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Motivational interviews to reduce alcohol

Submission date
26/02/2025

Recruitment status
No longer recruiting

Registration date
26/02/2025

Overall study status
Completed

Last Edited
26/02/2025

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We would like to find out if patients can reduce their alcohol intake if nurse led motivational interviews are offered following their hospital outpatient appointment with a Liver Specialist.

Currently, drinking harmful levels of alcohol is a major cause of deaths, ill health and disability in 15–49-year-olds. Alcohol causes many hospital admissions, cancer and other illnesses. Data from Public Health England shows that admissions to hospital are higher in Northeast England, than anywhere else in the country.

When a patient has a history of alcohol excess and deranged liver blood tests, they are referred to see a liver specialist in their closest hospital. The Dr will encourage the patient to reduce their alcohol intake and may suggest that the patient self refers to a community addiction centre. This can be difficult for many patients if they don't know what the acceptable limits for alcohol intake are, or if they are drinking for mental health or social reasons.

Motivational interviewing is used to support and motivate people to change their own behaviour. The specially trained nurse will develop a relationship with the patient to develop goals, celebrate successes and develop strategies to work through problems. This form of counselling is used to treat patients admitted to hospital and by community addiction centres.

Who can participate?
We would like to approach patients attending appointments in the liver clinics in a hospital in Northeast England.

What does the study involve?
The patients will be offered weekly Motivational interviews over a 12-week period as an outpatient or through telephone calls.
The patients will complete questionnaires at the start of the study to ensure safety and to measure patient alcohol intake. These will be monitored 4 weekly to gather data for analysis. On completion the patients will be asked to evaluate the 12-week program to inform future programs.

What are the possible benefits and risks of participating?
The research participants may benefit if they reduce their alcohol intake. If the patient is able to

reduce their alcohol intake, they would enjoy a better quality of life and prevent further liver disease and complications. While they may not have stopped drinking alcohol completely, it is hoped that they develop strategies to continue to reduce their alcohol intake.

If the patient wasn't ready to participate in the study during the recruitment period, it is hoped that the information sheet will have given them the information and methods to reduce their alcohol intake in the future while also addressing the stigma of alcohol use disorder.

The potential risks of participating could be reducing alcohol intake too quickly. Not everyone will experience symptoms of alcohol withdrawal, but some may become ill requiring a hospital admission. Your doctor will ask you about physical symptoms, and one of the questionnaires at the start of the study will assess physical dependence. However, as part of the study, we are asking you to reduce your alcohol intake slowly.

If you are drinking alcohol to help with any mental health problems, you may find that your mental health worsens. We are using a questionnaire which will help us to measure your mental health, and if the nurse becomes worried about you or your questionnaire score shows that your mental health has worsened, we will speak to you and your GP about that.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2022 to December 2025

Who is funding the study?
LIVErNORTH (UK)

Who is the main contact?
sarah.hogg1@nhs.net

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
338437

Protocol serial number
CPMS 65806

Study information

Scientific Title
A pilot study of nurse led motivational interviews in secondary care outpatient units to reduce alcohol intake

Acronym
MIRA

Study objectives
We would like to find out the acceptability, adherence and success of offering Motivational Interviews to Reduce Alcohol Intake within Secondary Outpatient clinics.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/02/2025, East Midlands- Derby research Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8283; derby.rec@hra.nhs.uk), ref: 24/EM/0271

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Alcohol related liver disease

Interventions
At the First Visit:
The nurse will review the study to ensure full understanding.
The Informed Consent form will be signed by both the participant and the nurse.
Four short questionnaires will be completed:
Severity of Alcohol Dependence Questionnaire: Ensures the participant scores under 16, indicating suitability for community alcohol reduction. Scores above 16 will result in exclusion from the study, with standard follow-up care by Hepatologists.
Hospital Anxiety and Depression Score (HADS): A validated tool to monitor mental health.
Alcohol Use Disorders Identification Test for Consumption (Audit-C): Identifies 'at risk' drinkers who may not be alcohol dependent.
Timeline Followback (TLFB): Identifies drinking patterns and measures consumption.
The first Motivational Interview will take place to discuss alcohol use, triggers, and support systems. Methods to reduce alcohol intake will be tailored to the participant.
Arrangements for the next appointment will be discussed. This visit is expected to last approximately 1 hour.

Weeks 2 and 3:
The nurse will review the participant's week and work through the TLFB questionnaire to identify successes and triggers.
The nurse will help celebrate successes and plan for the next week. These visits should last approximately 30 minutes.

Week 4:
The participant will complete the HADS questionnaire to monitor mental health, especially if drinking to ease mental health issues.
The TLFB questionnaire will be completed, followed by a Motivational Interview. This appointment will last approximately 45 minutes.

Weeks 5, 6, and 7:
Same as Weeks 2 and 3.

Week 8:
Same as Week 4.

Weeks 9, 10, and 11:
Same as Weeks 2 and 3.

Week 12:
The participant will complete the HADS, AUDIT-C, and TLFB questionnaires.
The final Motivational Interview will be conducted, with advice on further alcohol reduction and encouragement to seek additional support.

The participant will complete an evaluation of the study and schedule to inform future studies. The participant will return to usual clinical care with a scheduled appointment with the liver team.

Recruitment and Study Timeline:
Recruitment will take place over 3 months as part of a Masters research project.
The intervention period will last 3 months.
Data analysis will take 3 months, followed by 3 months to publish the results.

Intervention Type
Behavioural

Primary outcome(s)
1. Number of patients that accept and decline the intervention and whether patients reduce their alcohol intake. We will measure the patients who accept and refuse the intervention over a 3 month period.
2. We will measure the patients adherence by measuring how many visits they attend over the 12 week period.
3. Success will be measured with patient reported alcohol use in the TimeLine Follow Back questionnaire

Key secondary outcome(s))
At baseline and 12 weeks:
1. Hospital Anxiety and Depression Score (HADS)
2. Alcohol Use Disorders Identification Test Consumption (AUDIT C)
3. TimeLine Follow Back (TLFB) score

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Over 18 years old (the legal age for drinking alcohol in England)
2. Capacity to give informed consent
3. Able to speak and understand English for the Motivational Interviews
4. They drink over 25 units of alcohol per week
5. Deranged liver function blood tests or fibroscan measurement over 8KPa
6. Reviewed in Hepatology Outpatient Clinic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. They show physical signs of dependence
2. Are currently part of an alcohol reduction program such as AA, or community addiction services
3. Have underlying mental health problems such as schizophrenia, psychosis, or have been hospitalised with mental health problems
4. Patients who have been hospitalised with an alcohol related liver complication within the previous year as they will have been reviewed by the substance misuse nurses during admission

Date of first enrolment
01/03/2025

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
LIVErNORTH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Within the patient information sheet and informed consent form, we have not sought consent or permission from the patient or within the IRAS form and Caldicott application.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.8	31/12/2024	26/02/2025	No	Yes