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Developing a service in community pharmacies to increase earlier identification of alcohol-related liver disease

Submission date
24/08/2022

Recruitment status
No longer recruiting

Registration date
26/10/2022

Overall study status
Completed

Last Edited
14/05/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Liver disease is a frequent and ever more common reason for dying in the United Kingdom (UK). The most common cause of liver disease in the UK is alcohol. Death from liver disease can be prevented if liver disease is found at an early stage. Alcohol-related liver disease can be found earlier by assessing for it in people who drink too much alcohol. This is advised in national guidelines.
Local pharmacists are one of the most accessible health professionals. Lots of pharmacies are in areas where more people have alcohol problems. Local pharmacists can identify people who drink too much alcohol and provide them support to drink less. However, it is not known if local pharmacists can get these people assessed for alcohol-related liver disease.
We want to understand how local pharmacists could get people assessed for alcohol-related liver disease to help develop a novel service that aims to achieve this. We will then test the service on a small scale. To do this we will:
-Explore how stakeholders think the service could work
-Explore acceptability and feasibility of delivering the service on a small scale
-Work out whether we can collect the alcohol-related liver disease assessment results required to test whether the service is effective

Who can participate?
Patients with Alcohol-related liver disease (ArLD), community pharmacy users, and community pharmacy staff and healthcare professionals involved in the care of patients with ArLD.

What does the study involve?
We will interview stakeholders to explore their views of how the service could work. We will then introduce the service in local pharmacies and interview staff involved with delivering it and members of the public that use it.
We will also collect service use data. We will analyse this with the interviews to understand how the service worked and how it can be improved.
The work will also inform how to undertake future research to see if the service is more effective than what is currently done.

What are the possible benefits and risks of participating?
The study is not expected to directly benefit participants. Participants will contribute to developing the service. In the long term we aim for the service to increase earlier diagnosis of alcohol-related liver disease. Earlier diagnosis can prevent patients with the disease from developing harmful complications.
We believe this study is low risk but we know conversations done for research can sometimes bring up difficult or sensitive issues. If this was to occur the research team will endeavour to help or refer
you to those you can. This would be done with your consent.

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

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

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

Who is the main contact?
Dr Alexander Smith, Alexander.smith@soton.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
310684

Central Portfolio Management System (CPMS)
53272

National Institute for Health and Care Research (NIHR)
302286

Study information

Scientific Title
Community pharmacy alcohol-related liver disease risk identification and linkage to care through development of a complex intervention (CIPLINC) study

Acronym
CIPLINC

Study objectives
People at risk of alcohol related liver disease can be identified in community pharmacies and be connected with existing pathways of care for further assessment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/07/2022, South Central - Oxford B Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square Bristol, BS1 6PN, UK; +44 207 104 8118; oxfordb.rec@hra.nhs.uk), ref: 22/SC/0222

Study design
Observational qualitative

Primary study design

Observational

Study type(s)
Other

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

Interventions
The community pharmacy alcohol-related liver disease (ArLD) risk identification and linkage to care through development of a complex intervention, or 'CIPLINC', study will use the structure of the Medical Research Council (MRC) guidance on developing and evaluating complex interventions
The proposal uses mixed methods research to inform the design of the novel service (the CIPLINC intervention) and then establish the feasibility and acceptability of the novel service in a pilot implementation period.
This will be done in 2 work packages (WP). WP1 will be pre-implementation interviews and WP2 will be postimplementation interviews, telephone survey, researcher led observation and service use data as detailed below.
Participants eligible for the study will be from one of 4 groups:
Group 1 - Patients diagnosed with ArLD (WP1 only)
Group 2 - Community pharmacy users
Group 3 - Community pharmacy staff
Group 4 - Healthcare professionals involved in the care of patients with alcohol-related liver disease

WP1 Pre-implementation interviews:
Participants will be purposively sampled. For groups one and two this will include both genders and a range of genders, ages and levels of deprivation. For groups three and four this will include a range of genders, ages, profession, years of experience, and for group 3 a range of level of deprivation of the pharmacy location. Interviews will take place at a time convenient to each participant and be conducted either face-to-face, via telephone or online using Microsoft Teams. Where face-to-face these will be in a private room either at the University of Southampton, in a community pharmacy or in the clinical research facility at University Hospital Southampton (Group 1 participants only). All interviews will be audio-recorded and transcribed verbatim. All participants interviewed will be offered a £20 voucher.

