

Update on COVID-19 research in Suffolk – 10/12/2020

Key Updates:

[637,379 participants from across the UK have now taken part in public health research into the effects of, and treatment for, COVID-19 in just over 8 months.](#)

- The **Novavax** study reached the **national target of 15,000 participants**. A huge effort from the three Eastern sites (NNUH, ESNFT, and one GP practice in Cambridgeshire) resulted in 781 volunteers being recruited in less than 2 months. The NNUH hosted the trial at their Clinical Trials Unit (as recently featured on BBC Look East) with support from the CRN and staff from local Trusts. The team at NNUH in collaboration with the CRN have formed a patient panel to support the trial in Norfolk and Waveney and have collected feedback in real time from participants to provide insight into their experience of taking part in the study which to help inform the continued delivery of the study and to inform the delivery of future vaccine studies.
- **Information for people interested in vaccine studies in light of news about other promising COVID vaccines**
Information for patients and the public has been issued on the [NIHR Be Part of Research](#) website, highlighting the importance of continuing participation in all ongoing and future COVID-19 studies to gain better understanding of the disease as well as the effectiveness of the vaccines. There is a useful Q&A section about what the developments mean for [those](#) taking part, or considering taking part in vaccine studies – this information will be updated on an ongoing basis and specific information is being prepared for participants in individual trials such as the Novavax study.
- **NEW! RECAP (REmote Covid Assessment in Primary Care)**. This research aims to develop a score for GPs to use when assessing how badly a patient is affected with COVID, to use over the phone or by video consultations. The most widely used 'early warning score' is NEWS2 but this wasn't designed for use in COVID, and it's a hospital score. The research team will use features of COVID that are known to be markers of more serious disease.
Practices need to be signed up to the Royal College of GPs (RCGP) Research Surveillance Centre (RSC) network to participate in this trial. More information and how to join [on the RCGP website](#). Some practices have already been approached directly by the RSC, others are being contacted by Clinical Research Network Eastern. More information can be found on the [RECAP website](#).
10 practices in Eastern have been greenlighted for this study so far.
- **Virus Watch Study**

The first set of preliminary findings from the Virus Watch [study were published here on the study website](#) on Wednesday 25 November. These results have also been shared with all 43,000+ participants that are taking part in the study.
The study is being supported by Primary care teams in the Eastern region now offering appointments to participants in round 3 of the blood sampling cohort and GPs recently sending text messages to their patients to promote the study.
- **The RECOVERY trial updates:**

The **Azithromycin** arm closed on 27 November, and the results of data analysis should be available soon.
Colchicine, a commonly used anti-inflammatory treatment, has been added to the study in order to be investigated. Colchicine has a wide range of anti-inflammatory effects and

has been used for centuries to treat gout and, more recently, other inflammatory conditions.

The RECOVERY trial has been selected as one of ten finalists in the Special COVID-19 response category in the 2020 National Project Awards. The award specifically recognised RECOVERY’s work to investigate whether the cheap steroid dexamethasone was an effective treatment for patients hospitalised with severe COVID-19. The trial compared over 2100 patients who received dexamethasone and usual standard-of-care with more than 4,300 patients who received usual standard-of-care alone. On 16 June, the trial announced the [result that dexamethasone reduces death by up to a third for severely ill COVID-19 patients](#). Dexamethasone is now recommended for COVID-19 patients worldwide, potentially saving many thousands of lives. The public vote is now open.

The tables below give an overview of all COVID-19 research activity across Suffolk. Please note that this information is provided for reference only and not for external publication.

Primary Care Studies

	Study Title	Study aim	Study setting	Local status		Recruitment ^[1]
1	<p>Principle: Platform randomised trial of Interventions against Covid-19 with older people https://www.phctrials.ox.ac.uk/principle-trial</p>	<p>To test different medications to see whether this reduces the need for hospitalisation or will speed up recovery in older patients (65+ or 50-64 with a pre-existing condition) hydroxychloroquine – recruitment paused Azithromycin – recruitment started Other medications may be added to the trial at a later point.</p>	Primary Care	<p>Sites activated: Suffolk: The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive Haven Health Derby Road</p>	<p>NEE: Colchester Medical Practice Castle Gardens Medical Centre; Parsons Health Medical Centre; Shrub End Surgery; Wimpole Rd Surgery; Great Bentley Surgery Ambrose Group</p>	<p>23 across Suffolk & NEE Nationally: 2,473 Study is now looking to engage care homes</p>

^[1] Data collected from national research database – figures may lag behind actual figures

