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Randomised controlled trial of active case management to link hepatitis C notifications to treatment in Tasmania, Australia: a study protocol

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ABSTRACT

Introduction By subsidising access to direct acting antivirals (DAAs) for all people living with hepatitis C (HCV) in 2016, Australia is positioned to eliminate HCV as a public health threat. However, uptake of DAAs has declined over recent years and new initiatives are needed to engage people living with HCV in care. Active follow-up of HCV notifications by the health department to the notifying general practitioner (GP) may increase treatment uptake. In this study, we explore the impact of using hepatitis C notifications systems to engage diagnosing GPs and improve patient access to treatment.

Methods and analysis This study is a randomised controlled trial comparing enhanced case management of HCV notifications with standard of care. The intervention includes phone calls from a department of health (DoH) specialist HCV nurse to notifying GPs and offering HCV management support. The level of support requested by the GP was graded in complexity: level 1: HCV information only; level 2: follow-up testing advice; level 3: prescription support including linkage to specialist clinicians and level 4: direct patient contact. The study population includes all GPs in Tasmania who notified HCV diagnosis to the DoH between September 2020 and December 2021. The primary outcome is proportion of HCV cases who initiate DAAs after 12 weeks of HCV notification to the health department. Secondary outcomes are proportion of HCV notifications that complete HCV RNA testing, treatment workup and treatment completion. Multiple logistic regression modelling will explore factors associated with the primary and secondary outcomes. The sample size required to detect a significant difference for the primary outcome is 85 GPs in each arm with a two-sided alpha of 0.05% and 80% power.

Ethics and dissemination The study was approved by University of Tasmania's Human Research Ethics Committee (Protocol ID: 18418) on 17 December 2019. Results of the project will be presented in scientific meetings and published in peer-reviewed journals.

Trial registration number NCT04510246.

Trial progression The study commenced recruitment in September 2020 and end of study expected December 2021.

Strengths and limitations of this study

- This is the first randomised study using disease notifications data to determine effectiveness of supporting linkage to hepatitis C virus care and treatment.
- This trial is examining the effectiveness of guiding care pathways for prospectively notified diagnoses.
- There is a risk of contamination of the intervention if general practitioner (GPs) at the same clinic are randomised to different arms of the study, which might underestimate the true benefit.
- The study runs a risk of high lost to follow-up particularly with locum GPs as they move across practices.

INTRODUCTION

Hepatitis C virus (HCV) affects approximately 71 million people globally causing 400 000 deaths each year.[1] In Australia, approximately 180 000 people were estimated to be living with HCV in 2017.[2] The availability of direct-acting antiviral medications (DAAs) on the Pharmaceutical Benefits Scheme since March 2016, has revolutionised HCV care.[3] The simplicity and tolerability of these new treatments, combined with Australia providing largely unrestricted access to DAAs in primary care, makes it possible for Australia to eliminate HCV as a public health threat.[4 5]

To realise this once-in-a-generation opportunity, it is imperative that sufficient numbers of people complete treatment in order to interrupt transmission.[5] While in the initial year of DAA subsidy in 2016 over 32 000 treatments were prescribed, the number of people commencing treatment has declined considerably; in 2019, 11 580 DAA treatments were prescribed,[6] below the estimated 13 680 annual treatments needed to achieve HCV elimination in Australia by 2030.[7] As such, initiatives are needed to actively engage

people living with hepatitis C in care and ensure that healthcare providers are appropriately equipped to prescribe DAAs or link patients to treatment.

DAAs can be prescribed by general practitioners (GPs) in Australia and they provide an additional accessible and convenient HCV care and treatment pathway. The proportion of Australians receiving DAA treatment via their GP increased from 8% at the introduction of DAAs in March 2016 to 40% in May 2017, but has remained stable since.[6] There are clear guidelines available for hepatitis C treatment, and the introduction of pan-genotypic regimens in August 2017 has further simplified treatment options.[3] However, DAA access barriers remain, particularly for people who inject drugs who are a key group for hepatitis C elimination efforts.[5] Qualitative research among both consumers and providers of healthcare has suggested that a lack of provider follow-up and support is a barrier to treatment uptake after diagnosis.[8–10]

