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

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ABSTRACT

Introduction Heavy drinkers in contact with alcohol services do not routinely have access to testing to establish the severity of potential liver disease. Transient elastography by FibroScan can provide this information. A recent systematic review suggested providing feedback to patients based on markers of liver injury can be an effective way to reduce harmful alcohol intake. This randomised control trial (RCT) aims to establish the feasibility of conducting a larger national trial to test the effectiveness of FibroScan advice and Alcohol Recovery Video Stories (ARVS) in changing high-risk drinking behaviour in community alcohol services common to UK practice.

Methods and analysis This feasibility trial consists of three work packages (WP). *WP1*: To draft a standardised script for FibroScan operators to deliver liver disease-specific advice to eligible participants having FibroScan. *WP2*: To create a video library of ARVS for use in the feasibility RCT (WP3). *WP3*: To test the feasibility of the trial design, including the FibroScan script and video stories developed in WP1 and WP2 in a one-to-one individual randomised trial in community alcohol services. Semi-structured interviews will be conducted at 6 months follow-up for qualitative evaluation. Outcomes will be measures of the feasibility of conducting a larger RCT. These outcomes will relate to: participant recruitment and follow-up, intervention delivery, including the use of the Knowledge of LIver Fibrosis Affects Drinking trial FibroScan scripts and videos, clinical outcomes, and the acceptability and experience of the intervention and trial-related procedures. Data analysis will primarily be descriptive to address the feasibility aims of the trial. All proposed analyses will be documented in a Statistical Analysis Plan.

Ethics and dissemination This trial received favourable ethical approval from the West of Scotland Research Ethics Service (WoSRES) on 20 January 2021, REC reference: 20/WS/0179. Results will be submitted for publication to a peer-reviewed journal.

Trial registration number ISRCTN16922410.

Strengths and limitations of this study

► The Knowledge of LIver Fibrosis Affects Drinking (KLIFAD) trial is the first randomised control trial to evaluate the feasibility of using non-invasive liver stiffness measurement and alcohol recovery video stories as a behavioural intervention.
► The mixed-methods design of the KLIFAD trial will enable us to test the acceptability of trial-specific procedures to participants and key alcohol workers.
► The KLIFAD trial will enable a definitive trial to establish the effectiveness of non-invasive screening for liver fibrosis in community alcohol services.
► The primary limitation of the KLIFAD trial is that it is a single-centre trial which could limit the generalisation of findings.
► Due to the nature of the KLIFAD intervention, blinding is not possible.

INTRODUCTION

Alcohol-related liver disease (ARLD) is the most common cause of cirrhosis in the UK, and mortality from ARLD has risen significantly over the past three decades. It is now the second most common cause of working life years lost in men and fifth in women.[1 2] Europe has one of the highest prevalence of Alcohol Use Disorders (AUD), involving 15% of men and 3.5% of women.[2] Around 25% of the UK population drink above the UK recommended level of 14 units per week, and 10% are harmful drinkers.[3] The UK's total per capita pure alcohol intake for people age ≥15 years is 11.4 L/annum per person, which is twice the global average of 6.4 L/annum per person.[2 3] Approximately 20%–30% of lifelong drinkers develop liver cirrhosis, and the risk is even higher (35%) among harmful drinkers.[4 5]

ARLD causes no symptoms in its earlier stages; indeed, patients are often unaware they have serious physical health problems until they present with the complications of cirrhosis, for example; ascites, jaundice,

encephalopathy, variceal bleed and liver failure, when the opportunity for treatment and recovery of liver health is significantly reduced.[1 5 6] It is estimated that the cost to the UK of alcohol on health is £3.5 billion per year,[3 7] consuming 3.6% of the National Health Service (NHS) annual budget.[8] In England, there were 5698 alcohol-specific deaths in 2018, the alcohol-specific age-standardised death rate was 11.9/100 000 (male=16.4 female=7.6). Nottingham (UK) has one of the highest (total=18.6, male=26.8 and female 10.2) alcohol-specific age-standardised death rate/100 000 in the country.[9] A recent trial from the USA predicted a 75% increase in age-standardised annual mortality and a 65% increase in decompensated cirrhosis due to ARLD over the next two decades.[10]

Systematic reviews of randomised controlled trials (RCTs) have established that delivering brief advice about alcohol to harmful drinkers helps them reduce their alcohol consumption.[11 12] Most studies were conducted in primary care settings where the prevalence of liver disease is likely to be markedly lower than in specialist alcohol treatment services. In alcohol services, where high levels of physical and psychological dependence on alcohol are frequent, National Institute of Clinical Excellence guidelines state adults with high levels of alcohol dependency should be assessed and offered intensive structured community-based interventions (with or without medical therapy) as these provide the best chance of achieving and maintaining abstinence from alcohol.[13] Most clinical services in the UK are based on these principles. Individual programmes vary by locality with many of these services delivered by non-NHS providers. Despite the delivery of brief advice and other alcohol-related interventions in clinical practice for over two decades, mortality and morbidity due to alcohol misuse continues to rise in the UK.[3] There is a pressing need to optimise existing interventions to reduce harmful alcohol intake and examine effective alternative options.

Early diagnosis of liver fibrosis provides an opportunity to intervene and reduce or stop alcohol intake. This is known to be the most effective way of preventing liver disease progression.[14] Transient elastography by Fibro-Scan (Echosens, France) has been used in primary care (General Practice) settings to detect liver disease in populations identified as having liver disease risk (heavy drinkers and those with type 2 diabetes). These studies showed that screening asymptomatic individuals based on risk for liver disease doubles the rates of liver cirrhosis diagnosis in the primary care populations studied.[15 16] Moreover, a recent systematic review suggested providing feedback to patients based on markers of liver injury can be an effective way to reduce harmful alcohol intake.[17] Access to recovery stories can help address mental health problems and support recovery from addiction.[18 19] Peer support from people who have recovered from alcohol misuse is beneficial in modifying high risk drinking behaviour.[20]

This trial aims to investigate the feasibility and acceptability of conducting an RCT in community specialist alcohol services settings run by Nottingham Recovery Network (NRN) and to test the acceptability of trial interventions (FibroScan and Alcohol Recovery Video Stories, ARVS).

Selection of the term 'alcohol misuse'

We acknowledge the heterogeneity in language used to describe alcohol use, and also the stigma associated with some commonly used terms, which itself can act as barrier to change.[21] Some terms, such as alcohol use Disorder (AUD), are not well understood in the general population. The concept for this feasibility trial was developed in collaboration with Patient and Public Involvement (PPI) groups. After extensive discussion between the study team and PPI groups, we have opted for the term 'alcohol misuse' as a general term to cover excess alcohol intake, harmful alcohol intake, drinking problems, alcohol dependence, and AUD.

