

Performance in Initiating Clinical Trials Q4 2020-2021
First participant recruited

Ethics Committee Number	IRAS Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site confirmed by Sponsor	Date Site confirmed	Date Site Ready to Start	Date of First Patient Recruited	Source of Delay	Comments
20/SC/0158	281958	Platform Randomised trial of INterventions against COVID-19 In older peoPLE	30/06/2020	30/06/2020	26/03/2020	16/09/2020	14/09/2020	03/12/2020			
20/SW/0086	1003226	A Phase 2, Randomized, Double-Blind, Multiple-Dose, Placebo-Controlled Study to Evaluate the Safety and	02/07/2020	02/07/2020	01/07/2020	24/08/2020	24/08/2020	04/01/2021			
19/LO/1354	262807	Internet-delivered Cognitive Therapy (iCT) for young people with Post-Traumatic Stress Disorder (PTSD) - feasibility randomised controlled trial	10/07/2020	10/07/2020	07/01/2020	17/09/2020	17/09/2020	17/09/2020			
19/EE/0177	260067	HOMESIDE: A home-based family caregiver-delivered music intervention for people living with dementia: a randomised controlled trial	02/07/2020	02/07/2020	14/08/2019	18/08/2020	22/09/2020	22/09/2020	14/01/2021	Both NHS and Sponsor	Delay - site capacity issues and sponsor delays.
20/NW/0399	288793	A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1 Adjuvant in Adult Participants 18-84 Years of Age in the United Kingdom	24/09/2020	24/09/2020	23/09/2020	08/10/2020	08/10/2020	09/10/2020	14/10/2020		
20/NS/0049	279374	Online treatment of sleep (Sleepio) to improve adolescent mental health: a first step intervention.	17/04/2020	20/04/2020	17/04/2020	11/06/2020	13/08/2020	13/08/2020	20/10/2020		
20/SC/0281	281235	Treating sleep problems in young people at ultra-high-risk of psychosis: a feasibility randomised controlled trial	19/08/2020	19/08/2020	19/08/2020	09/11/2020	09/11/2020	09/11/2020	09/12/2020		
20/LO/1044	287176	A Randomized, Double-Blind, Placebo-controlled Study Evaluating the Efficacy and Safety of SAGE-217 in the Treatment of Adults with Severe Postpartum Depression	02/09/2020	02/09/2020	25/11/2020	29/01/2021	29/01/2021				Site declined to participate - national approvals outstanding.
20/LO/0853	275697	Multisite Randomised Controlled Trial of Trauma-Focused Cognitive Behaviour Therapy for psychosis to reduce post-traumatic stress symptoms in people with co-morbid post-traumatic stress disorder and psychosis, compared to Treatment as Usual: the STAR (Study of Trauma And Recovery) trial	19/08/2020	19/08/2020	24/07/2020	09/11/2020	09/11/2020	09/11/2020	02/12/2020		
20/HRA/4431	288074	Child Anxiety Treatment in the context of COVID-19 (Co-CAT): Enabling Child and Adolescent Mental Health Services (CAMHS) to provide efficient remote treatment for child anxiety problems	02/09/2020	22/09/2020	04/09/2020	27/08/2020	19/11/2020	23/11/2020	06/01/2021		
19/SC/0572	252332	Evaluating an early social communication intervention for young children with Down syndrome (ASCEND): a feasibility study	14/10/2020	25/11/2020	05/06/2020	05/11/2020	09/12/2020	09/12/2020	03/12/2020		

Performance in Initiating Clinical Trials Q4 2020-2021
 First participant recruited

Ethics Committee Number	IRAS Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site confirmed by Sponsor	Date Site confirmed	Date Site Ready to Start	Date of First Patient Recruited	Source of Delay	Comments
18/LO/0575	213457	A Validation Study of a computerized, Artificial Intelligence assisted cognitive assessment test compared to a widely used cognitive assessment test and specialist clinical diagnosis in patients with Alzheimer s Dementia and Mild Cognitive Impairment	06/01/2021	06/01/2021	16/05/2018	09/03/2021	09/03/2021	17/03/2021	05/05/2021		