

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting
22nd February 2021

Agenda

1. Introductions
2. Update on progress
3. Tocilizumab
4. REGN-COV2
5. Next version of the protocol
6. Trial procedures
7. Pregnancy update
8. Q&A

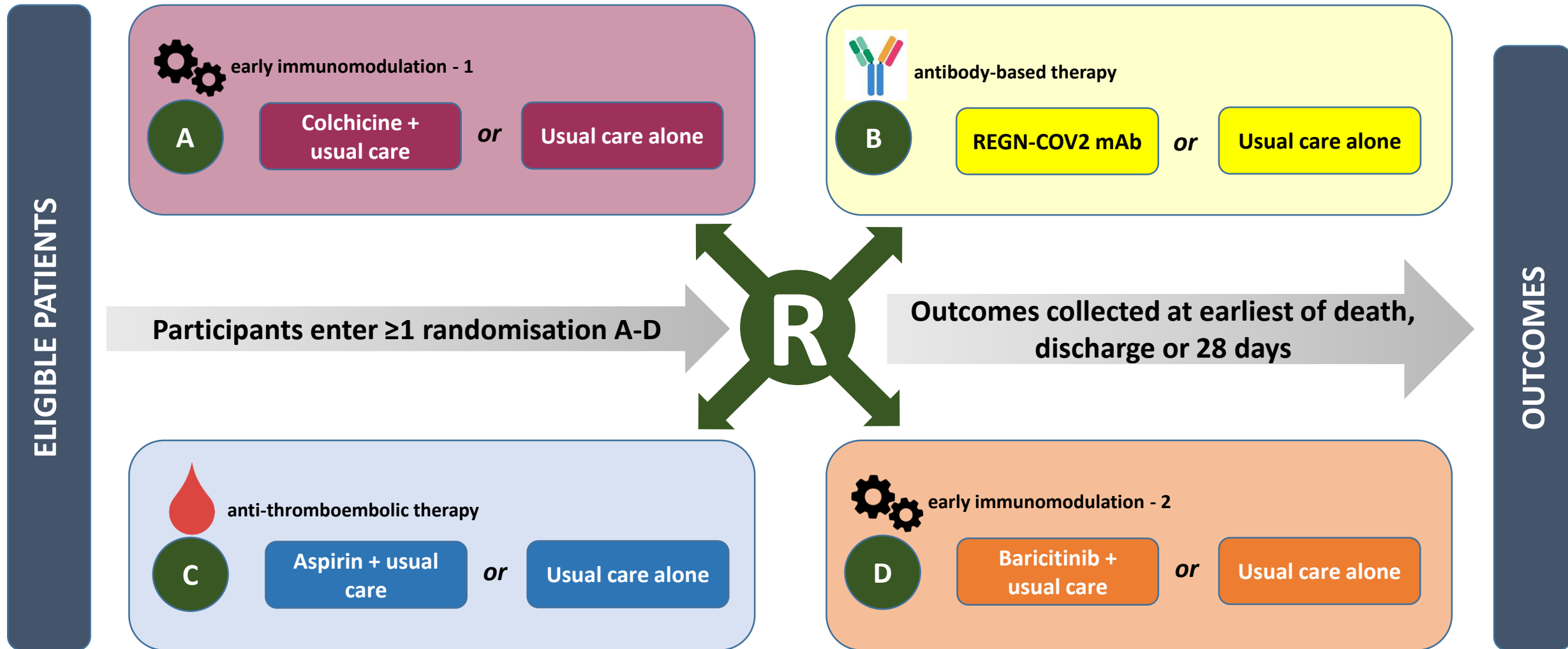
Introductions



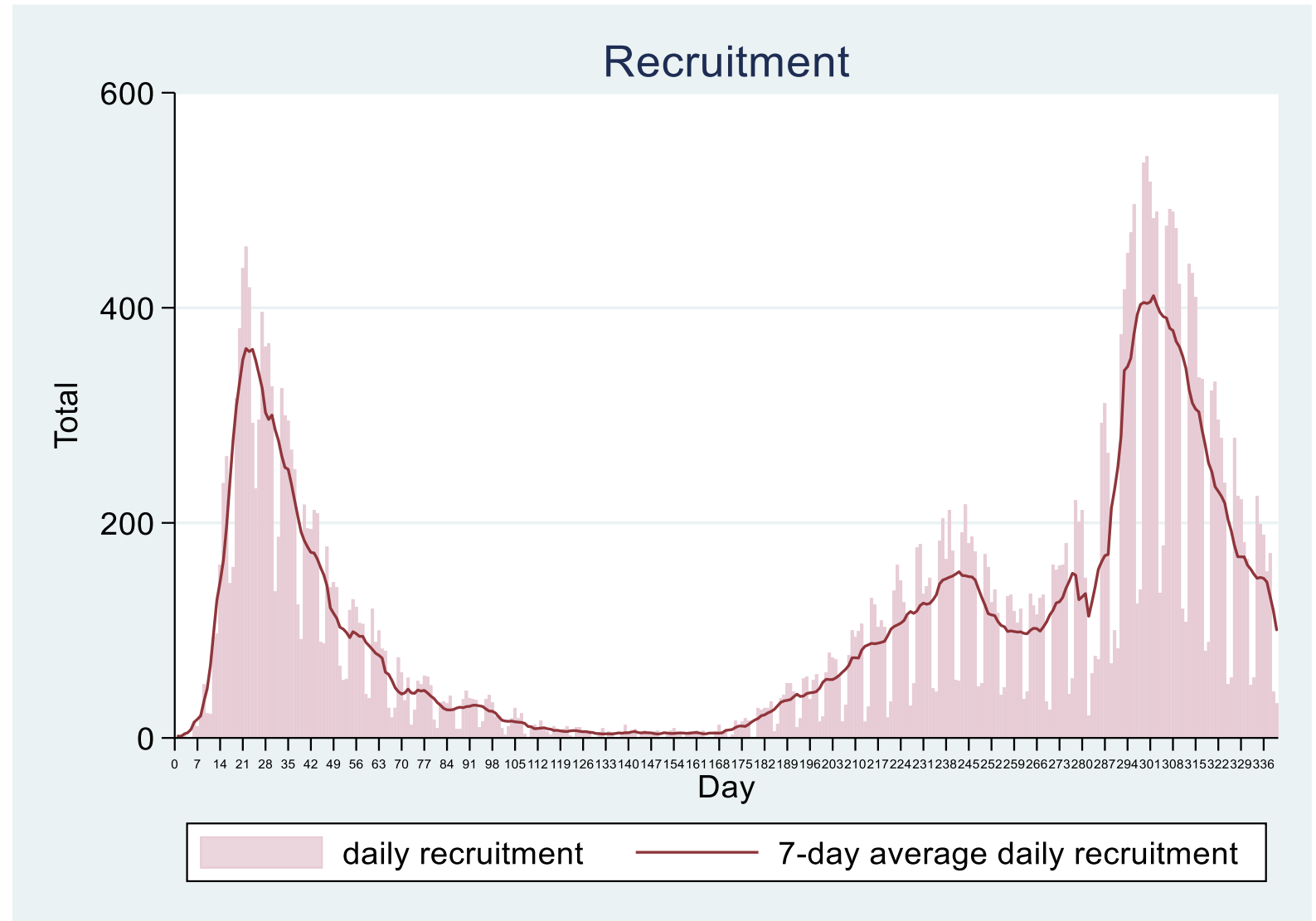
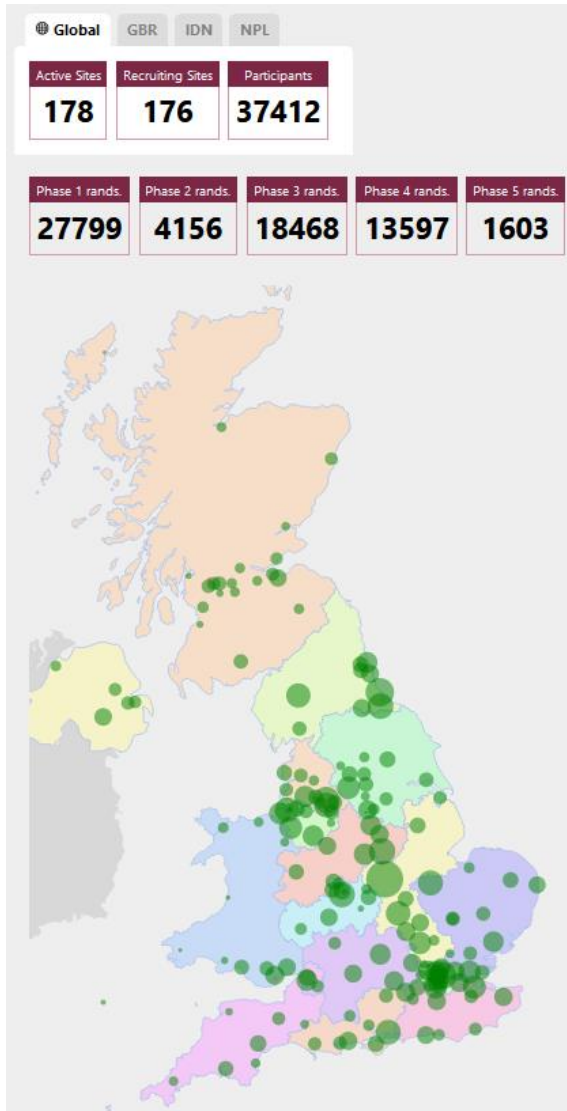
- One of the central study team will talk to the agenda
- If you have questions please enter them into the “Q&A” on the right side of your screen.
- Questions may be answered directly or to the whole group

