CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the
caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

* Required

Your name *
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Title of your manuscript *
Provide the (draft) title of your manuscript.
Remote consultations versus standard face-to-face appointments for liver transplant patients in routine hospital care: a feasibility randomised controlled trial of myVideoClinic
Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

MyVideoClinic

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Your answer

Language(s) *
What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English

URL of your Intervention Website or App
e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

Your answer

URL of an image/screenshot (optional)

Your answer
Accessibility *
Can an enduser access the intervention presently?

- access is free and open
- access only for special usergroups, not open
- access is open to everyone, but requires payment/subscription/in-app purchases
- app/intervention no longer accessible
- Other:

Primary Medical Indication/Disease/Condition *
e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Liver transplant patients

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

Changes in patient satisfaction scores

Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Recruitment, retention, crossover rates, clinical contacts, system performance, feasibility of obtaining clinical tests locally, questionnaire completion rates, data completeness, feasibility of collecting patient-reported data on health service use, HRQoL and costs
Recommended "Dose" *
What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- “as needed”
- Other: For each scheduled outpatient appointment
Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- Other:
Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Other:

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- not submitted yet - in early draft status
- not submitted yet - in late draft status, just before submission
- submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
- published
- Other:
Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- not submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- JMIR mHealth and UHealth
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal
- Other:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- Pilot/feasibility
- Fully powered
CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Other: JMIR ms#19232

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- yes
- Other:
### 1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

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| subitem not at all important |   |   |   |   |   |
| essential                     |   |   |   |   |   |

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Remote consultations" versus standard face-to-face appointments for liver transplant patients in routine hospital care: a feasibility randomised controlled trial of myVideoClinic

### 1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).

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| essential                     |   |   |   |   |   |
Does your paper address subitem 1a-ii?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Remote consultations versus "standard face-to-face appointments" for liver transplant patients in routine hospital care: a feasibility randomised controlled trial of myVideoClinic

1a-iii) Primary condition or target group in the title
Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”)
Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Video clinics versus standard face-to-face appointments for "liver transplant patients" in routine hospital care: a feasibility randomised controlled trial of myVideoClinic

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.
1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Clinically stable liver transplant patients were randomised to "real-time remote consultations with their hospital physician using secure videoconferencing software (intervention) or standard face-to-face appointments (usual care)".

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)
Does your paper address subitem 1b-ii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

remote consultations "with their hospital physician"

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT
Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it).

Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This study evaluated the feasibility of using real-time remote consultations between patients and secondary care physicians "for routine patient follow-up at a large hospital in the UK".
"Participants were recruited from four outpatient liver clinics at the Queen Elizabeth Hospital Birmingham (QEH) – primary sclerosing cholangitis, primary biliary cholangitis, alcohol-related liver disease, and autoimmune hepatitis"
"Participants were asked to complete post-appointment questionnaires over 12 months."
1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Fifty four patients were randomised: 29 (54%) to receive remote consultations and 25 to usual care (46%) (recruitment rate 27%). Crossover from intervention to usual care was high (13/29; 45%). 129 appointments were completed with 64% of questionnaires returned (82/129). Patient satisfaction at 12 months had increased in both intervention (25 points) and usual care groups (14 points). Within-group analysis showed the increases to be significant for both intervention (p<.0001) and usual care patients (P=.020) but the between-group difference was not significant after controlling for baseline scores (P=.098). the qualitative process evaluation showed that remote consultations were perceived by patients as saving them time and money, were less burdensome, and caused fewer negative impacts on their health. Technical problems with the software were common, and only 5 patients (26%) received all appointments over video. Both clinicians and patients saw remote consultations as positive and beneficial."
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

“Our findings with regard to the advantages and challenges of using remote consultations for routine-follow-up of liver transplant patients has important implications for service organisation and delivery in the post-pandemic NHS”

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale
2a-i) Problem and the type of system/solution
Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods” under 5)

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Does your paper address subitem 2a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

