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DRIE 2 (Dehydration Recognition In our Elders Re-test)

Submission date
18/03/2014

Recruitment status
No longer recruiting

Registration date
21/05/2014

Overall study status
Completed

Last Edited
24/07/2020

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
When people don't drink enough water for their needs, they become dehydrated. A number of studies have shown that dehydration can cause disability and even death in people of all ages. In older people, it can cause them to fall or become confused. It can also lead to poorer wound healing, infections, bad reactions to any drugs they are taking (drug toxicity) and a general poorer quality of life. Being able to quickly notice the signs of dehydration in older people, prevent it and treat it in the community would be beneficial to themselves and reduce NHS costs. Being able to measure dehydration by assessing blood osmolality (the amount of salts and water in the blood) is not often available in residential care homes. A simple tool has been created to predict when a person is becoming dehydrated (a decision tree of tests). An earlier study interviewed 200 older people living in care homes, assessed their hydration status and carried out a range of tests and assessments that might help to find out how hydrated they are. These data on potential signs, conditions and tests were analysed, and it was found that no single test or sign was capable of diagnosing dehydration on its own. It is from these results that several possible decision trees have been made that could be used to identify dehydration. Decision trees can accurately predict how hydrated someone is without the need for a lot of tests for the person themselves. This study tests the best two decision trees on another 200 older people living in residential care homes.

Who can participate?
People aged 65 or over, who are living in residential care (care homes, nursing homes and mixed homes) including people with dementia.

What does the study involve?
This study tests how well the best two decision trees predict dehydration in older people in care homes. Participants are tested for dehydration by measuring blood osmolality, carrying out all the assessments needed for the decision trees and collecting relevant health and demographic information. These data are used to assess how accurately the diagnostic trees are at identifying whether a person is dehydrated.

What are the possible benefits and risks of participating?
Participating will help other older people by improving the recognition of dehydration.

Participants receive a £10 voucher or equivalent for attending each of the two interviews. The blood test could be slightly painful, and could cause bleeding or bruising.

Where is the study run from?
A number of residential care homes in Norfolk or Suffolk (UK)

When is the study starting and how long is it expected to run for?
May 2014 to April 2015

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

Who is the main contact?
Dr Lee Hooper
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Study website
http://driestudy.appspot.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIHR-CDF-2011-04-025

Study information

Scientific Title
Testing of a simple tool for diagnosis of water-loss dehydration: a diagnostic accuracy study

Acronym
DRIE 2

Study objectives
A short decision tree can usefully assess the presence of dehydration in older people living in care homes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 7, 29/04/2014, ref: 14/WA/0145

Study design
Cross-sectional diagnostic accuracy study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
http://driestudy.appspot.com/Files/Participant_info.pdf

Health condition(s) or problem(s) studied
Water-loss dehydration, signified by raised serum osmolality (>300 mOsm/kg).

Interventions
The trialists will test for water-loss dehydration (through blood osmolality) and also carry out the assessments needed for the decision trees, as well as collecting health and demographic information. The trialists will use these data to assess diagnostic accuracy of the proposed decision trees to diagnose or rule out dehydration.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Whether the simple decision tree usefully predicts dehydration in care home residents.

Secondary outcome measures
1. Acceptability and invasiveness of the individual assessments to older people living in residential care
2. The relationship between nutritional status (assessed by change in weight over the past 6 months, body mass index, Mini Nutritional Assessment, Malnutrition Universal Screening Tool, haemoglobin) and hydration status in care home residents
3. Assessing some additional promising clinical and/or physical signs or questions (such as assessing foot skin turgor, dry lips, asking participants whether they feel out of sorts, and whether they drink as much as they need to stay healthy, completing the mini-mental state exam, observing whether participants taste their drink immediately and recording their Barthel score and number of medications prescribed) so that if the current decision tree does not prove useful we have a strong evidence base (from 200 participants in the DRIE study, and a further 200 participants in DRIE 2) to allow development of a better decision tree.

Overall study start date
01/05/2014

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. People aged 65+ living in residential care (care homes, nursing homes and mixed homes) in Norfolk or Suffolk (UK)
2. Participants will be included regardless of their capacity to provide informed consent, although the study is designed to protect all participants and include them only if they find the research acceptable
3. Inclusion of those with dementia was strongly encouraged by the NIHR interview panel that awarded the funding for this research, as those with dementia are at greatly increased risk of dehydration, so it is vital that the tool developed is applicable to those with dementia as well as those without. This decision has been strongly supported by care home managers and staff before and during the course of the original DRIE study. We will only include adults who can provide their own informed and signed consent OR whose consultee has provided signed consent that they believe that the resident would have consented if they were able to make the decision themselves
4. The trialists do not plan to stratify inclusion by age group (as most of those living in residential care will be either physically or mentally frail, all will be at some increased risk of dehydration), or by gender (although the samples are likely to be weighted towards women, as more care home residents are women). While they are aiming for a representative sample of care home residents, they will not exclude any interested participants on this basis. The sample of care home residents is likely to be rather less frail than the average resident as those with better physical and cognitive capacities are more likely to feel able to participate, but they will collect a small amount of data on all residents in the homes we work in to assess the representativeness of the study sample.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Those who the care home manager is aware have been diagnosed with renal failure or heart failure, as fluid physiology changes with these conditions (and fluid retention is more likely)
2. Those in receipt of palliative care, or with illnesses that suggest they are unlikely to survive for at least 3 months will not be recruited
3. Who are unable to provide their own consent, and are known to be frightened of, or upset by, needles or blood tests as we will assume that the process of the interview and blood sample will be upsetting to them

Date of first enrolment
01/05/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norwich Medical School
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Sponsor information

Organisation
University of East Anglia (UK)

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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Career Development Fellowship; Ref: NIHR-CDF-2011-04-025

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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