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Show results to participants engaged in clinical trials

Submission date
01/02/2019

Recruitment status
No longer recruiting

Registration date
26/02/2019

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
We know that many people who take part in clinical trials want to be able to find out the results of their trial. We also know that, in many cases, this does not happen. It can be difficult for trial teams to provide the results to the people who took part. This is for a number of reasons, including:
1. Practical challenges such as losing touch with people
2. Lack of time and/or money
3. Worry about upsetting people
4. Difficulties explaining complex results
5. Protecting the privacy of people taking part in trials
6. Data protection laws
7. Keeping track of people's wishes on whether or not to be told results

There is little evidence on how best to feedback results to the people who took part in the trial, either from a practical perspective, or on what people taking part in a trial prefer. The evidence that we do have is weak. This means that people running trials do not know how best to do it.

The Show RESPECT study is aiming to find practical ways to share the results of clinical trials with the people taking part in it. It is doing this by testing several different approaches within a large ovarian cancer trial (the ICON8 trial).

Who can participate?
1. Women who are taking part in the ICON8 ovarian trial at hospitals that are part of the Show RESPECT study in the UK
2. Staff who have worked on communicating the ICON8 results to ICON8 participants at hospitals that are part of the Show RESPECT study in the UK
3. Staff working at the trials unit who have worked on communicating the ICON8 results to participants

What does the study involve?
Each hospital that is taking part in ICON8 in the UK will be allocated at random to share the results of the study in one or more of the following ways:

1. Giving people taking part in the trial a link to a basic webpage that contains a simple summary of the results
2. Giving people taking part in the trial a link to an 'enhanced' webpage that contains a simple summary of the results, links to further information, a short video of a doctor explaining the results, and a 'frequently asked questions' section that answers questions people send in
3. Giving people taking part in the trial a simple printed summary of the results
4. Inviting people taking part in the trial to join an email list, where a summary of results and updates will be sent out

Participants will then be sent a questionnaire to ask them their views about how the results were communicated to them. Staff involved in communicating the results to ICON8 participants will also be asked to complete questionnaires.

We will also invite a small number of ICON8 participants and hospital staff to be interviewed about their views and experiences on this topic.

What are the possible benefits and risks of participating?
The potential benefits of taking part are:
1. Having an opportunity to give feedback on their experience and views of finding out trial results
2. Helping us improve how researchers communicate with people taking part in trials in the future
3. Potentially having access to extra ways of finding out the ICON8 results than would normally be the case

The possible risks of taking part are:
1. Some participants may find the ICON8 results, or talking about receiving the results, upsetting
2. Completing the questionnaire or being interviewed by a researcher will take some time (around 10 minutes for the questionnaire, and up to 90 minutes for the interviews).

Where is the study run from?
This study is being run by the Medical Research Council Clinical Trials Unit at UCL. It is being carried out in hospitals in the UK.

When is the study starting and how long is it expected to run for?
The study started in late 2018, and is expected to run until September 2019.

Who is funding the study?
The study is being funded by the MRC Clinical Trials Unit at UCL from their core funding from the Medical Research Council for trial conduct methodology research (grant number MC_UU_12023 /24).

Who is the main contact?
Annabelle South, a.south@ucl.ac.uk

Contact information

Type(s)
Public

Contact name

Mrs Annabelle South

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Additional identifiers

Protocol serial number
18/0261

Study information

Scientific Title
Show RESults to Participants Engaged in Clinical Trials: A cluster randomised factorial trial of different modes of communicating results to participants of the ICON8 phase III ovarian cancer trial

Acronym
Show RESPECT

Study objectives
Each of the interventions (method of providing the ICON8 results to participants) is superior to the relevant control. The interventions are the following:
1. Basic webpage (control) vs enhanced webpage
2. No printed summary (control) vs printed summary posted to participant
3. No email list invitation (control) vs invitation to join email list

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/08/2018, NHS Health Research Authority London – Chelsea Research Ethics Committee (Research Ethics Committee (REC) Bristol Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; nrescommittee.london-chelsea@nhs.net; 0207 1048055), ref: 18/LO/1011.