However, current evidence does not clearly show the benefits of video consultations in secondary care, and there is a lack of well-designed studies assessing their effectiveness*

2a-ii) Scientific background, rationale: What is known about the (type of) system
Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

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The aim of this study was to evaluate the feasibility of using real-time remote consultations between clinically stable liver transplant patients and their hospital physicians using secure videoconferencing technology for routine follow-up appointments, and to assess whether patient satisfaction differed for intervention patients vs. those receiving usual care (face-to-face consultations). Study objectives were to: i) assess rates of recruitment, retention and crossover between arms; ii) assess appointment numbers and the technical performance of the remote consultation software; iii) assess patients' ability to complete clinical testing locally; iv) explore patient satisfaction across key domains of the RAND Visit-Specific Satisfaction Instrument (VSQ-9) [21]; v) monitor questionnaire return rates and data completeness, and vi) assess the feasibility of collecting patient-reported data on health service use, health-related quality of life (HRQoL) and costs. An embedded qualitative process evaluation explored patient and staff experiences.
Does your paper address CONSORT subitem 3a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A two-armed, parallel group, statistician-blinded feasibility RCT of the provision of real-time remote appointments via videoconferencing software compared with standard face-to-face consultations (usual care) for delivering routine follow-up for clinically stable liver transplant patients."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The published study protocol outlined a definitive trial to evaluate the effectiveness of remote consultations, with a recruitment target of 180 patients (90 in each arm) that would provide sufficient power to detect a statistically (and clinically) significant difference between groups in the primary outcome measure. However, once underway, poor recruitment meant that the study design was changed to a feasibility RCT with an emphasis on evaluating recruitment and retention, crossover, the feasibility of administering the intervention and collecting outcomes data, and an embedded process evaluation."
3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

![Rating scale](https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_Oimq...S&formkey=dGIKd2Z2Q1INSQ0THI1azM5M51aWVc6MA&rm=full#gid=0)

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Technical issues reported by questionnaire respondents related to problems with software/browser compatibility, audio-visual issues, system freezes/crashes, login problems, and system timeouts. "Many video appointments became telephone consultations"

4a) Eligibility criteria for participants
Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Clinically stable adult patients (aged 18 or over) who received a liver transplant 1 to 5 years before baseline were eligible for the study if they: i) could access the myhealth@QEHB patient portal [18]; ii) could arrange for local clinical testing (blood tests, weight, blood pressure) via their GP or a dialysis centre; iii) had an internet-enabled computer with camera, running an operating system compatible with the remote consultation software; iv) had follow-up appointments every 3 or 6 months, and v) could give informed consent. 

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Clinically stable adult patients (aged 18 or over) who received a liver transplant 1 to 5 years before baseline were eligible for the study if they: i) could access the myhealth@QEHB patient portal [18]; ii) could arrange for local clinical testing (blood tests, weight, blood pressure) via their GP or a dialysis centre; iii) had an internet-enabled computer with camera, running an operating system compatible with the remote consultation software; iv) had follow-up appointments every 3 or 6 months, and v) could give informed consent. 

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"Before each clinic, hospital staff screened the day's appointment list to identify potentially eligible patients according to time since transplant. Clinical stability was assessed by the consultant using their judgement of the patient's liver function, adherence to immunosuppressant medication, and blood test results. Clinically eligible patients were introduced to the study during their appointment by their consultant, who assessed their further eligibility against the other inclusion criteria."

