(s) studied**

Dehydration

## **Interventions**

Care-home residents tell us we must explain to residents and staff why drinking is crucial, and provide clear, consistent prompts – a “pro-drinking” environment. We will work with care-home residents, activity co-ordinators and care-staff to make drinking fun, and to create a varied, interesting, potentially low-cost, intervention package to support “pro-drinking” environments in residential and nursing care-homes. This intervention will be an enjoyable drinking-focused activities programme (the pro-drinking activities toolkit) supporting engagement, activity and mental health which can make drinking fun for residents and staff. We will also work with residents, relatives, staff and managers to discuss ways we can all work together to make drinking more sociable & fun.

We will work with three activities co-ordinators or active members of care staff (ACs, from three different homes) to brainstorm drinking-related activities based on their own experience, and inspired by the College of Occupational Therapists toolkit ([www.cot.co.uk/publication/cot-publications/living-well-through-activity-care-homes-toolkit](http://www.cot.co.uk/publication/cot-publications/living-well-through-activity-care-homes-toolkit)). Concurrently we will collate East Anglian Film Archive footage around drinking (including twentieth century tea shops, milk bars, wartime coffee, fetes, public houses) onto a DVD (with appropriate copyright approvals) to be used as a basis for reminiscence, discussion and tastings around drinks. Additional activities for the activities pack may include (but not be limited to):

1. Setting up a tea club (regular social occasions where residents are supported to socialise, and share drinks and cakes)
2. Recordings of popular programs with a hydration or drinking theme (e.g. an episode of ITV's 'Doc Martin' featuring dehydration in an older person)
3. Discussion around drinking
4. Socialising with drinks
5. Drinks-themed music (e.g. Tea for Two)
6. Self-assessment of drinks intake using a Drinks Diary
7. Quizzes/games
8. Posters to remind residents and staff of the importance of drinking
9. Continence workshops (including use of self-monitoring bladder diaries, discussion of effects of caffeine, orange and tomato juice on continence, trials of low-caffeine tea and coffee, discussions with staff on prompted voiding),
10. Meetings between residents and staff to choose drinks for the home
11. Making drinks more accessible
12. Ensuring drinks are always available for existing favourite activities and exercise sessions
13. Discussions with residents on how drinking well could help with their own health problems (such as constipation, urinary incontinence, urinary tract infections, kidney stones, respiratory infections)
14. Performing familiar tasks (such as making drinks for each other)

Alongside toolkit development we will hold open meetings with residents, relatives and staff, where we discuss the importance of hydration and making drinking fun, development of the pro-

drinking activities toolkit, and we also discuss ways that residents, relatives and staff can help to make drinking fun over the next few months. We will work to support them in carrying out their plans.

Once developed, we will try out the intervention in three care-homes, to find out if it is acceptable and practical. We will also find out if there are potential effects on resident engagement, cognition, mood, drinking and hydration.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Assess the feasibility of using the intervention and proceeding to a larger RCT, which will depend on our ability to run the intervention in the 3 testing homes, and numbers of residents providing various types of outcome data, and resident impact. As such, there are no formal efficacy analyses for the feasibility study but statistics regarding recruitment, data availability etc. will be presented with 95% confidence intervals. These will be used to inform the design of a future trial. An initial estimate of potential efficacy will be derived through considering changes in outcomes between baseline and 12 weeks.

## **Secondary outcome measures**

Outcomes planned for use in the full scale RCT (the ability to collect these data are part of the primary outcome of the feasibility study)

1. Health data. Each of urinary tract infections, respiratory infections, falls, GP contacts, nurse contacts and unplanned hospital admissions
2. Engagement with the activity, with care staff or the activities coordinator, and with other residents will also be assessed during each activity
3. Drinks intake over 24 hours (assessed by staff and also by residents)
4. Functional status (Barthel Index)
5. Cognitive function using the mini-mental state exam (MMSE)
6. Mood using the Geriatric Depression Scale (GDS)
7. Resident impact recorded by one or two resident researchers at each care home
8. Hydration status using a blood test (serum osmolality, sodium, potassium, urea and glucose)
9. Care home impact will be assessed using interviews with the AC, a senior carer and the manager at each intervention home. These 9 interviews will focus on the NPT concepts of implementation, embedding and integration as well as positive, neutral and negative effects to residents, staff and relatives
10. Resources required to provide the intervention including staff time and consumables (recorded by ACs)
11. Health economics. For care home impact and resources we will assess effects on costs and separate out costs of taking part in the research, from the costs of the intervention

## **Overall study start date**

25/01/2016

## **Completion date**

24/07/2017

# **Eligibility**

## **Key inclusion criteria**

Residents of care homes taking part in the research who are well enough to approach to discuss the study.