Hepatitis C is a notifiable disease in Australia and notifications represent an opportunity to link patients to treatment. Consistent with other Australian jurisdictions, in Tasmania, the setting for this study, laboratories conducting hepatitis C testing notify positive hepatitis C test results to the Department of Health (DoH) using the details of the GP who ordered the test[11] in accordance with Communicable Disease Network of Australia Hepatitis C surveillance case definition.[12] This study is the first randomised controlled trial to assess the impact of active case follow-up of hepatitis C notifications using a jurisdiction-wide disease notifications system to support linkage to care and treatment. A non-randomised pilot study in England explored the use of a half-time facilitator who trained key workers, supported hepatology appointments, and interacted directly with clients.[13] The half-time facilitator led to increased engagement and treatment uptake among people who inject drugs with hepatitis C. Other studies used strategies to increase HCV testing and treatment using community drug services and not surveillance data[14 15] and were not prospective study designs.[16 17]

This study designates a DoH specialist HCV nurse embedded within the Tasmanian DoH to contact GPs and provide supported assistance after a hepatitis C diagnosis is notified. The study will evaluate whether active follow-up of providers with enhanced case management is more effective in enhancing uptake of hepatitis C treatment compared with current standard of care for new notifications by the DoH. The study will also compare the cost-effectiveness of the enhanced case management compared with current standard of care for positive hepatitis C antibody notifications.

METHODS AND ANALYSIS

This study is a two-arm, cluster randomised controlled trial with randomisation at the level of the GP who notifies the DoH (directly or through a laboratory) of a hepatitis C antibody positive case.

Study setting

The study will be conducted in the Australian state of Tasmania with a population of approximately 530 000[18] and an estimated 3349 people living with hepatitis C.[2] The preceding 10 years have seen an average 260 new hepatitis C notifications in Tasmania annually, with a new notification rate of 48.6 per 100 000 population, slightly higher than the national average of 43.3 per 100 000 population.[2] The entire state will be included in the trial, as all notifications are received and managed by a central body at the Tasmanian DoH.

Standard of care

When a laboratory in Tasmania has a positive hepatitis C antibody test result, they formally notify this case to the DoH. A ‘hepatitis C notification’ requires laboratory definitive evidence of a positive hepatitis C antibody test or hepatitis C RNA test in a person with no prior evidence of hepatitis C virus infection.[12] Notifications can be further classified by DoH as ‘newly-acquired’, which is defined by laboratory or clinical evidence that infection occurred within the preceding 24 months,[19] and notifications where a person has prior evidence of hepatitis C infection are classified as a ‘repeat’ notification. Under the Communicable Diseases Network Australia case definitions, ‘unspecified’ hepatitis C is a confirmed case that is not notifiable, similar to ‘repeat’ notifications.[20] At present, repeat notifications receive no further follow-up by the DoH. In this protocol, the term ‘new’ notification is used to indicate all notifications that meet the case definition (regardless of whether they are ‘newly acquired’ or not), and use the term ‘repeat’ notifications if the patient has prior evidence of hepatitis C virus infection.

After receipt of a hepatitis C notification, surveillance officers check the details of the case to determine whether the test represents a new or repeat notification. For cases determined to represent a ‘new’ notification, a request for further details of the case is mailed to the medical practitioner who requested the test. A routine surveillance letter and an enhanced surveillance data collection form are mailed to the GP. The aim of this request is to accurately capture surveillance data that pertains to testing history and risk factors. Advice on how to manage hepatitis C is also included in the routine surveillance letter. On assessment of returned enhanced surveillance data collection form, the DoH may undertake further risk assessment, investigation and response activities. If the practitioner does not return the enhanced surveillance data collection form within 20 days, the form is reposted to the practitioner. If cases are determined to be a repeat notification the current standard of care is to conduct no further activities regarding this case. Other jurisdictions around Australia follow a similar algorithm and process for managing new notifications.

Participant eligibility

All GPs who have requested a hepatitis C antibody test that leads to new or repeat notification to the Tasmanian DoH