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

subitem not at all important  ○  ○  ○  ○  ○  essential
Does your paper address subitem 4a-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Clinically eligible patients were introduced to the study during their appointment by their consultant, who assessed their further eligibility against the other inclusion criteria. Patients interested in participating gave written consent to a member of the research team after their appointment, and completed a baseline questionnaire before randomisation."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Patients interested in participating gave written consent to a member of the research team after their appointment, and completed a baseline questionnaire before randomisation"

4b-i) Report if outcomes were (self-)assessed through online questionnaires
Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

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Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

All patients completed baseline questionnaires recording socio-demographics (postcode, sex, age, ethnicity, employment status), time since transplant, VSQ-9 scores, HRQoL (EQ-5D-5L), healthcare use in the previous 3 months and costs (travel/personal expenses) associated with their baseline appointment. Patients on a 3-month follow-up schedule received questionnaires via myhealth@QEHB [17] up to 7 days after their 3, 6, 9 and 12 month appointments. Patients seen every 6 months received questionnaires at 6 and 12 months. The 6 and 12 month questionnaires collected data on VSQ-9, HRQoL, costs, IT issues and health service use. Three and 9 month questionnaires covered VSQ-9 and costs only. A short questionnaire was also sent to eligible patients who chose not to participate, to understand their decision. 

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

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Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Your answer
5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).

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Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Intervention patients were registered on the myVideoClinic system and given instructions to access online software training. All patients were registered on the myhealth@QEHB system for administration of follow-up questionnaires. Myhealth@QEHB is a patient records portal developed by the Trust informatics department, currently used by around 10000 patients across 40 clinical specialties.

"For their appointment, patients logged in to myhealth@QEHB to speak to their consultant using an embedded secure videoconferencing platform provided by Vidyo. The Vidyo platform has been used for remote consultations by many healthcare providers and is underpinned by a comprehensive information governance policy which protects the confidentiality and security of end users according to national and international governance and data protection standards."
5-ii) Describe the history/development process
Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

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Does your paper address subitem 5-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study

5-iii) Revisions and updating
Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

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Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study.
5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

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subitem not at all important o o o o o essential

**Does your paper address subitem 5-v?**

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

N/A - the research team evaluated the feasibility of implementing remote consultation and had no access to source code etc. as this was developed by the hospital Trust.

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

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subitem not at all important o o o o o essential
Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

Clinically stable adult patients (aged 18 or over) who received a liver transplant 1 to 5 years before baseline were eligible if they: i) could access the myhealth@QEHB patient portal" "Intervention patients were registered on the myVideoClinic system and given instructions to access online software training."
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Patients were required to have their clinical tests locally, and make results available through myhealth@QEHB before their appointment. For their appointment, patients logged in to myhealth@QEHB to speak to their consultant using an embedded secure videoconferencing platform provided by Vidyo. The Vidyo platform has been used for remote consultations by many healthcare providers and is underpinned by a comprehensive information governance policy which protects the confidentiality and security of end users according to national and international governance and data protection standards. Patients could submit three questions before their appointment, and consultation audio recordings were available afterwards through the myhealth portal. When technical issues occurred during a consultation, the consultant telephoned the patient to finish the appointment and scheduled a face-to-face consultation if necessary."
Usual care patients "received standard face-to-face care at the hospital, standard letters notifying them of their appointment, and routine text reminders".
5-ix) Describe use parameters

Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"For their appointment, patients logged in to myhealth@QEHB [18] to speak to their consultant using an embedded secure videoconferencing platform provided by Vidyo. The Vidyo platform has been used for remote consultations by many healthcare providers and is underpinned by a comprehensive information governance policy which protects the confidentiality and security of end users according to national and international governance and data protection standards."

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as “type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered”. It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Patients must have been able to "arrange for local clinical testing (blood tests, weight, blood pressure) via their GP or a dialysis centre".
Appointments took place between patients and their consultant.

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Intervention patients received appointment details through the post and standard text appointment reminders." "Usual care patients received standard face-to-face care at the hospital, standard letters notifying them of their appointment, and routine text reminders.*
5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

The primary outcome was the combined satisfaction score for three domains of the VSQ-9 (convenience of location, getting through to the ozce by phone and length of time waiting). Participants rated their satisfaction on a 5-point scale (poor, fair, good, very good, excellent) which was transformed into a 0-100 linear scale, with higher scores denoting greater satisfaction. A 10-point difference between groups at 12 months was considered clinically significant. Secondary outcomes included recruitment; retention and crossover rates; questionnaire completion rates and return format; system performance; health service use; feasibility of obtaining clinical tests locally; clinical contacts; satisfaction in the other six VSQ-9 domains, and the feasibility of collecting data on patient costs and HRQoL (using EQ-5D-5L).

