ISRCTN10911773 https://doi.org/10.1186/ISRCTN10911773

AlcoChange: a smartphone app and breathalyser device to reduce alcohol-related harm

Submission date 12/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/07/2021	**Overall study status** Ongoing	
Last Edited 09/05/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Deaths from liver disease in the UK are rising at an alarming rate, with an increase of 400% since 1970. In the same period, death rates from other major killer diseases, such as heart disease and cancer, have either remained stable or decreased. This is primarily due to increasing alcohol consumption.
This study is exploring ways of helping people drinking at harmful levels to cut down and stop. AlcoChange is a new smartphone app with an optional breathalyser (breath alcohol meter) that allows people to monitor their alcohol use; the app also provides motivational messages to encourage people to stay sober. AlcoChange has already been shown to have positive benefits in an initial study carried out at the Royal Free Hospital in London, but still needs to be tested in a much larger trial with a greater number of hospitals and patients. This study aims to find out whether AlcoChange can help reduce alcohol consumption in patients with liver disease. This could help reduce the number of hospital admissions and deaths associated with alcohol-related liver disease. The researchers will also speak to patients and care providers to examine the actual experiences with AlcoChange and will use this information to guide the use of AlcoChange within the NHS.

Who can participate?
Patients aged 18 years or older admitted to hospital with alcohol-related liver disease (ArLD) who have used alcohol within the past month and have been referred to the alcohol care team

What does the study involve?
Participants will attend two clinic visits over the next 6 months and complete one telephone questionnaire with a member of the study team.
At the first clinic visit a member of the study team will check the study is suitable for the patient and the patient will be asked to sign a consent form to take part. Participants will give a small blood sample (5 ml, about a teaspoon) so that the team can check how well their liver is working. They will give a saliva sample so the team can assess the severity of their ArLD. They will complete a questionnaire about their alcohol use, how well they are feeling and their use of healthcare services. Participants are given a breathalyser and access to the AlcoChange app and

a member of staff will explain how to use them (if they are in the intervention group). About 6 weeks after Visit 1 the study team will check the results of blood tests from the participant's most recent routine clinic visit to check how well their liver is working.
After 90 days a member of the study team will call the participant who will be asked to complete a questionnaire about their use of alcohol, how well they are feeling and their use of healthcare services over the phone. The study team will use the results of blood tests from the participant's most recent routine clinic visit to check how well their liver is working. Participant's data from the AlcoChange app will be downloaded for analysis (if they are in the intervention group). About 6 weeks after the telephone call the study team will check the results of blood tests from the participant's most recent routine clinic visit to check how well their liver is working.
At the last clinic visit on day 180 participants will give a small blood sample (5 ml, about a teaspoon) so that the team can check how well their liver is working. They will give a saliva sample so the team can assess the severity of their ArLD and give a urine sample so the team can check their alcohol use. Participants complete a questionnaire about their alcohol use, how well they are feeling and their use of healthcare services. Their data from the AlcoChange app will be downloaded for analysis (if they are in the intervention group). They will receive a £20 voucher 'thank you' for taking part in the study.

What are the possible benefits and risks of participating?
The AlcoChange app may help patients reduce their alcohol intake and stop drinking and be beneficial for their health. Participant questionnaire results will help the study team to better understand alcohol consumption in patients with ArLD. This could help reduce the number of hospital admissions and deaths associated with ArLD. Participants will need to give up some extra time to come in for two clinic visits, complete a telephone call and answer the feedback questionnaires.

Where is the study run from?
University of Southampton (UK)

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

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

Who is the main contact?
Dr Fay Chinnery
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Study website
https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/alcochange.page

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
287605

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49610, IRAS 287605

Study information

Scientific Title
Real-world implementation of AlcoChange: a smartphone digital therapeutic to improve outcomes from alcohol-related liver disease

Acronym
AlcoChange

Study objectives
There are no effective pharmacological therapies to maintain abstinence amongst patients with alcohol-related liver disease (ArLD). Behaviour change interventions (BCIs) are effective tools for reducing alcohol consumption in individuals without ArLD. However, only around 6% of individuals with harmful drinking receive a BCI, and this face-to-face intervention is difficult to scale. Smartphone applications as a digital therapeutic are an effective way to remotely deliver BCIs and are easily scalable. The AlcoChange device (smartphone app and breathalyser) may help to reduce alcohol use in patients with ArLD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/08/2021, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, HRA NRES Centre Manchester, M1 3DZ, UK; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), REC ref: 21/NW/0177

Study design
Randomized; Both; Design type: Treatment, Device, Health Economic

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)

Treatment

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-related liver disease

Interventions
Current intervention as of 03/03/2022:
The AlcoChange trial is a multicentre, 2 arm individually randomised controlled trial comparing usual care against usual care plus the AlcoChange intervention (breathalyser and app) in patients with ArLD.

