A Nurse Led FibroScan® Outreach Clinic Encourages Socially Deprived Heavy Drinkers to Engage with Liver Services

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Key words: liver cirrhosis, alcoholic, screening, FibroScan®, transient elastography, nursing assessment

Abstract

Aims and Objectives

To determine if a portable FibroScan® device can be an acceptable screening tool for chronic liver disease (CLD) in a community alcohol support service, through recording uptake, determining apparent prevalence of undiagnosed fibrosis/cirrhosis in participants and report engagement following referral to specialist liver services of those individuals referred because of a FibroScan® reading ≥ 7.1kilopascals (kPa).

Background

Alcohol related liver disease, including cirrhosis, is a major cause of death in the UK. Liver disease is silent and usually presents late. Socially deprived patients with alcohol related liver disease are a "hard to engage" population and at higher risk of death than less deprived. A FibroScan® device is a non-invasive tool for measuring liver stiffness. A result of ≥7.1kPa can indicate possible CLD.

Design

Prospective observational study

Method

Individuals who self-identified as harmful drinkers were recruited. Consented individuals attended for a liver FibroScan®. Those with a reading ≥7.1kPa were referred to a nurse-led liver clinic for further investigations, results of which determined referral to a liver specialist in secondary care. Participants referred were monitored for compliance over a six-month period.

Results

Seventy-nine consented individuals participated, an uptake of 67% of those informed of the study. Of the 79 scans performed, three were unreliable leaving 76 participants. After scanning, 20/76 (26%) had a FibroScan® ≥7.1kPa requiring referral on to the nurse led clinic. All 20 (100%) engaged in further assessment. Of those, 12 required onward referral to specialist services. Subsequent compliance with specialist services in this sample (n=12) was ≥ 90%.

Conclusion

A nurse led FibroScan® outreach clinic encourages socially deprived drinkers to engage with liver services.

Relevance to clinical practice

A 67% uptake suggests a nurse led FibroScan® service in a community alcohol service is acceptable. High engagement gives potential for early intervention and improved health outcomes.

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Introduction

Liver disease, including cirrhosis, is the third commonest cause of premature death in the UK and mortality rates have increased by approximately 500% in those under the age of 65 years since 1970 (Williams et al 2014). As such, it stands as an exception to the improved prognosis of those with other chronic illnesses such as chronic heart disease, stroke and some cancers (Williams et al 2014). Deaths from chronic liver disease (CLD), including cirrhosis, increased globally between 1990 and 2013 from 1.5 million to 2.1 million (Cowie et al 2015). Within the European Union, standardised death rates from chronic liver disease were 13 per 10^5 in 2013, compared to 16 per 10^5 in the UK alone (WHO 2017). Alcohol related liver disease (ALD) is a major contributor to morbidity and mortality in the UK. Current data for death rates due to alcohol in the UK, including ALD, report rates at 14 per 10^5 since 2012 (ScotPHO 2017). This pattern is mirrored in Scotland, but with rates higher than in the rest of the UK. Death rates in men are 30 per 10^5 in Scotland and 18 per 10^5 in England and for Scottish women are 13.3 per 10^5 and 9.1 per 10^5 in England (ONS 2017). In 2015, mortality rates from CLD in Scotland in the most deprived decile were six times those of the least deprived (34 v 6 per 10^5) and morbidity rates were five times higher (435 v 88 per 10^5) (ScotPHO 2017). These data demonstrate the impact deprivation and health inequality issues have on CLD.

Cirrhosis is often asymptomatic, and, in most cases, treatable liver disease goes undiagnosed and untreated. This can result in most patients with liver disease presenting at an advanced stage (Williams et al 2014). The three main causes of cirrhosis are obesity, viral hepatitis or excess alcohol consumption (BASL-BSG 2009). Excessive alcohol consumption can cause inflammation of the liver and an accumulation of fats within the liver cells which, if persistent, can lead to fibrosis before development of cirrhosis through an insidious process of replacement of liver cells with connective tissue (Sargent 2009). Fibrosis is often a precursor to cirrhosis, if the cause of liver damage continues. Identification of fibrosis therefore plays an important part in the early detection of the disease process.

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Long term complications of cirrhosis include oesophageal varices, secondary to portal hypertension; the most common lethal complication of cirrhosis through gastrointestinal bleeding (Garcia-Tsao et al 2007). Further complications include liver failure and hepatocellular carcinoma (hepatoma), a primary liver cancer (Muir 2015). Early diagnosis of cirrhosis triggers assessment for complications, initiation of regular hepatoma and variceal surveillance, treatment and lifestyle changes to prevent progression of the disease; thus improving survival, even in advanced cases of cirrhosis (Verrill et al 2009). Early identification and prevention of liver disease is also key in reducing the financial burden to the NHS, where the cost of alcohol related health problems alone are predicted to be around £17 billion (Lancet Commission 2017).