PROGRESS UPDATE

Current design (adults)



Recruitment by site and by time



Current numbers in comparisons



- Colchicine vs usual care: ~10,500
- REGN-COV2 vs usual care: ~8500
- Aspirin vs usual care: ~13,500
- Baricitinib vs usual care: ~1600

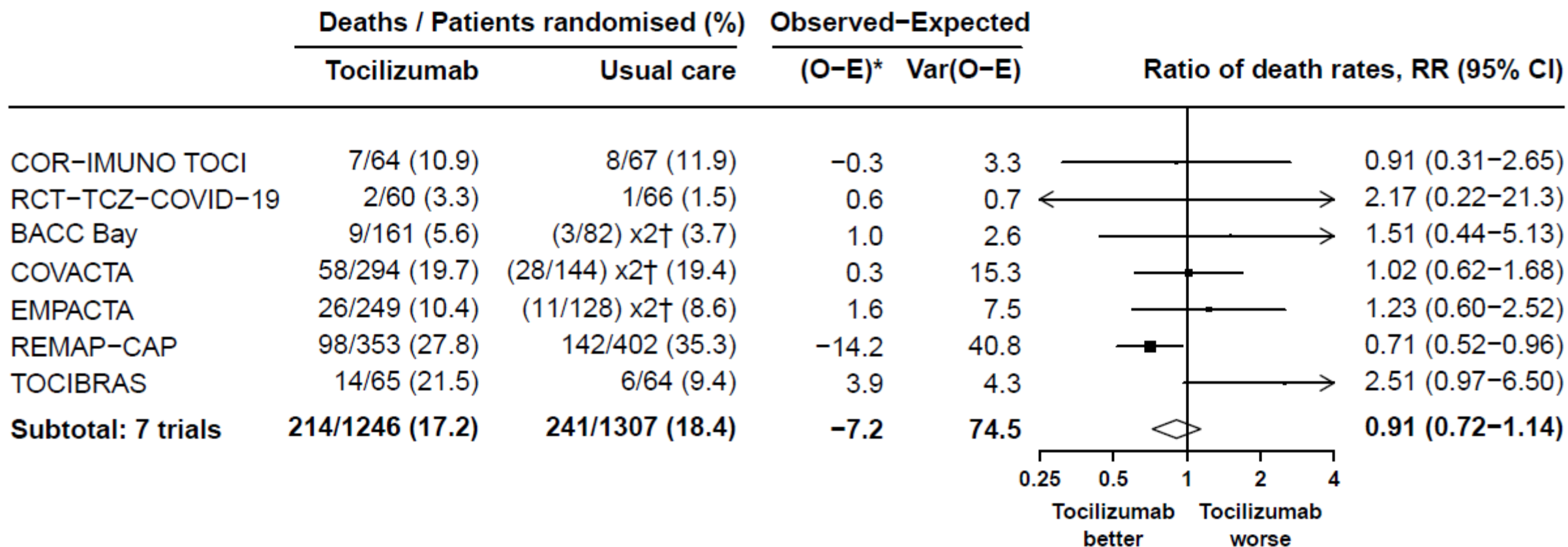
Recruitment



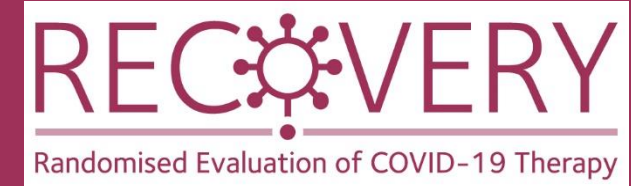
- Please continue to prioritise RECOVERY in accordance with its Urgent Public Health Priority 1A status (same as vaccine trials)
- Average recruitment remains at about 10% of all COVID-19 admissions, but with significant variation between regions and sites
- Recruitment is really important as the epidemic shrinks: it is vital we get answers to our current comparisons before cases become uncommon.
This means the next few weeks are crucial.