Patients will be recruited from up to 18 UK hospitals over 12 months. Patients will be individually randomised to either usual care or usual care plus the AlcoChange device, via the interactive web response system (IWRS) in ALEA on a 1:1 allocation using minimisation. Stratification factors are:
1. Hospital site
2. Severity of liver disease at baseline:
2.1. Child-Pugh Score = A, and patients with alcoholic hepatitis but no cirrhosis
2.2. Child-Pugh Score = B
2.3. Child-Pugh Score = C

AlcoChange allows self-monitoring of craving, alcohol use/abstinence, and breath alcohol, and provides motivational messaging in response to patient triggers. Additionally, there are a number of behaviour change 'nudges' built into the app. Behaviour change interventions (BCIs), are delivered in real-time, in response to patient triggers such as cravings or geographical location. Users of the AlcoChange device are encouraged to record cravings for alcohol, and in response to cravings, they are sent motivational messages containing pre-designed content including pictures of family or connecting to named supportive friends or the charity helpline 'Drinkline'.

Participants will attend 2 clinic visits over 6 months (baseline and at 180 days) and complete one telephone questionnaire with a member of the study team (at 90 days).

The baseline clinic visit involves
1. Informed consent (including clinical assessment of participant's capacity)
2. Eligibility evaluation
3. Participant characteristics (age, sex, height, weight, and ethnicity)
4. Liver function blood tests
4.1. Serum chemistry
4.2. Haematology
5. Recording if participant received alcohol detox treatment during their admission
6. Recording if participant has comorbidities
7. Concomitant medications check (from clinical notes or discharge summary)
8. Presence of ascites assessment
9. Hepatic encephalopathy assessment (West Haven score)
10. Severity score for liver disease (MELD; UKELD; Child-Pugh – calculated in the database)
11. Saliva sample - for microbiome analysis, correlated with severity of ArLD

12. Hospital admissions
13. Randomisation
14. Timeline Followback (TLFB) - self-reported alcohol use over the previous 28 days
15. Patient questionnaire:
15.1. Drink-free days (DFDs, over the past 90 days)
15.2. EQ-5D-5L
15.3. Chronic pain questionnaire
15.4. Digital literacy and patient empowerment measurement questionnaire
15.5. Resource use questionnaire
16. Other procedures:
16.1. Training participant to use the AlcoChange device (if participant was allocated to the intervention arm)
16.2. Record the participant's discharge destination
16.3. Letter and copy of PIS to participant's GP informing them of their patient's participation

Liver function blood test data will be collected from a participant's routine clinic visits (at ~6 weeks, ~12 weeks and ~18 weeks), for patients who receive routine follow up.

The 90 day telephone call will involve:
1. Clinical assessment of participant's capacity
2. Patient questionnaire (member of site study team to complete the paper forms with the participant's answers; same questionnaire as baseline).
3. Other procedures
3.1. App usage data will be collected (if the participant was allocated to the intervention arm)
3.2. Hospital admissions
3.3. Serious Adverse Events (SAEs)

The 180 day clinic visit will involve:
1. Clinical assessment of participant's capacity
2. Participant characteristics (height and weight only)
3. Liver function blood tests
3.1. Serum chemistry
3.2. Haematology
4. Concomitant medications check (clinical notes or participant-reported, may be facilitated by recent clinic letter or discharge summary)
5. Presence of ascites assessment
6. Hepatic encephalopathy assessment (West Haven score)
7. Severity score for liver disease (MELD; UKELD; Child-Pugh – calculated in the database)
8. Saliva sample - for microbiome analysis, correlated with severity of ArLD
9. Urine sample for ethyl glucuronide measurement (biomarker of recent alcohol use)
10. Hospital admissions (notes check)
11. Site team will check for SAEs
12. Timeline Followback (TLFB) - self-reported alcohol use over the previous 28 days
13. Patient questionnaire (same questionnaire as baseline)
14. Other procedures
14.1. App usage data will be collected (if the participant was allocated to the intervention arm)
14.2. Participant receives £20 voucher 'thank you'
14.3. At the end of the 180 day visit, participants in the control arm to be offered access to the app and trained how to use it, if they are interested.

Previous intervention:
This is a 'cluster stepped wedge' trial. Each of the 6 'clusters' will include 3 hospitals to give a total of 18 sites.

All clusters will start in the 'control' condition - not using AlcoChange. At evenly distributed points in the recruitment period, one cluster selected at random, will switch to the 'intervention' condition and start using AlcoChange. At the end of the trial all clusters will have experience of AlcoChange.