Study design
2 by 2 by 2 factorial cluster randomised controlled trial, multicentre

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Communicating trial results to participants

Interventions
In Show RESPECT, ICON8 sites will be randomised using 2 by 2 by 2 factorial cluster randomisation. Therefore there will be 8 possible intervention combinations. The interventions within the study are:
1. Basic webpage vs enhanced webpage
2. No printed summary vs printed summary posted to participant
3. No email list invitation vs invitation to join email list

To randomise sites, we shall generate a randomisation sequence within each volume stratum based on randomly permuted blocks of size 8 (no surplus stratum is used in this scenario). Once many sites have approvals in place, and the rate of further approvals being obtained has slowed, then we would randomise all sites with approvals in place. We would apply the randomisation sequence to sites after randomly permuting them within each stratum in Stata software. We anticipate conducting this initial randomisation for all three strata at the same time. However in the event that approvals accumulate quickly in some strata but not in others, and in particular if in one or more strata fewer than 8 sites are ready to be randomised, we may perform the initial randomisation for some strata earlier than for others. After the initial randomisation for each stratum, as further sites obtain approvals we shall allocate them in real time to the next allocation in the sequence.

Link to the Basic Webpage:
Participants randomised to receive a link to a basic webpage will be given the URL of a webpage in their Patient Update Information Sheet. It will be up to participants as to whether they access it. Each site randomised to this will be given a different URL (pointing to the same page), to allow us to monitor uptake by site, as well as overall number of hits.

The information on the page will follow the structure and 'friendly' versions of the headings for lay summaries mandated by the European Parliament Regulation (EU) No 536/2014 Article 37 (4):
1. Study name
2. Who sponsored this study?
3. General information about the study
4. What patients were included in this study?
5. Which medicines were studied?
6. What were the side effects?
7. What were the overall results of the study?
8. How has this study helped patients and researchers?
9. Are there plans for further studies?
10. Where can I find further information about this study?
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf

The content of the webpage will be written following the principles of Plain English, and will be reviewed by patient representative(s).

The web page will be laid out with clear headings, and the body text will be Arial 12pts, black against a white background. Section 10 of the webpage will link to the entry on the clinical trial register, and the peer-reviewed paper (when available).

Link to enhanced webpage
Participants randomised to receive a link to an enhanced webpage will be given the URL of a webpage in their Patient Update Information Sheet. Each site randomised to this will be given a different URL (pointing to the same page), to allow us to monitor uptake by site. The enhanced webpage will not be linked from other pages on the website, will not be findable via the site navigation, and search engines will be discouraged from indexing it, so people will need to know the URL to access it, to reduce crossover. It will be up to participants who have been told the URL as to whether they access it.

The information on the webpage will follow the structure and language of the 'Participants Results Summary template', adapted for the ICON8 trial. This template has been adapted from the MRCT Center Guidance and Toolkit[19] and the CISCRP template, based on a focus group with cancer trial participants.
1. Thank you
2. What was the study about?
3. Why was the study needed?
4. Who took part in the study?
5. How was the study carried out?
6. What did the study find?
7. How sure can we be about these results?
8. What do these results mean?
8.1. What do these results mean for you?
8.2. What do these results mean for other people?
9. What difference will these results make?
10. Thank you
11. Further information

The enhanced webpage will use tables and/or graphics to illustrate key points. It will use in-text links to websites aimed at patients with explanations of key terms or concepts (e.g. Cancer Research UK, Target Ovarian Cancer, Ovarian Cancer Action). It will also provide links in the further information section to the support that is available for patients and their loved ones via these organisations, as well as to the trial register entry, the peer-reviewed journal article, and any additional sources of information about the trial and its results (e.g. accurate news stories on trusted websites). The webpage will include a short, simple video of a trial clinician explaining the main results of the trial in lay language. This video will just feature one clinician talking to the camera, covering:
1. Introducing themselves and their role in the trial
2. Thanking participants for taking part
3. Explaining what the trial was testing and how
4. Summarising the main results
5. Saying what this means for future patients, and why the research results are important

The webpage will also contain a Frequently Asked Questions section, which will invite participants to send any additional questions they have by email or post to the trial team. Questions can be submitted anonymously via an online form using the Opinio survey system. Answers to the questions received will be posted on the website within 3 weeks of receiving them.