Screening for Chronic Liver Disease

While liver biopsy is considered the gold standard diagnostic tool for cirrhosis (Castera 2011) the invasive nature and risk of complications renders it unsuitable for use as a screening tool in a community setting. A range of less invasive and non-invasive methods are available for the detection of fibrosis or cirrhosis, ranging from blood tests to more sophisticated methods including magnetic resonance imaging (MRI) (EASL-ALEH 2015). Of these, Liver Function Tests (LFTs) are the most commonly used blood tests. Many of these tests rely on biochemical changes induced by altered liver function. In a large population based retrospective cohort study (n= 95,977) the link to outcomes of liver disease and mortality from a large database in primary care in Tayside from 1989 -2003 suggested that, while specificity of these tests was generally high, sensitivity was low with gamma glutamyl transferase (GGT) having the best sensitivity at 72% (Donnan et al 2009). In addition, interpretation of LFTs can be difficult and confusing for non-liver specialists. Referral to specialist liver services often relies on the GP or health practitioner's ability to interpret these results (Cook et al 2015). Due to the size and cost of MRI equipment this method of screening is not appropriate in a non-acute setting.

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Cirrhosis develops because of increased fibrotic tissue and, as a result of this, liver stiffness increases (Muir 2015). Several liver fibrosis scoring systems have been derived, the two most commonly used being METAVIR (F0-F4) and Ishak (F0-F6). Although these are derived from histological features on liver biopsies, the following terminology is widely used in non-invasive assessment techniques: F0 = no fibrosis; F1 = mild fibrosis; F2 = moderate fibrosis; F3 = severe fibrosis; F4 = cirrhosis. Non-invasive assessment of liver fibrosis can use blood tests or imaging techniques (Sargent 2009). Hyaluronic acid (HA) is one such blood test used in specialist services but is non-specific for the liver and can be raised in cases of arthritis (Adams 2011).

Transient Elastography (TE), measured by a FibroScan® device is a non-invasive imaging test of fibrosis which is currently used in specialist centres as a screening and diagnostic tool for liver disease. It measures liver stiffness in kilopascals (kPa), using the propagation of an elastic shear wave through liver tissue from an ultrasound transducer probe. This is a quick, painless, non-invasive assessment for cirrhosis using liver stiffness measurements (LSM) which gives an instant result. TE has been validated as a reliable marker for fibrosis and cirrhosis in a heavy alcohol using group (Nguyen-Khac et al 2008, Thiele et al 2015). The FibroScan® device is available in portable form which, if used in a community setting, could reduce the need for attendance at specialist centres. The portable FibroScan® has been demonstrated to elicit equivalent readings when compared to a static FibroScan® (Parra-Ruiz et al 2014). Nurses trained in the use of FibroScan® have been shown, through research, to elicit comparable readings to their medical colleagues (McCorry et al 2012). This evidence suggests that FibroScan® could be used by nurses in the community.

A subject which continues to foster debate in the literature is the agreement on the lower cut off measurement for FibroScan® readings which corresponds to any degree of hepatic fibrosis (F1-F4). This lower cut off measurement determines whether someone is discharged or requires further clinical investigation. Recent studies have used 8.0 kPa as the lower measurement (Harmen et al 2015, Roulot

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et al 2013); however the threshold can vary depending on the cause of fibrosis. A small study comparing FibroScan® with liver biopsy in alcohol related liver disease suggested a lower cut-off for severe fibrosis (F3) of 12.9kPa (Nahon et al 2008). When offering this intervention in a community alcohol support setting, as the sole initial screening test, without the back up of additional tests for those on or below the low cut off, it was considered best to abide by the lower cut off for any degree of liver fibrosis (F1-F4), of 7.1 kPa as suggested by Castera, Forns and Alberti (2008) to increase the likelihood that fibrosis is detected whatever the cause whether it be alcohol, obesity, viral hepatitis or other, less common, causes. Setting a lower cut off should also reduce the risk of non-detection in borderline cases. Setting this cut off also allows for the opportunity to add to the literature for detection of fibrosis with readings ≥7.1kPa and < 8.0 kPa.

Research context

The World Health Organisation (WHO) (2011) pledged to address health inequalities through developing strategies to promote effective partnerships with health and other sectors in achieving health through policies and actions on social determinants of health, specifically targeting vulnerable and high risk groups. In Scotland, the Public Bodies (Joint Working) Scotland Act (Scottish Government 2014) introduced a statutory duty for NHS Boards and Councils to integrate planning and delivery of health and social care services, strengthening the Scottish Government's commitment to community-based anticipatory care (Audit Scotland 2015). This care is to be provided jointly between the NHS, statutory and non-statutory social care providers with the aim of reducing the number of patients with long term conditions being admitted to acute services (Audit Scotland 2015).