The researchers will design condition-specific patient information packs. In the control condition, they will ask patients to consent to provide their data. In the intervention condition, they will ask patients to consent to providing their data and to using AlcoChange.

Ward staff will identify patients and refer them to alcohol specialist nurses. The nurses will discuss the study as it is currently presented at the recruiting site, and ask eligible patients to take part.

While the site is in the control condition, the message from the nursing staff will be along the lines of “we are currently taking part in a research study in this hospital to explore ways of helping excessive drinkers cut down. Would you like to take part in the study? We would ask you to fill in several questionnaires over the next 6 months. The study will not interfere with your treatment in any way - that would be agreed between you and your doctor.”

In the intervention condition the message from the nursing staff will be along the lines of “we are currently taking part in a research study in this hospital to explore ways of helping excessive drinkers cut down. Would you like to take part in the study? If so, we will provide you with an app and some equipment to plug into your phone, along with instructions on how to use them. We would ask you to fill in several questionnaires over the next 6 months. Apart from asking you to use the app, the study will not interfere with your treatment in any way - that would be agreed between you and your doctor.”

The researchers are not asking the patient to make a decision about randomisation - if they take part whether they receive AlcoChange is determined by the condition of their site. There is no individual-level randomisation. The patient decides whether they are willing to contribute data to the study, and when the site is in the intervention condition whether they are willing to contribute data and use the AlcoChange device, which will only be available to study participants.

Nursing staff will discuss the study with patients and if the patient consents, the nursing staff will assess eligibility. Eligible patients will be asked to complete a questionnaire to capture their data at the start of the study. They will also be taught how to use the AlcoChange device (if the site is in the intervention condition).

Patients will also be asked to complete a telephone questionnaire with the site team at 90 days and attend another clinic visit 180 days after entering the study so that primary outcome data can be collected. Those who do not respond in a timely way will be contacted by telephone.

Qualitative substudy - members of hospital staff and patients

The main study will be preceded by a qualitative sub-study, which will help us to design a training package to help hospital staff understand the intervention and aid them when teaching others how to use the device. The sub-study consists of 4 phases:

Phase I: Theory of change development and finalising design (0-2 months)
Phase II: Understanding system and develop training and materials (2-6 months)
Phase III: Delivery of training to staff (from month 7)
Phase IV: Observations during the trial (intermittent from month 8-31)

Interviews will be conducted remotely via phone or using Microsoft Teams or Skype (depending on participant preference). Written consent will be obtained as well as verbal consent, which will be recorded when interviews are conducted. Interviews will be expected to last 60-90 minutes and will be recorded using digital recorder, which will be transcribed verbatim for later analysis.

The interview will be loosely structured using a topic guide and recorded on a digital device. The topic guide may change as new comments emerge during the qualitative interviews.

Hospital staff will be asked questions about:
- The current treatment pathway for patients with alcohol-related liver disease (ARLD) at their hospital
- Barriers and solutions to running this trial and to implementing this intervention
- What they would want from the training guide (content and format)

The researchers will ask patients:
- What they want to know when they are being enrolled into the study
- What they want to know about the app

This will enable better design of process, content and format of training and any associated materials.

Intervention Type
Other

Primary outcome measure
Proportion of patients who are abstinent or reduced drinking to low-risk levels (<14 units/week), measured using the Timeline Follow Back method (TLFB) (data collected for the previous 28 days) at 180 days

Secondary outcome measures
Current secondary outcome measures as of 03/03/2022:
1. Self-reported alcohol use over the previous 28 days, using the Timeline Followback (TLFB) method, at baseline, 90 days, and 180 days
2. Self-reported alcohol use over the previous 14 days, calculated from TLFB data,at baseline, 90 days, and 180 days
3. Proportion of patients in the intervention condition achieving abstinence in the previous 28 days compared to control condition, calculated from TLFB data, at baseline, 90 days, and 180 days
4. Drink-free days over the previous 90 days, reported by the patient, at baseline, 90 days, and 180 days
5. Heavy drinking days over the previous 28 days, calculated from TLFB data and defined as ≥60 g alcohol/day for males and ≥40 g/day for females, at baseline, 90 days, and 180 days
6. App usage data (for participants allocated to the intervention arm), at 90 days and 180 days
7. Health-related quality of life (HRQoL), measured by EuroQoL (EQ-5D 5L) questionnaire, at baseline, 90 days, and 180 days
8. Quality-adjusted life years (QALYs), calculated from the EQ-5D-5L, at baseline, 90 days, and

180 days
9. Health care resource use and costs, calculated using the resource use questionnaire, at baseline, 90 days, and 180 days
10. Hospital admissions, using medical notes check, at 90 days and 180 days
11. Loss of capacity, determined by clinician decision, at 90 days and 180 days
12. Death/rehospitalisation composite, using medical notes check, at 90 days and 180 days.