We define alcohol misuse as 'weekly alcohol intake ≥14 units, or an Alcohol Use Disorder Identification Test (AUDIT) score of ≥8, or key alcohol worker and/or physician diagnosis or referral from any other services with problem drinking'.

The other definitions relevant to Knowledge of LIver Fibrosis Affects Drinking (KLIFAD) trial are provided in online supplemental material 1 (SP-Definitions).

METHODS AND ANALYSIS

KLIFAD is a parallel design feasibility RCT. The trial will be conducted in a single centre in the UK, carried out at three community alcohol services in Nottingham (the Wellbeing Hub, Edwin House and the Primary Care Alcohol Clinic run by the NRN) hosted by Framework and NRN and working in partnership with Nottinghamshire NHS Foundation Trust.
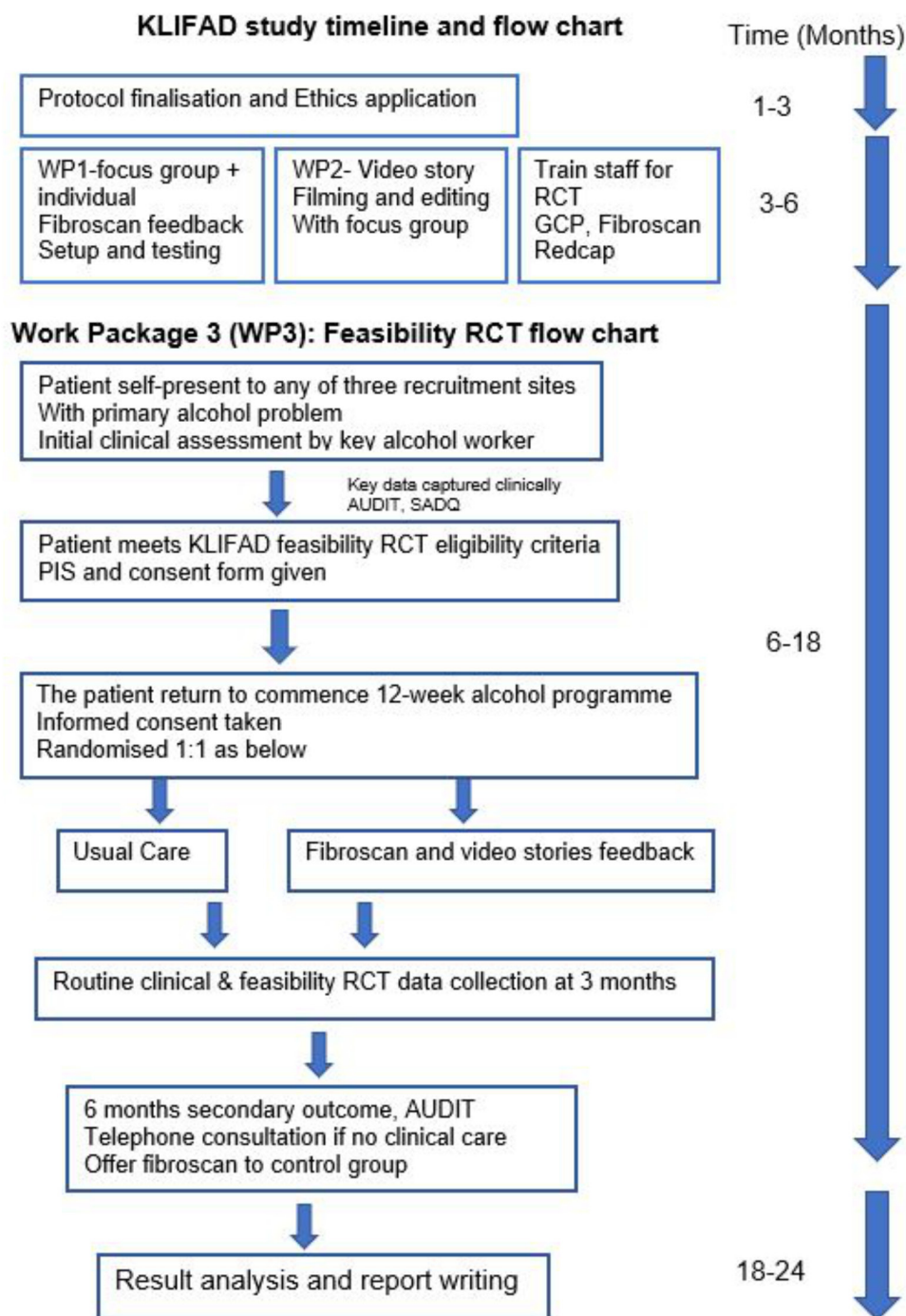
The KLIFAD trial consists of three work packages (WP) (figure 1).

Work package one (WP1)

WP1 aims to design a standardised script framework for FibroScan operators to deliver liver disease-specific advice to participants having FibroScan as part of the feasibility RCT (WP3).

FibroScan, is an ultrasound technology developed by Echosence, France, which non-invasively asseses liver stiffness. A prototype script for FibroScan has been created in consultation with the existing KLIFAD PPI group covering three ranges of FibroScan scores, normal ≤7 Kilopascal (kPa), intermediate fibrosis 8–15 kPa and advance fibrosis ≥15 kPa. online supplemental material 1 The trial flow chart for WP1 is provided in figure 2.

