Background and Aims
Most non-alcoholic fatty liver disease (NAFLD) is diagnosed after identification of abnormal liver function tests (LFT) in primary care (PC), with subsequent referral to secondary care (SC) for investigation. There is no standardised management pathway for abnormal LFT in PC. Following diagnosis of suspected NAFLD in PC the decision of whether to refer to hepatology or continue management in the community is at the discretion of the GP. Practice varies extensively resulting in unnecessary referrals to SC and suboptimal identification of patients who do require SC management. The Community-based Management of Non-alcoholic fatty liver Disease Study (COMMANDS) seeks to address this variation with 2 key aims:

1: Assess the impact of an e-consult Integrated Care Pathway (e-ICP) to guide PC diagnosis of suspected NAFLD

2: Prospectively describe a large cohort of people with NAFLD including long-term outcomes and identification of markers of progression.

Methods
The study comprises 3 stages:

1: Pilot phase in 8 participating PC centres to establish current practice, local NAFLD prevalence and test early ICP versions.

2: Randomised controlled trial (RCT) recruiting 300 patients presenting to PC with suspected NAFLD into e-ICP or standard of care (SOC) pathway (Fig 1).

3: Prospective observational cohort following all recruits over 5 years to track clinical outcomes (stable vs. progressive disease) and factors associated with disease progression, including testing of baseline and interval samples for existing/emerging biomarkers.

Results:
In the pilot study, 644 patients with abnormal ALT results were screened in 8 GP practices. Of these, 162 met criteria for further analysis (ALT ≥ 1.5 × upper limit of normal [ULN] or 2 readings > 70 IU/mL over 6 months). Following biomarker-based risk stratification, 85% (n=138) of the cohort were deemed suitable for SC referral. However, just 25 (15.4%) had a secure NAFLD diagnosis made due to a lack of exclusion of other causes of raised ALT, e.g. viral hepatitis or autoimmune disease. Analysis and PC feedback revealed that although the ICP listed all required investigations prior to diagnosing NAFLD, the paper based format did not allow gatekeeping at key points in the pathway. The ICP was therefore redesigned to ensure a robust diagnosis of NAFLD was made prior to RCT entry utilising an electronic version (e-ICP) that prevents progression through the pathway in the absence of key results (e.g. viral serology). Following diagnosis, additional referral advice and guidance was incorporated using NAFLD fibrosis score-based risk stratification and an option for virtual clinic (e-consult) review by a hepatologist where there is doubt surrounding need for specialist follow-up. RCT recruitment is currently ongoing, with data collection measuring the impact of the e-ICP and access to the e-consult clinic on correct NAFLD diagnosis, secondary care referral rates and clinical outcomes. Virtual clinic review has prevented several unnecessary SC referrals, and is now being rolled out across the wider hepatology service.

Conclusions:
Significant gaps in PC investigation of abnormal LFT prevented GPs from making a secure NAFLD diagnosis, thereby impacting ability to risk stratify patients, plan ongoing management and determine requirement for SC referral. A novel care pathway developed in response to the pilot study and feedback from GPs is now being tested within an RCT to establish if the e-ICP improves diagnosis, management and timely referral of patients with NAFLD. Early data from the RCT has shown improvements in clinical practice in the e-ICP arm compared to standard of care. Long term follow up of the cohort will improve understanding of disease progression in the local population.

Figure 1. Flow diagram for COMMANDS study
References