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Impact of knowledge of liver fibrosis on drinking behaviour

Submission date
21/01/2021

Recruitment status
No longer recruiting

Registration date
26/01/2021

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Heavy drinkers at risk of liver disease and in contact with alcohol services do not currently have access to testing to establish the severity of their liver disease. Fibroscan is a technology which can now provide this information. It is currently unknown if knowledge of the severity of liver disease in people who are at risk will affect their drinking behaviour. This study sets out to develop standardised fibroscan operator feedback of results and produce video patient stories to enhance feedback and then establish if the approach is feasible and deliverable via a feasibility randomised controlled trial.

Who can participate?
1. Participants who have successfully overcome their alcohol use disorder and had a fibroscan in the past
2. Participants self-presenting to any of the recruitment settings who have a history of alcohol misuse

What does the study involve?
Patients will be involved in the focus group to provide feedback on the prototype fibroscan script. The NRN alcohol keyworker in a focus group will give feedback on the final version. The researchers will record videos of alcohol recovery stories with participants who have successfully overcome their alcohol use disorder and had a fibroscan in the past.
Participants will be randomly allocated to the control group or the intervention group. Participants in the control group will continue with usual care which is provided as part of an alcohol management programme following national guidelines. Participants in the intervention group, in addition to usual care, will have a fibroscan and immediately after this will watch recovery video stories. All participants are followed up for 6 months

What are the possible benefits and risks of participating?
The researchers cannot guarantee that the study will benefit the participants. Participation in the study will contribute to improving knowledge in the field of alcohol misuse. It will provide an opportunity to test the effectiveness of new methods of helping and supporting people with a history of high-risk alcohol drinking behaviour.

Where is the study run from?
Nottinghamshire Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2019 to February 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Mohsan Subhani
mohsan.subhani@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Mohsan Subhani

ORCID ID
http://orcid.org/0000-0001-8739-7263

Contact details
NDDC BRU E Floor West Block
Queen’s Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)7572612429
Mohsan.subhani@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273765

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47834, IRAS 273765

Study information

Scientific Title

Does knowledge of liver fibrosis affect high-risk drinking behaviour (KLIFAD): a feasibility randomised controlled trial

Acronym
KLIFAD

Study objectives
The primary objective of this study is to investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) in community specialist alcohol services settings to compare the clinical and cost-effectiveness of the KLIFAD intervention delivered in addition to usual care with usual care only for adults presenting with a problem of alcohol misuse.

The objectives of this study are (all three work packages):
1. To establish a standardised script framework for fibroscan operators to deliver liver disease-specific advice to clients having fibroscan
2. To develop a collection of video stories describing how patients have responded to receiving a fibroscan score
3. To test the intervention (fibroscan plus feedback and video stories) in a feasibility randomised trial
4. To perform a qualitative evaluation of 1-3 above to inform a later, larger national randomised trial
5. Determine the feasibility of recruitment and randomisation to a large-scale RCT
6. Refine the eligibility criteria for a future definitive RCT
7. Determine the acceptability to patients/healthcare workers of randomisation
8. Determine the relevance and acceptability to patients/healthcare workers of the trial intervention
9. Determine the acceptability to patients/healthcare workers of the trial procedures
10. Assess the ability of community alcohol services to deliver the intervention
11. Assess training and support needs for community alcohol services keyworkers for delivering the intervention
12. Assess follow-up and outcome completion rates

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2021, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)1413140213; WoSREC5@ggc.scot.nhs.uk), REC ref: 20/WS/0179

Study design
Randomized; Both; Design type: Prevention, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Alcohol misuse

Interventions
Trial Design
The trial has the following work packages (WP):
1. WP1: Establish a standardised script framework for fibroscan operators to deliver liver disease-specific advice to eligible participants having fibroscan.
2. WP2: Develop and film patient video stories using fibroscan related information to aid recovery again using eligible participants.
3. WP3: Test the feasibility of the trial design including the script and video stories developed in WP1 and WP2 in a community based 1:1 feasibility randomised trial in alcohol treatment services. And to perform a qualitative evaluation of 1-3 above to inform a later, larger national randomised trial.

Trial setting
The feasibility RCT will be conducted at three community-based alcohol settings hosted by Framework and Nottingham Recovery Network and work in partnership with Nottinghamshire NHS Foundation Trust. The Framework housing association is a Registered Charity and Registered Social Landlord (regulated by the Regulator of Social Housing) which provides housing, health, employment and support services. Nottingham Recovery Network is the integrated drug and alcohol treatment pathway for Nottingham City, provided under contract from Nottingham City Council Crime and Drugs Partnership (CDP).
1. Primary care alcohol clinic run by NRN:
The community clinics including Clifton and the potential to expand from one site to others depending on the level of recruitment
2. The Wellbeing hub
A city-centre building where Framework provides Nottingham City's alcohol services
3. Edwin House
Edwin House is a 63-bed Care Quality Commission registered care home, proving residential care for people who have serious alcohol and drug-related health conditions

Randomisation
The participant in work package 3 will be individually allocated on a 1:1 ratio using minimisation with a probabilistic element. The minimisation variables will be age, gender, ethnicity and severity of alcohol misuse based on SADQ score.