					Ardleigh Colne Medical Practice West Mersea Rowhedge Riverside	
2	FLU-CATS: Evaluation and refinement of pandemic influenza community assessment tools	An observational study of pandemic influenza community assessment tools which is being amended to pick up COVID-19 patients	Primary care	Awaiting revised protocol for COVID-19		Not yet set up
3	VIVALDI COVID-19 in care homes	An observational study to understand SARS-COV-2 infection immunity and its duration in care home staff and residents in the uk	Care Homes	3 care homes in Suffolk / NEE are signed up.		North Court Care Home: 26 Catchpole Court Care Home: 36 Kingfisher House Care Home: 50 Local recruitment – 26 Nationally: 3,760
4	NEW RECAP (REmote Covid Assessment in Primary Care).	This research aims to develop a score for GPs to use when assessing how badly a patient is affected with COVID, to use over the phone or by video.	GPs and practices	Being set up across UK and Eastern		No recruits showed yet

Cross Sector Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ^[2]
1	Chloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study (COPCOV) http://copcov.org/	The aim of the study is to determine if hydroxychloroquine prophylaxis prevents symptomatic COVID-19 infection in front-line health care workers.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	East Suffolk and North Essex NHS Foundation Trust selected to participate; WSH in set-up	MHRA approved study to restart Nationally recruited: 88
2	CROWN CORONATION Chloroquine Repurposing to healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i>	The aim of the study is to determine the effectiveness of chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in healthcare workers at risk of SARS-CoV-2 exposure.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	ESNFT expected to take part	Not yet set up
3	Virus Watch	An observational study into understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour.	All sectors expected to be involved in collection of serum samples for participants	Sites to be confirmed	Not yet set up

^[2] Data collected from national research database – figures may lag behind actual figures

			ng households in Part 2 of the study. Part 1 is managed centrally		
4	Multi-centre European study of MAJOR Infectious Disease Syndromes (MERMAIDS): Acute Respiratory Infections in Adults	An observational study aims to identify host and pathogen related determinants of severity of community acquired acute respiratory infections in adults.	This study will enrol participants in both primary care and secondary care.	Trusts invited for expression of interest	Not yet set up Nationally: 47
5	Behavioural Activation in Social Isolation (BASIL-C19)	This study is part of the MODS (Multi-Morbidity in Older adults with Depression Study) programme, looking at whether a talking treatment called Behavioural Activation (BA) can help improve a person's physical and psychological functioning, for example self-care and mood. The study is asking 'can we prevent or ameliorate depression and loneliness in older people with long term conditions who are under enforced COVID-19 isolation?'	Looking for Trust sites; with potential cross-sector involvement with primary care	Trusts invited for expression of interest	Not yet set up
6	Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (PHOSP-COVID)	The aim is to understand and improve long-term outcomes for survivors of hospitalisation with COVID-19. The PHOSP-COVID study is aligned to the clinical follow-up provided, but does not alter clinical care.	TBC	TBC	Not yet set up
7	Psychological Impact of COVID-19 N.B. the study adopted on NIHR portfolio but	A survey to explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors.	Advertised through social media via local Trusts and CCGs	Norfolk & Suffolk NHS foundation Trust (NSFT)	NSFT: 104

	not badged with urgent public health status				
8	Novavax COVID Vaccine study – A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine	12-month placebo controlled trial to evaluate the safety and efficacy of the Novavax Vaccine in adults 18-84.	Study based at ESNEFT and supported by Primary Care team	ESNEFT; recruitment completed	ESNEFT: 168 Nationally: 15,203

Secondary Care Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ^[3]
1.	RECOVERY : Randomised Evaluation of COVID-19 Therapy	To test if existing or new drugs can help patients hospitalised with confirmed COVID-19; The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including: Lopinavir-Ritonavir (arm closed-shown no clinical benefit; read more here), Interferon β , corticosteroids^[4] , and Remdesivir, Hydroxychlor	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 80 Ipswich Hospital: 162 Nationally : 20,132

^[3] Data collected from national research database – figures may lag behind actual figures

^[4] Corticosteroids used in the trial are expected to be sourced by local pharmacy procurement team via their normal routes, all other medications for RECOVERY sourced centrally via PHE

		<p>oquine (arm closed; read more here), Tocilizumab, Dexamethasone, convalescent plasma. Other treatments may soon emerge that require evaluation. The supply arrangements for each medicine for RECOVERY trial are described here.</p>			
2	<p>RECOVERY-RS (Respiratory support)</p> <p>https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/</p>	<p>This study is aiming to determine if CPAP (continuous positive airway pressure) or HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO).</p>	Secondary care	Open sites: Ipswich Hospital Colchester WSH	ESNEFT:7 Nationally : 546
3.	<p>Re-MAP Cap: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia</p> <p>https://www.remapcap.org/</p>	<p>The trial will look at a number of different treatment categories with an aim to determine the best clinically effective treatment for</p>	Secondary care/ICUs	All sites running RECOVERY study are invited to participate	ESNFT (Colchester Hospital) :11 Nationally : 1,936