Nurse led clinics aim to provide, facilitate and expand access to quality care to an often vulnerable population who may not otherwise access care in mainstream services (Kleinpell et al 2014). Feedback from users of such services is generally very positive, with patients valuing the improved access to care and their increased opportunity to become partners in managing their condition through the person-

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centred approach. They value the time afforded to them during their consultation with the nurse, where an open, non-judgmental dialogue prioritises the patient's story, a characteristic of advanced practice (Kucera, Higgins and McMillan 2010).

As over 90% of cases of hepatitis C have been acquired through injecting drug use (Scottish Government 2015), nurse led services were set up in both community and acute settings in Scotland to increase the screening for and treatment of hepatitis C, as supported by the Sexual Health and BBV Framework (Scottish Government 2015).

Those infected with hepatitis C have a defined diagnosis elicited through a specific screening blood test, followed up by a confirmatory blood test which amplifies the hepatitis C virus through polymerase chain reaction (Sargent 2009). As screening tests for CLD with blood tests can be unreliable (Muir 2015) and would not be wholly relied upon in its diagnosis, those with alcohol related liver disease do not benefit from the same quality of screening. They may however benefit from nurse-led services where screening for liver disease is offered. At time of review and to date, there is no full text published literature on screening for liver disease with a FibroScan® device in a population of high alcohol consumption utilising community alcohol support services.

Foucher et al (2009), Marshall et al (2015) and Thurnheer et al (2015) conducted prospective cohort studies which targeted People Who Inject Drugs (PWIDs), with a high risk of hepatitis C, to determine the viability and acceptability of screening for liver disease with a FibroScan® device in community settings, including drug support centres in France (Foucher) and Australia (Marshall and Thurnheer). All studies found screening with FibroScan® to be acceptable in reasonably large cohorts of 298 (Foucher et al 2009), 235 (Marshall et al 2015) and 623 (Thurnheer et al 2015). Foucher et al (2009) demonstrated an increased uptake in engagement of hepatitis C treatment services for the duration of the study and concluded that uptake of screening and engagement with treatment for hepatitis C was a direct result of having a FibroScan®. However, it is unclear how participants were recruited other than that they were

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"offered" a FibroScan®. If they relied upon the clinicians directly delivering the services or those running

the study to recruit participants it is possible that the motivation of the participants could be influenced

by the motivation of the recruiting clinicians to engage this group over the study period and this may,

subsequently, have influenced the outcome; this needs further clarification. Marshall et al (2015)

offered participants a voucher to the value of $20 for their participation which may have influenced

their choice in taking part, and possibly their attitude towards the acceptability of the FibroScan®.

Thurnheer et al (2015) also sought to compare disease prevalence between tertiary clinics, community

clinics, clinics for PWIDs and regional clinics. Results showed that FibroScan® was feasible as a screening

tool within a community setting and that a higher level of more advanced liver disease was found in

what were described as "regional clinics"; a term not clarified further. Hepatitis C was a known factor

with this group, however while alcohol use was documented, it was not quantified. While higher

incidence of disease within the regional clinics may suggest lower socioeconomic status with poor access

to tertiary care this is not stated and cannot be assumed. In addition, the cause of liver disease varied

between the cohorts with those from community clinics more likely to be infected with hepatitis B from

birth and of different ethnic origin with different lifestyle factors and therefore not directly comparable.

Nonetheless, of interest is the higher prevalence of disease out with the tertiary setting suggesting acute

services may not be reaching those at most risk.

In their prospective cross sectional study in two primary care practices in Nottingham (n=504) Harman

et al (2015) targeted those at high risk of liver disease through hazardous alcohol use, type 2 diabetes or

a persistently elevated liver function enzyme (ALT). They demonstrated the inadequacy of screening

using LFTs alone with 26% of participants eliciting an elevated FibroScan® result (n=98) while 71/98

(72%) of these participants, had normal LFTs. The lower threshold for the FibroScan® result was 8.0kPa in

this study. In addition, 11 patients were identified with cirrhosis which had not been previously

diagnosed. While FibroScan® was not the initial screening tool in this study; it further demonstrates the

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current inadequacy of screening using LFTs alone. In addition, while they targeted those at high risk of liver disease, with a yield of 26% with raised liver stiffness measurements (LSM), Roulot et al (2013) offered screening using a FibroScan® device to all patients over the age of 45 years old attending a social medical centre in France for a routine medical check up. The prevalence of elevated LSM (with ≥ 8.0kPa cut off) was 7% in this large self-selected sample (n=1190). This suggests that offering targeted screening to higher risk groups could be more efficient in unearthing undiagnosed liver disease. Although both these studies were carried out in a primary care setting, neither study focused on the health inequalities aspect of liver disease.