- WP1 Interview recruitment:
Group 1 participants will be recruited from liver clinics at University Hospital Southampton. Patients meeting inclusion criteria will be passed an information sheet about the study by the clinician looking after them and asked to contact the research team if interested. The sheet will include contact information with which they can contact the research team. In addition the research team may also be on site at the recruiting locations to discuss the study directly with the potential participant if they have expressed an immediate interest in taking part to their clinician. Following contact with the research team patients will be invited for a semi-structured interview.
Group 2 participants will self-select for involvement in the study by responding to an advert in community pharmacies and put on twitter from the study twitter account. Pharmacy staff will also be able to signpost to the research team. Following contact with the research team potential participants will be sent a PIS by email and/or post and invited for a semi-structured interview.

Group 3 participants will be invited to participate through a gatekeeper (chief officer of the local pharmaceutical committee). Chain referral sampling using recruited participants will also be used and a flyer will be put on the study twitter account. Following contact with the research team potential participants will be sent a PIS by email and/or post and invited for a semi-structured interview.
Group 4 participants will be invited to participate through convenience sampling via approach of existing contacts of the research team and then chain referral sampling using recruited participants. Following contact with the research team potential participants will be sent a PIS by email and/or post and invited for a semi-structured interview.

WP2 - Post-implementation Interviews
Participants will be purposively sampled. For group two this will include a range of genders and ages, location of pharmacy where offered novel service and whether they engaged with the novel service. For groups 3 and 4 this will include a range of genders, ages, profession and years of experience.
Interviews will take place at a time convenient to each participant and be conducted either face-to-face, via telephone or online using Microsoft Teams. Where face-to-face these will be in a private room either at the University of Southampton, in a community pharmacy or in the clinical research facility at University Hospital Southampton (Group 1 participants only). All interviews will be audio-recorded and transcribed verbatim. All participants interviewed will be offered a £20 voucher.

- WP2 interview recruitment:
Group 2 participants will be identified during the pilot implementation period by pharmacy staff delivering the novel service. PIS will be provided by pharmacy staff with contact details of the research team provided for people to contact if interested. Following contact with the research team participants will be invited for a semi-structured interview.
Group 3 participants will be from pharmacies delivering the novel service. They will have been informed of the study when setting up the service. They will be invited to participate through a gatekeeper (chief officer of the local pharmaceutical committee). Chain referral sampling using recruited participants will also be used. Following contact with the research team potential participants will be sent a PIS by email and/or post and invited for a semi-structured interview
Group 4 participants will be invited to participate through convenience sampling via approach of existing contacts of the research team and chain referral sampling using recruited participants.
Group 4 participants from WP1 interviews who consented to be contacted for future involvement will be contacted directly by the research team.
Following contact with the research team potential participants will be sent a PIS by email and /or post and invited for a semi-structured interview.

WP2 - Telephone Survey
Only group 2 participants who engage with the novel service will be eligible for the telephone survey. Permission for contact details to be shared with the research team in order to be invited to participate will be asked as a function of the novel service. PIS will also be available from pharmacy staff and will also include contact details of the research team.
A member of the research team will contact all potential participants who have given permission for contact. We will confirm receipt of the participant information sheet and answer any questions regarding the research. PIS will be sent to potential participants if they did not receive it from pharmacy staff. Potential participants will be given at least 24hours following receipt of PIS to decide if they would wish to take part.

- Telephone survey data collection:
Participants consenting will undergo a baseline telephone survey and a follow up telephone

survey approximately 3 months later. They will receive a £10 for each survey completed. A letter will also be sent to the local liver pathway service to collect data on liver outcome data for consented participants. A purposive sample will also be invited for semi-structured interview and consented separately for this (see interviews section).

