ISRCTN14093266 https://doi.org/10.1186/ISRCTN14093266

Virtual clinics vs. face-to-face appointments for hospital follow-up of liver transplant patients: randomised evaluation of myVirtualClinic

Submission date
25/03/2018

Recruitment status
No longer recruiting

Registration date
29/03/2018

Overall study status
Completed

Last Edited
21/09/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
University Hospitals Birmingham (UHB) carry out over 250 liver transplants per year, and at any one time, there are around 3000 liver patients who need to come to the hospital every 3 or 6 months for routine follow-up appointments with their doctor. The hospital covers a large area, and many transplant patients need to travel long distances to attend their follow-up appointments. The hospital has developed a tool (called myVirtualClinic) to allow patients to have video consultations from their home without needing to travel to the hospital for their follow-up appointment. This study is an evaluation of whether virtual clinics can increase liver transplant patients' satisfaction with their care. Virtual clinics may also save patients and the hospital money.

Who can participate?
Patients aged 18 or over who have had a liver transplant at least 1 year and no more than 5 years before the start of the study

What does the study involve?
Participants are randomly allocated to one of two group. Participants in the virtual clinic group have their follow-up appointments from home via secure video link for 12 months. Participants in the standard care group carry on with the standard arrangements for follow-up and come to the hospital for face-to-face appointments for 12 months as normal. Satisfaction with care is measured to see if patients who have had virtual clinics are more or less satisfied with care compared to those who continued having standard care. Interviews are also carried out with patients, carers/family members and healthcare professionals involved in the study to find out about their thoughts and experiences of the study, and understand whether it would be worth expanding virtual clinics to other clinical areas or to other hospitals.

What are the possible benefits and risks of participating?
There is no direct benefit to patients participating in the study, but the information collected will show how virtual clinics may work if they become part of normal care. If the study shows that virtual clinics are effective, they may be used in the future as part of routine follow-up care

for transplant patients or those with other conditions. There are no potential risks associated with participating in the study.

Where is the study run from?
Queen Elizabeth Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
February 2018 to September 2020

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

Who is the main contact?
Elaine O'Connell-Francischetto

Contact information

Type(s)
Public

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 1.2

Study information

Scientific Title
Virtual clinics versus standard face-to-face appointments for liver transplant patients in routine hospital outpatient care: pragmatic randomised evaluation of myVirtualClinic

Study objectives

This randomised evaluation randomised evaluation is designed to assess the effectiveness of providing virtual clinics as an alternative to standard face-to-face consultations in delivering routine follow-up care for clinically stable liver transplant patients. The primary aim is to assess whether the option of myVirtualClinic can increase patient satisfaction in the VSQ-9 domains of 'convenience of location', 'getting through to the office by phone' and 'length of time waiting' compared to standard care (face-to-face consultations) for clinically stable liver transplant patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS Health Research Authority (HRA), 25/09/2017
2. West Midlands Solihull Research Ethics Committee, 24/10/2017, ref: 17/WM/0338
3. University Hospitals Birmingham NHS Foundation Trust, February 2018, ref: RRK6080

Study design
Pragmatic two-armed parallel group statistician-blinded randomised evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Liver transplantation

Interventions
After giving consent and completing a baseline questionnaire, participating patients (clinically stable patients who received a liver transplant between 1 and 5 years previously) will be randomised in a 1:1 ratio to either the intervention (myVirtualClinic) or control (standard care) arm of the study using the GraphPad online randomisation tool. Patients randomised to the intervention arm of the study will have routine outpatient appointments with their liver consultant from home via secure video link accessed through the patient portal at University Hospitals Birmingham NHS Foundation Trust instead of needing to attend the hospital for a face-to-face appointment. Patients randomised to standard care carry on with the standard arrangements for follow-up and will come to the hospital for face-to-face appointments for 12 months as normal. Satisfaction with care is compared in the two groups to see if patients who have had virtual clinics are more or less satisfied with care compared to those who continued

having standard care. Interviews are also carried out with patients, carers/family members and healthcare professionals involved in the study to see what their thoughts and experiences of the study were.