TOCILIZUMAB

What we knew before RECOVERY

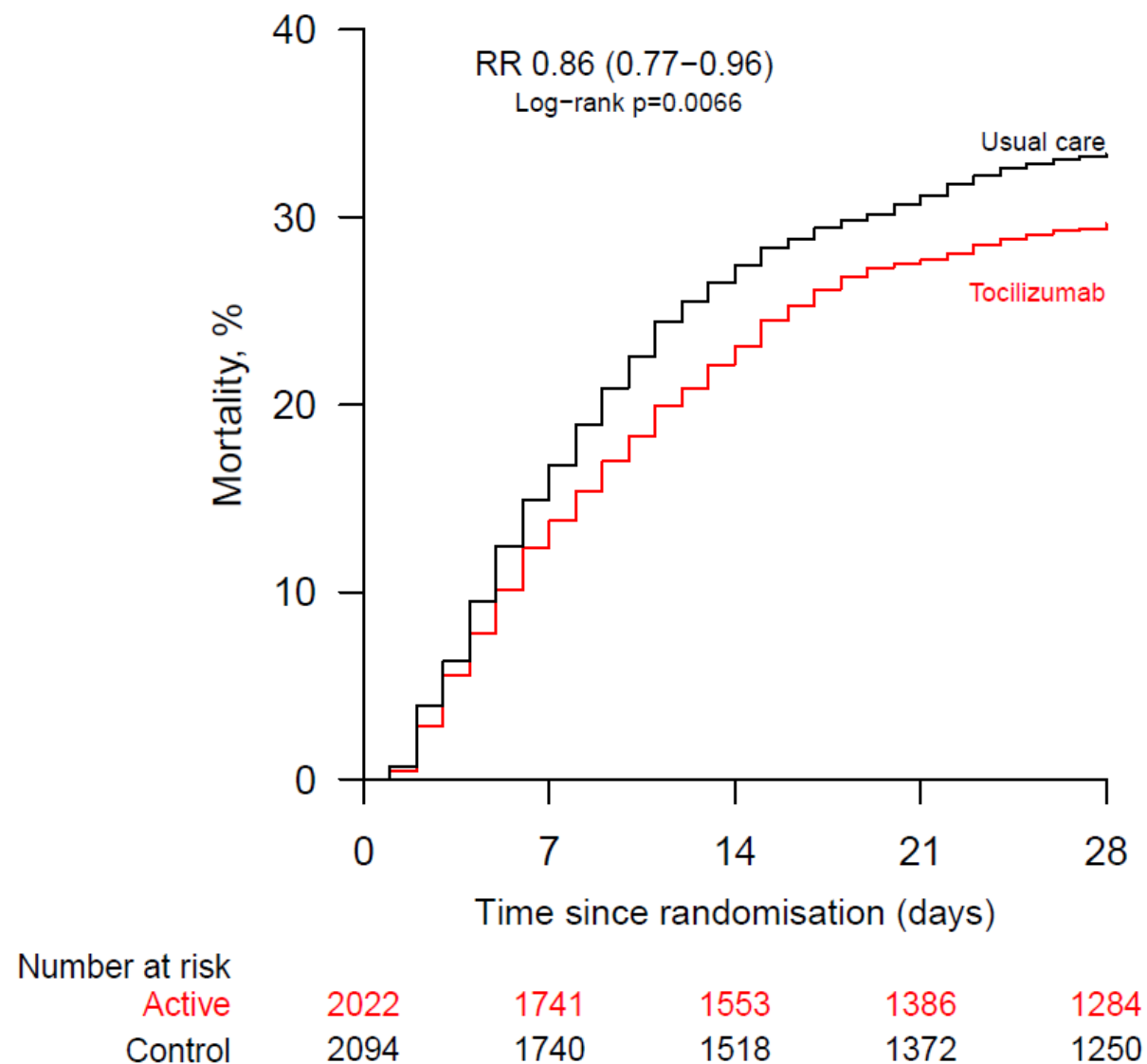


Tocilizumab in RECOVERY

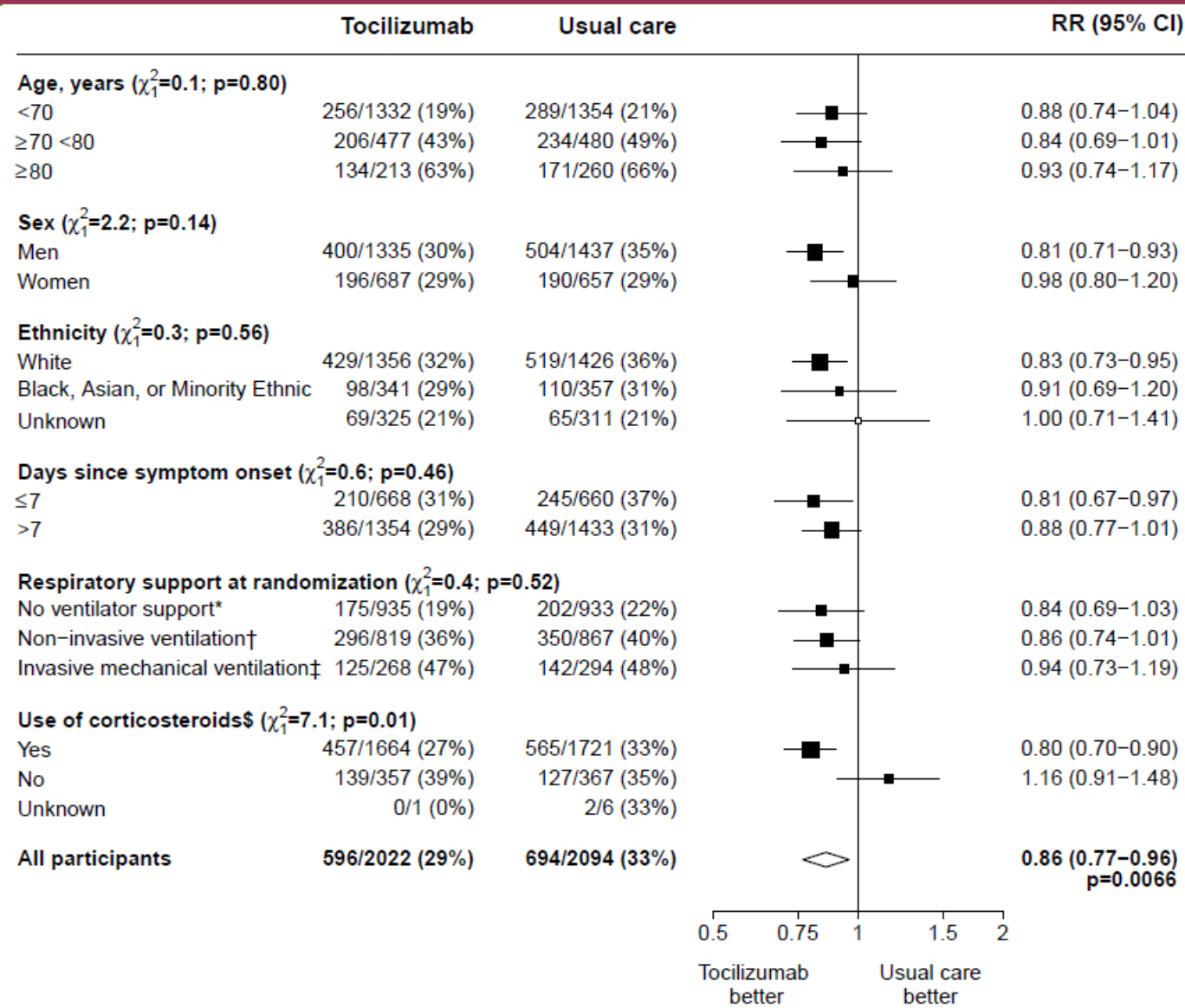


Baseline characteristic (mean [SD] or n [% or IQR])		Tocilizumab (n=2022)	Usual care (n=2094)
Age		63.3 (13.7)	63.9 (13.6)
Male sex		1335 (66)	1437 (69)
Ethnicity	White	1356 (67)	1426 (68)
	BAME	341 (17)	357 (17)
Days since hospitalisation		2 (1-5)	2 (1-5)
Respiratory support	No ventilatory support	935 (46)	933 (45)
	Non-invasive ventilation	819 (41)	867 (41)
	IMV or ECMO	268 (13)	294 (14)
CRP		143 (103-203)	144 (106-205)
Previous comorbidity		1100 (54)	1163 (56)

