ISRCTN18001753 https://doi.org/10.1186/ISRCTN18001753

Does an educational film encourage members of the South Asian community to have testing for viral hepatitis, a liver infection that they have an increased risk of carrying?

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
17/02/2020

Overall study status
Completed

Last Edited
11/05/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hepatitis B (HBV) and C virus (HCV) infections are infections of the liver and, if not diagnosed and treated, result in life-threatening liver scarring (cirrhosis), liver cancer and end-stage liver disease (ESLD). Previously, HBV and HCV infections have been difficult to treat successfully. Advances in the available and emerging therapies mean HCV infection is potentially curable and HBV infection treatable. HBV and HCV infection rates are rising disproportionately in the UK, with ethnic minorities having more HCV-related ESLD. The researchers' experience shows a that large number of first-generation South Asian (SA) patients come for the first time to the Liver Unit with advanced, untreated liver disease. This group typically have not previously engaged with health services. If people were tested and had the infection identified earlier, they could receive more effective treatment.
Through initial research, the researchers realised a lack of engagement by the SA population is due to cultural, language and educational barriers to disease awareness, testing and treatment. As set out by NICE, to prevent further death and disease spread the healthcare system needs to find new ways of informing this 'hard to reach' group.
In an earlier phase of this work, the researchers ran focus groups with the South Asian community to understand their current knowledge, concerns and expectations and used the results to inform the production of an educational video.
In this study, the researchers plan to show this video in community settings to understand whether a larger-scale study is possible and how that larger-scale study should be designed. The larger-scale study would test whether the video is successful in improving uptake of testing for viral hepatitis.

Who can participate?
Adults who speak English, Urdu or Hindi

What does the study involve?
People who agree to participate in this study will be contacted by a member of the research

team to arrange a time that suits them to watch the film together with other members of their community. Participants who come to the film screening will fill out a questionnaire including their knowledge, attitudes and behaviours relevant to HBV and HCV infections and testing. They will then watch the video, which takes 10-15 min, and afterwards they fill out another questionnaire. Participants will be offered a blood test for HBV and HCV there and then or at another time. The test involves a finger prick to collect a drop of blood. It takes up to 2 weeks to get the result. There is no obligation to get a blood test.

What are the possible benefits and risks of participating?
The researchers do not foresee any disadvantages or risks associated with taking part in this study. If a participant becomes distressed, they can withdraw from viewing/participating and will be offered immediate support. If someone is tested and has a positive result for HBV or HCV infection, they will be provided with support and will potentially benefit from earlier treatment.

Where is the study run from?
Royal Surrey County Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2015 to February 2020

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Claire Kelly, clairekelly4@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Claire Kelly

ORCID ID
http://orcid.org/0000-0002-0029-9597

Contact details
Department of Gastroenterology and Hepatology
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX
+44 (0)1483 571122
clairekelly4@nhs.net

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
224711

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 34774, IRAS 224711

Study information

Scientific Title
A novel educational intervention to improve the uptake of testing for viral hepatitis in South Asians (SA): A feasibility study

Study objectives
Hepatitis B (HBV) and C viruses (HCV) are infections of the liver and if not diagnosed and treated result in life threatening liver scarring (cirrhosis), liver cancer and end stage liver disease (ESLD). Previously, HBV & HCV have been difficult to treat successfully. Advances in the available and emerging therapies mean HCV infection is potentially curable and HBV treatable. HBV & HCV rates are rising disproportionately in the UK, with ethnic minorities having more HCV related ESLD. Our experience shows a that large number of first generation South Asian (SA) patients present to our Liver Unit with advanced, untreated liver disease. This group typically have not engaged with health services.
Through pilot work we realised a lack of engagement by the SA population is due to cultural, language and educational barriers to disease awareness, testing and treatment. As set out by NICE, to prevent further death and disease spread we need to find new ways of informing this 'hard to reach' group.
In an earlier phase of our work we ran focus groups with the South Asian community to understand current knowledge, concerns and expectations amongst this population and then inform the production of an educational video.
In this current phase of the work we plan to show this video in community settings as a feasibility for a randomized control trial to test whether it is successful in improving uptake of testing for viral hepatitis and to identify methodological issues, recruitment and retention figures.
Those who consent will complete pre-video questionnaires,watch the video and complete post video questionnaires. There will also be the option of dried blood spot testing for hepatitis on the day (or at a later date for those who wish more time to consider). Not all who watch the video are expected to undergo testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2017, London-Surrey Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol BS1 2NT; NRESCommittee.SECoast-Surrey@nhs.net), ref: 17/LO/0881