Intervention Type
Other

Primary outcome measure
The combined satisfaction score for three domains of the RAND modified Visit-Specific Satisfaction Instrument (VSQ-9) (convenience of location, getting through to the office by phone and length of time waiting). The VSQ-9 asks participants to rate their satisfaction with various aspects of their clinic appointment on a 5-point scale (poor, fair, good, very good, excellent). Scores are then transformed into a 0-100 linear scale where higher scores denote higher levels of satisfaction. VSQ-9 data will be collected at baseline and after every virtual clinic or face-to-face appointment via patient questionnaires. A difference of 10 points between the intervention and control groups in the three selected domains of the VSQ-9 at study end (12 months) will be taken as clinically significant.

Secondary outcome measures
1. Patient reported health-related quality of life measured through EQ-5D-5L patient questionnaires at baseline, 6 months and end of study
2. Patient satisfaction scores in the other six VSQ-9 domains not forming part of the primary outcome measure. Measured through patient questionnaires at baseline, 3 months (if applicable), 6 months, 9 months (if applicable) and 12 months
3. Routinely collected clinical outcomes collected via patient records at study end
4. Number and length of clinical contacts, instances of appointment non-attendance, collected via routinely collected metrics, clinician reporting throughout the study
5. Health service use, collected via patient questionnaires at baseline and end of study
6. Patient costs, collected via patient questionnaires at baseline, 3 months (if applicable), 6 months, 9 months (if applicable), 12 months
7. Secondary care costs, collected via routinely collected data at study end
8. MyVirtualClinic system performance, collected via routinely collected metrics at study end
9. Whether patients in the intervention arm have been able to have clinical tests carried out locally prior to their virtual clinic appointment, collected via clinician-completed case report form after each appointment
10. Patient, carer and clinician experience of the study, collected via semi-structured interviews at the end of the study
11. Questionnaire completion rates, assessed using information on the proportion of questionnaires completed by participating patients at the end of the study
12. Participants' travel requirements, assessed using patient questionnaire at baseline

Overall study start date
01/02/2018

Completion date
30/09/2020

Eligibility

Key inclusion criteria

1. Have had a liver transplant at least 1 year and no more than 5 years prior to study baseline
2. Aged 18 or over
3. Considered clinically stable by their consultant
4. Have access to myhealth@QEHB patient portal (or agree to sign up)
5. Able to arrange for clinical testing (blood tests, weight and blood pressure) to be undertaken locally at a GP practice or dialysis centre and the results uploaded to myhealth@QEHB prior to myVirtualClinic appointment
6. Have access to a computing device (e.g. desktop computer or laptop) running an operating system compatible with the virtual clinic software, as well as camera and internet connection
7. Able to consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Total final enrolment
54

Key exclusion criteria
1. Unable to speak and/or read English
2. Unable to comply with study follow-up procedure (completion of electronic questionnaires)
3. Involvement in another research study or clinical trial involving ongoing questionnaire completion

Date of first enrolment
12/03/2018

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital, Birmingham
Mindelsohn Way, Edgbaston
Birmingham
United Kingdom
B152GW

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

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
Current publication and dissemination plan as of 11/05/2021:
The protocol was published (see publication list below). The main results from the study are currently under review with a high impact factor journal, with an expectation that they will be published around autumn 2021.

Previous publication and dissemination plan:
The protocol is shortly to be submitted for open-access publication and will be publicly available online after publication. Study findings will be presented at academic conferences and published in an open-access high impact peer-reviewed journals within 12 months of the overall trial end date. Study results will also be disseminated to key stakeholders locally. A CLAHRC BITE (Brokering Innovation Through Evidence) will be produced. BITEs are designed to be accessible, bite-sized summaries of findings from published work undertaken by CLAHRC West Midlands. The BITE will be publicly available on the CLAHRC website and will be sent via the my health@QEHB system to all study participants.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as study participants are not being asked to give consent for their data to be used outside of the specific trial for which it is being collected. The study is an evaluation of a new service at a single hospital Trust, and secondary analysis of participant-level data is unlikely to be of wider interest or utility outside of this setting. However, the study findings will be published in an open-access journal, and results for the primary outcome and each of the secondary outcomes will be reported. Study data will be stored electronically on secure, password-protected University of Birmingham servers for 10 years after the conclusion of the study, as required by the University of Birmingham Code of Practice for Research.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/10/2018		Yes	No
Results article		17/09/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No