Fabrellas et al (2013) sought to determine the feasibility of a nurse led screening service for CLD using a FibroScan® device in a primary care nurse consultancy in Spain. Participants were randomly chosen from the health registry and asked to participate by telephone. With a lower cut off threshold of ≥ 6.8kPa, and in a large sample (n=502) they concluded that such a service was feasible with a prevalence of 5.7% of participants with elevated liver stiffness, suggestive of fibrosis in keeping with the lower prevalence found in Roulot et al (2013) as compared to Harman et al (2015) discussed earlier; further demonstrating that targeting high risk groups for screening is more efficient. While the nurse led aspect of this study is of interest it was conducted in a non UK primary care setting; In addition the participants were randomly selected, rather than targeted according to behaviour that may predispose them to liver disease.

While the studies reviewed suggest good acceptability of FibroScan®, questions remain, in some, regarding the possible influence of the motivation of those recruiting and the provision of a financial incentive on the success of their recruitment strategies. This, therefore, influenced the choice of recruitment strategy in this study; where the researcher was not actively involved in recruitment of potential participants. Reviewing the literature highlighted the inadequacy of serum markers in screening for liver disease and the higher prevalence of disease out with the acute setting. It also

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highlighted that targeting a high risk group is more efficient; an important consideration for cost effectiveness and another which influenced this study design. Finally, while one study suggests that a nurse led screening service with a FibroScan® device is feasible, this was conducted in a non UK primary care setting.

This review suggests nurse led clinics are acceptable to a variety of cohorts in a variety of settings. It also suggests that, with training, nurses are competent to deliver a service using a FibroScan® device. However, no studies directly investigated a nurse led FibroScan® service within the community alcohol setting where individuals present themselves for support.

Aims and objectives

The main aim of this pilot study was to determine the acceptability of a service providing screening for CLD, with a portable FibroScan® device, to a group concerned about the health of their liver due to elevated levels of alcohol consumption.

Subsequent aims were to:

1. Recorded the uptake of a FibroScan® in individuals accessing one community alcohol support service.

2. Determine the prevalence of undiagnosed CLD in a self-selected, convenience sample of individuals accessing one community alcohol support service

3. Reported attendance at 6 months following referral to Royal Infirmary of Edinburgh (RIE) specialist liver services, of those participants referred with a FibroScan® reading ≥7.1kPa.

Ethics
Ethical approval was gained from the South East Scotland Research and Ethics Committee (reference 14/SS/1021), NHS Lothian research & development department and Edinburgh Napier University ethics committee.

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Methods

Design

This was a prospective quantitative observational study. The study was active over the twelve month period from November2014 until the end of October 2015 with screening with FibroScan® offered during the first six months until April 2015; thereafter engagement with services of those requiring onward referral was monitored.

Sample

The sample was a convenience sample in one community alcohol support setting in Edinburgh. This recovery centre has a catchment area which includes an area of deprivation in Edinburgh (SIMD 2017); therefore, those at most risk through their liver disease could be targeted (Williams et al 2014).

As this study evaluated the acceptability of the cirrhosis screening intervention in this setting, no specific sample size was determined in advance. The sample size was limited to the number of individuals dropping in to the research clinics in a 24 week period after reading the participant information pack (PIP).

Inclusion criteria included individuals over age 16, with the ability to provide informed consent who were attending either the triage facility for assessment of their support needs, or who were currently undergoing alcohol support in the centre. Exclusion criteria included the possibility of or known pregnancy, known to have a pacemaker, ascites, an open wound close to right 8th-10th intercostal margins, known cirrhosis and no alcohol history (EASL-ALEH 2015 2015).

During the recruitment period 118 participant information packs were requested. Of these, 79 service users presented themselves for the study and subsequently provided consent, representing an uptake of 67% of those who requested information.

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Recruitment

The study was advertised on a rolling TV screen in the reception area, posters in reception and all consultation rooms. Potential participants could then volunteer. The advertising literature was designed to demonstrate that participants were not required to undress, merely that the upper left quadrant of the abdomen was exposed for access of the FibroScan® probe, in case this assumption was a barrier to participation.

PIPs were numbered and available in the reception area of the service and any staff member could distribute them. To assess uptake, the number of packs issued was recorded to allow response rate to be calculated. The format of writing in these packs was informed by guidelines from NHS Scotland (2014) information aimed at the general public i.e. the level was pitched at a reading age of seven years and for ease of accessibility, Arial font size 11 was used. Staff checked that individuals taking a PIP were given the opportunity to have the information read to them on the premises. If an individual wished to take part in the study, they could return to a research clinic on the same premises at their convenience on a Tuesday or Thursday between 11-2pm. This enabled potential participants to attend on an empty stomach to enhance the quality of the scan (Lemoine et al 2014); a full stomach did not exclude participation in the study, as is current practice in other specialist liver services.