Primary outcome

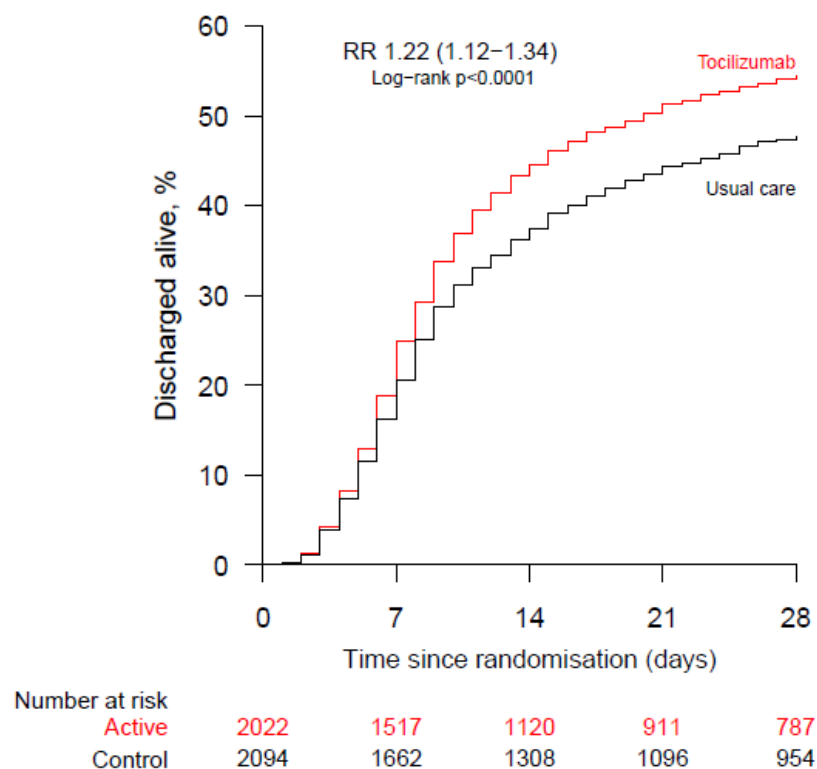


Primary outcome, by subgroups



Secondary outcomes

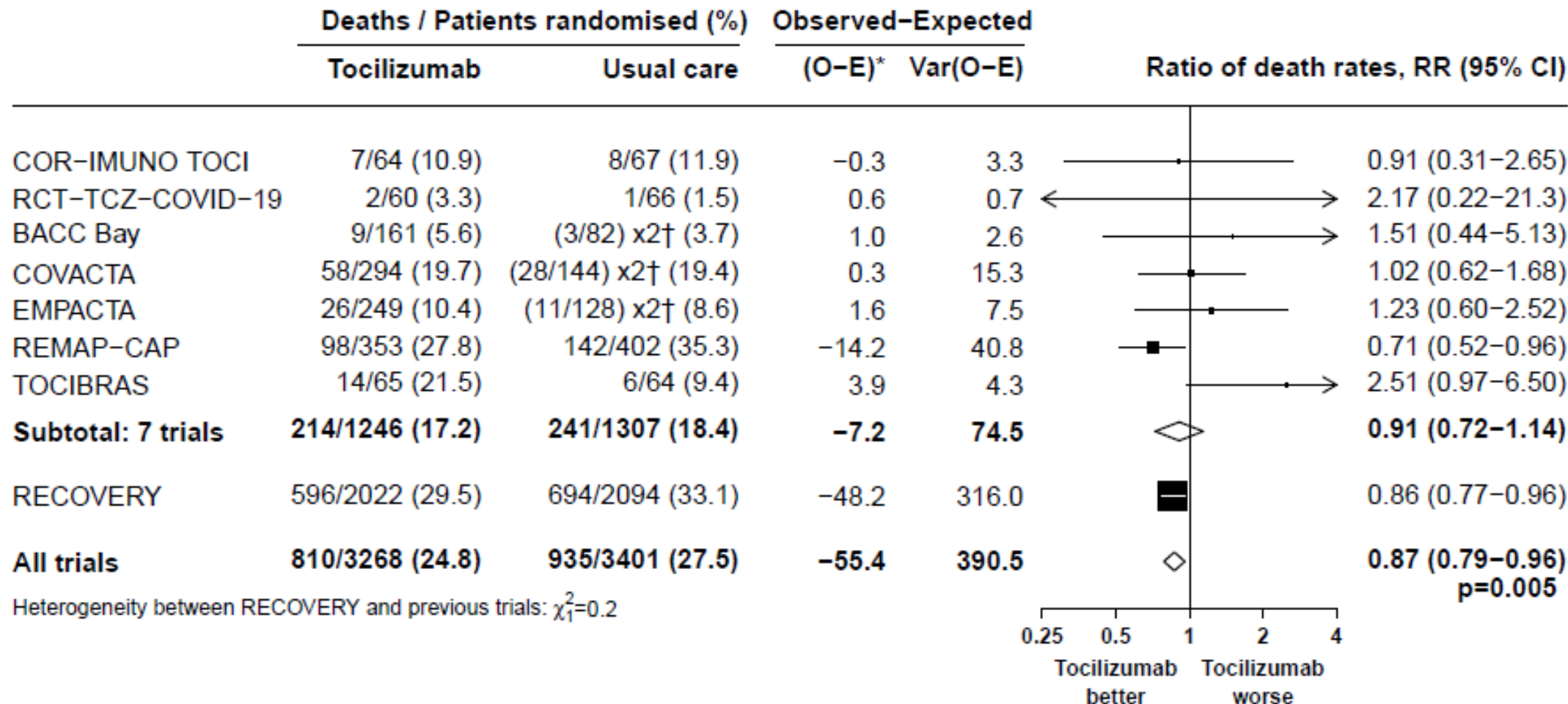
Time to discharge alive within 28 days



Receipt of IMV or death

Outcome		TCZ	Usual care	RR (95% CI)	p
	IMV	215	273	0.81 (0.68-0.95)	0.01
	Death	471	552	0.88 (0.79-0.97)	0.01
IMV or death		571	687	0.85 (0.79-0.93)	0.0005

Totality of evidence to date



REGN-COV2

- 8500 people in comparison to date
- Other data on REGN-COV2 suggests the biggest effect might be expected in antibody negative patients (but these cannot be identified reliably on admission)
- Aim is to recruit 12,000 participants

Serum samples

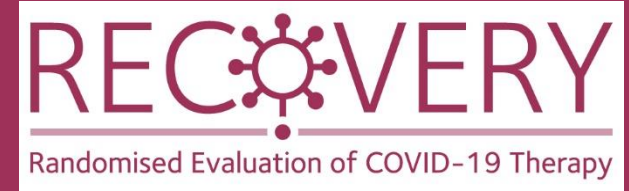
- **All** participants entering REGN-COV2 comparison need to have serum sample collected prior to randomisation
- Must be taken for all participants in that comparison (regardless of allocation)
- **Please check whether any samples have not been returned to the central lab**

NEXT VERSION OF PROTOCOL

Dimethyl fumarate

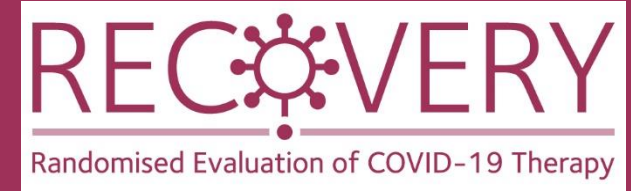
- Licensed for long-term oral immunomodulatory therapy in relapsing-remitting multiple sclerosis and plaque psoriasis
- Proposed modes of action: inhibition of NLRP3 inflammasome activation + anti-viral effect against SARS-CoV-2 *in vitro*
- Immunomodulatory agents have produced best therapeutic results for patients with COVID-19 so far
- Limited current clinical evidence with DMF in COVID-19: no other clinical trials worldwide

