The REFLEX study

Reflex testing for metabolic associated fatty liver disease (MAFLD) in patients living with type 2 diabetes compared to usual care – a randomised controlled trial.

Sponsor: University of Southampton	**CPMS ID:** 55453
Funding body: Echosens	
Chief Investigator: Professor Chris Byrne, Professor of Endocrinology and Metabolism	**Trial Manager/Coordinator:** Tina Reinson
Co-Investigators: Tina Reinson, Researcher Dr. Ryan Buchanan, Consultant Hepatologist Dr. Karen Malone, GP	**Tel:** 07751 009483 **E:** t.reinson@soton.ac.uk

Study Aims: To test a new way of identifying liver disease in people living with type 2 diabetes (T2DM). To compare testing everyone with T2DM for liver disease against the existing care pathway – where only those with another risk factor, e.g. harmful alcohol consumption, get tested for liver disease.

Study design: Unblinded Randomised controlled trial with a nested cost-effectiveness evaluation comparing reflex testing (i.e. testing all people living with T2DM) for liver disease against standard care.

Participants: Patients living with type 2 diabetes.

Planned sample size: 640 participants.

Who can be involved: All GP practices in the Wessex region.

Practice Involvement

All Sites:

- Attend virtual site initiation visit.
- Display promotional material: PowerPoint presentation (no audio) to run on the TV feed in the patient waiting room; summary patient information sheet; study webpage to host on surgery website and poster.
- Admin staff run a database query (provided by research team) to identify all potentially eligible participants.
- GP checks the list of patients identified by the database search to exclude any who would not be suitable to invite for study participation.
- Admin staff sends out a letter/email/text (provided by the research team) to eligible potential participants.
- Opportunistic recruitment – GP/Practice Nurse provide potentially eligible participants attending a surgery appointment information about the study.
- No additional work from the GP surgery is required.

Some GP surgeries

- Use of treatment room. One required for every 5 GP surgeries that are local to each other.

Patient involvement:

- Patients are randomised to either the intervention arm where they will receive a liver assessment, or the control arm where they will be managed via usual care and receive a liver assessment 12 months later.
- The liver assessment takes 40 minutes and will take place in the community. Each patient will have a Fibroscan, blood collection and full explanation of the FibroScan reading.

Specifics:

Target recruitment (practice):	*Approx 35 participants from a Practice with a list size of 10,000*
Study recruitment period:	1/9/2023 - 31/8/2025 *Sites will be phased in every 3 months. Anticipated time of recruitment at a site is approximately 3-4 months.*

Reimbursement:	**RCs** *Invoice Study Team*	**SSCs** *Payable by CRN Wessex*	**ETCs*:**
Per Practice costs:			
Site initiation visit	£36.00		
Database search and eligibility check		£124.20	
Opportunistic recruitment		£216	
Text out	£3.50		
Room hire fee *(for Practices that agree to host study visits)*	£30 half day, £50 full day		
Total:	**£39.50**	**£464.40**	
Per Patient costs: *(for Practices that agree to host study visits)*	Nil	Nil	£12

**Paid in arrears by CRN Wessex on a 6 monthly basis*

Benefits

Practice:

- An opportunity to take part in NHS approved research that has real world utility.
- All patients will have a diagnosis and management plan added to their record.
- You will be able to identify patients who are at risk of other comorbidities associated with non-alcoholic fatty liver disease.
- Previously unidentified liver disease will be identified and treatment offered. Any further tests required will be organised by the research team – there is no additional work for GPs.

Patient:

- A full liver assessment which includes: FibroScan, full lipid profile, HbA1c reading and ELF and FIB-4 scores.
- A diagnosis and management plan.
- £15 voucher

LCRN details:

LCRN contact:	CRN Wessex **Email:** studysupport5.crnwessex@nihr.ac.uk
RSI Contract:	This is PIC activity; therefore, recruitment will not be mapped to the participating Practices, unless they have agreed to host the study visits. Participation will count towards the RSI requirement.