Following discussion of the purpose of the study and an opportunity to ask questions, written consent was taken. Part of this consent requested to share information with the participant's GP and other health professionals, as appropriate.

Data Collection

 A focused medical and lifestyle history (Snadden et al 2013) was taken by the hepatology nurse practitioner and principal investigator (KM) using a data collection tool specifically designed for this study (Appendix 1). Development of this tool was adapted from by the four domains of the tool developed by Carneiro et al (2014) i.e. Identification, Clinical Data, Physical Exam and Interview, in line with Gordon's Functional Health Pattern taxonomy (Gordon 1994). This data collected were weight,

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height, alcohol, medical, smoking and family history, current medication and possible viral hepatitis risks. Each participant had a FibroScan® screen on day of consent. For the FibroScan®, participants were asked to lie on a couch with their upper left quadrant exposed. The FibroScan® probe was placed between the 8th and 10th intercostal margin in line with operator guidelines (EASL-ALEH 2015) and, to improve access to the liver through opening the intercostal space, their right arm placed behind their head, if possible. Prior to the scan, the participant was informed they would be given an immediate result at time of screening and their choices for follow up would be discussed after result.

A lower cut off measurement of 7.1kPa for referral to services was used in the study and aims to reduce the risk of non-detection in borderline cases, as discussed earlier. In the event of being unable to elicit a FibroScan® reading the participant's GP was informed and invited to refer participants to the liver unit at the RIE for further assessment, should they have any concerns regarding their liver health.

The portable FibroScan® device could not support an XL probe, resulting in an increased likelihood that readings from participants with a BMI >30kg/m^2 were unreliable with the medium probe (de Ledinghen 2012). Therefore the participant's BMI was calculated from recording of weight and height. BMI result could enable a discussion regarding the liver health implications of a raised BMI and discussion from a health promotion aspect.

Data analysis

These data were coded using a codebook developed for this study using descriptive statistics within the "Statistical Package for Social Sciences" (SPSS) version 21.Demographic data was reported on the initial 79 participants while subsequent data analysis of FibroScan® results and engagement of those requiring onward referral was undertaken on the 76 participants in whom reliable readings were obtained.

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Follow up based on FibroScan® result

For those participants who showed no signs of fibrosis or cirrhosis from their scan (≤ 7.0kPa), lifestyle

advice was reinforced through literature on the effects of alcohol on the liver offered at the research

appointment (Drinkaware 2013).

Any participants with a FibroScan® reading ≥ 7.1kPa were offered an appointment to attend a NHS nurse

led liver clinic within the same community service, on another day. The appointment date and time

were given on the day of the FibroScan®. A reminder telephone call for the clinic appointment was also

offered, in line with recommendations for improving engagement in harder to reach and engage groups

(Watt 2013).   In the event of a participant having a reading ≤ 7.0kPa but showing possible signs or

symptoms of CLD, such as current abdominal swelling, an appointment for follow up was also offered

(Muir 2015). No participants, with a FibroScan® ≤ 7.0kPa presented with current symptoms of concern.

At the appointment in the NHS nurse led liver clinic, blood was taken for a full liver profile, including

platelets, hyaluronic acid and the liver enzymes alanine aminotransferase (ALT), aspartate

aminotransferase (AST). To determine the degree of CLD those with a FibroScan® result ≥ 8.0kPa were

referred for an ultrasound and clinical evaluation by a consultant Hepatologist or senior registrar within

the Hepatology team. The blood results of participants with a FibroScan® result ≥7.1kPa and < 8.0kPa

were discussed with a consultant Hepatologist, in order to decide whether further investigations and

medical assessment were required. Liver biopsy was not required to determine the degree of CLD and

no biopsies were taken in the study period. Regardless of the FibroScan® result and if consent was

provided, the GP of each participant was informed of the participant's recruitment to study, result and

follow-up if required.

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All onward referral to specialist liver services and adherence to surveillance was monitored through checking participants' appointment details on Trak (online tracking system used by NHS Lothian for booking patient appointments and recording attendance) for the duration of the study.

Results

Uptake of FibroScan®

A total of 79 consented participants took part in the study. A valid FibroScan® reading could not be obtained in three participants; all of whom had a BMI >30kg/m^2. All results presented relate to the 76 participants with a valid FibroScan® reading. Table 1 provides demographics and key information elicited from the data collection tool created for this study

Prevalence of undiagnosed cirrhosis

Of the 76 participants, 56 (74%) elicited a FibroScan® reading of ≤ 7.0kPa, indicating no significant fibrosis and requiring no onward referral for further investigations.

Of those requiring blood tests, 19/20 (95%) attended the nurse-led clinic for a full liver blood profile, with one participant failing to attend either of the two initial appointments at the nurse-led clinic but attending their GP for baseline liver bloods and thereafter the nurse-led service for further assessment bloods.