The content of the webpage will be written following the principles of Plain English. The web page will be laid out with clear headings, and the body text will be Arial 12pts, black against a white background. Both the content and layout of the enhanced webpage will be reviewed by patient representatives, with the content also being reviewed by a nurse who specialises in providing information about ovarian cancer to patients.

Printed Summary
Participants at sites randomised to use the printed summary will be posted the printed summary by their current trial site, if their current address is known, around three weeks after they have been sent the Patient Update Information Sheet, unless they have opted out.

The printed summary will follow the structure and language of the 'Participants Results Summary template' (see Annex 1), adapted for the ICON8 trial. This template has been adapted from the MRCT Center Guidance and Toolkit[19] and the CISCRP template, based on a focus group with cancer trial participants.
1. Thank you
2. What was the study about?
3. Why was the study needed?
4. Who took part in the study?
5. How was the study carried out?
6. What did the study find?
7. How sure can we be about these results?
8. What do these results mean?
8.1. What do these results mean for you?
8.2. What do these results mean for other people?
9. What difference will these results make?
10. Thank you
11. Further information

The content of the printed summary will be written following the principles of Plain English. The text of sections 2-10 will be identical to that of the enhanced webpage. The further information section will contain information on relevant patient helplines, how to access the peer reviewed paper and the link to the trial registry entry.

The printed summary will be laid out with clear headings, plenty of white space, and the body text will be Arial 12pts, black against a white background. It may use graphics to illustrate key points. It will be two to four pages long, once formatted. It will be professionally printed on 150gsm paper. Both the content and layout of the printed summary will be reviewed by patient representatives and a nurse who specialises in providing information about ovarian cancer to patients.

Invitation to join email list
Participants randomised to be invited to join an email list will be given a URL to sign-up to the email list in their Patient Update Information Sheet. The URL will take them to a form where participants can enter their email address onto a secure MailMan database, which will not be linked to their trial data. We will use MailChimp to design the email newsletter in a way that works well in different email platforms, including mobile phones.

When participants sign up to the email list, they will receive an email, confirming their subscription and telling them how they can unsubscribe at any time.

The first email with a summary of results (using the same written content as the enhanced webpage, see above) will be sent 1 month after sites have received the Patient Update Information Sheets, to allow them time to distribute them to participants, and for participants to sign up. Questions about the results can be submitted anonymously via an online form using the Opinio survey system. An update email will be sent out a month later with answers to any frequently asked questions that have been received since the previous email, and any updates (e. g. links to publications or presentations). Participants who sign up to the email list after the first email has been sent will be sent a welcome email with a link to online copies of any email(s) that have previously been sent.

The content of the emails will be written following the principles of Plain English, and will be reviewed by patient representative(s). The email will be laid out with clear headings, plenty of white space, and the body text will be Arial 12pts, black against a white background. It will use a suitable MailChimp template.

The further information section will contain links to the peer-reviewed journal article and the entry in the trial registry.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measure is participant's satisfaction with the way they found out the results of ICON8, measured using a 5-point Likert scale one month after receiving the intervention.

Key secondary outcome(s))
1. The extent of participant's agreement with the statement 'the information about the trial results told me everything I wanted to know', measured using a 5-point Likert scale one month after receiving the intervention.
2. Participants' Ease of understanding of the results, measured using a 5-point Likert scale one month after receiving the intervention.
3. How upsetting participants found the results, measured using a 5-point Likert scale one month after receiving the intervention.
4. Participants' willingness to take part in another trial in the future, measured using a 5-point Likert scale one month after receiving the intervention.
5. Participants' likelihood of recommending taking part in a clinical trial to friends and family, measured using a 5-point Likert scale one month after receiving the intervention.
6. How glad participants are to have found out the results, measured using a 5-point Likert scale one month after receiving the intervention.
7. Participants' regret at finding out the results, measured using a 5-point Likert scale one month after receiving the intervention.
8. Reported uptake of the interventions offered, measured using self-report via a questionnaire one month after receiving the intervention.
9. Proportion of participants who reported wanting to find out the results but not having done so, measured using a questionnaire one month after receiving the intervention.
10. Proportion of participants who reported not wanting to find out the results who did find out the results, measured using a questionnaire one month after receiving the intervention.
11. Participants' reported ease of finding out the results, measured using a 5-point Likert scale one month after receiving the intervention.
12. Other ways participants would have liked to receive the result, measured using free-text