Additionally Table 1 details every outcome measure, its means of data collection and frequency/format of data collection.

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

This is not applicable to our study
6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoptions metrics are important process outcomes that should be reported in any ehealth trial.

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Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

Patient attendance at appointment was monitored by the consultant leading the appointment, via a case report form.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

An embedded qualitative process evaluation used semi-structured interviews to explore participants’ experiences of remote consultations (patients randomized to the intervention, patients randomized to usual care, and staff administering the intervention). Interviews with staff and patients were conducted using topic guides (Multimedia Appendices 2 and 3). Following their 12 month appointment, patients were contacted by the research team to ask if they were willing to take part in an interview. Patients were purposively sampled to ensure diversity in age and sex. At the end of the study, purposively sampled staff (hospital consultants, staff booking appointments and IT support personnel) were invited to take part in an interview. All participants provided written informed consent. Interviews were conducted by two experienced researchers (JJ, EOF). Neither interviewer knew the patient participants prior to the study. Field notes were made by the researcher following each interview. Interviews were audio-recorded, transcribed verbatim and checked against the recordings for accuracy. Participants did not have the opportunity to review and provide feedback on their interview transcript.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

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Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

The study reported in the paper is a feasibility RCT. These studies are not powered to detect a definitive outcome, so a formal sample size calculation is not required. We had originally planned the definitive trial which was powered "to detect a 10-point difference in VSQ-9 scores between groups at 80% power and 0.05 alpha. This was based on estimated annual figures of 267 clinically stable liver patients one to five years post-transplant attending routine follow-up in the clinics of interest; an estimated 60% participation rate, and 30% attrition"

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Interim analyses were not undertaken because of the small number of study participants and the fact this was a feasibility RCT. A data monitoring committee oversaw the study but no formal stopping rules were put in place.
8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants were randomised in equal numbers to the intervention (myVideoClinic) or usual care (standard face-to-face consultations) arm of the study using the GraphPad online randomisation tool"

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants were randomised in equal numbers to the intervention (myVideoClinic) or usual care (standard face-to-face consultations) arm of the study using the GraphPad online randomisation tool."
"The statistician analysing the primary outcome data was blinded to participants’ group allocation."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Randomisation was carried out by the research team member who took patient consent and enrolled them to the study. The research team member enrolled participants after eligibility had been assessed by the clinician. The research team member assigned participants to interventions

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment
11a-i) Specify who was blinded, and who wasn’t

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

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Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Participants were not blinded to their allocation, nor were clinicians administering the intervention. "The statistician analysing the primary outcome data was blinded to participants' group allocation"

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

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Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Patients allocated to the intervention were made aware that this was the option of having a remote consultation and that they could ask for a standard appointment if they wished, whilst still having subsequent appointments remotely.

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for eHealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study.

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed.
An intention to treat analysis was undertaken, using SPSS version 25. Participant characteristics at baseline were summarised descriptively and compared between study arms using t-tests or chi-squared tests as appropriate. Analysis of the primary outcome used ANCOVA to compare intervention and usual care group satisfaction scores at study end whilst controlling for baseline scores. For patients with missing 12-month VSQ-9 data, their most recently available data were used. Secondary outcomes were analysed descriptively, and feasibility outcomes are presented overall and by group with counts and percentages.

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

For patients with missing 12-month VSQ-9 data, their most recently available data were used.

