

# LOCATE - LOcal Care And Treatment Evaluation

<b>Submission date</b> 22/08/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The purpose of this study is to find out the possibility of integrating a new liver diagnostic pathway in GP practices using a liver health nurse in the practice team and a risk assessment tool. The aim is to improve upon patient outcomes and reduce costs in the early detection, diagnosis and treatment of patients with liver conditions within GP practices.

### Who can participate?

Patients are approached by the participating practices to attend clinic for a liver health check-up

### What does the study involve?

The practices are randomly allocated to either the control group or the intervention group. Patients with suspected liver disease are invited to undergo a liver health check performed by a liver health nurse. Intervention group practices direct their patients for further investigation and disease management with the specialist supervisors of the study and their own General Practitioners. It is anticipated that this level of access to specialist liver experts is the same as attending a liver clinic with all the benefits involved.

### What are the possible benefits and risks of participating?

There are no guaranteed benefits to participants from taking part in this study, but there is a small chance that their liver might be unhealthy or damaged. If this is the case, by taking part in this study they will find out more about the health of their liver.

### Where is the study run from?

This study takes place in selected GP practices in Southampton and is coordinated by the University of Southampton (UK)

### When is study starting and how long is it expected to run for?

November 2013 to December 2021

### Who is funding the study?

British Liver Trust (UK)

Who is the main contact?

Ms Tina Reinson

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## Contact information

### Type(s)

Scientific

### Contact name

Ms Tina Reinson

### ORCID ID

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## Additional identifiers

### Protocol serial number

14131

## Study information

### Scientific Title

A community based study to determine the feasibility of remodelling the diagnosis and management of liver disease in primary care to improve patient outcomes and reduce service delivery costs

### Acronym

LOCATE

### Study objectives

LOCATE is a cluster randomised service intervention in a primary care setting. The primary objective is to evaluate the feasibility of integrating a new diagnostic pathway in primary care with the implementation of a liver health nurse and a liver risk stratification tool. The secondary objective is to determine if the new pathway improves the effectiveness of the detection and management of chronic liver disease and leads to improved long-term outcomes together with the net NHS costs.

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

First MREC approval date 05/07/2013, ref: 13/SC/0012

**Study design**

Both; Interventional; Design type: Diagnosis, Screening

**Primary study design**

Interventional

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

**Interventions**

10 GP practices will be randomised to either the intervention or control arm. Both groups will undertake two audits of liver care, one before the intervention and one after.

Control: The practices randomised to the control arm will follow their existing local map of medicine.

Prior to randomisation, all practices will undertake an audit of liver care at their site.;  
Intervention, The intervention practices will receive the services of a liver health nurse, who will facilitate three intervention modules:

**Intervention Module 1**

Improved access to liver health assessment for incident liver abnormalities arising from routine care.

**Intervention Module 2**

Nurse led case finding using data already available in the clinical records to identify those at risk of significant liver disease.

**Intervention Module 3**

Nurse-led population screening for excess alcohol use using t; Study Entry : Other; Details: Identified in an initial audit of liver care and contacted with a letter and information leaflet.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Effectiveness and cost effectiveness of the detection and management of liver disease;  
Timepoint(s): 12 months

**Key secondary outcome(s)**

1. Impact of risk stratification on behaviours in patients consuming harmful/hazardous alcohol levels; Timepoint(s): 12 months
2. Increased detection rate of serious liver disease; Timepoint(s): 12 months

**Completion date**

31/12/2021

## Eligibility

**Key inclusion criteria**

Pre-Intervention Audit and Post-Intervention Audit

1. Elevated ALT (above ULN), other abnormal liver function test (Alk Phos or bilirubin above ULN, or Albumin <LLN) or new diagnosis of liver disease coded on the GP system within a twelve month period between the last 18 and 6 months.

**Intervention Module 1**

1. Clinical liver disease
2. Any patient newly identified by the practice with suspected liver disease in the one year of the prospective phase.

**Intervention Module 2**

1. All patients identified with a positive cTL on tests in the previous 6m

A sample from each of the following groups:

1. pre-existing abnormalities in liver function but without liver diagnosis and management plan identified in the practice audit
2. Type 2 diabetes
3. obesity BMI > 40 and no type 2 diabetes
4. patients with clinical record suggestive of hazardous alcohol use will be enrolled in Module 3 where appropriate

**Intervention Module 3:**

1. A sample (1000) of patients aged 30 to 65 together with any patients with suspected alcohol misuse from clinical records will be sent a postal invitation as part of the practice liver health programme. The invitation will include an AUDIT questionnaire
2. WHO AUDIT score either > 15 or >7 with alcohol intake on 4 days or more (AUDIT Q1), and alcohol intake of 7 units or more on a drinking occasion (AUDIT Q2) or estimated weekly alcohol intake > 28 units.

Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 30 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

910

**Key exclusion criteria**

Pre-Intervention Audit and Post-Intervention Audit:

1. Patients with known terminal illness.

Intervention Module 1:

1. Patients with known terminal illness.

Intervention Module 2:

1. Patients with known terminal illness.
2. Patients with alcohol misuse will be enrolled via Module 3 where appropriate

Intervention Module 3:

1. Patients with known terminal illness
2. Patients identified on GP system as having pre-existing liver disease.
3. Those invited for a check in module 2

**Date of first enrolment**

04/11/2013

**Date of final enrolment**

01/10/2016

## **Locations**

**Countries of recruitment**

United Kingdom

**Study participating centre**

The participating GP surgeries are anonymous

United Kingdom

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## **Sponsor information**

**Organisation**

University of Southampton (UK)

ROR

## Funder(s)

### Funder type

Charity

### Funder Name

British Liver Trust (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the consented patients only agreed that a member of the study team could have access to their data and the data is disclosive and cannot be put in the public domain.

### Previous publication and dissemination plan:

El-Gohary, M; Moore M; Roderick P; Watkins, E; Dash, J; Reinson, T; Newell, C; Kim, M; Stuart, B; Becque, T; Sheron, N. Local CARE and Treatment of liver disease (LOCATE) – a feasibility study to discover, assess and manage early liver disease in primary care. PLOS One - under peer review. Contact Tina Reinson for a copy of the submitted paper.

Reinson, T; Bradbury, K; Moore, M; Sheron, N. Healthcare practitioners' experiences of an intervention to detect and treat patients with liver disease (the LOCATE intervention): a qualitative process evaluation. Ready for submission to BMJ Open; expected to submit August 2018.

### IPD sharing statement

The datasets generated during and/or analysed during the current study are not expected to be made available because the consented patients only agreed that a member of the study team could have access to their data and the data is disclosive and cannot be put in the public domain.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	21/12/2018		Yes	No
<a href="#">Results article</a>	qualitative results	01/05/2019	12/05/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No