

# Home monitoring in encephalopathy

<b>Submission date</b> 28/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year
<b>Registration date</b> 28/01/2015	<b>Overall study status</b> Completed	
<b>Last Edited</b> 02/09/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Hepatic encephalopathy (HE) is a complication of advanced liver disease. It happens when the liver is not able to break down toxins from the bowel which then enter the blood stream and travel to the brain. It can cause the patient to become confused and lead to a reduced level of consciousness. HE often results in emergency admission to hospital and can result in reduced quality of life. The first-line treatment of HE is the laxative lactulose which increases stool frequency and reduces absorption of toxins produced by bacteria in the gut. However, in spite of this treatment, HE often worsens, leading to readmission into hospital. One potential contributing factor is that large doses of lactulose can be unpleasant for patients to take, meaning that they are less likely to take it, particularly when there appears to be no evidence of ongoing confusion. The aim of this study is to investigate the use of a home monitoring system to direct lactulose treatment in patients who have had a previous episode of HE.

### Who can participate?

Patients aged 18-80 with advanced liver disease who have had a previous episode of HE

### What does the study involve?

Participants take a simple cognitive (thinking) test on a daily basis and they record their stool frequency using a tablet PC. This information is used to adjust lactulose dose where appropriate. In situations where there is evidence of increasing confusion which is not responding to treatment, a clinician intervenes.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University of Newcastle upon Tyne (UK)

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

November 2014 to July 2015

### Who is funding the study?

1. European Commission Information Society and Media Directorate General
2. National Institute for Health Research (UK)

Who is the main contact?  
Dr James Orr

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr James Orr

**Contact details**  
University of Newcastle upon Tyne  
Institute of Cellular Medicine  
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Newcastle Upon Tyne  
United Kingdom  
NE1 7RU

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**  
156104

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
17803, IRAS 156104

## Study information

**Scientific Title**  
Home Monitoring in Encephalopathy: a randomised controlled trial

**Acronym**  
d-LIVER HoME

**Study objectives**  
This pilot evaluation aims to investigate the use of a home monitoring system to direct lactulose therapy in patients with a previous episode of overt hepatic encephalopathy.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 29/09/2014, North East - Newcastle & North Tyneside 1 Research Ethics Committee,  
REC ref: 14/NE/1114

**Study design**

Randomised; Interventional; Design type: Treatment

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Topic: Gastroenterology, Hepatology; Subtopic: Hepatology, Gastroenterology; Disease: All Gastroenterology, All Hepatology

**Interventions**

Electronic home monitoring: Using a tablet PC, patients will carry out a cognitive test and a health enquiry on a daily basis. Based on this treatment for hepatic encephalopathy will be optimised.

Follow Up Length: 6 month(s)

**Intervention Type**

Behavioural

**Primary outcome measure**

Patient acceptability; Timepoint(s): 8 weeks, 16 weeks, 24 weeks

**Secondary outcome measures**

1. Admission rates; Timepoint(s): throughout study
2. Completion rate; Timepoint(s): throughout trial
3. Health related quality of life; Timepoint(s): 8 weeks, 16 weeks, 24 weeks
4. Healthcare resource utilisation; Timepoint(s): 8 weeks, 16 weeks 24 weeks
5. Rate of change of therapy; Timepoint(s): throughout study

**Overall study start date**

17/11/2014

**Completion date**

31/07/2015

**Eligibility**

**Key inclusion criteria**

1. Age 18-80 years
2. Patient has capacity and provided written informed consent for participation in the study prior to any study specific procedures
3. Cirrhosis defined either histologically on liver biopsy OR clinically by 2 of:
  - 3.1. Imaging suggestive of cirrhosis (irregular outline and/or spleen >12cm)
  - 3.2. Fibroscan >17.6kPa
  - 3.3. Oesophageal or gastric varices or portal hypertensive gastropathy
  - 3.4. Platelets <120
  - 3.5. Ascites
  - 3.6. Encephalopathy
4. Inpatient at Freeman Hospital, Newcastle or Royal Victoria Infirmary, Newcastle due to overt hepatic encephalopathy (OHE), treated with lactulose

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

80 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 20; UK Sample Size: 20

**Key exclusion criteria**

1. Age <18 or >80
2. Unable to provide informed consent
3. Unable to understand written English
4. Malignancy (including HCC)
5. Participating in another interventional study
6. Previous participation in this study

**Date of first enrolment**

17/11/2014

**Date of final enrolment**

31/07/2015

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

England

United Kingdom

**Study participating centre**

**University of Newcastle upon Tyne**

Institute of Cellular Medicine

Claremont Road

Newcastle Upon Tyne

United Kingdom

NE1 7RU

## **Sponsor information**

**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

**Sponsor details**

Leazes Wing

Royal Victoria Infirmary

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05p40t847>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

European Commission Information Society and Media Directorate General

**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

**Publication and dissemination plan**

Not provided at time of registration

2015 abstract in [https://doi.org/10.1016/S0168-8278\(15\)31503-8](https://doi.org/10.1016/S0168-8278(15)31503-8) (added 02/09/2020)

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