We will organise separate participant and FibroScan operator focus groups to collect feedback on the prototype scripts. The participant focus group will allow us to investigate the key messages to be included in the script
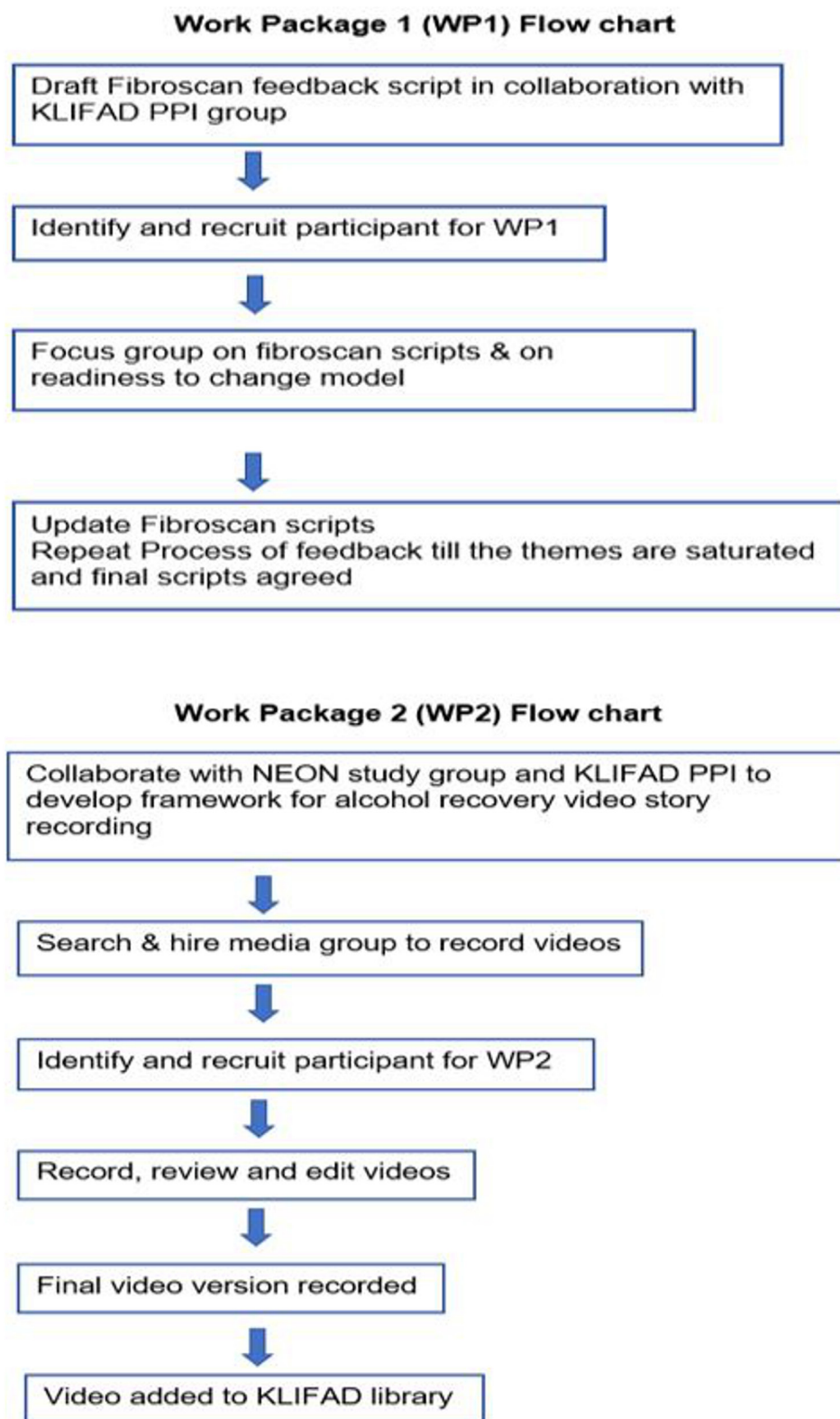
Figure 1 The KLIFAD trial timeline and flow chart. The trial has three work packages (WP), WP3 is in randomised feasibility trial. AUDIT, Alcohol Use Disorder Identification Test; GCP, good clinical practice; KLIFAD, Knowledge of LIver Fibrosis Affects Drinking; RCT, randomised control trial; SADQ, Severity of Alcohol Dependence Questionnaire.

and feedback, as well as considering how best to present the FibroScan results (eg, graphically, in the text). The FibroScan operator focus group will specifically discuss implementation in clinical practice. In addition, to evaluate the stage of change that each participant has reached, a validated readiness to change model will be piloted.[22]

Following Krueger's (1988) focus group guide, each focus group will include five to eight participants and will last for a maximum of 2 hours.[23] Depending on the latest COVID-19 guidelines, the focus group will be either virtual or face-to-face. A topic guide will be used (SP-Focus Group Guide WP1 V.2.0). We aim to arrange two participant focus groups and one FibroScan operator focus group. The focus groups will be facilitated by two members of the research team. Examples of questions include: (a) If you were a participant in the trial, would the script make sense to you? (b) Are there any parts of the script that you do not understand, and if so, why? (c) What is the best way to present the results of the FibroScan (eg, graphically, in the text)?

Work Package 1 (WP1) Flow chart

```
Draft Fibroscan feedback script in collaboration with
KLIFAD PPI group
                            ↓
Identify and recruit participant for WP1
                            ↓
Focus group on fibroscan scripts & on
readiness to change model
                            ↓
Update Fibroscan scripts
Repeat Process of feedback till the themes are saturated
and final scripts agreed
```