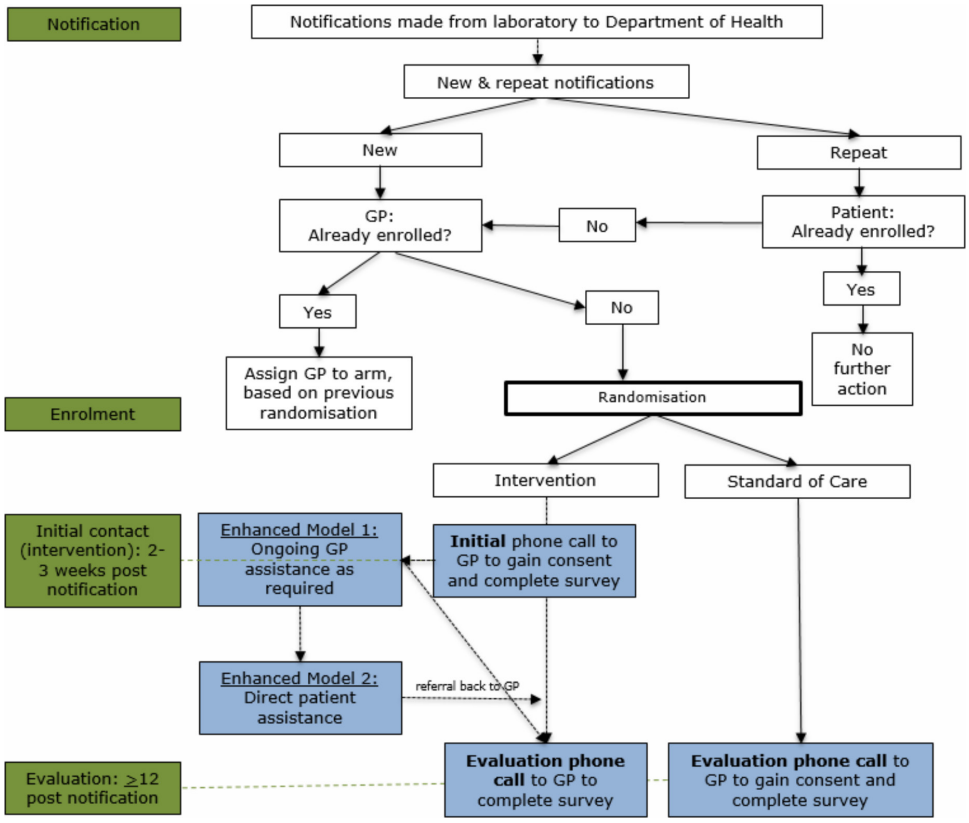

Figure 1 Flow chart of study activities green coloured boxes indicated the critical time points in the study. Blue boxes indicate the intervention activities and the evaluation phone call which is made in both study arms. GP, general practitioner.

will be eligible for participation in this study. Notifications by GPs not based in Tasmania, from correctional services, sexual health or family planning services as well as specialists, trainees and nurse practitioners will be excluded.

Randomisation and allocation

The unit of randomisation is at the GP level and will be done within 3 weeks of HCV notification receipt by the DoH and by the order they are received. GPs will be allocated one-to-one at their first notified case during the follow-up period and all subsequent notifications will receive either standard or care or intervention arm case management consistent with the initial randomisation. This will ensure that standard of care and intervention arms are not cross-contaminated by GPs that make multiple notifications. The sequence will be performed using the randomisation function within Research Electronic Data Capture (REDCap). A representation of randomisation and the study process and activities in each arm is shown in figure 1. Randomisation will not done for GPs already enrolled and no further action will be required for the enrolled patients (HCV notifications).

Blinding

Given the nature of the intervention, it is impossible to blind either the DoH specialist HCV nurse or the GP to allocation. Analyses will be independently conducted by analyst statistician at the Burnet Institute who will be blinded to intervention allocation.

Description of intervention

Intervention arm

GPs randomised to the intervention arm will receive the standard of care surveillance letter, enhanced surveillance data collection form for new hepatitis C notifications, and a study information letter (online supplemental appendix A). In addition to standard of care procedures, all notifications (new and repeat) will be offered further enhanced case management support by a DoH specialist HCV nurse. Support is offered at the initial phone call, and is made available over a 12-week period during which the DoH specialist HCV nurse can do follow-up calls with the GP or directly with the patient.

Initial phone call

Within 3 weeks of the HCV notification being received by the DoH, GPs randomised to the intervention arm will receive an initial phone call from the DoH specialist HCV nurse. During this call, GPs are consented into the study and offered enhanced case management support in line with approved guidelines for hepatitis C management.[3] Three attempts will be made to contact the practitioner within a 30-day period before they are classified as lost to follow-up.