Early Phase assessment



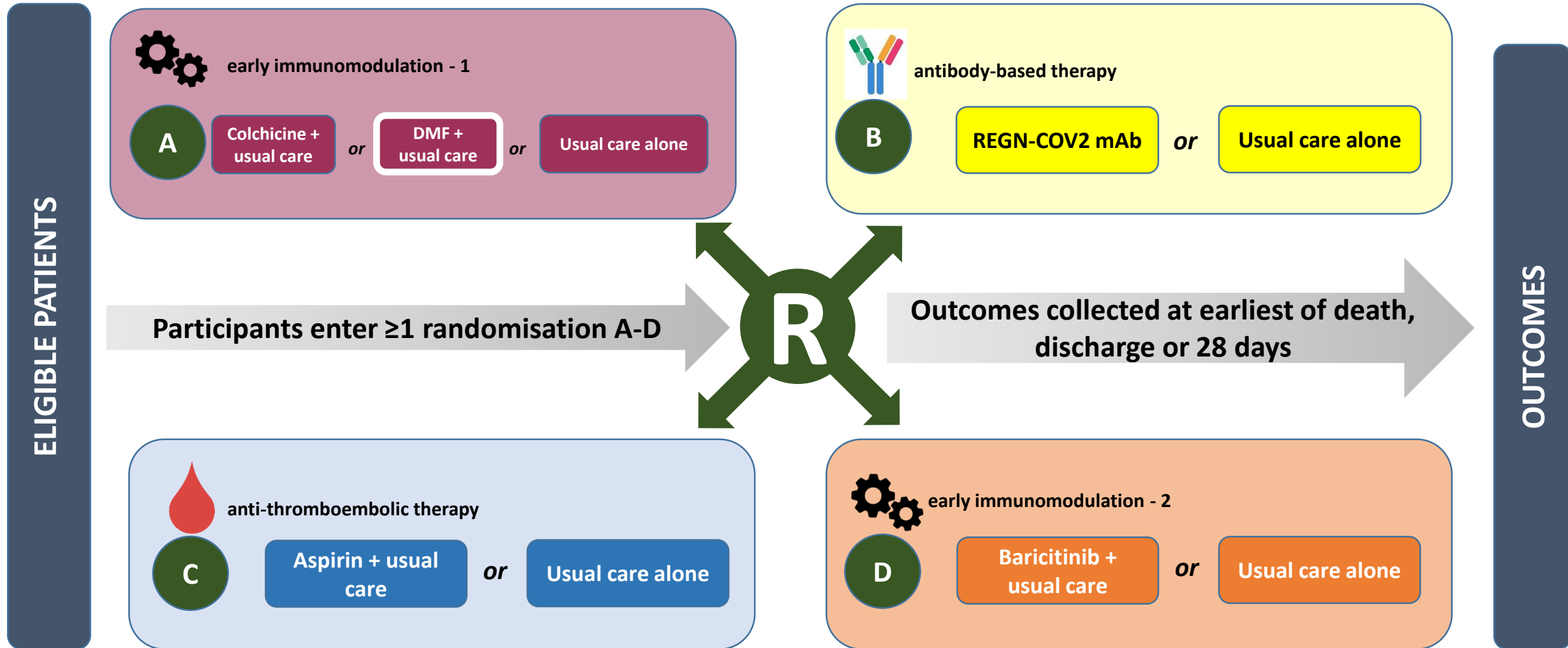
- UK CTAP request for RECOVERY to perform early phase assessment of DMF
- Additional information is required before considering large-scale assessment of impact on mortality
- Estimated to need 400 participants
- Review results for decision as to whether to include in main trial

Early Phase assessment



- Many study procedures as for main trial:
 - Eligibility criteria
 - Consent process and Patient Information Sheet (updated to include DMF information)
 - Randomisation website – DMF included in Part A randomisation for selected sites
 - SSAR reporting
- Specific outcome measures and follow-up form
 - Primary outcome:
 - Non-invasive, bedside measure of patient oxygenation: the S/F_{94} ratio
 - Similarities to $PaO_2:FiO_2$ ratio but not requiring arterial blood gases
 - Other outcome measures:
 - Simple ordinal scale clinical progression score
 - Laboratory results: CRP, Creatinine, ALT/AST
 - Incidence of adverse side effects and treatment adherence

Design including DMF



Plans

- **Site selection:**
 - Initial plan is to roll out this in 3-4 local CRNs
 - Depending on progress and experience, we may contact other sites
- **Drug supply:**
 - Under discussion with DHSC and NHSE
- Aim to start no later than next week

Baricitinib in RECOVERY












- Excellent progress to date
- Change to eligibility criteria around previous or planned tocilizumab use:
 - **No longer contraindicated**
 - May be used together according to clinician discretion
 - Additional information about non-COVID infections will be captured on Follow-up form from now on
- The changes go 'live' from **Wednesday**

TRIAL PROCEDURES

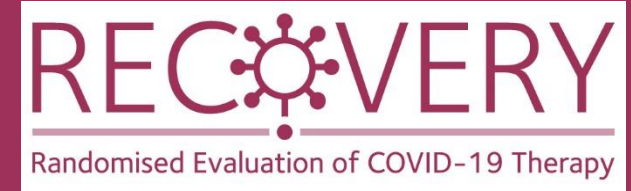
Completeness of follow-up

- Weekly reminders highlighting participants randomised >28 days ago without complete form
- NB 72h antibody safety forms are no longer required

Follow-up form completion summary

Days Since Rand.	 FU Not Completed	 FU Completed	Total Rands.	 Not Completed  Completed
7 ≤ 14	3 (100.0%)	0 (0.0%)	3	
14 ≤ 21	15 (88.2%)	2 (11.8%)	17	
21 ≤ 28	26 (56.5%)	20 (43.5%)	46	
28 ≤ 35	13 (34.2%)	25 (65.8%)	38	
> 35	1 (7.1%)	13 (92.9%)	14	
Total	58 (49.2%)	60 (50.8%)	118	

Carry on recruiting!



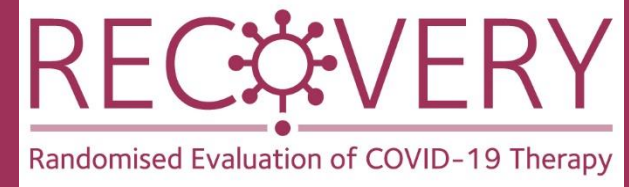
- RECOVERY remains the largest global trial in COVID-19 and is an exemplar of what trials can do (both in and after pandemic)
- Current therapies are exciting, but need reliable data before they should be used routinely
- We need a focus on maximising recruitment now to have answers of national and international relevance
- THANK YOU!

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

22 February 2021

RECOVERY for pregnant women



1. Update on covid-19 and pregnancy
2. Update on adaptations
3. Update on UKOSS
4. Future plans
5. Q&A

Covid-19 and pregnancy

RESEARCH

OPEN ACCESS

Check for updates

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,¹ Kathryn Bunch,¹ Nicola Vousden,² Edward Morris,³ Nigel Simpson,⁴ Chris Gale,⁵ Patrick O'Brien,⁶ Maria Quigley,¹ Peter Brocklehurst,⁷ Jennifer J Kurinczuk,¹ On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

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Cite this as:
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Accepted: 23

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BMJ Yale

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BMJ: first published as 10.1136/bmj.m3305 on 24 August 2020

Comment on this paper

The incidence, characteristics and outcomes of pregnant women hospitalized with symptomatic and asymptomatic SARS-CoV-2 infection in the UK from March to September 2020: a national cohort study using the UK Obstetric Surveillance System (UKOSS)

Covid-19 in pregnancy, ¹Nicola Vousden, Kathryn Bunch, Edward Morris, Nigel Simpson, Christopher Gale, Patrick O'Brien, ²Maria Quigley, Peter Brocklehurst, Jennifer J Kurinczuk, ³Marian Knight

doi: <https://doi.org/10.1101/2021.01.04.21249195>

**Maternal, Newborn and
Infant Clinical Outcome
Review Programme**



MBRRACE-UK
Mothers and Babies: Reducing Risk through
Audits and Confidential Enquiries across the UK

Saving Lives, Improving Mothers' Care

Rapid report: Learning from SARS-CoV-2-related
and associated maternal deaths in the UK

OPEN ACCESS

Check for updates

FAST TRACK

Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis

John Allotey,^{1,2} Elena Stallings,^{3,4} Mercedes Bonet,⁵ Magnus Yap,⁶ Shauna Chatterjee,⁶ Tania Kew,⁶ Luke Debenham,⁶ Anna Clavé Llavall,⁶ Anushka Dixit,⁶ Dengyi Zhou,⁶ Rishab Balaji,⁶ Siang Ing Lee,¹ Xiu Qiu,^{7,8,9} Mingyang Yuan,^{1,7} Dyuti Coomar,¹ Madelon van Wely,¹⁰



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

BMJ: first published as 10.1136/bmj.m3305 on 24 August 2020

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Additional material is published online only. To view please go to the journal online.