Work Package 2 (WP2) Flow chart

```
Collaborate with NEON study group and KLIFAD PPI to
develop framework for alcohol recovery video story
recording
                            ↓
Search & hire media group to record videos
                            ↓
Identify and recruit participant for WP2
                            ↓
Record, review and edit videos
                            ↓
Final video version recorded
                            ↓
Video added to KLIFAD library
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Figure 2 Flow diagram for; work package one to create FibroScan scripted feedback and work package two to create alcohol recovery videos stories. KLIFAD, Knowledge of LIver Fibrosis Affects Drinking; NEON, narrative experiences online; PPI, patient and public involvement; WP1, work package one.

Eligible participants (table 1) will be identified and recruited through multiple channels. For example, via existing patient forums at all three recruitment settings, the KLIFAD PPI group, by offering information to patients self-presenting to any of the trial treatment settings, snowball methods and via Black, Asian and minority ethnicity/ Framework PPI groups. The focus group meeting will be recorded and transcribed verbatim either by automated

Table 1 KLIFAD trial eligibility criteria

Inclusion criteria	Exclusion criteria
Work package one	
A person age ≥18 years	Other primary substance misuse even where alcohol is a factor
Primary problem of alcohol misuse‡	Lacks capacity to confirm consent
Had FibroScan in past	
Work package two	
A person age ≥18 years	Lacks capacity to confirm consent
Primary problem of alcohol misuse	
Had FibroScan in past	
A person with lived experience of alcohol problems	
A person willing to consent to the recording and public use of their video recording	
Work package three: the randomisation phase	
A person age ≥18 years	Other primary substance misuse even where alcohol is a factor
Primary problem of alcohol misuse	Lacks capacity to confirm consent
	Referrals from driving offences and student referrals*
	Out of area clients at Edwin House†
	Participants unable to comply with trial procedures

*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.
†In whom we cannot obtain follow-up data due to lack of follow-up availability.
‡Alcohol misuse was defined as, weekly alcohol intake ≥14 units, or an AUDIT score of ≥ 8, or key alcohol worker and/or physician diagnosis or referral from any other services with problem drinking.
AUDIT, Alcohol Use Disorder Identification Test; KLIFAD, Knowledge of LIver Fibrosis Affects Drinking.

software or an independent sponsor-approved transcriber. After the first participant focus group, the FibroScan script will be edited considering feedback and a second focus group will then be held to review iterated scripts. The final scripts will be sent via email to participants of focus groups for any final thoughts. We will then organise a FibroScan operator focus group of key alcohol workers working at any of the recruitment settings who are willing to give informed consent, to discuss any specific implementation issues.

After the focus groups, we will collect participant feedback on the change model (SP-Change Model Questionnaire (CMQ) V.1.0) to get an initial sense of the applicability of readiness to change following discussion about the scripts.

Work package two (WP2)

WP2 aims to create a video library of ARVS from people with a history of alcohol misuse. These ARVS will be used in the feasibility RCT (WP3).

Receiving mental health recovery stories can provide benefits to some people experiencing mental health distress,[18 24 25] and the effectiveness of mental health recovery stories as an intervention to increase quality of life has been examined in a clinical trial.[26] However, equivalent evidence is not available for the impact of ARVS. So that we can explore the impact of stories of recovery from alcohol misuse, in WP2 we will develop a set of recovery stories from participants who have successfully overcome their alcohol misuse. These videos will be peer-reviewed by the KLIFAD PPI group which will include input from Nottingham University Hospitals NHS Trust (NUH) Black, Asian and minority Ethnic PPI group. Based on feedback, the videos will then be edited ready for use in the feasibility RCT (WP3). All edits will be agreed on with the story narrators.

For each narrator, we will follow their preference to create either:
► A recovery story that starts with an open-ended question where narrators have the liberty to tell their story without interruption *or*
► A recovery story in which the participant is asked a set of standard questions.

Drinking history and last FibroScan reading will be included at the start of each video. Eligible participants (table 1) will be recruited through the channels used in WP1. Those who took part in WP1 will also be invited to take part in WP2. A purposive sample based on demographic and liver disease severity of six to nine individuals will be selected.[27] We will arrange a meeting with the KLIFAD PPI group to discuss what makes a video impactful. The outline of WP2 is given in figure 2.

The ARVS will be recorded either at Nottingham Digestive Diseases Biomedical Research Centre (NDDC) Biomedical Research Centre Nottingham University Hospital, the University of Nottingham or the participant's usual place of residence. Each video will be of 2–5 min duration. Videos will be titled based on FibroScan score (low-risk, medium and high-risk score). Videos will be subtitled and depending on the final video format, after the feedback, we envisage adding a photograph of the storyteller and a short-associated text on the title page with informed consent from the participant. The video stories will be brought together in a single-tablet computer-based package from which the participant will be able to choose their most preferred video after receiving a FibroScan score. Collaborative work between a clinician and patient can make a significant impact on

Work Package 3 (WP3): Feasibility RCT flow chart
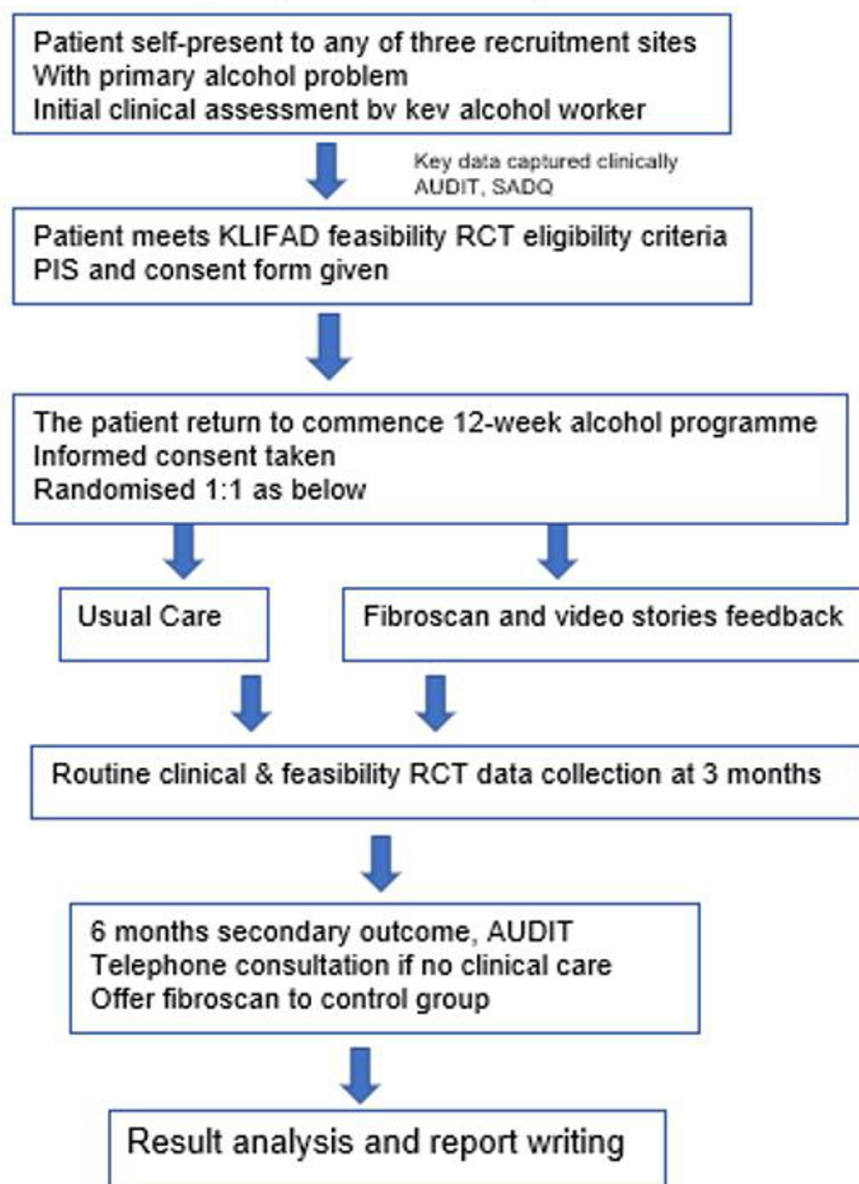
Figure 3 Flow diagram for work-package-three, the randomised control trial flow chart. Work package three is feasibility randomised control trial. AUDIT, Alcohol Use Disorder Identification Test; GCP, good clinical practice; KLIFAD, Knowledge of LIver Fibrosis Affects Drinking; RCT, randomised control trial; SADQ, Severity of Alcohol Dependence Questionnaire.

the recovery process[28] and hence in some videos, and with consent by narrators, we will include sections of a video narrated by a clinician the narrator has worked with.

All video stories recorded as part of the KLIFAD trial will have peer review by the trial team and KLIFAD/ Black, Asian and ethnic minority PPI groups. The videos will be shown in the same format that they would be used in WP3.

Work package 3 (WP3): feasibility RCT

A feasibility RCT of parallel groups (one-to-one) will compare usual care (assessment and entry into an alcohol reduction programme which does not include information on liver disease severity) to usual care plus feedback

from the FibroScan and ARVS. The eligibility for WP3 is provided in table 1 and the attached flow chart (figure 3).

Objectives

Bowen *et al*'s guide for feasibility studies was used to decide objectives.[29]
1. *Test*: the intervention (FibroScan plus feedback and ARVS) in a feasibility RCT.
2. *Acceptability*: of feasibility RCT-related procedures and interventions among patients and healthcare workers.
3. *Feasibility outcomes*: to establish recruitment rate, consent rate, dropout rate and completion rate for accurate sample size calculation for future large-scale RCT.

4. *Refine*: the eligibility and randomisation criteria for a future large-scale RCT.
5. *Implementation and practicality*: to assess the ability of community alcohol services to deliver the intervention, and training and support needs for community alcohol services keyworkers for delivering the intervention.
6. *Adaptation*: of KLIFAD trial interventions, FibroScan feedback and ARVS format and access as per suggestions from participants and key alcohol workers
7. *Limited efficacy*: to test limited efficacy of KLIFAD interventions

Intervention group