		adult patients with CAP admitted to participating intensive care units with suspected or microbiological testing confirmed COVID-19 infection.			
4.	CCP-UK Clinical Characterisation Protocol for Severe Emerging Infection' study/(ISARIC-4C)	An observational study collecting samples and data from confirmed COVID-19 patients	Secondary care	All acute Trusts in the Eastern region activated;	ESNFT: 910 WSH: 292 Nationally : 114,906
5.	UKOSS: Pandemic Influenza in Pregnancy https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy	An observational study via the UK Obstetric Surveillance System to collect information on pregnant women admitted to hospital with confirmed COVID-19	Secondary care / Trusts with Maternity Units	Open sites: Colchester; Ipswich hospitals; WSH	No recruitment data showing
6.	GenOMICC Genetics of susceptibility and mortality in critical care	An observational study to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury.	Secondary care	Ipswich Hospital open WSH reviewing	Ipswich Hospital: 23 WSH:1 Nationally : 6,399

7.	Coronavirus infection in primary or secondary immunosuppressed children.	An observational study designed to allow families of immunosuppressed children and young people to self-record their experiences of COVID-19 and other viral respiratory illnesses during the COVID-19 epidemic.	Secondary care	Not open to new sites currently	Recruitment now complete Nationally recruited: 1,633
8.	PAN COVID : Pregnancy and Neonatal Outcomes in COVID-19 https://pan-covid.org/	A global registry of women with suspected or confirmed SARS-CoV-2 infection in pregnancy and their neonates, understanding natural history to guide treatment and prevention	Secondary care	Open sites: WSH ESNFT (Ipswich & Colchester)	ESNEFT: 26 West Suffolk: 2 Nationally : 4,579
9.	Neonatal Complications of Coronavirus Disease (COVID-19) Study	This is a national surveillance programme using the standard British Paediatric Surveillance Unit (BPSU) approach. This study will run alongside and be cross-linked with	Secondary care	Open sites: WSH	There will be no consenting (no recruits) for this study as linked to another study

		the maternal surveillance study run through the United Kingdom Obstetric Surveillance System (UKOSS; CPMS: 14162), which is already in progress.			
10.	TACTIC-R (Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs)	The TACTIC-R clinical trial is testing whether existing drugs, which are already used to treat other immune-related conditions, can prevent the development of severe symptoms in patients hospitalised with confirmed/strongly suspected COVID-19. This approach, known as repurposing, is a way of finding out whether existing therapies, which are likely to be readily available in	Secondary care	Several sites in Eastern are being set up Opened sites: WSH	WSH: 1 Nationally recruited: 137

		hospitals, are effective in treating the disease.			
1 1.	SIREN: Sarscov2 Immunity & REinfection Evaluation - The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers	An observational study which aims to find out whether healthcare workers who have evidence of prior COVID-19 infection, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection. For SARS CoV2 infection it is not yet known if the detection of antibodies protects people from future infection. This study aims to provide this very important information, which will help to understand	Secondary care	Currently is being set up in secondary care – all trusts expected to take part as part of Trust wide antibody screening processes Open sites: WSH ESNEFT	WSH: 500 ⁵ ESNEFT: 484 Nationally recruited: 29,483

		the future impact of COVID-19 on the population.			
1 2	NHS CHECK: Health & Experiences of staff working at NHS Trusts and Nightingale Hospitals https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff	Aims to establish a cohort of NHS-affiliated staff to investigate the short, medium and longer term psychosocial impact of the COVID-19 pandemic on staff performance and wellbeing. NHS staff will be invited to participate, to complete an online survey module and an intervention evaluation module	Secondary care	Open sites: ESNEFT	ESNEFT: 356 Nationally recruited: 23,598

⁵Local update

A full list of all DHSC priority COVID-19 studies can be found at <https://www.nihr.ac.uk/covid-studies/>

Gosia Majsak-Newman
Research & Development Officer/ NIHR GCP Facilitator

Norfolk and Suffolk Primary and Community Care Research Office
NHS Norfolk and Waveney Clinical Commissioning Group | Lakeside 400, Broadland Business Park |
Norwich NR7 0WG |

Mobile: 07552 008271

E-mail: g.majsak-newman@nhs.net
Team email: nwccg.RandDoffice@nhs.net
Website: <http://nspccro.nihr.ac.uk>

Follow us on Twitter [@NHS_NSResearch](https://twitter.com/NHS_NSResearch)

The Norfolk & Suffolk Primary & Community Care Research Office at NHS Norfolk and Waveney CCG undertakes research management, design and delivery services for Primary and Community Care across Norfolk & Suffolk.