question in a questionnaire one month after receiving the intervention.
13. Participants preferred way to receive the results, measured using a multiple choice question one month after receiving the interventions.
14. Site staff's concerns about the interventions or process, measured using a free-text question in a questionnaire immediately after delivering the intervention(s) and 2-3 months after delivering the intervention(s).
15. Site staff's time spent delivering the interventions, measured using multiple choice questions in a questionnaire immediately after delivering the intervention.
16. Role of staff involved in delivering the interventions, measured using a multiple choice question in a questionnaire immediately after delivering the intervention.
17. Challenges in implementing the interventions reported by site staff, measured using a free-text question in a questionnaire immediately after delivering the intervention(s) and 2-3 months after delivering the intervention(s).
18. Number of queries received from patients by site staff relating to the ICON8 results, measured using a questionnaire 2-3 months after delivering the intervention.
19. Costs incurred by the site in implementing the intervention, measured using a free-text question in a questionnaire immediately after delivering the intervention.
20. Site staff's views on what they would like to do differently for the next trial they are involved in communicating the results for, measured using a free-text question in a questionnaire immediately after delivering the intervention(s) and 2-3 months after delivering the intervention (s).
21. Proportion of patients the Patient Update Information Sheet is distributed to, measured in a log completed by staff at time of distribution of Patient Update Information Sheets.
22. Proportion of patients at sites randomised to distributed a printed summary who were sent the printed summary, measured in a log completed by staff at time of distribution of the printed summary.
23. Proportion of patients at sites randomised to distributed a printed summary who opt out of receiving the printed summary, measured in a log completed by staff at time of distribution of the printed summary.
24. Site staff's preferred method of communicating results to participants, measured via a multiple choice question in a questionnaire immediately after delivering the intervention(s) and 2-3 months after delivering the intervention(s).
25. Site staff's views on whether the interventions they were allocated to should become standard practice, measured via a multiple choice question in a questionnaire immediately after delivering the intervention(s) and 2-3 months after delivering the intervention(s).
26. CTU staff's reported concerns about the process of communicating results to participants, measured via a free text question in a questionnaire immediately after the first sites deliver the interventions and 2-3 months after the last site delivers the interventions.
27. Time taken by CTU staff to implement the interventions, measured via a categorical question in a questionnaire immediately after the first sites deliver the interventions and 2-3 months after the last site delivers the interventions.
28. CTU staff's views on challenges faced implementing the intervention, measured via a free text question in a questionnaire 2-3 months after the last site delivers the interventions.
29. Number of queries received by CTU staff from participants or sites about the interventions or results, measured via numerical questions in a questionnaire 2-3 months after the last site delivers the interventions.
30. Costs incurred by the CTU in implementing the interventions, measured via an expenditure tracker completed during the course of the study, as expenditures occur.
31. CTU staff's views on what they would like to do different for the next trial they are involved in communicating the results of, measured via a free text question in a questionnaire 2-3 months after the last site delivers the interventions.
32. Uptake of the basic and enhanced webpages, by site, measured via analytics data from site-

specific links, at one, two and three months after the Patient Update Information Sheet is distributed.
33. Number of sign-ups to the email list, measured via email list data monthly after the first set of Patient Update Information Sheets are distributed until the end of September 2019.
34. CTU staff's preferred method of communicating the results to participants, measured via a multiple choice question in a questionnaire 2-3 months after the last site delivers the interventions.
35. CTU staff's reported concerns about the process of communicating results to participants, measured via a free text question in a questionnaire 2-3 months after the last site delivers the interventions.
36. CTU staff's reported views on whether they would prefer to have given participants a different way to find out the results, measured via a free text question in a questionnaire 2-3 months after the last site delivers the interventions.