Following analysis of the blood results taken at the nurse-led liver outreach clinic, none of the eight participants with a reading ≥7.1kPa and < 8.0kPa required onward referral for medical assessment. Of the remaining 12 participants seven (9%) had a reading ≥8.0kPa and < 12.5kPa indicating possible significant fibrosis and five (7%) had readings ≥ 12.5kPa indicating possible cirrhosis.

On completion of the study the diagnostic outcomes (Table 2) were monitored for the 20 participants requiring referral to the nurse-led clinic and subsequent onward referral to specialist liver services. Within this group six (8%) were diagnosed with definite cirrhosis. One participant was discharged back to their GP following a period of alcohol reduction over a six-month follow up period. One participant

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did not engage with their medical assessment and therefore never received a definite diagnosis. The

remaining four (5%) were diagnosed with fibrosis and remain in follow up with specialist services.

Engagement of participants requiring onward referral

Of the 20 participants referred to the nurse-led service clinic within the alcohol service, 19 attended. Of

the 12 patients expected to attend the RIE for medical assessment, 11 did so and of 10 patients

expected to attend for six monthly follow up, nine did so. All 12 patients referred for abdominal

ultrasound attended. This is illustrated in Table 3.

Discussion

Uptake of routine health screening is low in areas of deprivation (Watt 2013), suggesting low self-

efficacy, i.e. the confidence in one's ability to exert control over their behaviour (Bandura 1997). This

could be attributed to low confidence, poor literacy and financial difficulties which make negotiation

through the process of health care delivery and travel to appointments difficult (Watt 2013). Therefore,

an uptake of 67% in this screening study for those who received information, suggests that this

intervention is acceptable to prospective participants in this setting. In addition, this appears to

demonstrate a level of self-efficacy in this cohort, as suggested by their current engagement with

alcohol support services. According to the Health Belief Model (HBM) perceived susceptibility to disease

influences health behaviour (Sharma 2011) and may be another factor in the level of uptake in this

cohort who, by their engagement with alcohol support are likely to be aware of the effects of alcohol on

the health of the liver, through access to health promotion materials and consultations with support

staff at community alcohol support service. The Theory of Planned Behaviour suggests that intention

and self-efficacy are the best predictors of behaviour change in addition to other external control factors

i.e. barriers or facilitators to change (Marks et al 2015). This is a self selected group who, through their

attendance with the alcohol service, demonstrated a level of self-efficacy and motivation to change their

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behaviour in a setting where specialised support is available and, in this respect this screening intervention appears to be in the right place at the right time.

As participants were recruited through a "drop in" system, it is beyond the scope of this study to determine the number of potential participants who did not request research information, and their reasons for this, and is acknowledged as a limitation. The study results on acceptability are consistent with other studies demonstrating the acceptability of offering FibroScan® as a screening tool in community drug services (Foucher et al 2009, Marshall et al 2015, Thurnheer et al 2015) and would appear to show it could be an effective way of encouraging initial engagement with liver services.

At a time when mortality from CLD, including cirrhosis, has increased by 500% since 1970 in the under 65 age group (Williams et al 2014), the mean age of 46 years in this cohort of participants seems optimal for consideration of screening. With male mortality rates for CLD being almost twice as high as those reported for women (ONS 2017) the proportion of male to female attendees for 63% to 37% would appear to be representative of this population. Participant alcohol histories confirmed this to be a heavy drinking group, as targeted. Those with a FibroScan® reading ≥ 7.1kPa and < 8.0 kPa did not require onward referral once their blood profile was assessed by a Consultant Hepatologist (AMacG); supporting studies using a threshold of 8.0kPa (Harmen et al 2015 and Roulot et al 2013) and adding to the literature regarding the lower cut off for FibroScan® in general screening.

Obesity is one of the most common causes of CLD through fatty infiltration of liver cells (Muir 2015). Levels of obesity are highest for those living in deprived areas (ScotPHO 2017), often due to poor diet and lack of exercise. Within this cohort the prevalence of obesity was 21.1%, while the current prevalence of obesity is 29% in the general population of Scotland (ScotPHO 2017). The portable FibroScan® device used in this study (FibroScan® 402) could not support an XL probe. While only three scans were unreliable, according to criteria in (Schwabl et al (2015), each of these participants had a BMI

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higher than 30kg/m^2. It would seem advisable, given the level of obesity, that an XL probe is available in future.

