ISRCTN10363786 https://doi.org/10.1186/ISRCTN10363786

Home monitoring in encephalopathy

Submission date	Recruitment status	[ ] Prospectively registered
28/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2020	Nutritional, Metabolic, Endocrine	[ ] 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
University of Newcastle upon Tyne
Institute of Cellular Medicine
Claremont Road
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 (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?
HRA research summary			28/06/2023	No	No