Cite this as: *BMJ* 2020;370:m3305

<http://dx.doi.org/10.1136/bmj.m3305>

Accepted: 23 August 2020

COVID-19

Cases, Data & Surveillance

US Cases & Deaths

Cases & Deaths by County

Testing Data in the US

Hospitalizations & Emergency Dept Visits

Serology (Antibody) Surveillance

Data on COVID-19 during Pregnancy: Birth and Infant Outcomes

Updated Feb. 18, 2021 Languages Print

Health departments report cases of COVID-19 to CDC using a form that identifies pregnancy status. State and local health departments have the option of reporting additional information on pregnant women with COVID-19 and their infants. These data are collected as part of CDC's [Surveillance for Emerging Threats to Mothers and Babies Network \(SET-NET\)](#). Data provided below include information about the timing of infection during pregnancy, pregnancy outcomes, and whether the n

[What CDC is d](#)

Check for updates

¹ National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK
² Institute of Applied Health Research, University of Birmingham, Birmingham, UK
³ UK Obstetric Surveillance System Steering Committee, National Perinatal Epidemiology Unit, Oxford, UK
⁴ School of Life Course Sciences, King's College London, London, UK
Correspondence to: L C Chappell
lucy.chappell@kcl.ac.uk
Cite this as: *BMJ* 2020;370:m3305
<http://dx.doi.org/10.1136/bmj.m3305>
Published: 25 August 2020

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight,¹ R Katie Morris,² Jenny Furniss,³ Lucy C Chappell⁴

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting that women are denied investigations and life preserving treatments simply because they are pregnant or breastfeeding.^{1,2} These inquiries emphasise that the default position should be to investigate and treat pregnant and breastfeeding women in the same way as non-pregnant women, unless there are clear reasons not to.¹

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women—meaning data are unavailable

or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals.

Even if regulatory barriers have been overcome, gatekeeping or inertia may occur if local ethics committees take an overwhelming precautionary approach, overriding recognition of the potential benefits of including pregnant and breastfeeding women. This problem can be mitigated by a strong network of maternity researchers, familiar with delivering drug trials in pregnancy, who can be rapidly mobilised to help implement studies.

BMJ: first published as 10.1136/bmj.m3305 on 24 August 2020

Pregnant women – moderate risk group

People at moderate risk (clinically vulnerable)

People at moderate risk from coronavirus include people who:

- are 70 or older
- have a lung condition that's not severe (such as asthma, COPD, emphysema or bronchitis)
- have heart disease (such as heart failure)
- have diabetes
- have chronic kidney disease
- have liver disease (such as hepatitis)
- have a condition affecting the brain or nerves (such as Parkinson's disease, motor neurone disease, multiple sclerosis or cerebral palsy)
- have a condition that means they have a high risk of getting infections
- are taking medicine that can affect the immune system (such as low doses of steroids)
- are very obese (a BMI of 40 or above)
- are **pregnant** – see [advice about pregnancy and coronavirus](#)

Unlike people at high risk, you will not get a letter from the NHS.

Covid-19 and pregnancy: headlines



- Covid-19 affects pregnant women
- No change in additional risk factors previously identified (ethnic minority groups, increasing gestation, higher maternal age, high BMI, pre-existing comorbidities)
- Impact on preterm birth continues to be major impact
- RECOVERY trial is one of few trials to include pregnant women, and has changed clinical practice, including for pregnant women

Covid-19 and pregnancy: RCOG



Royal College of
Obstetricians &
Gynaecologists

Coronavirus (COVID-19) Infection in Pregnancy

Information for healthcare professionals

Version 13: Published Friday 19 February 2021

- Corticosteroid therapy should be considered for 10 days or up to discharge, whichever is sooner; for women who are unwell with COVID-19 and requiring oxygen supplementation or ventilatory support. One suggested steroid regimen is:
 - If steroids are not indicated for fetal lung maturity, oral prednisolone 40 mg once a day, or IV hydrocortisone 80 mg twice daily, for 10 days or until discharge, whichever is sooner.
 - If steroids are indicated for fetal lung maturity, intramuscular dexamethasone 6 mg every 12 hours for four doses, then oral prednisolone 40 mg once a day, or IV hydrocortisone 80 mg twice daily, to complete a total of 10 days or until discharge, whichever is sooner.

- The interleukin-6 receptor antagonist (anti-IL6) tocilizumab has been shown to improve outcomes, including survival, in hospitalised patients with hypoxia (oxygen saturation below 92% on air or requiring oxygen therapy) and evidence of systemic inflammation (C-reactive protein at or above 75 mg/l). Although data for the use of tocilizumab in pregnancy in this situation are limited, there is currently no compelling evidence that tocilizumab is teratogenic or fetotoxic. For women meeting the criteria above (hypoxic with systemic inflammation), the use of tocilizumab should be considered. It is recommended that any decision to treat with anti-IL6 agents should be taken by an MDT to include obstetric and infection specialists, and given if the benefits outweigh the risks.

- Other therapies are being investigated for the management of COVID-19, and pregnant women should be offered the opportunity to enrol in clinical trials (such as the RECOVERY trial) for which they are eligible. Hydroxychloroquine, lopinavir-ritonavir and azithromycin have been shown to be ineffective in treating COVID-19 infection and should not be used for this purpose.

RECOVERY for pregnant women



Site teams

This page contains additional information for RECOVERY site team members. Follow these links for guidance on [randomisation](#) and [how to collect follow-up data](#).

[RECOVERY Privacy Notice for Trial Staff](#)

INTERVENTION INFORMATION

[RECOVERY intervention sheet - colchicine](#)
[RECOVERY intervention sheet - aspirin](#)
[RECOVERY intervention sheet - baricitinib](#)
[RECOVERY intervention sheet - tocilizumab](#)
[RECOVERY Laboratory Standard Operating Procedure \(SOP\) v3](#)

GUIDES FOR SPECIFIC PATIENT GROUPS

[RECOVERY for paediatric patients](#)
[RECOVERY for patients with chronic kidney disease](#)
[RECOVERY for pregnant and breastfeeding women](#)
[RECOVERY and remdesivir](#)

COLLABORATORS' MEETINGS SLIDES

We apologise if you were unable to join the meetings.

25 January 2021	26 January 2021
4 January 2021	5 January 2021
7 December 2020	8 December 2020
16 November 2020	17 November 2020
26 October 2020	27 October 2020
5 October 2020	6 October 2020

Pregnancy information document

RANDOMISED EVALUATION OF COVID-19 THERAPY ([RECOVERY](#))

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Marian Knight

With support of UK Teratology Information Service (Dr Ken Hodson, Medical Director)

	RECOVERY trial protocol	Adaption for pregnancy
Eligibility	Patients are eligible if all of the following are true: i. Hospitalised ii. SARS-CoV-2 infection (clinically suspected or lab confirmed) iii. No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if they were to participate in the trial	Same eligibility
Interventions	First randomisation part A <ul style="list-style-type: none">Colchicine First randomisation part B <ul style="list-style-type: none">Synthetic neutralising antibodies (REGN-COV2) First randomisation part C <ul style="list-style-type: none">Aspirin First randomisation part D <ul style="list-style-type: none">Baricitinib	Interventions for pregnant women <ul style="list-style-type: none">Synthetic neutralising antibodiesAspirin <i>Not recommended in pregnancy</i> <ul style="list-style-type: none">ColchicineBaricitinib
Follow-up/ outcomes	Ascertained at the time of death or discharge or at 28 days after randomisation (whichever is sooner): <ul style="list-style-type: none">➤ Vital status (alive/ dead, with date and presumed cause of death, if appropriate)➤ Hospitalisation status (inpatient/ discharged, with date of discharge, if appropriate)➤ Use of ventilation (none/ previous/ ongoing, with days of use and type, if appropriate)➤ Use of renal dialysis or haemofiltration (none/ previous/ ongoing)	Same follow-up and outcomes, with addition of UKOSS COVID-19 case number (for pregnancy and baby information) to allow later data linkage

Eligibility = same

2.1 Eligibility

Patients are eligible for the study if all of the following are true:

- (i) Hospitalised
- (ii) SARS-CoV-2 infection (clinically suspected¹ or laboratory confirmed)
- (iii) No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial

- Hospitalised, with symptoms (no criterion for 'requiring oxygen')