Participants randomised to the intervention arm will receive a FibroScan, feedback on FibroScan results and watch ARVS immediately after. The ARVS will be made available should a participant wish to watch them later.

Control group
Participants randomised to the control arm will continue with standard treatment (usual care) provided at the three treatment settings. The participants in this arm will be offered FibroScan at 6 months.

As part of standard treatment, the recruitment settings provide different types of interventions to participants in line with the National Drug Treatment Monitoring System Data set (NDTMS) and Public Health England (PHE) guidelines.[30] Existing treatment programmes can run for up to 12 weeks.

For adult drug and alcohol services, there are three main categories of standard intervention (usual care) delivered by the NRN: (a) Psychological: which includes motivational interventions, family and social network interventions and cognitive and behavioural-based relapse prevention interventions (substance misuse specific). (b) Recovery support: which includes 12-step work and counselling.

(c) Pharmacological: which involves prescribing medication for drug and/or alcohol relapse prevention support. For example, naltrexone, acamprosate, disulfiram as part of alcohol or opioid relapse prevention therapy and Chlordiazepoxide for acute alcohol withdrawal.

Specific treatment programmes are started after an initial assessment and based on the participant's needs. The duration of contact with services varies, most participants stay with services for 12 weeks, some get discharged early and a few stay longer than 6 months.

Methods
Sample size
As this is a feasibility trial, a formal sample size calculation for between-group comparisons of a primary outcome is not appropriate. Researchers have previously recommended sample sizes between 24 and 50 to satisfactorily achieve feasibility outcomes.[31–33]

After discussion with community alcohol services data manager and considering variation in number of patients presenting per week, we aim to approach 40 eligible participants per month. Assuming a 50% consent rate, we anticipate randomising 20 participants per month (10 per month per arm) for a recruitment period of 6 months. With an estimated sample size of 120, we will be able to calculate a dropout rate of 80% within a 95% CI of ±7.1%. Assuming a non-differential follow-rate of 80%, this target sample size should provide follow-up outcome data on a minimum of 48 participants in each of the two arms.

Randomisation
The participants will be individually allocated on a one-to-one ratio using minimisation with a probabilistic element. The minimisation variables will be age, gender, ethnicity and severity of alcohol misuse based on the Severity of Alcohol Dependence Questionnaire (SADQ) score. To minimise selection bias, the randomisation will be externally performed by a data manager from NRN.

Schedule of visits
Baseline
The baseline visit will be on the day when the participant starts standard treatment at any recruitment setting. At this visit, written informed consent will be given by participants and participants will be randomised to the intervention or control group. Participants in both arms will have an initial detailed assessment (SP-NRN assessment form online supplemental material 2) as part of their standard care. This includes the collection of baseline demographic and clinical data (eg, age, gender, ethnicity). Participants randomised to the control arm will continue with usual care, while participants randomised to the intervention arm will have the usual care and FibroScan followed by standardised script feedback with ARVS watched immediately after the FibroScan result.

Three months
This visit will be part of usual care, no research specific activity will be carried out. The research data will be extracted from routinely collected data from three treatment settings.

Six months
This will be a telephone consultation or in-person appointment by the research team. Participants in the control arm will be offered a FibroScan after completion of outcomes. The 6-month follow-up is specifically to cover those who were lost to follow-up at NRN from the treatment programme.

A detailed schedule of the visits is given in table 2.

Data collection
At baseline, 3 and 6 months, the following data will be collected (table 2)
► Demographics (including address, email address and contact number).
  This will be archived and kept separate from the main database.
► AUDIT scores.
► SADQ scores.

Table 2 Work-package-three (feasibility RCT) schedule of visits and variables for data

Trial activity	Baseline visit	3* months	6† months
Control group			
Date and time	Yes	Yes	Yes
Baseline consent	Yes	–	–
FibroScan+feedback	–	–	Yes
Watching video stories	–	–	Yes
Qualitative interview	–	–	Yes
Demographics	Yes	–	–
AUDIT score	Yes	Yes	Yes
SADQ score	Yes	Yes	Yes
Self-reported alcohol intake‡	Yes	Yes	Yes
Breath alcohol test	Yes	Yes	Yes
Substance misuse other than alcohol	Yes	Yes	Yes
Data on feasibility outcomes	Yes	Yes	Yes
Intervention group			
Date and time	Yes	Yes	Yes
Baseline consent	Yes	–	–
FibroScan+feedback	Yes	–	–
Watching video stories	Yes	–	–
Qualitative interview	–	–	Yes
Demographics	Yes	–	–
AUDIT score	Yes	Yes	Yes
SADQ score	Yes	Yes	Yes
Self-reported alcohol intake	Yes	Yes	Yes
Breath alcohol test	Yes	Yes	Yes
Substance misuse other than alcohol	Yes	Yes	Yes
Data on feasibility outcomes	Yes	Yes	Yes

*3-months visit: this will be routine visit no trial-specific procedure will be carried out.
†6-months visit: will be a telephone consultation and/or if possible/required in person. The participant in the control group will be offered a FibroScan at 6 months if they attend it will be in-person appointment.
‡Self-reported alcohol intake in gram and units per week.
AUDIT, Alcohol Use Disorder Identification Test; RCT, randomised controlled trial; SADQ, Severity of Alcohol Dependence Questionnaire.

▶ Self-reported alcohol intake (gram and unit per week).
▶ Substance misuse other than alcohol.
▶ Breath alcohol testing where participants are still attending.

Breath alcohol testing is a strength of this trial; most studies have relied on self-reporting of alcohol intake. This means we can correlate breath alcohol readings with self-reported alcohol consumption, providing substantial additional information.
▶ Data on feasibility outcomes (eg, screening rate, recruitment rate retention rate).

All the above measurements are part of routine outcome data collected by all three recruitment settings, apart from the 6-month data collected for those who are no longer in a treatment programme at 6 months. All three services included in this trial record all of the above outcomes as part of the 12-week programme standard data set and report these to commissioners. Follow-up data are obtained at every attendance and includes the above data set and breath alcohol testing.

Qualitative data

We will conduct one-to-one semi-structured interviews to evaluate participant's experiences of being part of the trial (eg, 'Overall, how do you feel about taking part in the KLIFAD trial?') and any changes they may have made to their lives (eg, 'Do you think the KLIFAD trial changed your use of alcohol in any way?'). The preliminary qualitative interview schedule topic guide is provided in online supplemental material 1 (SP: qualitative interview guide). It will be piloted before use by the PPI group to check structure and wording of questions. A readiness to change model used in WP1 will also be piloted. Focus groups and interviews will be audio-recorded and transcribed by an independent transcriber approved by the sponsor, to enable thematic analysis.

Health economics

Routine NHS data collected for the standard care 12-week treatment programmes will be used together with resources utilisation derived from the NHS digital linked data to derive healthcare costs and the potential benefits of the intervention.

Outcomes

The outcomes are designed to assess the feasibility and acceptability of the KLIFAD intervention and research processes to help inform a future large-scale RCT. The following outcomes will be reported:
▶ Recruitment rate.
▶ Retention rate.
▶ Consent rate.
▶ Acceptability of the intervention (FibroScan and ARVS).
▶ The willingness of participants to be randomised to trial arms.
▶ Acceptability of the intervention to patients.
▶ Participant adherence.