Study design

Non-randomised; Interventional; Design type: Screening, Diagnosis, Prevention, Education or Self-Management

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hepatitis B virus (HBV) and hepatitis C virus (HCV) testing

Interventions
We will advertise our study by placing flyers in community centres. We will also work with PPI and stakeholders from earlier phases of the work to identify appropriate venues to show the film. We have calculated we require n=200 and we propose to run sessions showing the video until this target recruitment is met. To allow adequate time to fully discuss and consent the processes, in particular blood testing, we will limit each individual session to a maximum of n=30.

Potential participants will be provided with contact details for the research team (this will include Urdu-speaking members of the team). Initially a discussion on what is involved will take place with potential participants who show interest and a PiS (viewing the film) will be given. This PiS will include contact details for the research team in case further questions arise. The participant will then be able to ask any questions and if still interested a date and venue suitable to the potential participant and research team will be identified. This will be at least 24 hours later to allow time to consider participation.

On the day of the film showing those who attend the event will be given the opportunity to discuss further and thereafter sign the consent form if they are willing to participate. A pre film questionnaire will be filled out with help as needed (e.g. interpreter). The questionnaire will take approximately 15 minutes to complete. Thereafter the participants will watch the film alongside other participants. The video will last 10-15 minutes. At the end of the video we will announce to participants the opportunity for testing now, later or not at all. All participants will be asked to complete the post-intervention questionnaire. At this point we will remind participants they are free to leave and are not obliged to be tested. Blood testing areas will be located elsewhere in the building so that participants can leave without explanation.

On completion of the post-intervention questionnaire, those participants who wish to discuss further will be asked if they wish to be tested. Various options will be given to participants: testing on the day, testing on another occasion and not getting testing. Research team members will be present and participants can ask any questions on blood testing. Given the potential

significance of testing the discussion around this is important and we expect will take a minimum of 15 minutes per participant. It will be strongly emphasized that this is not compulsory and it is possible to come back on another day for testing to allow more time for those who are unsure. We feel it is important to offer testing on the day as well as later after discussion with our PPI and stakeholder groups who both felt a period of time waiting for a test after deciding to test after watching our film may be unduly stressful for some participants.

Those who choose to be tested will be taken to the blood testing area for consenting which will include consent for informing the GP of results. The process will be explained again to them. A finger-prick blood test (dried blood spot) will then be taken and labelled (pseudonymised). The participant will be asked for their preferred contact method to arrange attendance for the results. It will be explained that results will take up to 2 weeks. The participant will be given contact details for the research team after testing so that they have a point of contact if they require more information or support between testing and obtaining the results. They will receive the results in person and will be able to bring a family member if they wish to. For those who test negative that is the end of their involvement. For those who test positive the results and further steps will be explained to the participant.

Intervention Type
Behavioural

Primary outcome measure
Proportion of people taking up testing after viewing the film assessed using testing centre records during the 1 month after the film has been shown

Secondary outcome measures
1. Prevalence of viral hepatitis in the South Asian Surrey population assessed by analysing results of our testing population
2. Attitudes, knowledge and behaviours before and after exposure to the film by distributing a pre- and post-film (time 1) questionnaires incorporating 5-point Likert scale scoring

Overall study start date
07/09/2015

Completion date
29/02/2020

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Able to consent to participation
3. Able to speak English, Urdu or Hindi

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
219

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/02/2018

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU27XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

Sponsor details
Department of Research, Development and Innovation
Leggett Building
Daphne Jackson Road
Guildford

England
United Kingdom
GU2 7WG
+44 (0)1483 686729
sarah.martin33@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.royalsurrey.nhs.uk/

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1013-32094

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2020	11/05/2021	Yes	No
HRA research summary			28/06/2023	No	No