Other provisions for dealing with missing data were not made since this was a feasibility RCT in which several of the outcomes related to the feasibility of collecting data and reporting the extent to which this was complete.
12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *  
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Sub-group analyses were not undertaken due to small participant numbers

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

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subitem not at all important  essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This study received a favourable ethical opinion from the West Midlands Solihull Research Ethics Committee on October 24, 2017 (Ref: 17/WM/0338). Research governance approval was obtained from the University Hospitals Birmingham NHS Foundation Trust in February 2018 (Ref:RRK6080). The study was sponsored by the University of Birmingham.

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_Oimq...&formkey=dGIKd2Z2Q1NSGQ0THl1azM5MS1aWWc6MA&rm=full#gid=0
x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"patients were introduced to the study during their appointment by their consultant, who assessed their further eligibility against the other inclusion criteria. Patients interested in participating gave written consent to a member of the research team after their appointment".

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

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subitem not at all important ○ ○ ○ ○ ○ essential
Does your paper address subitem X26-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

For their appointment, patients logged in to myhealth@QEHB to speak to their consultant via an embedded video link using the secure Vidyo system as the videoconferencing platform*. Completed questionnaires and interview transcripts were anonymised.

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Fifty-six patients (28% of total) were recruited; 29 allocated to receive the intervention, and 27 allocated to usual care.

13b) For each group, losses and exclusions after randomisation, together with reasons
Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Two usual care patients withdrew after randomisation, giving an adjusted recruitment rate of 54/203 (26.6%)"

"All remaining patients continued in the study until it closed

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13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

![Attrition Diagram]

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Participant flow diagram is included as a multimedia appendix.

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14a) Dates defining the periods of recruitment and follow-up

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* Please note: The above text is extracted from a template and is not intended to represent the final submission or publication format.
Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Recruitment took place between 12th March and 19th July 2018. The study closed on 1st November 2019. " "Patients were in the study for 12 months"

14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

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subitem not at all important  O  O  O  O  O  essential

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

14b) Why the trial ended or was stopped (early)
Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

15) A table showing baseline demographic and clinical characteristics for each group
NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes this is addressed in Table 2

15-i) Report demographics associated with digital divide issues
In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

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|---------|---|---|---|---|---|
| not at all important | ○ | ○ | ○ | ○ | ○ |
| essential |   |   |   |   |   |

https://docs.google.com/forms/d/e/1FAIpQLSfZBSU1bwOc_Oimq...&formkey=dGIlZ22Q1I1NGQ0THI1azM5MSaW6MA&rm=full#gid=0
Patients in the intervention arm were slightly younger than those receiving usual care, and a greater proportion were male although none of the baseline characteristics showed a statistically significant difference between groups when means or proportions were assessed.

29 allocated to receive the intervention, and 27 allocated to usual care.
16-ii) Primary analysis should be intent-to-treat
Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 16-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

An intention to treat analysis was undertaken

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The mean VSQ-9 baseline score for the three domains of ‘convenience of location’, ‘getting through by phone’, and ‘length of time waiting’ was 49.7 (SD 17.9) for patients in the intervention arm, and 50.3 (SD 19.5) for usual care patients. At each subsequent timepoint, scores were substantially higher for intervention patients vs usual care. At 12 months, scores had increased from baseline in both groups: by 24.7 points for intervention patients (74.4; CI: 66.3 to 82.5), and by 14.2 points for usual care (64.5; CI: 55.7 to 73.2). Within-group analysis showed the increase to be significant for both intervention (P<.0001) and usual care patients (P=.020). ANCOVA analysis showed no significant difference in satisfaction between groups after controlling for baseline (f=2.84; P=.098). However, the study was underpowered given its feasibility design. "

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwoOc_Oimq...&formkey=dGIKd2Z2Q1NSGQ0THI1azM5MS1aWWc6MA&rm=full#gid=0
17a-i) Presentation of process outcomes such as metrics of use and intensity of use
In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

Does your paper address subitem 17a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable to our study

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Fifteen interviews were conducted with intervention patients (8/15; 53%), usual care patients (3/15; 20%), consultants (2/15; 13%), IT support (1/15; 7%) and hospital administrators (1/15; 7%) for the qualitative process evaluation.