The DoH specialist HCV nurse will initially confirm the notification made by the with GP and ask if the: (1) patient had been recalled for further management; (2) whether a hepatitis C RNA test has been ordered and (3)

of any RNA positive patient, whether treatment options had been discussed, offered or initiated. A tailored level of enhanced case management support is then offered depending on RNA status (if no RNA testing, offer level 1 and 2), GPs needs (offer level based on GP preferences after assessing RNA status) and familiarity with HCV prescribing (model 1), and support needed for their patient (model 2). Level 4 is optional for the GP and will be offered on request or when the DoH specialist HCV nurse identifies a need based on assessment.

Enhanced case management support for GP (model 1)

Level 0: No assistance required, GP already confident in managing HCV treatment.

Level 1: General information on hepatitis C care and treatment.

Level 2: Further diagnostic testing advice and support to conduct pretreatment workup assessment.

Level 3: DAA prescription guidelines including that treatment can be prescribed by the GP and when/how to refer for specialist care.

- Advising on conducting postcure management including methods of follow-up to manage risks; including harm minimisation, reducing reinfection risk, opioid substitution therapy.
- Linking/referral to resources for patients with cirrhosis or other concerns to specialist support for ongoing management.

The GP may indicate the preference to receive the enhanced case management support via several phone calls or emails.

Enhanced case management for patient (model 2)

Level 4: Direct patient contact

The GP will also be offered the option of the DoH specialist HCV nurse contacting the patient directly with their consent to notify them of their result and inform them about further testing and treatment options and referral back to their GP or other primary care or specialist. Model two is an option for GPs at any level of support in model 1.

Evaluation follow-up (intervention)

As with the standard of care arm, GPs in the intervention arm will be contacted by telephone call 12 weeks after an HCV notification date to complete the details of the patient outcomes for the specific case. Details provided or missing from the standard DoH enhanced surveillance data collection form will be confirmed with the GP at this phone call (see figure 1). Similar to the standard of care arm, three call attempts will be made to contact the practitioner within a 30-day period prior to classifying the GP as lost to follow-up.

Evaluation follow-up (standard of care)

All GPs randomised to the standard of care arm will be contacted by telephone 12 weeks after the HCV notification date (see figure 1). Two weeks prior to the evaluation phone call, a study information letter (online supplemental appendix A) will be sent to the GP. This is not current standard practise but will be performed by the DoH specialist HCV nurse for the project outcome evaluation. During this phone call consent will be sought for the GP to provide information about their clinical management of the notified patient. Details provided or missing from the standard enhanced surveillance data collection form would be confirmed with the GP at this phone call. Three attempts to contact the practitioner will be made within a 30-days of receipt of the hepatitis C notification before they are classified as lost to follow-up.

Outcomes

Primary outcome

The primary outcome is the proportion of cases notified with hepatitis C who commence hepatitis C treatment within 12 weeks of HCV notification as evidenced by confirmation from the GP. This will be assessed using the information provided by GPs at the evaluation phone call and will be compared across the two arms and the model and level of support offered.

Secondary outcomes

At the evaluation phone call for both the standard of care and intervention arm, additional outcome measures will be collected which we will collate into:

- Proportion of people diagnosed with hepatitis C antibody with a documented HCV RNA test result.
- Proportion of people diagnosed with hepatitis C (HCV RNA+) completing treatment workup blood tests.
- Proportion of people diagnosed with hepatitis C (HCV RNA+) completing an appropriate course of hepatitis C treatment as prescribed.

To evaluate patient factors that may have an impact on the likelihood of people commencing hepatitis C treatment, the project will use deidentified aggregated data from the DoH obtained through the standard surveillance procedures in determining risk exposures, age, gender and date of diagnosis. The likelihood of commencing support will also be evaluated by model and level of support and number and types of contacts made.

Data collection

The first data point collection will be completed by the DoH specialist HCV nurse when conducting the initial telephone call to the GPs in the intervention arm to confirm eligibility and consent (online supplemental appendix B). No identifying patient details will be recorded for the evaluation of the project: any clinical information that the DoH specialist HCV nurse and the GP discuss for clinical management of individuals is not collected for the purpose of this project. Data collected from participating GPs will be allocated a study identification (ID) and a patient ID for the case with HCV (online supplemental appendix C).

