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Mental imagery to reduce alcohol-related harm in patients with alcohol-related liver damage (MIRAGE)

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
12/03/2021

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Alcohol-related liver disease is caused by long-term heavy alcohol use and is the commonest cause of liver disease in the UK. The only cure to prevent worsening this type of liver disease is reducing or stopping drinking alcohol. Current support for people trying to stop drinking alcohol is insufficient. The goal of this study is to test a new form of psychological support to help patients stop drinking. The new treatment, which is called Functional Imagery Training (FIT), is a psychological therapy that improves motivation to change a behaviour.

The study will tell us if people find FIT helpful and if they continue using FIT after leaving hospital. This information will help design a future, larger trial to answer whether FIT is better than the current support offered and is good value for money, as a treatment for alcohol-dependence in people with alcohol-related liver disease.

Who can participate?
Adults over 18 years who have alcohol-related liver disease and alcohol dependence

What does the study involve?
In this study, a trained nurse will deliver FIT by talking to the participant about why they want to stop drinking, and what ideas they have for doing that. During the conversation, the nurse will help the participant develop vivid images in their mind showing the first steps they will take towards their goal, how they will use their personal strengths to overcome obstacles, and how they will feel when they have successfully reduced their alcohol use. Participants will be trained to practice this imagery regularly, ready for use when they experience a craving for alcohol or a lack of motivation. The initial training in FIT takes less than an hour and is then strengthened by eight further top-up sessions.

What are the possible benefits and risks of participating?
We don’t know yet if FIT treatment is effective but participants allocated to the FIT group may find it helps to reduce their alcohol use and may improve quality of life. Even if participants do not benefit directly, their participation will help us learn more about the treatment and so may

help others in the future to reduce their alcohol use.
FIT has been used before and shown to be safe and beneficial in a variety of settings. We are not aware of any risks to patients of taking part in this study or using FIT. However, this therapy is new and not currently routine care for patients with alcohol-related liver disease and we will carefully monitor that it is safe during the research.

Where is the study run from?
University Hospitals Plymouth NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2020 to November 2022

Who is funding the study?
The Jon Moulton Charity Trust (Guernsey)

Who is the main contact?
Dr Angela King, mirage.penctu@plymouth.ac.uk

Study website
https://www.plymouth.ac.uk/research/penctu

Contact information

Type(s)
Scientific

Contact name
Dr Angela King

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293042

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48393, IRAS 293042

Study information

Scientific Title
Pilot randomised trial of functional imagery training plus treatment as usual versus treatment as usual alone to reduce alcohol-related harm in patients with alcohol-related liver disease admitted to hospital

Acronym
MIRAGE

Study objectives
The study aim is to conduct a randomised pilot trial of functional imagery training and treatment as usual versus treatment as usual

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2021, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048088; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0044

Study design
Interventional randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Reducing alcohol use in patients with alcohol-related liver disease

Interventions
When the potential participant's medical condition has been stabilised (for example, after they have been treated for alcohol withdrawal), they will be referred to the Hospital Alcohol Team and assessed by an Alcohol Liaison Nurse (ALN). The ALN or a member of the medical team will discuss the MIRAGE study with the participant and answer any questions they may have about it, and give them the Participant Information Sheet.

If the patient agrees to take part and meets the eligibility criteria, the doctor, nurse or ALN will ask them to sign a consent form confirming that they have agreed to take part in the study. They will be given a copy of their consent form and the information sheet to keep.

One of the research team will then collect some information from the participant about their general health.

The participant will be allocated at random by computer to one of two groups. Half of the participants in this study will be in one group and half in the other.

In one group, all participants will receive the usual care (brief intervention and advice), also known as treatment as usual (TAU). This is the current treatment provided by the NHS and consists of a trained nurse (usually an ALN) asking some questions about the participant's awareness of alcohol use and trying to help motivate the participant to change, and informing them about community alcohol services.

In the other group, all participants will receive the usual care and Functional Imagery Training (FIT) treatment over a period of up to six months. This will be delivered by an ALN who has been trained in FIT. There will be nine sessions altogether, detailed below.
Session 1: This session will take place while the participant is still in hospital and will last up to one hour. This will be a private conversation with an ALN who has received FIT training. The participant will be taught how to use mental imagery to increase their motivation, mentally practice ways of coping when they meet obstacles, and boost their confidence.
Session 2: This session will take place around a week after hospital discharge, either face-to-face in a hospital outpatient department, or by telephone or video call, and will last up to 45 minutes. During this session, the ALN will review the participant's progress and help them to use imagery to solve problems and motivate new goals.
Session 3: This session will take place by telephone around two weeks after hospital discharge and lasts less than 30 minutes. The ALN will check the participant's progress and develop imagery about recent successes, problem solutions, new goals or behaviours, and encourage practice.

Sessions 4-9: These 6 booster sessions will take place by telephone at roughly monthly intervals, and will last less than 15 minutes.

Participants in both groups will be asked to complete some questionnaires at the beginning and end of the 6-month study period, including questions about their alcohol use, mental and physical wellbeing, quality of life and use of health and social care services. These questionnaires will be completed at a face-to-face visit with a research nurse lasting approximately 1 hour.