Considering the uptake of screening by FibroScan®, Health Behaviour Theory, suggesting self-efficacy and high motivation in this cohort supports the encouraging engagement in specialist services for those requiring onward follow up. In addition, this is in line with the findings from Foucher et al (2009) who concluded that uptake of hepatitis C treatment in a group who previously had not engaged, was a direct result of having a FibroScan®. Sheron et al (2013) used a serum panel test to screen for liver disease conducted across nine GP surgeries (n=4630). They found that feedback about liver health may be a useful prompt for behaviour change, with the biggest reductions in drinking being seen in the group with heaviest drinking behaviour up to one year following the intervention. They conclude that combining a screening intervention for liver disease with ongoing support in alcohol recovery could have a positive impact on behaviour change. As Sheron et al (2013) recruited participants through their GP surgery with an invitation letter and a subsequent postal questionnaire their cohort is not directly comparable to that in this study. Nonetheless, in light of their findings, the early engagement with assessment and follow up in specialist services in this study was extremely encouraging as a possible predictor of health behaviour change. However, it is important to continue research beyond this study to determine what, if any, impact this type of intervention has on the longer term drinking behaviour of this or a similar cohort.

In preparing for implementation of the study it was important to consider possible facilitators and barriers (Dogherty and Estabrooks 2015). The research venue consists of multiple agencies, playing an important role as the study hosts. As the only room suitable for carrying out a FibroScan® was the largest in the building and the one used for the various therapies on offer in the service, KM was concerned that this had the potential for conflict as the study progressed with possible competing demands for the use of the room. While there will be no randomised control trial following on from this study, guidance in its

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development was sought using the MRC (2008) guidelines in developing and evaluating a complex intervention. Practical effectiveness, whether the intervention will work in everyday practice, is a key question to consider; therefore, designing the study to be as low maintenance as possible for staff at the venue was considered to be important to developing a sustainable service which would continue beyond the research phase and could be integrated into routine services offered there. Through KM's attendance at staff meetings and informal discussion, in advance of the study, the venue staff were aware of its purpose and able to describe the intervention to service users. Feedback from staff was positive throughout the study, illustrating that staff thought it was a good idea. Their continued willingness to provide the room for screening, moving the time of some of their own activities to accommodate this booking combined with their continued enthusiasm in promoting the intervention through discussion with service users and displaying the study posters demonstrated cognitive participation, collective action and reflexive monitoring, key elements identified in Normalisation Process Theory (NPT) where normalisation is the willingness to integrate a new intervention into everyday practice (May 2015). The support by venue staff in continuing the intervention beyond the study phase has prompted discussion with the stakeholders involved in the study to consider the possibility of continuing the provision of screening as a service; particularly in view of the unexpectedly high levels of engagement with services for those requiring onward referral in this study. This is currently being piloted as a service delivered by a team of specialist community nurses and is currently being evaluated.

While devising and developing this study required the advanced practice skills of negotiation and leadership (NMC 2005), in their competency framework for working in liver disease, the RCN (2013) suggest that all nurses, regardless of clinical background have skills and talents to integrate liver health into routine clinical practice. Public Health England's (PHE) "Make Every Contact Count" (MECC) agenda (PHE 2016) suggests that nurses are integral in making an impact on liver disease through discussion of

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possible risks and lifestyle choices to improve liver health. In addition to alcohol intake, healthy eating,

keeping to a healthy weight and being physically active are deemed to be three of the lifestyle issues

which can make the greatest improvement to an individual's health and, as such, are factors which

should be included in every patient contact, according to PHE (2016). This is also in line with the Scottish

Government's "2020 vision" where a strong focus on prevention, anticipation and supported self-

management is recommended in order to improve the health of the nation (Scottish Government 2017)

and the NHS Scotland Healthcare Quality Strategy (NHS Scotland 2010) which emphasises the use of the

most appropriate interventions and supports in providing quality healthcare. This suggests, therefore,

that in the context of an alcohol support centre and with appropriate training, nurses are well placed to

deliver not only liver screening but more general lifestyle discussion to a group at high risk of liver and

other chronic disease through their alcohol intake and obesity levels.

In complex health interventions (MRC 2008) the success, or otherwise, is dependent on many factors

and it is important to consider optimisation of the intervention, in order to progress it to an embedded

service or further research (Levati 2016, MRC 2008). Sermeus (2015) acknowledges that an increasing

number of components characterising interventions leads to them being harder to implement and it is

important, not only to establish the key components, but also the inactive components in the

intervention. In this study, one possible key factor is the acceptability of the non-invasive, painless

FibroScan® device which gives an immediate result; as opposed to blood tests which can be painful and

do not elicit results immediately. In addition to this KM offered the FibroScan® and also delivers the liver

clinic at the community alcohol service and, in this respect, is motivated to work with harder to engage

groups and familiar with some of the challenges posed (Watt 2013). In particular, this is reflected in the

recruitment process where participants were not approached directly by KM as it was important that

vulnerable, potential participants should not feel coerced into taking part. The ability of the nurse to

engage with the participant's own motivation in considering changing their behaviour (Lau-Walker et al

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2016) and continuity of care offered by seeing the same nurse in the initial stages of the pathway may be a crucial factor in gaining the trust of participants and may also account for the level of engagement seen. As discussed, another key component may be the choice of venue, the influence and support of staff and, importantly, the self-efficacy and motivation of the self-selected cohort of participants.