Completion date
25/09/2019

Eligibility

Key inclusion criteria
1. Participant in the ICON8 trial
2. Currently being followed up at an ICON8 trial site in England, Scotland, Wales and Northern Ireland
2.1. Including those with reduced follow-up arrangements
3. Aged 18 years or older

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
182

Key exclusion criteria
1. Participant has previously informed their site that they do not wish to attend any further visits in relation to the ICON8 trial
2. Lost to follow-up from the ICON8 trial
3. Site staff consider the patient to be too unwell to be contacted about this study

Date of first enrolment
07/01/2019

Date of final enrolment
25/09/2019

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
THE CHRISTIE NHS FOUNDATION TRUST
550 WILMSLOW
ROAD
WITHINGTON
MANCHESTER
GREATER
MANCHESTER
Manchester
United Kingdom
M20 4BX

Study participating centre
BARTS HEALTH NHS TRUST
THE ROYAL
LONDON
HOSPITAL
WHITECHAPEL
LONDON
GREATER
LONDON
London
United Kingdom
E1 1BB

Study participating centre
THE ROYAL MARSDEN NHS FOUNDATION TRUST
FULHAM ROAD
LONDON
GREATER

LONDON
London
United Kingdom
SW3 6JJ

Study participating centre
THE CLATTERBRIDGE CANCER CENTRE NHS FOUNDATION TRUST
CLATTERBRIDGE
ROAD
BEBINGTON
WIRRAL
MERSEYSIDE
Wirral
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CH63 4JY

Study participating centre
MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST
MAIDSTONE
HOSPITAL
HERMITAGE LANE
MAIDSTONE KENT
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ME16 9QQ

Study participating centre
EAST AND NORTH HERTFORDSHIRE NHS TRUST
LISTER HOSPITAL
COREYS MILL
LANE
STEVENAGE
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SG1 4AB

Study participating centre
TAUNTON AND SOMERSET NHS FOUNDATION TRUST
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TAUNTON
SOMERSET

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Study participating centre
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Study participating centre
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HEADQUARTERS
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Study participating centre
GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST
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ROAD
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IPSWICH
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NORFOLK
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Study participating centre

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DEVON
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United Kingdom
EX31 4JB

Study participating centre
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Study participating centre
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Study participating centre
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COMBE PARK
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VELINDRE NHS TRUST
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CHARNWOOD
COURT
HEOL
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CARDIFF SOUTH
GLAMORGAN
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Study participating centre
MID ESSEX HOSPITAL SERVICES NHS TRUST
BROOMFIELD
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COURT ROAD
CHELMSFORD
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United Kingdom
CM1 7ET

Study participating centre

NORTHAMPTON GENERAL HOSPITAL NHS TRUST
CLIFTONVILLE
NORTHAMPTON
NORTHAMPTONSHIRE
Northampton
United Kingdom
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Study participating centre
TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
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Study participating centre
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Study participating centre
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WARWICKSHIRE
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Study participating centre
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SOUTH WING

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Study participating centre
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YO31 8HE

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TRUST HQ
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CHELTENHAM
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United Kingdom
GL53 7AN

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Annabelle South mrcctu.showrespect@ucl.ac.uk. Requests will be processed in line with the MRC CTU's Data Sharing policy and application process which is documented https://www.ctu.mrc.ac.uk/our-research/other-research-policy/data-sharing/ The criteria for data sharing are:
1. No data should be released that would compromise an ongoing trial or study.
2. There must be a strong scientific or other legitimate rationale for the data to be used for the requested purpose.
3. Investigators who have invested time and effort into developing a trial or study should have a period of exclusivity in which to pursue their aims with the data, before key trial data are made available to other researchers.
4. The resources required to process requests should not be under-estimated, particularly successful requests which lead to preparing data for release. Therefore adequate resources must be available in order to comply in a timely manner or at all, and the scientific aims of the study must justify the use of such resources.
5. Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.

Data specific to Show RESPECT will be available for sharing following publication of the main Show RESPECT results in a peer-reviewed journal. Researchers wishing to access these data should contact the Study Management Group in the first instance.

Some data used in Show RESPECT have been collected primarily for the ICON8 clinical trial. Any researchers also wishing to access these data should contact the ICON8 Trial Management Group.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/10/2021	05/10/2021	Yes	No
Results article	Cost and feasibility results	29/07/2023	31/07/2023	Yes	No
Results article	results of free-text questions in an embedded explanatory qualitative study	10/07/2024	16/07/2024	Yes	No
Basic results		01/12/2020	02/12/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Protocol (other)		20/08/2018	09/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes