

Home monitoring in encephalopathy

Submission date 28/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/09/2020	Condition category 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

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

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United Kingdom
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Additional identifiers

Integrated Research Application System (IRAS)

156104

Protocol serial number

17803

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

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**

United Kingdom

England

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

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

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