

Summary of Open Studies and Studies in Set Up by Service Area in Berkshire Healthcare for FY2021/22

COVID-19 – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio status	Study end date
<p>PRINCIPLE (PI – Dr Sandeep Sandhu)</p>	<p>As yet, there are currently no known treatments for COVID-19 that have been proven to be effective. Our trial aims to evaluate potential treatments as they are identified. To be able to do this, we aim to test one or more suitable, potential treatments for COVID-19, as soon as they become available.</p> <p>We will evaluate drugs that are well known and have been used for many years around the world. We aim to find out whether selected treatments given to those at higher risk of becoming more ill when they are infected with COVID-19 helps reduce the need for hospitalisation and the length of stay required, helps people recover quicker and get fewer complications.</p>	2020-17	Portfolio	25/03/2022
<p>Virus Watch (PI – Dr Sanjoo Chengappa)</p>	<p>The Virus Watch study will recruit a community cohort of 25,000 across England. In this population we will measure the frequency of respiratory infection syndromes and related behaviours. Through linkage with NHS Digital, we will measure the impact of infections on hospitalisations and deaths.</p> <p>In a nested sub-cohort of 10,000, we will measure the incidence of PCR confirmable COVID-19, its clinical symptom profiles, the proportion of the population infected after each wave of the pandemic and the protective effect of antibodies acquired through natural infection. In a subset of people, we will conduct a household contact follow up survey & PCR to measure the extent of pre-symptomatic and asymptomatic viral shedding in household contacts.</p> <p>We will also monitor population movement and assess the extent to which public contact increases the risk of infection.</p>	2020-30	Portfolio	30/09/2021 (In follow up)

<p>Child Anxiety Treatment in the Context of COVID-19 (CO-CAT) (LC – Emma Donaldson)</p>	<p>This study worked with children, parents, and NHS clinicians to develop a brief online parent-led cognitive behavioural treatment (CBT) delivered by the OSI platform that parents/carers of children with anxiety disorders work through with remote support from a CAMHS therapist. We will now test whether access to the OSI platform together with therapist support works as well as what CAMHS are otherwise offering to help children with anxiety problems (whatever this might be while social distancing measures are in place and in the post COVID-19 recovery phase), and whether OSI as delivered with therapist support brings economic benefits. We will also provide an understanding of parents' and therapists' experiences of digital treatments in CAMHS in the context of COVID-19.</p>	<p>2020-38</p>	<p>Portfolio</p>	<p>30/08/2021</p>
<p>BASIL-C19 (PI – Nick Woodthorpe)</p>	<p>URGENT PUBLIC HEALTH. This COVID study looks at social isolation in older adults.</p>	<p>2021-01</p>	<p>Portfolio</p>	<p>03/10/2022</p>
<p>EMHeP COVID (LC – Emma Donaldson)</p>	<p>This study will explore how the COVID-19 pandemic has affected the quality and efficiency of services provided by Mental Health Trusts.</p>	<p>2021-11</p>	<p>Portfolio</p>	<p>28/02/2022</p>
<p>Psychological Impact of COVID</p>	<p>Researchers are inviting you to take part in a short, online questionnaire about the impact coronavirus has had on your life. This information will be used to support our understanding of how the pandemic and changing restrictions may be affecting our mental health and wellbeing.</p>	<p>2020-14</p>	<p>Portfolio</p>	<p>25/09/2021</p>

Dementia – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio Status	Study end date
BDR3 (LC – Shani McCoy)	Brains for Dementia Research is a study whereby participants have donated their brains to the research project following their death. In a longitudinal approach participants are reviewed on an annual basis to understand their cognitive function, physical health and other specified markers which are then paired with brain tissue analysis following harvest of the brain.	2018-14	Portfolio	31/03/2026 (In follow up)
NIDUS-Family (PI – Leena Reddy)	The study will recruit 297 family/friend carers and people with dementia (dyads) who live at home through memory services, GP practices, home care agencies and Join Dementia Research. 198 participant dyads will be randomly chosen to receive the intervention (NIDUS-family) alongside usual care, and 99 participant dyads will be randomly chosen to receive usual care without NIDUS-family. We will compare if participants who receive NIDUS-family have better outcomes (goal attainment, quality of life, activities of daily living, symptoms and service use) than those who do not receive it at 6 and 12-months.	2020-22	Portfolio	28/02/2023