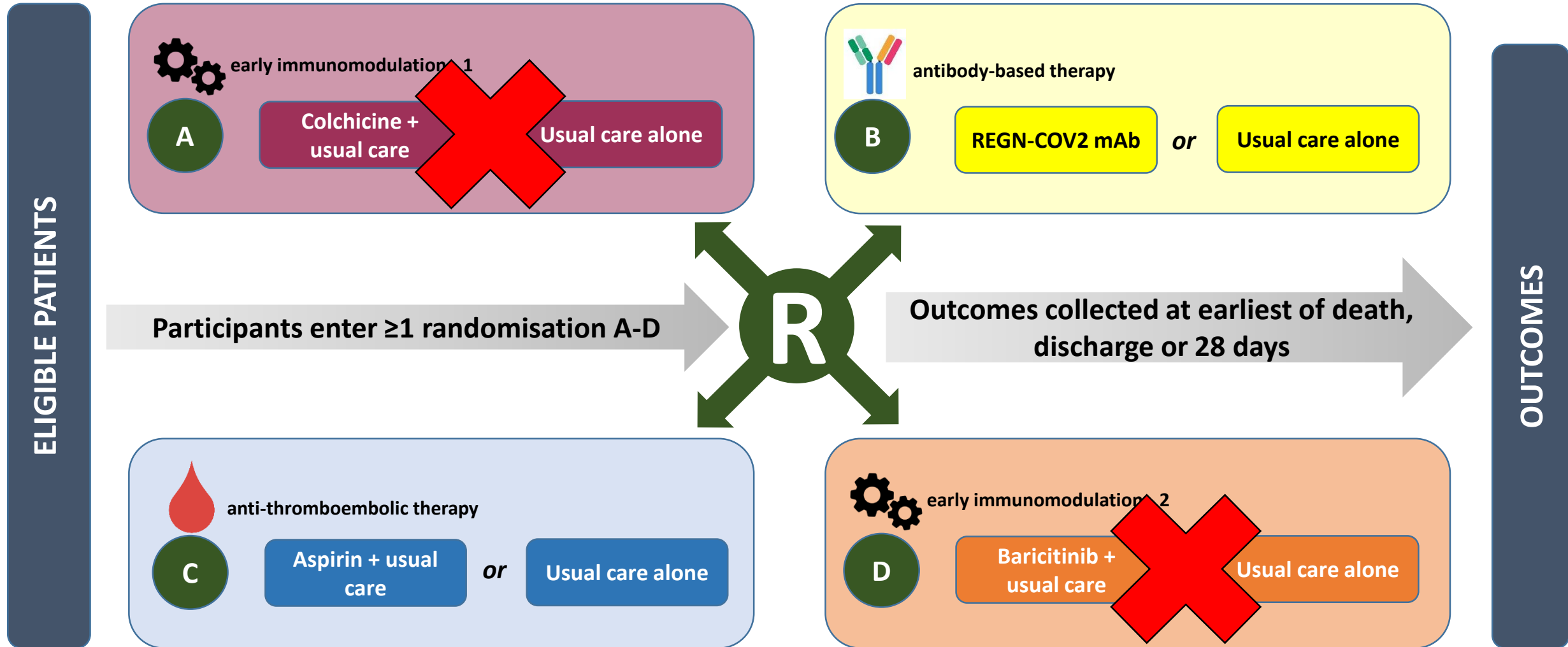
Offer the RECOVERY trial if...



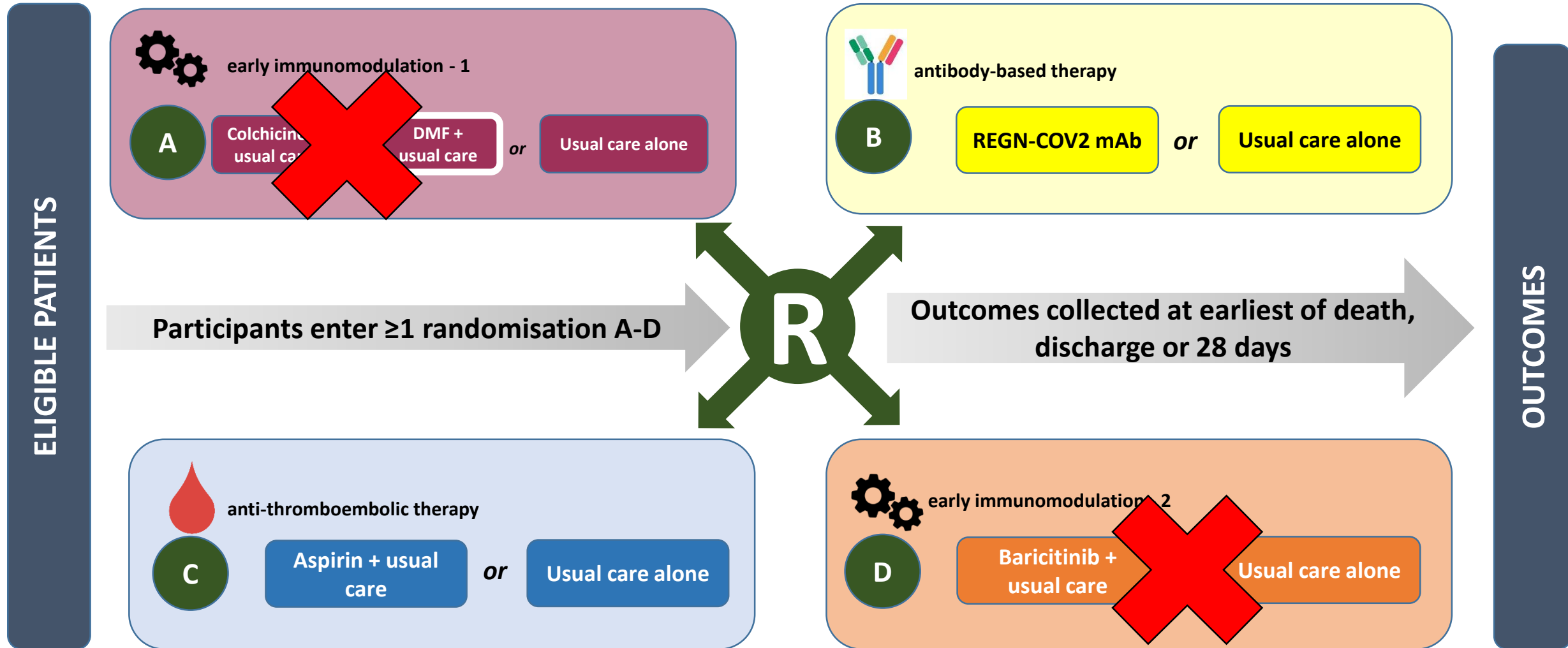
- Are you uncertain about the benefits of treatment or not for this woman, and whether it might 'treat' or prevent deterioration?
- If you are uncertain, then provide the trial information to the woman, offer the trial and make a shared decision.
- **For any woman reportable to UKOSS, ask yourself whether you can offer her participation in RECOVERY**

Interventions = almost the same

Current design (adults)



Design including DMF



Live infant vaccines possible after REGN

The previous version (V12.1) of the RECOVERY protocol stated: *Pregnant women that are administered REGN10933 and REGN10987 must be advised that live vaccines should be avoided in children with in utero exposure to biologics for at least the first 6 months of life.* This sentence has now been deleted, following review of the biological rationale. The synthetic monoclonal antibodies (REGN10933+REGN10987) bind to the SARS-CoV-2 spike protein on the surface of cells, blocking the interaction between the spike protein and its canonical receptor angiotensin-converting enzyme 2. There are no human protein targets of the Regeneron monoclonal antibodies. This is in contrast to infliximab, a biologic drug implicated in a single case report of a 4 month old infant in London who died of probable disseminated TB following maternal infliximab use in pregnancy and infant BCG vaccination at 3 months of age.[7] Infliximab targets human TNF-alpha, such that if used in later pregnancy, the immune system of the neonate may be compromised, leading to potential systemic disease following administration of live vaccines. Regeneron monoclonal antibodies are similar in type to other immunoglobulins that are commonly given in pregnancy such as anti-D, varicella zoster immunoglobulin etc., for which an advisory warning against live vaccine administration in the infant is not required. Therefore, women do not need to be advised that live vaccines should be avoided in their infant following administration of these synthetic monoclonal antibodies.