Previous secondary outcome measures:
1. Self-reported alcohol use over the previous 28 days measured using TLFB at 90 and 180 days
2. Self-reported drink-free days over the previous 90 days measured using patient questionnaire at 90 and 180 days
3. Heavy drinking days over the previous 28 days, calculated from the TLFB and defined as ≥60 g alcohol/day for males and ≥40 g/day for females; at 90 and 180 days
4. App usage data (for participants recruited under the intervention condition) at 90 and 180 days
5. Liver function measured using Model For End-Stage Liver Disease (MELD) score, United Kingdom Model for End-Stage Liver Disease (UKELD) score, and Child-Pugh score at 180 days
6. Health-related quality of life (HRQoL) measured using EuroQoL (EQ-5D 5L) questionnaire at 90 and 180 days
7. Quality-adjusted life years (QALYs) measured using HRQoL data from the EQ-5D-5L questionnaire combined with survival data at 180 days
8. Health care resource use and costs measured using questionnaire at 90 and 180 days
9. Hospital admissions measured using medical notes check at 90 and 180 days
10. Loss of capacity measured by clinician assessment at 90 and 180 days
11. Alcohol use measured using biomarker analysis (urine ethylglucoronide measurement) at 180 days

Exploratory outcomes:
1. Severity of ArLD measured using saliva sample for microbiome analysis at baseline and 180 days

Overall study start date
29/05/2019

Completion date
31/10/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 02/03/2022:
1. Adults aged 18 years or older
2. Non-elective admission with ArLD (alcoholic hepatitis or cirrhosis – diagnosed clinically or by imaging/biopsy)
3. Alcohol use within 1 month of admission, and referred to alcohol care team
4. Access to appropriate smart phone
5. Willing and able to give written informed consent
6. Sufficient English to understand the instructions for using the AlcoChange device

Previous participant inclusion criteria:
1. Adults aged 18 years or older

2. Admission with ARLD (alcoholic hepatitis or cirrhosis – diagnosed clinically or by imaging /biopsy), alcohol use within 1 month of admission, referred to alcohol care team
3. Access to appropriate smartphone
4. Willing and able to give written informed consent
5. Sufficient English to understand the instructions for using the AlcoChange device

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment
324

Key exclusion criteria
Current participant exclusion criteria as of 02/03/2022:
1. Taking part in another interventional study
2. Referred for palliative care
3. Referred for inpatient alcohol rehabilitation

Previous participant exclusion criteria:
1. Taking part in another interventional study
2. Referred for palliative care
3. Referred to rehabilitation

Date of first enrolment
06/12/2022

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

-
-
-
United Kingdom
-

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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201002

Results and Publications

Publication and dissemination plan

The protocol paper will be published in the future. A formal statistical analysis plan will be written and agreed with the trial governance committees before data lock.

The aim of the dissemination and communication plan is to disseminate the results of the study to relevant specialist healthcare groups and patient groups. Additionally, if the primary endpoint is met, the results and the cost-effectiveness analysis will be used to secure the necessary investment to support commercialisation. The strategy will involve quality improvement methodology for sustaining and spreading interventions. Specific examples of this include:
1. Leadership: the researchers have engaged with thought leaders in alcohol and public health (e.g. Sir Ian Gilmore, chair of Alcohol Health Alliance; Prof. Kevin Moore, UCL alcohol lead; Prof. Annie Britton, UCL alcohol lifecourse group) to join the trial steering committee and, if positive, to play a role in disseminating the results of the study.
2. Engagement: the researchers aim to involve patients, families, clinicians and commissioners in the dissemination plan for the project. An example is a symposium to be held with these key stakeholders towards the end of the i4i project, to relay the results of the study and further inform the plan for sustainability and spread.
3. Dissemination and exploitation: the researchers will publish the results in peer-reviewed manuscripts, as well as present the findings at appropriate conferences, exhibitions and to private-sector technology investment groups.

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.
In order to meet our ethical obligation to responsibly share data generated by interventional clinical trials, SCTU operate a transparent data sharing request process. As a minimum, anonymous data will be available for request from 3 months after publication of an article, to researchers who provide a completed Data Sharing request form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate a signed Data Sharing Agreement. Data will be shared once all parties have signed relevant data sharing documentation.
Researchers interested in our data are asked to complete the Request for Data Sharing form (CTU/FORM/5219) [template located on the SCTU web site, www.southampton.ac.uk/ctu] to provide a brief research proposal on how they wish to use the data. It will include; the objectives, what data are requested, timelines for use, intellectual property and publication rights, data release definition in the contract and participant informed consent etc. If considered necessary, a Data Sharing Agreement from Sponsor may be required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No