▶ Feasibility of outcome measures.
These feasibility outcomes will enable the trial team to:
▶ Determine the best primary endpoint for the future definitive trial.

- ► Provide sample size estimates for the future definitive trial.
- ► Record ARVS which will contribute to the video library used in a later large-scale RCT.

Statistical and data analysis plan

The analyses of the quantitative data will be in line with Consolidated Standards of Reporting Trials guidelines for pilot and feasibility trials.[34] Sekhon *et al*'s framework for acceptability testing will be used.[35] The primary descriptive analyses will be on an intention-to-treat basis (ie, participants are analysed in the group to which they were originally allocated). Data will be summarised using frequency (%), mean (SD) or median (IQR) depending on the distribution of the data. Summary measures will be presented along with their 95% CIs whenever appropriate. Results of the data analysis will be presented using appropriate tables and graphs.

The trial is not powered to investigate statistical significance between the two arms. As this is a feasibility trial, no subgroup analysis is planned. However, the results of the feasibility variables will be presented by categories of different variables (age, gender, ethnicity severity of alcohol misuse).

Different techniques will be followed to maximise the completeness of data collection (eg, via staff training). The level of missing data will be assessed. This is especially useful for the proposed primary outcome variables. An interim analysis is not planned for this trial, but the progress of the trial will be reported to the oversight committee who can assess any concerns.

Thematic analysis of qualitative data will be conducted following Braun and Clarke's standard methods.[36] Care will be taken to integrate updated guidelines about thematic analysis including a transparent appreciation of researcher reflexivity.[36] If the trial management group feel the analysis requires external validity, a sample of transcripts identified by a random number generator with the codebook will be given to a researcher independent of the trial. This will allow us to calculate the % agreement and Cohen's Kappa value (using criteria by Cohen, 1960).[37] The Consolidated Criteria for Reporting Qualitative Studies will be used to ensure thorough and explicit reporting of qualitative data in reports and manuscripts for publication.[38]

Ethics and dissemination

Ethical approval

The trial received favourable ethical approval from the West of Scotland Research Ethics Service (WoSRES) on 20 January 2021, REC reference: 20/WS/0179.

Informed consent

All participants will provide a written or online (e-consent) informed consent before any research activities are initiated. A patient infomation sheet (PIS) written in plain language will be provided and it will be ensured the participant has understood the trial information and had enough time to make an informed decision. The Site Investigator will be available to answer any questions about trial participation.

Data handling and record-keeping

In compliance with the ICH/Good Clinical Practice guidelines, regulations and following the Nottinghamshire Healthcare NHS Foundation Trust SoPS, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the trial. These will be retained for at least 24 months or for longer if required. If the responsible investigator is no longer able to maintain the trial records, a second person will be nominated to take over this responsibility. The routinely collected clinical data will be treated in the same way as other clinical case records are treated in the NHS following relevant policies developed by Nottinghamshire Healthcare NHS Foundation Trust, the UK Government and the National Institute for Health Research (NIHR).

The Trial Master File and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the NDDC at Nottingham University Hospital NHS Trust (NUHT). This archive shall include all trial databases and associated meta-data encryption codes.

An index will be created for Case Report Forms and paper trial data before storage. All online and IT-based data will be password protected and access will only be granted to people directly involved in trial and data analysis. All patient identifiable data will be pseudonymised with a trial-specific participant number.

The information will be copied to the research database (REDCAP cloud) run by the NUHT. We will delete any information that identifies participants by the end of the KLIFAD trial (currently expected October 2022). All relevant UK data protection laws will be followed, including the 2018 Data Protection Act.

Participant safety

There is a risk that being given a normal FibroScan result may provide false reassurance and encourage participants to maintain their current level of harmful drinking or encourage them to drink more. It is also possible that a high reading will generate anxiety. The trial is designed to minimise these risks by providing scripted feedback (WP1) and watching ARVS (WP2).

Cirrhosis diagnosis and FibroScan: It is anticipated that a small number of people will be identified who have previously unknown cirrhosis and so would be at risk of complications of liver disease. This will be mitigated by offering onward referral to out-patient Hepatology for all participants with a FibroScan reading >15 kPa. This will be via contact with the participant's GP and would follow the current NUHT Nottinghamshire adult liver disease stratification pathway for referral.[39] Some risk mitigations will be through the feedback included in this trial which covers cirrhosis.

For WP1 and WP2, we cannot foresee any potential risks except possible emotional distress during participation in a focus group or semi-structured interview. Participants can choose to skip any question that they prefer not to answer. If distress occurs during the WP3 trial visit, we will ask the participant to take a break to recover, or they can choose to terminate the process. We do not expect that the trial will cause any discomfort or pose any disadvantages, however, contact details for the trial team are provided should the participant have any questions before, during or after taking part. We have also provided a list of locally relevant support services at the end of each patient information sheet, which participants can consult.

Patient and public involvement (PPI)

The trial has a dedicated PPI group and has considerable regular input from the PPI group at every stage of the study.

Dissemination

The results of the feasibility trial will be submitted for publication to a peer-reviewed journal and presented at relevant conferences. A separate manuscript on the qualitative aspect of the trial will be written as well. This work is part of a PhD for the lead author (MS) who will present and submit data as a PhD thesis to the University of Nottingham. The work will also be made available to trial participants via the NDDC Biomedical Research Unit website.

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Supplemental material

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SP-Definitions

The following definitions are relevant to the KLIFAD trial:

Recovery Definition
For the KLIFAD trial we adopted the following definition of "Recovery"

"A period of sustained abstinence from alcohol creating a deeply personal, unique process of change, a way of living a satisfying, hopeful and contributing life even with limitations caused by illness. A process involving the development of new meaning or purpose in one's life which maximises health and wellbeing and participation in the rights, roles and responsibilities of society"[1-4].

Recovery story
A story told by a person about their journey of recovery.

In KLIFAD we are using recovery stories which are primarily first-person lived experience accounts, which include elements of both adversity/struggle and of strength/success/survival related to AUD, and which refer to events or actions over a period. Some stories will include brief fragments presenting clinical perspectives on a case, provided by a clinician who worked with the narrator[5].

Story narrator
The person telling their own recovery story.

Story recipient
The person viewing, reading or listening to someone else's recovery story.

KLIFAD Library