Mental Health – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio Status	Study end date
Autism				
ASC-UK: Learning about the lives of adults on the autistic spectrum (PI – Trevor Powell)	<p>In this project, we will undertake the first stage of a programme of research into the life-course experiences of people with ASD. Experts in ageing and life-course, experienced ASD researchers, and people with ASD and relatives will undertake this project.</p> <p>We will engage with people with ASD, their parents, siblings and partners, and meet and discuss with them to understand much more about how ASD affects people’s daily lives as they age.</p>	2015-15	Portfolio	31/12/2021 (In follow up)
Females with Autism Spectrum Disorder and Borderline Personality Disorder – the overlap (PI- Trevor Powell)	<p>SPONSORED STUDY. Using Interpretative Phenomenological Analysis, explore and identify themes around how females with both ASD and BPD perceive self-harm, abandonment and their diagnosis, in order to learn more about the overlapping features of ASD and BPD.</p>	2019-17	Non Portfolio	30/12/2021
Elucidating the relationship and co-development of sensory reactivity and mental health symptoms in autism (PI -Teresa Tavassoli)	<p>This project will explore if sensory reactivity, such as being oversensitive to sounds, is associated with anxiety and related mental health symptoms. To do so we will follow 100 3-4 year old autistic children and 100 5-6 year old autistic children for 5 years.</p>	2019-23	Non Portfolio	01/05/2023

<p>Speech and Language access for preschool children with Autism (Academic Project, PhD - Iona Wood)</p>	<p>This qualitative study aims to provide an in-depth understanding of the individual, service, organisational and structural factors impacting on access to Speech and Language Therapy for preschool children with Autism from the perspective of a range of stakeholders.</p>	<p>2021-03</p>	<p>Non Portfolio</p>	<p>02/06/2023</p>
<p>Depression</p>				
<p>Genetic Links to Anxiety and Depression (GLAD) (PI - Dr Amir Zamani)</p>	<p>Kings College London will explore genetic and environmental factors associated with risk for depression and anxiety disorders in the UK, to understand these common disorders and help develop better treatments.</p> <p>The participants will be recruited into an existing biobank, the NIHR BioResource for Translational Research in Common and Rare Diseases, a re-contactable biobank.</p> <p>Our recruitment will help towards forming the largest re-contactable biobank of participants diagnosed with or suffering from two very common disorders, depression and anxiety, who will be primarily recruited through an online platform.</p>	<p>2019-13</p>	<p>Portfolio</p>	<p>01/09/2028</p>
<p>An Observational, Prospective UK Study Examining Clinical Outcomes of patients, Carer Burden and Direct Health Care Costs for Patients with Symptoms of Moderate to Severe Major Depressive Disorder (MDD) that have Active Suicidal</p>	<p>COMMERCIAL. Patients observed in this study will be those with a working diagnosis of MDD (or moderate-to-severe depression) and deemed to have active suicidal ideation with intent at the point of enrolment based on the clinical judgment of the healthcare team. Where identified, informal carers of these patients will also be invited to participate in the study to assess carer burden. Patients will be followed for a period of approximately 13 weeks/90 days in total and included carers will also be asked to provide data over the same time period. The end of the study will be the last data collection time point within the study for the last participating patient/ carer.</p> <p>The overall duration of the study, including recruitment and follow up, is expected to be 7 months.</p>	<p>TBC</p>	<p>Portfolio</p>	<p>In set up</p>

Ideation with Intent (PI – Sanjoo Chengappa)				
Learning Disabilities				
Online Support Group Use and Wellbeing of Carers of People with ID (PI – Dr Jon Codd)	<p>The research aims to explore the importance of carer networks and peer support as an adjunct to existing service support in health care. The Support Hope and Resources Online Network (SHaRON) is an online support network used across services in Berkshire Healthcare. SHaRON will be implemented with learning disabilities services with a platform for relatives and paid carers initially and then a separate platform for people with an intellectual disability.</p>	2020-20	Non Portfolio	03/02/2023
Experiences of Online Therapy with people with ID (Staff project – Hope Blocksidge and Lara Willis)	<p>The aim of this study is to explore the experiences of psychologists working with individuals with intellectual disability online during COVID-19.</p>	2021-08	Non Portfolio	01/01/2022
Safer Online Lives (PI – Aparna Wighe)	<p>This research is investigating internet use and safety for adults with intellectual disabilities.</p>	2021-12	Portfolio	01/03/2023