Follow-up = the same, + linkage



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COVID-19 in Pregnancy



Key points

- Covid-19 is an infectious disease caused by a new strain of coronavirus.
- Covid-19 had not been detected in humans before the outbreak in December 2019.
- As the virus is new, little is known about its effect on certain groups of people, including pregnant women.

Surveillance period

1st March 2020 – 31st March 2021

Background

On this page

- [Key points](#)
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- [Objective](#)
- [Research questions](#)
- [Case definition](#)
- [Funding](#)
- [Ethics committee approval](#)
- [Study registration](#)
- [Lead investigator](#)
- [Download the Data Collection Form \(DCF\)](#)
- [References](#)

Update on progress



- 160 pregnancy leads identified, supported by research midwives
- Midwife champions on board
- 105 antenatal women recruited
- ≈20 (or more) postpartum women

Thank you



Ashford and St Peter's Hospitals NHS Foundation Trust	Kingston Hospital NHS Foundation Trust	Pennine Acute Hospitals NHS Trust
Barts Health NHS Trust	Leeds Teaching Hospitals NHS Trust	Royal Berkshire NHS Foundation Trust
Bolton NHS Foundation Trust	Liverpool University Hospitals NHS Foundation Trust	Royal Free London NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust	Liverpool Women's NHS Foundation Trust	Sheffield Teaching Hospitals NHS Foundation Trust
Calderdale and Huddersfield NHS Foundation Trust	London North West University Healthcare NHS Trust	Sherwood Forest Hospitals NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust	Luton and Dunstable University Hospital NHS Foundation Trust	Shrewsbury and Telford Hospital NHS Trust
Chelsea and Westminster Hospital NHS Foundation Trust	Manchester University NHS Foundation Trust	St George's University Hospitals NHS Foundation Trust
Chesterfield Royal Hospital NHS Foundation Trust	Medway NHS Foundation Trust	The Newcastle Upon Tyne Hospitals NHS Foundation Trust
County Durham and Darlington NHS Foundation Trust	Milton Keynes University Hospital NHS Foundation Trust	The Royal Wolverhampton NHS Trust
Croydon Health Services NHS Trust	NHS Greater Glasgow and Clyde: Glasgow Royal Infirmary	United Lincolnshire Hospitals NHS Trust
Epsom and St Helier University Hospitals NHS Trust	NHS Lothian: Royal Infirmary of Edinburgh	University College London Hospitals NHS Foundation Trust
Frimley Health NHS Foundation Trust	North Cumbria Integrated Care NHS Foundation Trust	University Hospitals Of Leicester NHS Trust
Great Western Hospitals NHS Foundation Trust	North Tees and Hartlepool NHS Foundation Trust	Western Sussex Hospitals NHS Foundation Trust
Guy's and St Thomas' NHS Foundation Trust	North West Anglia NHS Foundation Trust	Wirral University Teaching Hospital NHS Foundation Trust
Imperial College Healthcare NHS Trust	Northampton General Hospital NHS Trust	Worcestershire Acute Hospitals NHS Trust
James Paget University Hospitals NHS Foundation Trust	Northumbria Healthcare NHS Foundation Trust	Wrightington, Wigan and Leigh NHS Foundation Trust
Kettering General Hospital NHS Foundation Trust	Nottingham University Hospitals NHS Trust	Wye Valley NHS Trust
King's College Hospital NHS Foundation Trust	Oxford University Hospitals NHS Foundation Trust	

Update from UKOSS this week



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Medical Sciences Division

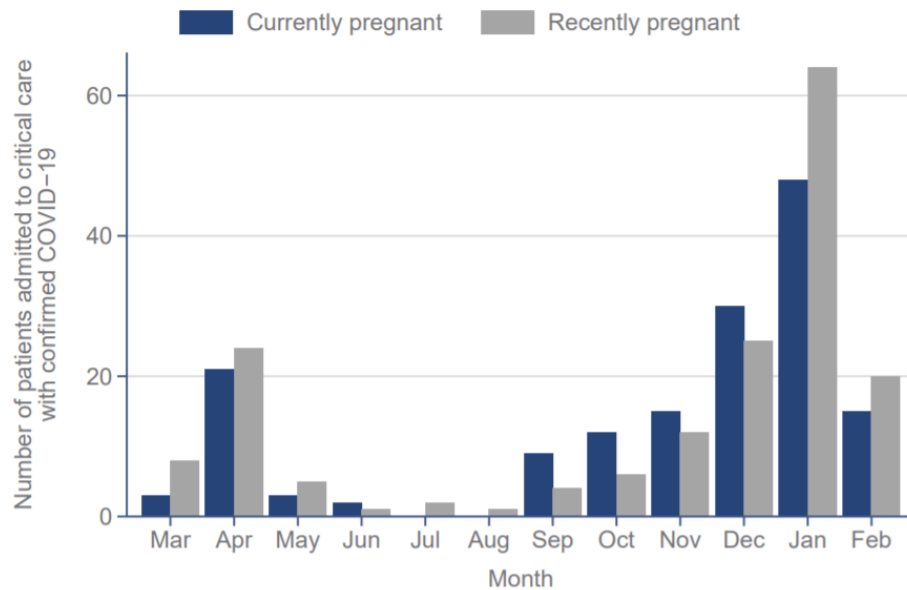


Notifications by week



ICNARC data (critical care)

ICNARC report on COVID-19 in critical care: England, Wales and Northern Ireland 19 February 2021

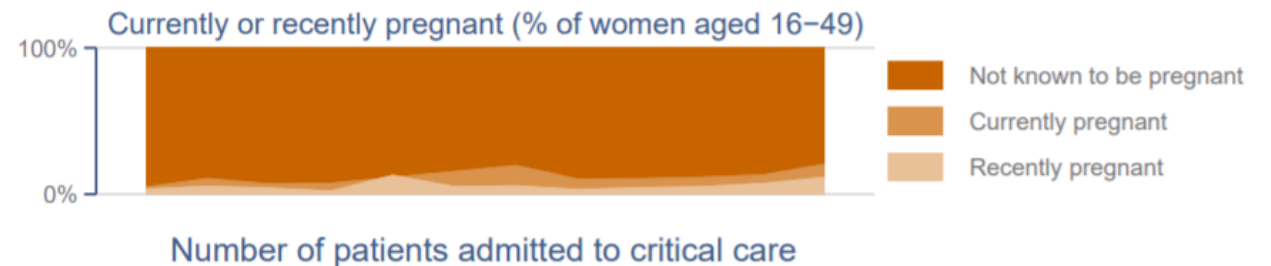


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Figure 35. Numbers currently and recently pregnant

Monthly trend in the number of women reported to be currently or recently pregnant on admission to critical care.

Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=22,695)	Admitted up to 31 Aug (N=10,928)
Currently or recently pregnant, n (% of females aged 16-49) [N=1919]		
Currently pregnant	128 (6.7)	29 (3.7)
Recently pregnant (within 6 weeks)	131 (6.8)	41 (5.2)
Not known to be pregnant	1660 (86.5)	720 (91.1)



Feedback from sites



- Many sites seeing more asymptomatic women
- Admissions of symptomatic women continue
- Sites liaising with their main RECOVERY research teams
- Maternity healthcare professionals providing input into care of pregnant women on general wards

PLEASE:

- Use UKOSS as prompt to help (and for outcomes)
- **Please add UKOSS number to ALL RECOVERY women recruited**
- Embed into usual practice
- Offer trial

Q&A