The second format of data collection will concurrently record the nature of the activities (level of support, HCV notification details) and time taken to complete them

by the DoH specialist HCV nurse as part of the hepatitis C management assistance provided to the practitioner. This will be recorded in an excel spreadsheet, using the numerical participant's/GP 's study ID (online supplemental appendix D). This information will enable determination of the costs of the intervention, to inform cost-effectiveness estimates. No identifying patient details will be sought or recorded for the purpose of the evaluation of the project.

The DoH specialist HCV nurse will collate deidentified information for the purpose of the evaluation of the project from the participant/GP of the outcome of HCV care of the notifications. Also, from the DoH standard enhanced surveillance data collection form, any missing data will be collected for standard of care purposes; for example, dates of testing, the patient's age, gender and risk exposures. For the purpose of the project, deidentified data will be collated from this form for the purpose of the project evaluation. These data will be extracted and stored with a unique patient study number.

Linkage between the patient ID and the GP's study ID will permit evaluation at service provider level which will maintain confidentiality of the participants/GP and patient data.

Data management

The data from the phone surveys will be collected using REDCap software, and stored in a secure, password protected server at the Burnet Institute. It will be accessible to the DoH specialist HCV nurse, the study coordinator, data analysts at the Burnet Institute and the Institute's data manager. This data will be stored with a unique numerical GP study ID and patient ID.

All data entry will be performed by the DoH specialist HCV nurse based at Tasmanian DoH. A Burnet Institute researcher will check the data quality every month and liaise with the DoH specialist HCV nurse if there are any errors or inconsistencies.

The participant/GP log (online supplemental appendix D) and record of activities and time spent will be kept on a password protected server accessible only to the DoH specialist HCV nurse and study investigators at the Tasmanian DoH.

Data will be monitored by a Burnet Institute staff member reviewing the collected data monthly to identify any errors or inconsistencies. Any issues or uncertainties will be followed up with the DoH specialist HCV nurse to clarify meaning of data and ensure robust entry processes.

Statistical analysis

Sample size

Data supplied by the Tasmanian DoH indicate that in the period from January 2018 to November 2018, taking both repeat and new notifications combined, 274 GPs notified at least one case of hepatitis C; 174 had notified one case, 65 had notified two cases, 14 had notified three cases, and 21 had notified four or more cases. On this basis, an estimated 224 GPs were expected to notify at least one case of hepatitis C during the 9 month study recruitment period.

The sample size required for a parallel design comparing HCV treatment uptake in the standard of care arm of 8% and 25% in the intervention arm is 85 GPs in each study arm with a two-sided alpha of 0.05% and 80% power (see online supplemental appendix E). To account for measured correlation between different notifications clustered within the same GP, we used an intraclass correlation coefficient of 0.10. Existing data estimates between 3% and 8% of people start therapy within 3 months (when our primary outcome will be assessed): data on national treatment uptake by specialists and GPs,[21] among people who inject drugs,[22] and in traditional referral to outpatient services all estimate treatment uptake of 8% or under at 3 months.[23] In this study, we will assume the higher (and therefore more conservative, biasing towards the null hypothesis) estimate of treatment uptake of 8% at 3 months in the standard of care arm. Treatment uptake in intervention arm is estimated at 25% based on best estimates of intervention acceptance by GPs and follow-up, RNA prevalence among those notified with HCV antibody, community treatment eligibility and best estimate of intervention effect.[24–26] Based on the estimates of 224 unique GPs notifying hepatitis C cases in a 9-month period, there is ample power to detect significant difference between arms even with the presence of clustering of notifications within clinicians.

Analysis of primary outcome

The primary analysis will be assessed as a binary outcome comparing the proportion of patients who commenced treatment in an intention to treat analysis in the Intervention arm compared with the standard of care arm.

Analysis of secondary outcomes

Other secondary outcomes will be analysed using the same intention to treat method. A per-protocol analysis is proposed.

Multiple logistic regression modelling will explore factors predicting success of aspects of the cascade of care based on information obtained through the notification system, as well as information on the practitioner, associated with the primary and secondary outcomes. Factors to be explored in the multiple regression model include patient sociodemographic, GP's HCV care experience, number of notifications per practitioner, and time taken to reach GP/patient post HCV notification.

There will be no interim analysis or stopping guidelines.

Subsequent research following study completion

Data collection will permit future economic evaluation and cost-effectiveness modelling. Subject to further ethics review, consent may also be sought to contact participants/GPs later to assess rates of treatment success (sustained virological response (SVR)) among notified cases who received treatment.

