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Research paper

DOT-C: A cluster randomised feasibility trial evaluating directly observed anti-HCV therapy in a population receiving opioid substitute therapy from community pharmacy☆

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ABSTRACT

Background: Direct-acting antiviral therapy (DAAs) for hepatitis C infection (HCV) have a much smaller burden of treatment than interferon-based regimes, require less monitoring and are very effective. New pathways are required to increase access to treatment amongst people prescribed opioid substitution therapy (OST).

Methods: An exploratory cluster randomised controlled trial with mixed methods evaluation was undertaken to compare the uptake of dried blood spot testing (DBST) and treatment of people with genotype 1 HCV infection in a conventional service pathway versus a pharmacist-led pathway in a population receiving OST.

Results: Pharmacies randomised to the conventional pathway obtained 58 DBST from 244 patients (24%):15 new reactive tests and 33 new negative tests were identified. Within the pharmacist-led pathway, 94 DBST were obtained from 262 patients (36%): 26 new reactive tests and 54 new negative tests were identified. Participants in the pharmacist-led pathway were more likely to take a DBST ($p < 0.003$). Of participants referred for treatment through the conventional pathway, 4 patients from 15 with new reactive tests (27%) attended clinic for assessment. In the pharmacist-led treatment pathway, 20 patients from 26 with new reactive tests (77%) attended for assessment blood tests. Participants in the pharmacist-led pathway were more likely to proceed through the assessment for treatment ($p < 0.002$). One participant completed treatment through the conventional pathway and three patients completed treatment through the pharmacist-led pathway. The process evaluation identified key themes important to service user completers and staff participants.

Conclusion: The study provides evidence that testing and treatment for HCV in a pharmacist led-pathway is a feasible treatment pathway for people who receive supervised OST consumption through community pharmacies. This feasibility trial therefore provides sufficient confirmation to justify proceeding to a full trial.

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Introduction

Hepatitis C (HCV) is a blood-borne viral infection (BBV) causing liver disease. Around 0.8% of the Scottish population are chronically infected with HCV (Scottish Intercollegiate Guidelines Network (SIGN), 2013). A recent Public Health England report highlighted that less than 3% of those known to be infected with HCV are being treated and less than half of those infected are known (Hepatitis C annual report progress made, but much more to do. Public Health England). The largest single infected group are those on opioid substitution therapy (OST) (Arain & Robaeys, 2014). Research suggests around 40% of people receiving OST have HCV infection (Aspinall et al., 2015; Edlin et al., 2005).

The world-wide burden of HCV infection has been estimated as 71.1 million infections (62.5–79.4), with the largest group being genotype1 (The Polaris HCV Collaborators, 2017). The increased morbidity, mortality and economic impact of the infection are of concern to both industrialised and developing countries (Lavanchy, 2009).

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The paradigm shift resulting from the introduction of Direct-Acting Antiviral therapy (DAAs) has changed the narrative around HCV, with a realisation that HCV could be eliminated in people who inject drugs (Lima et al., 2015). There is optimism that the use of DAAs offers a high chance of clearance of HCV infection from the population (Grebely & Dore, 2014). Treating all patient groups with HCV would yield substantial benefits (Van Nuys, Brookmeyer, Chou, Dreyfus, & Goldman, 2014) but there are concerns that the infrastructure and treatment capacity to deliver the required health outcomes are not generally available or of insufficient scale (Leask & Dillon, 2016).

Treatment uptake for HCV amongst people who inject drugs is currently low (Wiessing et al., 2014) and prospective patients may have a number of barriers to overcome in order to access care (Fernandez-Montero et al., 2013). There are identified deficiencies in the extent of screening and diagnosis of at-risk populations, as well as improvements required in access to treatment initiation and clinical monitoring (Artenie et al., 2015): People who inject drugs may find it difficult to consistently attend medical clinics (Papatheodoridis, Tsochatzis, Hardtke, & Wedeyer, 2014). However, the delivery of HCV testing and treatment through community-based care pathways has been shown to be feasible (Wade, Veronese, Hellard, & Doyle, 2016) and Dried Blood Spot Testing (DBST) has been demonstrated to increase the uptake of testing from high-risk populations (Coats & Dillon, 2015).