All participants will be asked to give a urine sample at the end of the study to measure markers of alcohol use.

The research team will take the participant's contact details so that they can contact them. Towards the end of the six month follow-up period, one of the research team may also ask if the participant would be happy to talk to a researcher by telephone about their experiences of being in the study. These interviews are optional and are designed to help the research team learn about the participant's experiences of being in the study and, for those receiving FIT, what works
well or not so well. A separate information sheet will be provided to those that agree to be interviewed and informed consent will be obtained before the interview takes place.

If, after reading the information sheet, a patient decides not to take part in the study, they will be asked if they would be happy to talk to a researcher by telephone, to understand their reasons for declining. This information may help the research team to improve any future trial of FIT treatment. These interviews are optional. If a patient agrees to be interviewed, an information sheet will be provided and informed consent will be obtained before the interview takes place.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes:
1. Number of patients screened and recruited
2. Retention rate at 90 and 180 days measured by number of recruited patients attending follow-up visits
3. Fidelity of delivery of FIT and TAU (trained FIT practitioner will check each ALN's fidelity early in the trial using dedicated fidelity assessment tools). Feedback and supervision throughout the trial
4. Intervention engagement – number of successful FIT phone calls and visits by 180 days
5. Completeness of data collection by 180 days (to include number of completed questionnaires, number of missing items within a questionnaire by time point)

Secondary outcome measures
Participant reported and other clinical outcomes:
Primary outcome measure:
Alcohol use (grams of pure alcohol/week) at baseline and 180 days post-baseline. Alcohol use will be assessed using the Timeline Follow-Back technique which is used to determine a patient's alcohol use over the 7 days preceding days. Completed at 28, 90 and 180 days post baseline
Secondary outcome measures:
1. Severity of Alcohol Dependence Questionnaire (SADQ) baseline, 28, 90 and 180 days
2. EQ-5D-5L questionnaire to measure health-related Quality of life at baseline, 28, 90 and 180

days
3. Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) to measure mental wellbeing (including short form version (SWEMWBS)) at baseline, 28, 90 and 180 days
4. Health, social care and wider care services utilisation will be determined using a resource use questionnaire completed at baseline, day 90 and day 180
5. Self-reported re-hospitalisation within 180 days post-baseline or, if unobtainable, determined using hospital records at 180 days
6. Self-reported time to relapse to regular alcohol use at 28, 90 and 180 days
Exploratory biochemistry outcomes:
7. Urinary biomarkers (ethyl glucuronide/sulphate) at 180 days

Overall study start date
01/10/2020

Completion date
23/11/2022

Eligibility

Key inclusion criteria
1. Adult patients >=18 years
2. Able and willing to provide informed consent
3. Clinical diagnosis of ArLD by at least one of the following methods
3.1. Radiological appearance of fatty infiltration of the liver or cirrhosis
3.2. Histological findings of cirrhosis or alcoholic steatohepatitis
3.3. Signs consistent with chronic liver disease on physical examination
4. High risk alcohol consumption (>50 units/week for males and >35 units/week for females) within 4 weeks prior to hospital admission
5. AUDIT score >15 during current hospital admission
6. Diagnosis of alcohol dependence as defined in ICD-10 meeting at least three of the following conditions:
6.1. Strong desire or sense of compulsion to take alcohol
6.2. Difficulties in controlling alcohol-consuming behaviour in terms of its onset, termination, or levels of use
6.3. A physiological withdrawal state when alcohol use has ceased or been reduced, as evidenced by: the characteristic withdrawal syndrome; or use of alcohol with the intention of relieving or avoiding withdrawal symptoms
6.4. Evidence of tolerance, such that increased doses of alcohol are required in order to achieve effects originally produced by lower doses
6.5. Progressive neglect of alternative pleasures or interests because of alcohol use, increased amount of time necessary to obtain or consume alcohol or to recover from its effects
6.6. Persisting with alcohol use despite clear evidence of overtly harmful consequences

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
54

Key exclusion criteria
1. Any condition with an estimated life expectancy of less than 6 months
2. Patients participating in concurrent interventional research
3. Participants who have significant difficulties in adequate understanding of English such that they are unable to benefit from the trial intervention or sufficiently understand the trial documentation

Date of first enrolment
19/04/2021

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol and Weston NHS Foudnation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
St James's Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University Hospitals Plymouth NHS Trust

Sponsor details
Derriford Hospital
Derriford Road
Plymouth
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PL6 8DH
+44 (0)1752 432842
plh-tr.rd-office@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.plymouthhospitals.nhs.uk/home

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Charity

Funder Name
The Jon Moulton Charity Trust (Guernsey); Grant Codes: 140

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
Available on request to Ashwin.dhanda@nhs.net from the date the final results paper is published (expected Spring 2023). Data will be anonymised. Consent has been obtained from participants for data to be shared anonymously with other researchers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1	28/01/2021	12/03/2021	No	No
Protocol article		18/05/2022	20/05/2022	Yes	No
Protocol file	version 3.2	16/08/2022	08/09/2022	No	No
Protocol file	version 3.3	30/09/2022	03/01/2023	No	No
Statistical Analysis Plan	version 1.1	21/03/2023	30/05/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		29/01/2024	09/02/2024	Yes	No