Cost-effectiveness analysis

The cost of this intervention will be compared with the current standard of following up HCV notifications. As cost-effectiveness will depend on the benefits of initiating treatment and SVR,[27 28] our estimates will adapt an existing dynamic, deterministic model of HCV transmission, progression and HCV treatment among people living with hepatitis C in order to evaluate the impact of the intervention.[29] The model will stratify HCV notifications by HCV RNA status and intervention pathway and will incorporate HCV infection and disease progression. HCV disease stages will be further divided by HCV RNA status, treatment initiation and SVR depending on the intervention pathway. A Bayesian parameter sampling and model calibration process will be used to take account of uncertainty in key factors (eg, HCV disease progression rates, health utilities, death rates and HCV prevalence) to generate the HCV epidemic profile. Transition rates between disease stages will be taken from previous Australian or UK economic evaluations.[30] Data on treatment uptake, SVR and costs will be collected by the study. Results will be presented as mean incremental cost-effectiveness ratio (ICER). Probabilistic uncertainty analyses will be used to estimate the uncertainty around the ICER, accounting for uncertainty in the intervention outcomes as well as other cost, behavioural and epidemiological inputs.

Ethics and dissemination

The study was approved by the University of Tasmania's Human Research Ethics Committee (Protocol ID: 18418) on 17 December 2019. GPs in either the standard of care arm or in the intervention arm will be contacted by the DoH specialist HCV nurse will contact the GP by phone, provide an explanation of the study and if the practitioner is interested in participating, verbal consent will be obtained. The project will also use surveillance data collected by the DoH for hepatitis C notifications. The researchers are requested a waiver of consent for the use of the data as it is an existing methods of public health programme surveillance.

The results of the project will be presented in scientific meetings and published in peer-reviewed journals. Publication of data derived from the study will be supervised by the Protocol Steering Committee. All published quantitative data will be non-identifiable grouped data, none of which will be specific to a participant/GP. A plain English summary of study outcomes, as well as abstracts from publications, will be available on the Burnet Institute website. Authorship for publications arising from this study will adhere to the International Committee of Medical Journal Editors guidelines.[31]

Patient and public involvement

There was no direct patient and public involvement in this protocol development. However, a qualitative exploration of the acceptability of hepatitis C notification systems study conducted with key informants including those with hepatitis C lived experience informed the study intervention.[32]

DISCUSSION

Reaching the WHO HCV elimination targets will require additional strategies to increase linkage to care and treatment uptake. This is the first prospectively randomised study exploring the utilisation of HCV surveillance data to enhance linkage to HCV treatment. In Australia, HCV is a notifiable infection and the health departments receive notification information which is captured by the surveillance systems. This provides an opportunity to use existing patient information to enhance linkage to care and treatment.

HCV treatment accessed through primary healthcare which includes GPs is fundamental in the Australian healthcare system. Identifying strategies to increase linkage to care and HCV treatment uptake using primary healthcare systems may have a high impact. This study trials an intervention which is post HCV-testing, nurse led from the DoH. Demonstrating that this nurse-led intervention using existing surveillance systems is feasible can inform further public health strategy planning. The health departments who are custodians of the surveillance data can use a nurse or a public health officer to follow through diagnosing clinicians or patients to encourage RNA testing and treatment initiation. If the intervention is shown to be effective, health departments will need to further develop the strategy using appropriate staff and a decision on following up prospective and/or historic HCV notifications.

Trial progress

The study commenced enrolments in September 2020 and the study end is expected in December 2021. Full data analysis will be conducted after the protocol has been published.

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Contributors JD, MAS, MH, AEP, WVDB, LO and AT were involved in the development of the initial idea, methodological design, and drafting the trial protocol for ethics. TM, JD and MAS prepared the initial protocol manuscript and KPM, JR, KT, SM, FHJ, NS, DI, MV and TS reviewed and edited the manuscript. TS is the trial statistician. KPM is responsible for data collection and TM is the study coordinator. All authors reviewed and approved the manuscript.

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Competing interests JD, MAS and MH report investigator-initiated research funding to their institution from Gilead Science, AbbVie and Merck. JD reports honoraria for speaking to his institution from Gilead Sciences and AbbVie and

MAS reports consultant fees from Gilead Sciences. AEP has received investigator-initiated grant funding from Gilead Sciences, MSD and Abbvie and speaker fees from Gilead Sciences for unrelated work.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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