**Participant type(s)**

Other

**Age group**

Senior

**Sex**

Both

**Target number of participants**

We have not conducted a formal sample size assessment for this feasibility study, however these are our baseline plans for participant numbers within this study. In the development phase we will not be formally including care home residents, but in the testing phase we will be. We will be testing in 3 care homes, and an average care home in our area houses around 35 residents, so in the testing phase the potential population of residents will be around 105 older adults. We estimate that we may get informed consent from 25, send consultee letters to the consultees of a further 50, with 30 declining (opting out) or being too ill. From the consultee letters we hope to get a positive consultee opinion from 23, a negative one from 4 and not get a response from 23. This will give 23 residents with anonymous observational data collection, and 48 with pseudonymised observational data collection. Observational data collection includes health, engagement, drinks intake and functional status data. Collection of interview data on resident impact, mood and cognitive function requires separate consent, and we hope to include 30 participants with this consent. The blood test, for assessment of hydration status, requires separate consent again, and we hope for 20 participants at this level of consent.

**Key exclusion criteria**

1. Care home residents who are too ill to be approached
2. Care home residents who state they would prefer not to take part

**Date of first enrolment**

01/09/2016

**Date of final enrolment**

31/10/2016

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of East Anglia**

Norwich Medical School

Norwich Research Park

Norwich  
United Kingdom  
NR4 7TJ

## Sponsor information

### Organisation

University of East Anglia

### Sponsor details

Research and Enterprise  
Norwich  
England  
United Kingdom  
NR4 7TJ

### Sponsor type

University/education

### ROR

<https://ror.org/026k5mg93>

## Funder(s)

### Funder type

Charity

### Funder Name

The Dunhill Medical Trust (UK)

## Results and Publications

### Publication and dissemination plan

Outputs:

1. A tested activity-based hydration intervention (the pro-drinking activities toolkit) to support pro-drinking care-home environments – the range of activities will include some suitable for men and women, those with and without dementia, and activities for individuals, pairs and bigger groups.
2. Working with a charity to produce the pro-drinking activities toolkit for sale on a “not for profit” basis
3. Articles on the pro-drinking activities toolkit, written with ACs and residents, published in newsletters & websites of charities, relatives’ organisations and care-homes

4. Open access academic publication
5. Presentation at one care-home conference and one international academic conference
6. Funding application for full-scale pro-drinking activities toolkit RCT to underpin evidence base

Participating residents, relatives, care staff, activities coordinators and managers will receive information on the progress of Making Drinking Fun, and its findings. We will send around a newsletter to all participating residents and care homes, at least twice during the study, and will re-visit each home once we have analysed the results of the test phase to hold an open meeting to discuss our findings in person.

The dissemination plan covers all outputs and focuses on the aim to publicise drinking, the pro-drinking activities toolkit and their potential benefits in the short term. Longer term goals include establishing the effectiveness and cost-effectiveness of the activity-based intervention (through sourcing funding for, and running, a full scale RCT with health economic analysis), then making the pro-drinking activities toolkit available to all UK care-homes, to improve fluid intake and reduce dehydration. Specific health benefits of improved hydration may include fewer urinary tract and respiratory infections, acute kidney injuries, unplanned hospital admissions and falls, as well as improved urinary continence and constipation.

We aim to develop the intervention in a format that can be distributed and implemented by care homes in conjunction with instructions or a training pack. We hope to work with a charity or training organisation to produce and distribute it. We will work with our activities co-ordinators, Advisory Groups and Steering Group to formally plan dissemination, and to co-author short articles for newsletters & websites of charities, relatives' organisations and care-homes discussing use of the activities pack, the research and its results. We will formally publish the research in a high impact open access journal, as well as presenting the results at a care-home conference and an academic conference. Further, we will seek funding for a full-scale pro-drinking activities toolkit randomised.

## Intention to publish date

31/07/2018

## 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |