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LOCATE - LOcal Care And Treatment Evaluation

Submission date	Recruitment status	[X] Prospectively registered
22/08/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2020	Digestive System	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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

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

Secondary outcome measures
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

Overall study start date
04/11/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1500; UK Sample Size: 1500

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
-

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
University Road
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
British Liver Trust (UK)

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 12/05/2020:
Feasibility study results and qualitative process evaluation publication details can be found below.

Intention to publish date
31/12/2018

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?
Results article	results	21/12/2018		Yes	No
Results article	qualitative results	01/05/2019	12/05/2020	Yes	No
HRA research summary			28/06/2023	No	No