This was a fixed term study, not designed to assess whether the encouraging level of engagement continues and whether the lifestyle changes required for improving the participant's liver health were instigated and continued over a longer period of time and this is acknowledged as a limitation. Further work is required in determining the key components of screening and to gain insight into its acceptability and reasons for the encouraging level of engagement. This may be possible through a qualitative study, collecting data using one to one interviews with consented participants to understand the participant experience. In addition, a longitudinal study, designed to monitor changes in lifestyle behaviour beyond the six months post screening in this study, would help to establish whether engagement and lifestyle changes were sustained.

Conclusion

This study suggests that cirrhosis screening using a portable FibroScan® device in the outreach setting of a community alcohol service in an area of high deprivation is acceptable both to participants and alcohol support staff. It can identify significant liver disease in the targeted population and results indicate a high level of early engagement in NHS liver services in a cohort of heavy drinkers, previously considered hard to engage. Nurse led screening in this setting provides an opportunity for education and discussion regarding lifestyle factors in liver disease with a cohort who seem motivated to improve their liver health. Further work is needed to optimise this intervention to understand, more fully, what are the essential active components necessary to replicate this outcome (Levati 2016, Sermeus 2015).

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Relevance to Clinical Practice

This study demonstrates that nurse led screening with a portable FibroScan® device in a community

alcohol service assists heavy drinkers to engage in specialist liver services. This suggests it is an

acceptable service development for participants, enabling early diagnosis of liver disease. As such, it is

an intervention with the potential to be integrated into the practice of nurses working with this

population if they receive the appropriate education, preparation and induction in its application;

moving towards improving liver health of people in a high risk group with subsequent reduced health

cost for liver disease to the NHS.

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Table 1: Participant Demographics of the 79 participants who consented to having a FibroScan®

Participant information	Female (n=29)		Male (n=50)		Total cohort (n=79)	
Mean age in years	46 (SD=11yrs)		46 (SD=8yrs)		46 (SD=9yrs)	
Currently receiving alcohol support at the community service	24(83% of female cohort)		45 (90% of male cohort)		69 (87% of total cohort)	
Attending triage facility – first step in accessing support	5 (17%)		5 (10%)		10 (13%)	
Previous detox from alcohol	20 (69%)		35 (70%)		55 (70%)	
Pattern of drinking	Daily	22 (76%)	Daily	37 (74%)	Daily	59 (75%)
	Binge	4 (14%)	Binge	13 (26%)	Binge	17 (22%)
	Intermittent	3 (10%)	Intermittent	0	Intermittent	3 (4%)
Levels of drinking in units per week (recommended limits 14 units for female and 21 units for male at time of study)	1-100	10	1-100	14	1-100	24
	101-200	11	101-200	21	101-200	32
	201-300	5	201-300	8	201-300	13
	301-400	1	301-400	4	301-400	5
	401-500	1	401-500	0	401-500	1
	501-600	0	501-600	1	501-600	1
	Unsure	1	Unsure	2	Unsure	3
Median (IQR: percentile 25, percentile 75) length of drinking in years	10 (7,20)		15 (5,20)		12 (6,20)	
Possible symptoms of CLD	6 (21%)		7 (14%)		13 (16%)	
Reported risks of BBVs	12 (41%)		35 (70%)		57 (72%)	
Mean BMI of cohort in kg/m²	26.5 (SD=5.6)		26.6 (SD=5.2)		26.5 (SD=5.3)	
Prevalence of cohort obesity (≥ 30kg/m²)	8 (28%)		9 (18%)		17 (22%)	

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Table 2: Diagnostic Outcomes following FibroScan® full liver blood profile & specialist liver service appointment

	Diagnostic Outcomes					
	Cirrhosis	Fibrosis	Discharged following medical assessment	Nurse only assessment no further referral	No diagnosis	No onward referral
FibroScan ≥7.1kPa < 8kPa (n= 8)	0	0	N/A	8	N/A	0
FibroScan ≥8kPa <12.5kPa (n= 7)	1	4	1	0	1	0
FibroScan ≥ 12.5kPa (n= 5)	5	0	0	0	N/A	0

Table3: Engagement of Participants in FibroScan® Requiring Onward Referral to Specialist Services

Engagement of those requiring onward referral	Expected number	Number attended	Percentage
Attended nurse appointment at the Venue	20	19	95%
Attended first medical appointment at RIE	12	11	92%
Attended six month follow up	10	9	90%
Attended USS/CT/MRI	12	12	100%

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