WP2 - Pharmacy observation
Researcher-led observation of the pharmacy environment will be undertaken in each of the pharmacies delivering the novel service.
- Pharmacy observation data collection:
Observation will focus on how the service is offered to pharmacy users and difficulties in delivering the service.
Observation data will be as field notes taken by the researcher during and immediately after observation.
No personal information will be collected during observation. No private areas in the pharmacies will be observed.

WP2 - Service Use Data
Anonymous service use data of the novel service will be sent to the research team by each of the pharmacies delivering the novel service. This will be an automated process through the pharmacy software used for the service. Anonymous service use data of the Southampton ArLD care pathway will be sent to the research team by the UHS hepatology clinical team through collaborators within the team.

Quantitative data analysis
Descriptive statistics of the service use data and telephone survey data will be created using SPSS version 27.

Qualitative Data Analysis
Braun and Clark's 6 step thematic analysis method will be used to analyse interview transcripts and field notes from observation. A descriptive coding scheme will be developed from the transcripts and based on participants' perceptions and experiences.
In the second phase of analysis emergent data themes will be mapped to the NPT framework. Data analysis will take place in two phases to avoid forcing the data into the constructs of NPT.
NVivo software will be used for the qualitative data analysis.
Analysis of WP1 interviews will be used to develop the service before the pilot implementation period.
WP2 qualitative results will be integrated with the quantitative results using a hybrid convergent /explanatory mixed methods design to understand the feasibility and acceptability of the novel service.

Intervention Type
Other

Primary outcome(s)
1. Pharmacy recruitment rate recorded as the number of eligible pharmacies recruited to deliver the novel service. Timepoint 31/09/2024
2. Acceptability of the novel service to service providers and service users measured using qualitative interviews. Timepoint 31/03/2025
3. Feasibility of implementing the novel service measured by analysis of service use data. Timepoint 31/03/2025

Key secondary outcome(s))

1. Number of people assessed in the service measured from service use data. Timepoint 31/03/2025
2. Number of people assessed in the service identified as at risk of alcohol related liver disease measured from service use data. Timepoint 31/03/2025
3. Number of people identified in the service as at risk of alcohol related liver disease connected to alcohol related liver disease pathways of care measured from service use data. Timepoint 31/03/2025
4. Recruitment rate of telephone survey recorded as the number of eligible participants who consent to participate in the telephone survey. Timepoint 31/03/2025

Completion date
31/03/2025

Eligibility

Key inclusion criteria
All participants:
1. Age 18 years or over
2. Able to give written consent in English

Specific to participant groups:
Group 1 - Patients with Alcohol-related liver disease (ArLD)
1. Diagnosis of ArLD
2. Under the care of gastroenterology/hepatology outpatient clinic

Group 2 - Community Pharmacy users
1. Attended a community pharmacy at least once in the last year
2. Drink alcohol
3. Offered novel service*
4. Engaging with novel service*#

Group 3 - Community Pharmacy staff
1. Currently working in a community pharmacy as pharmacist, pharmacy assistant or pharmacy technician
2. Member of staff in a pharmacy delivering the novel service*

Group 4 - Healthcare professional involved in ArLD Care Pathways
Currently employed as any of:
1. General Practitioner
2. Primary care nurse practitioner
3. Hepatology consultant
4. Hepatology specialist nurse
5. Alcohol care team worker
*only applies to participants being recruited after implementation of the novel service
#requirement for participants for telephone surveys only

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
26

Key exclusion criteria
All participants:
1. Age <18 years
2. Unable to understand written and spoken English to consent for or complete the study
3. Lacking capacity to consent

Specific to participant groups:

Group 2 Community Pharmacy users
1. Currently working as a member of pharmacy team (pharmacist, pharmacy technician, pharmacy support staff)
2. Current healthcare professional involved in ArLD Care Pathways

Group 3 Community Pharmacy staff
1. Member of staff not involved in delivering the novel service*
*only applies to participants being recruited after implementation of the novel service

Date of first enrolment
01/10/2022

Date of final enrolment
10/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
University of Southampton
University Road
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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

Study outputs

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