Control arm:
Participants in the control arm will continue with usual care which is provided as part of an alcohol management programme at these centres following national guidelines as described above.
Standard treatment at the Nottingham Recovery Network:
As part of standard treatment, the NRN provide different types of interventions to clients in line with the National Drug Treatment Monitoring System Dataset (NDTMS) and Public Health

England (PHE) guidelines. For adult Drug and alcohol services there are three main categories of standard interventions delivered by the NRN:
1. Psychological
2. Recovery Support
3. Pharmacological

Psychological Interventions
This involves the following sub interventions:
1. Motivational interventions
2. Family and social network interventions
3. Cognitive and behavioural based relapse prevention interventions (substance misuse specific)

Recovery Support Interventions
This involves the following sub interventions:
1. 12-step work
2. Counselling – British Association for Counselling and Psychotherapy (BACP) accredited

Pharmacological Interventions
This type of intervention involves prescribing medication for drug and/or alcohol relapse prevention support, such as naltrexone, acamprosate, disulfiram as part of alcohol or opioid relapse prevention therapy and chlordiazepoxide for acute alcohol withdrawal.

Intervention arm:
Participants in this arm, in addition to usual care, will have a fibroscan and immediately after this will watch recovery video stories.

Fibroscan: Fibroscanning will be undertaken on the day of commencing the programme or detoxification regimen. Fibroscan is performed in a designated clinical area where the client lies on a clinical coach which is available in all the three locations involved in the study. Fibroscan takes 10-15 minutes to perform and does not involve the client undressing hence it is anticipated that it will have minimal impact on the clinical service. This impact will be explored in the qualitative component of the study. The key member had trial-specific training and will provide feedback on a standardised script developed as part of WP1.

Video stories: In all centres, the video stories will be provided in a designated private waiting area. They will be available on a dedicated tablet computer. It is envisaged that the client will have a menu with a choice of the story with pictures of the storyteller and a brief description in the text. This will be part of WP2 and based on PPI group feedback on the stories to ensure diversity of person and liver disease stage. The client will be able to view all or select stories without restriction. Video stories will be made available for later viewing by the clients via a weblink. Impact and frequency of viewing will be explored in the qualitative interviews.

Duration of follow up:
Total duration of follow up: 6 months
Health economics data taken from HES database at 12 months and 24 months

Intervention Type
Mixed

Primary outcome measure
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 12 months

2. Retention rate: number of participants who consent to participate that remain in the study until the end of follow up at 6 months
3. Acceptability of the intervention measured using qualitative interview at 6 months
4. Feasibility of outcome measures measured by analysing the feasibility of outcomes outlined as primary and secondary at baseline, 3 months and 6 months

Secondary outcome measures
1. Weekly alcohol intake measured using self-reported alcohol intake at baseline, 3 months and 6 months
2. Alcohol misuse measured using AUDIT score at baseline, 3 months and 6 months
3. Severity of alcohol misuse measured using SADQ score at baseline, 3 months and 6 months

Overall study start date
02/10/2019

Completion date
01/02/2025

Eligibility

Key inclusion criteria
Work package 1 (WP1):
1. A person aged 18 years and over attending with a primary problem of alcohol misuse as defined by initial clinical assessment and had a fibroscan in past
2. Willing to participate in a focus group

Work package 2 (WP2):
1. A person aged 18 years and over attending with a primary problem of alcohol misuse as defined by initial clinical assessment.
2. A person who previously had a fibroscan
3. A person with lived experience of alcohol problems, willing to consent to the recording and public use of video recording (identified via KLIFAD PPI group, existing NRN networks or research networks at Nottingham University Hospital)
Participants from WP1 will also be invited to participate in WP2

Randomised feasibility trial (WP3):
1. A person aged 18 years and over attending with a primary problem of alcohol misuse as defined by initial clinical assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
184

Key exclusion criteria
Work package 1 (WP1):
1. Other primary substance misuses even where alcohol is a factor
2. Lacks the capacity to give confirmed consent

Work package 2 (WP2):
1. Lacks the capacity to give confirmed consent

Randomised feasibility trial (WP3):
1. Other primary substance misuses even where alcohol is a factor
2. Referrals from driving offences and student referrals as these individuals are essentially not self-presenting, may have different motivation and have lower overall levels of alcohol use and so are substantially lower risk of having liver disease
3. Out of area clients at Edwin house in whom we cannot obtain follow up data due to lack of follow up availability
4. Participants unable to comply with study procedures
5. Lacks the capacity to give confirmed consent

Date of first enrolment
01/04/2021

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham Recovery Network
Wellbeing Hub Nottingham
73 Hounds Gate
Nottingham
United Kingdom
NG1 6BB

Study participating centre

Framework HA
Edwin House
House, 56, Edwin
57 Millers Ct
Nottingham
United Kingdom
NG7 3DP

Study participating centre
Nottingham Recovery Network
Primary care alcohol clinic
Wellbeing Hub Nottingham
Nottingham
United Kingdom
NG1 6BB

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details
The Resource, Trust HQ
Duncan Macmillan House
Porchester Road
Nottingham
England
United Kingdom
NG3 6AA
+44 (0)7920454530
mark.howells@nottshc.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nottinghamshirehealthcare.nhs.uk/

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type

Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201146

Results and Publications

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

Intention to publish date
30/11/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publications.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/11/2021	05/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		30/06/2023	17/07/2023	Yes	No
Other publications	Intervention development	04/10/2023	05/10/2023	Yes	No
Other publications	Application and Extension of the Alcohol Recovery Narratives Conceptual Framework	08/09/2023	12/03/2025	Yes	No