Creating the complex interventions necessary to eliminate HCV infection requires that well-designed cross-disciplinary programmes are put in place (Suther & Harries, 2015) using different strategies to increase screening, testing and diagnosis (Brouard et al., 2015). The potential of community pharmacy practices to make a greater contribution to the health of their local populations has been recognised for some time (Anderson, Blenkinsop, & Armstrong, 2009; Anderson, Mandeville et al., 2009). Pharmacists have long had a major role in delivering OST to this group of patients with a high prevalence of HCV (Anderson, 2007) and pharmacist involvement in delivering HCV treatment through multi-disciplinary clinics has been described for some time (Arora et al., 2011; Kolor, 2005).

The Tayside region of Scotland has sequentially developed integrated HCV treatment services over the last two decades, moving from standard secondary care-based hospital outpatients, onto nurse-supported treatment services, then to a HCV managed care network (MCN) including a widespread dry blood spot testing programme in drug services and development in our outreach services across the region. This most recent development includes providing treatment within drug services and prisons (Tait et al., 2016). The network aims for wide involvement in BBV testing and follow-up, with healthcare professionals such as drug workers, GPs, prison nurses and social workers taking the opportunity to discuss referral and treatment with patients.

A cluster randomised feasibility trial was therefore designed to optimise the research design and consider whether a pharmacist-led testing and treatment pathway could be both effective and successful, before being more widely implemented (Bowen et al., 2009). The study was designed with a mixed methods approach to evaluate: whether people who receive OST for pharmacies could be recruited to the study; whether pharmacies could successfully complete all elements of the testing and treatment pathway; which elements of the pathway work well and which elements are less successful; to make an estimate of the effect size in terms of how many participants complete each stage of the pathway (Arain, Campbell, Cooper, & Lancaster, 2010; Eldridge et al., 2016).

In preparing to undertake this study, work was undertaken using a co-production approach in partnership with OST patients (Radley, Melville, Easton, Williams, & Dillon, 2016) and has developed the intervention through using the views of patients and staff to identify barriers and facilitators to effective care (Radley et al., 2017). The DOT-C study utilises the existing pharmacy environment and therapeutic relationships to smooth the pathway into HCV therapy and co-administer OST with anti-HCV therapy under the supervision of the pharmacist. The conventional care pathway requires referral and attendance of the patient at another site and treatment according to the established standard of care. This feasibility study therefore aims to address questions about increasing testing and uptake of treatment, through a simplified community pharmacist-led care pathway for patients with genotype 1 HCV and to incorporate these colleagues into the work of the MCN.

Methods

Trial design

A cluster randomised feasibility trial of directly observed anti HCV therapy versus conventional care in HCV positive patients attending a pharmacist delivered OST program.

Study protocol

Ethics approval was received for this study (15/ES/0086) from East of Scotland REC2 on 2 July, 2015. Caldicott Guardian approval was given on 25 July, 2015.

Participants

Approximately 2200 patients are prescribed OST within the Tayside region of North East Scotland. Around 85% of these patients receive daily supervision of their OST consumption through the 92 community pharmacies. At least 40% of these patients will be infected with HCV, 40% of infections are Genotype 1 virus (Hutchinson et al., 2006).

Trial inclusion criteria

Pharmacies were eligible to participate in the study if they could offer DBST for HCV or be trained to do so. Pharmacies required around 30 patients to ensure adequate recruitment.

Patients were eligible to be consented to the study if they were prescribed OST with supervised administration by a pharmacist and had a reactive DBST. Only genotype 1 patients were included. Genotype 3 patients were excluded because of the requirement to provide interferon-based regimes at the time of the study.

Randomisation

Eight pharmacies were randomised into two groups: conventional care and pharmacist-led care. Randomisation was carried out using http://www.randomization.com. The subjects were randomized into one block using the seed 12,576 along with the number of subjects per block/number of blocks and (case-sensitive) treatment labels. The pharmacy provided the level of randomisation, so patient allocation was dependent on the pharmacy attended.

Interventions

All pharmacy staff involved with the study received training on good clinical practice, study procedures and documentation. Patients confirmed as having genotype 1 HCV infection were

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