A collection of recovery stories intended for use in the KLIFAD feasibility trial.

Alcohol misuse
The National Institute on Alcohol Abuse and Alcoholism (NIAAA) define alcohol misuse as "alcohol consumption that puts individuals at increased risk for adverse health and social consequences"[6]

Alcohol use disorders
The NIAAA define AUD as "a chronic relapsing brain disorder characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences" [6].

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SP-Focus Group Guide WP1 V2.0

Focus group Guide participants
Work Package 1 (WP1)
Version 2.0 Date:14/10/2020

Study title: **Does knowledge of liver fibrosis affect high-risk drinking behaviour (KLIFAD)? A feasibility randomised controlled trial**

To begin

Welcome to the focus group session. Thanks for taking the time to join us to talk about liver disease screening.

You were invited here today because you attended a liver scan appointment and were given your level of risk for liver disease using a Fibroscan machine. We would like to understand how to provide the best experience for patients undergoing the scan. This includes how the person operating the Fibroscan machine discusses the scan itself and then delivers the results of the scan to patients. We will ask you to read through a script we have prepared to help operators talk through the scan and also a document that provides patients with their results.

Everyone's risk of liver disease may be different. Because everyone has very different life experiences, there are no wrong answers to these questions, but rather different points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we're just as interested in negative comments as positive comments, and at times the negative comments are the most helpful.

Logistics

- Focus group will last about 2 hours
- Feel free to move around
- Where is the bathroom? Exit?
- Help yourself to refreshments

Ground Rules
- Hope that everyone feels comfortable enough to participate.
- Information provided in the focus group must be kept confidential
- Stay with the group and please don't have side conversations
- Turn off mobile phones if possible
- This is an opportunity to help contribute to the treatment of liver disease!

You've probably noticed the microphone. I'm tape recording the session because I don't want to miss any of your comments. People often say very helpful things in these discussions and I can't write fast enough to get them all down.

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If you talk about anyone else during the focus group by name (such as a friend or member of staff) – then we will keep their name anonymous when we write up the results by providing them with a false name. Likewise (the participant) we will also keep your identity anonymous during the write-up by giving you a false name in any reports resulting from this study

Are you okay with this? Do you have any questions?
- o   Answer any questions they have
- o   If they do not want to participate, thank them for their time and escort them out of the venue. If they have participated via telephone or over video conferencing – finish the call.

Beginning the focus group

Start recording the interview on the Dictaphone.

Firstly, I want you to think back to your liver scan appointment.

1. Did you understand why you were undergoing a fibroscan and what the scan involved?
2. What was your experience of the scan? Was there anything about the way the operator conducted the scan or talked to you about the scan that you liked/disliked/found helpful?
3. After the scan, what information were you provided with? Including your results, any feedback from the scan operator, and any other information about liver disease?
    a. Was any of this difficult to understand? What information did you find most helpful?
4. Did the scan and/or scan results prompt you to make some changes to improve your liver health?
    a. If you received normal scan results, did you still want to make lifestyle changes?

Now I'd like us to spend the rest of the session today reviewing the documents in front of you. Please take some time to read through these documents and write any thoughts you have about the wording or how the information is presented on the document.

Provide participants with pens
Give participants approximately 10-15 minutes to read through script and fibroscan results

Let's review the operator script. Imagine you were receiving this information from a fibroscan operator.

1. Do you understand the information presented in the script?
    a. What did you like/dislike about the script? What information was helpful/unhelpful? Was anything unclear?
2. Was there any information you felt was missing or that you think would make a useful addition to the script?

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   a. Do you have any suggested changes or improvements to the script?

Now let's review the fibroscan result documents. There are three different results a patient can receive, depending on their liver stiffness. Imagine you were receiving this information from a fibroscan operator.

1. Do you think the results made sense for each level of liver disease stiffness?
   a. Did you understand the information? What information was helpful/unhelpful? Was anything unclear?
2. How did the documents make you feel?
   a. Did anyone have a negative reaction/positive reaction?
3. Did you like the way the results were presented (e.g. graphically, visually)?
   a. What would you change? Would you prefer the results to be presented as a value, on a scale, on a graph etc.?
4. Would you feel confident knowing what your result was and how to go about making lifestyle changes from this information?
   a. If not, why and what could we include that would help improve your confidence? Do you think the results documents would need explaining further by the operator?
5. Does anyone have additional thoughts about a specific result document (normal, likely fibrosis, likely cirrhosis)?
   a. Do you think the information reflects the level of risk and need for behaviour change?
6. Is there any other information we should include in the results document?
   a. Do you have any suggested changes or improvements to the results?

Close

Okay, that reaches the end of the questions I wanted to ask today. Is there anything else you wanted to add or talk about that we didn't talk about today?

If you're okay to end the focus group there, I'll switch the Dictaphone off, thank you!

Debriefing

- Thank you for speaking to us.
- Provide participants with a sheet which outlines the range of services etc, go through it with them. If there is any particular service/resource that they have expressed an interest in – then signpost them to it.
    - If they have participated via telephone– a state that they can be sent this via email if this wish or it can be read out to them.
- Thank them again, and ask if they are feeling okay to leave the building/ or hang up/exit the call.

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SP-Change model questionnaire (CMQ) V1.0

Change model questionnaire

Work package 1 (WP1) V1.0 26/10/2020

Study title: Does knowledge of liver fibrosis affect high-risk drinking behaviour (KLIFAD)? A feasibility randomised controlled trial

Your doctor may have asked you to cut down how much alcohol you are drinking. Please find the statement that best describes the way you feel right now about cutting down your alcohol use to the amount the research team recommends

- ☐ I am continuing to drink at the same level and right now I am not considering reducing how much I drink

- ☐ I am continuing to drink at the same level but and right now I am considering reducing how much I drink

- ☐ I am continuing to drink at the same level but I am planning to reduce how much I drink

- ☐ Right now I have reduced how much alcohol I drink, and have maintained this for less than six months

- ☐ Right now I have reduced how much alcohol I drink, and have maintained this for more than six months

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SP- Qualitative interview guide

Qualitative interview Guide
Work package 3 (WP 3) Feasibility RCT

***Study title:* Does knowledge of liver fibrosis affect high-risk drinking behaviour (KLIFAD)? A feasibility randomised controlled trial**

To begin

- Go over the study information again with the participant:
    - Thank you for coming to/agreeing to take part in the interview today…
    - Explain what will happen:
    - 'You'll be asked brief questions about your experience of taking part in the KLIFAD study and some questions about how you felt about taking part in this study and how it might have had an impact on you".
    - There are no 'right' or 'wrong' answers – I am not here to judge you, but to listen to your experiences as everyone's experience is valuable.
    - You can tell us as little or as much information as you want to during this interview, it is kept confidential in the research team. We may use a transcription service, but they are required to sign a confidentiality agreement and identifiers are removed from the typed-up transcript.
    - You can pause or stop the interview at any time if you want a break, you feel uncomfortable or don't want to continue with the interview.
    - After the interview, I will provide you with information about services and resources – that you may find useful if you have any concerns about what you have told us.
- Are you okay with all this? Do you have any questions?
    - Answer any questions they have
    - If they do not want to participate, thank them for their time and escort them out of the venue. If they have participated via telephone or over video conferencing – finish the call.

- Note: We will ask our PPI group about whether to include clarification of specific terms at this point. For example, relapse or lapse or teetotal/sober etc to ensure we ask questions in the participant's preferred way of talking about their alcohol use.
- If you talk about anyone else during the interview by name (such as a friend or member of staff) – then we will keep their name anonymous when we write up the results by providing them with a false name. Likewise (the participant) we will also keep your identity anonymous during the write-up by giving you a false name in any reports resulting from this study
- If you are satisfied with this, please confirm that you still consent to take part.
    - They will have already consented to take part when they signed up. Check you have received this consent (if was by e-mail or post).
    - If unsatisfied and does not want to take part – thank them for their time and guide them out of the venue/end the call.

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Beginning the interview

Start recording the interview on the Dictaphone.

Here we can ask an introductory question to establish some rapport.

Your experience of the KLIFAD study

Q. Have you ever taken part in a research study before?

Q. Can you take me through what you remember about the KLIFAD study? (If they get into specifics of the results…. We'll touch on that later, for now, I'd like you to think about your experience of the scan process as a whole, for example how you felt about the scan or the staff who scanned you.)

Q. Overall, how do you feel about taking part in the KLIFAD study?

Follow up questions: If positive feedback: What did you particularly like?

If negative feedback: What did you not like/thought could be different?

Q. In regard to the fibroscan, did you understand why you were invited to have this scan? Did the staff give you enough information about the scan? Was there anything about the whole process you liked/didn't like?

Q. Where did you watch the stories? Did you watch it with anyone else? What was your response to them?

Your feelings about getting the KLIFAD study

Q. Can you tell me what you remember about your fibroscan scan result?

Follow-up questions: Can you remember the specific value, scale, what the value meant (potential liver disease etc)? Was the result explained clearly, did you understand it? Can

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you think of ways to improve how we give people their scan results? Is there anything else you think would be helpful to know when you receive your scan result?

Q. Do you remember how you felt when you first got your fibroscan result? Explore their thoughts and feelings here by using reflection 'So, I'm hearing that you felt confused and a bit frightened'. Also can use follow-up questions if appropriate e.g., Can you talk a bit more about why you felt scared? Can you describe your feeling of relief? Etc.

Q. What did it feel like watch stories describing other people's experiences of receiving a fibroscan? Follow up questions: Which stories can you remember accessing? Can you describe any ways in which these made an immediate impact on you? Can you describe any ways in which these have made a longer-tem impact on you? Did you learn anything from the stories?

Q. Did you discuss the KLIFAD study with anyone?

Follow up questions: What part did you talk about? (Scan/story/both?). Who did you talk to about it? How did they feel about it? If they didn't talk to anyone about it, ask why they didn't

Q. Now that a bit of time has passed, how do you feel about taking part in the KLIFAD study?

Your use of alcohol since you took part in the KLIFAD study

Q. Can you talk about your use of alcohol at a few different time points? It may be hard to remember this far back so sometimes it's helpful to look at a calendar and plot out some key dates (e.g. birthdays, trips away) that can help you remember.

1. Your use of alcohol (if any) just before you had your fibroscan result
2. Your use of alcohol (if any) on the day or days after you had your fibroscan result
3. Your use of alcohol (if any) two weeks after you had your result
4. Your use of alcohol (if any) over the last month

Q. Do you think the KLIFAD study changed your use of alcohol in any way?

If yes: explore, how, why do they think it affected it. If no: invite them to talk about that.

Explore if they sought out additional supports e.g. AA

Follow-up: Had you thought about changing before taking part in this study?

Q. If yes to changes, what were your main reasons for making these changes?

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Q. If no, tell me more about why you didn't want to or didn't feel able to make changes at that time.

Follow-up questions: Was there anything that helped you make the changes? Was there anything that was a barrier to making changes?

Close

Okay that reaches the end of the questions I wanted to ask you. Is there anything else you wanted to add or talk about that we didn't talk about today?

If you're okay to end the interview there, I'll switch the Dictaphone off, thank you!

Debriefing

- Thank you for speaking to us.
- How are you feeling – is there anything in the interview has troubled you or upset you?
- Provide participant with sheet which outlines range of services etc, go through it with them. If there is any particular service/resource that they have expressed an interest in – then signpost them to it.
  - If they have participated via telephone– state that they can be sent this via email if this wish or it can be read out to them.
- Thank them again, and ask if they are feeling okay to leave the building/ or hang up/exit the call.

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Nottingham Recovery Network

Assessment Form

Clean Slate
Criminal Justice Substance Misuse Service

OFFICE USE ONLY	
Date received:	Client Id:
Referred by:	Assessed by:
If SELF, how did they hear about the service:	
Specific risk / need identified: Probation Y / N	Assessment location: Date:

CLIENT DETAILS

GDPR: There is a privacy notice in each room - please read it

DRUG ☐   If drug(s) please state type:

DRUG & ALCOHOL ☐

ALCOHOL ☐

Title: Mr / Mrs / Ms / Miss / other (please state)	**G.P Name:**
First name: **Surname:**	**Address:**
Prefers to be known as:	
Gender: Male ☐ Female ☐ Other ☐ Not specified ☐	
Date of Birth: **Age:**	**Tel:**
Address:	Currently receiving treatment? Y / N Currently on prescribed medication? Y / N Seen by GP in last month? Y / N GP aware of substance misuse? Y / N
Postcode:	
Home Tel:	**Pharmacy current/preferred:**
Mobile Tel:	
Email address:	

Permission to be contacted: Home Visit ☐   Letter ☐   Telephone ☐   Text ☐   Email ☐

Emergency Contact:	**Telephone:**

Medication: Current ☐ Recent Past ☐ Past ☐ None ☐	**Known Allergies:** Y / N
Type & Dosage – List	List: ....
Prescribed by:	
Barriers to Accessing Treatment? (include any disabilities)	**Preferred Language:** **Is an interpreter required** Y / N