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

This is not applicable to our study.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)
Does your paper address CONSORT subitem 19? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"No harms or adverse events were reported during the study"

19-i) Include privacy breaches, technical problems
Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 19-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"24 took place at least partially over the telephone due to technical issues". One of the aims of the study was to assess the incidence of technical issues. There were no privacy breaches recorded.
19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

1  2  3  4  5
subitem not at all important  ○  ○  ○  ○  ○ essential

Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Fifteen interviews were conducted with intervention patients (n=8), usual care patients (n=3), consultants (n=2), IT support (n=1) and hospital administrators (n=1) for the qualitative process evaluation."

Themes relate to: the study recruitment process; software use; perceptions of video appointments; local clinical testing; impacts on patient costs; perceived benefits to the hospital, and implications for wider implementation.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Recruitment to this study was lower than expected: the pool of eligible patients was comparatively small and the recruitment rate was 26.6% (54/203). Consequently, the study design was altered from a planned definitive trial to one that focused on the feasibility of administering the intervention and collecting evaluative data. Although no participants left the study, the crossover rate from intervention to usual care was high (45%), with most changes to study arm made at the request of the patient before their first remote appointment. This impaired our ability to fully assess processes and outcomes for patients in the intervention group.

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential
Does your paper address subitem 22-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"...implies that future evaluations of outpatient remote consultations may benefit from a cohort rather than randomised design."
"Unanswered questions remain regarding the equity of access to virtual consultations (particularly for rural patients who may live far from hospital sites but also experience poor technological infrastructure), and their suitability for diverse clinical specialties in which face-to-face consultation may continue to be a necessity."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials
Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

|   |   |   |   |   |   |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | essential |

subitem not at all important
Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Many patients were ineligible due to clinical or technology issues, and recruitment rates were low, with only 54 patients recruited in total. There was substantial crossover from intervention to usual care, leaving just 16 patients receiving the intervention. Consequently, the study was unable to evaluate definitively the impact of remote consultations on patient satisfaction, and the prevalence of technical issues that impacted on the mode or quality of remote consultations was not objectively measured. Similarly, although we know that the baseline characteristics of patients in each study arm were comparable, we were not able to compare the characteristics of patients recruited to the study against the characteristics of the wider liver transplant patient cohort at QEHB. This impacts on the external validity of our findings"

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

1 2 3 4 5

subitem not at all important  ○ ○ ○ ○ ○ essential
Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"Similarly, although we know that the baseline characteristics of patients in each study arm were comparable, we were not able to compare the characteristics of patients recruited to the study against the characteristics of the wider liver transplant patient cohort at QEHB. This impacts on the external validity of our findings"

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21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

1 2 3 4 5

subitem not at all important  ◯  ◯  ◯  ◯  ◯  essential

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Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"for conditions where the results from clinical tests must be available during consultations, a robust system for patients to obtain these tests locally should be put in place. As has been reported by others, technical issues with the video clinic software were frequently experienced by both clinicians and patients"

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OTHER INFORMATION

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_Oimq...&formkey=dGIKd2ZQ1INSGQ0THl1azM5MS1aWWc6MA&rm=full#gid=0
23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Abstract: "ISRCTN: 14093266" and in methods section

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Study protocol is referenced in the paper https://doi.org/10.1186/s13063-018-2953-4

25) Sources of funding and other support (such as supply of drugs), role of funders
Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"This research was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West Midlands (NIHR CLAHRC WM), now recommissioned as the NIHR Applied Research Collaboration West Midlands (ARC WM)*.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5

subitem not at all important 〇 〇 〇 〇 〇 essential

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"The authors are distinct from the developers/sponsors of the myVideoClinic software. Dr Ferguson uses the software for remote outpatient video consultations. "

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- yes, major changes
- yes, minor changes
- no

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Your answer

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

It took one hour to complete

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