Psychosis				
THRIVE (PI – Gwen Bonner)	A randomised controlled trial comparing Virtual Reality Confidence Building with VR Mental Relaxation for people with fears about others	2018-19	Portfolio	30/12/2021 (In follow up)
Molecular Genetics of Adverse Drug Reactions (MoGen) (PI- Dr Sharif Ghali)	A biomarker study that aims to define the genetic and non-genetic risk factors predisposing to adverse drug reactions to clozapine.	2013-04	Portfolio	30/04/2023
PPiP2 (PI- Dr Sanjoo Chengappa)	A study that aims to establish the prevalence of pathogenic antibodies in patients with first episode psychosis.	2017-44	Portfolio	30/11/2022
The Game Change Trial (LC – Emma Donaldson)	A randomised controlled trial testing automated virtual reality cognitive therapy for patients with fears in everyday social situations.	2019-22	Portfolio	31/12/2021 (In follow up)
Hearing Nasty Voices (PI – Sanjoo Chengappa)	A questionnaire study to better understand the problem of hearing derogatory or threatening voices	2020-09	Portfolio	29/10/2021
PREFER: Patient preferences for voice hearing therapies (LC – Emma Donaldson)	This study aims to explore patient preferences for psychological therapies for the experience of hearing distressing voices	2019-44	Portfolio	30/11/2021

<p>The SleepWell Trial</p> <p>(LC – Emma Donaldson)</p>	<p>The SleepWell trial will now work with forty young people (aged 14-25 years) to test the feasibility of treating sleep problems in young people at high risk of psychosis. The results of this study will determine whether a larger and more conclusive trial of our psychological intervention can take place.</p>	<p>2020-32</p>	<p>Portfolio</p>	<p>01/11/2022</p>
<p>Inpatient CBTp Delphi Study</p> <p>(PI – Catherine Evans Jones)</p>	<p>A Delphi study examining key competencies for the delivery cognitive behavioural therapies for psychosis in acute psychiatric inpatient settings.</p>	<p>2020-39</p>	<p>Non Portfolio</p>	<p>31/12/2021</p>
<p>What are the experiences of people from black and minority ethnic groups with a diagnosis of psychosis leading up to their recovery?</p> <p>(Staff project – Ranjan Baruah)</p>	<p>The intent of the proposed study is to learn about patients experiences with a diagnosis of psychosis from different ethnic backgrounds who has attained recovery.</p>	<p>2019-18</p>	<p>Non Portfolio</p>	<p>31/01/2022</p>
<p>Parents with Psychosis</p> <p>(PI – Nicola Collett)</p>	<p>This research aims to look at the relationship between parenting related stress and mental health in parents with psychosis, and whether certain factors, like coping strategies and child behaviour, affect this relationship. It will use Experience Sampling Methodology where participants use mobile phones allowing them to track their stress and symptoms multiple times a day on a moment-by-moment basis.</p>	<p>2021-09</p>	<p>Portfolio</p>	<p>31/12/2021</p>

<p>Understanding Experiences of Feeling Exceptional</p> <p>(PI – Nicola Collett)</p>	<p>Over 500 patients with diagnoses of psychosis will answer questionnaires (20-40 minutes) measuring grandiose beliefs and six psychological mechanisms that we think drive grandiose beliefs.</p>	<p>2021-13</p>	<p>Portfolio</p>	<p>31/03/2022</p>
<p>PTSD</p>				
<p>OPTYC Online PTSD Treatment for Young People and Carers</p> <p>(LC – Dorothy King)</p>	<p>Post Traumatic Stress Disorder (PTSD) is prevalent and impairing in children and young people. Effective face to face treatments exist, including Cognitive Therapy for PTSD (CT-PTSD), developed by our group. However, few young people access effective treatments. We are therefore developing a website and smart-phone App that will improve accessibility of this treatment by allowing trained therapists to deliver CT-PTSD over the internet (iCT) to young people (12-17 years old) with PTSD. In this study we want to evaluate iCT. We propose to do this by running a 3-arm randomised controlled trial to compare iCT to face-to-face CT to a Wait List condition.</p>	<p>2020-23</p>	<p>Portfolio</p>	<p>26/02/2022</p>
<p>Internet treatment for PTSD in IAPT (OVERCOME-PTSD)</p> <p>(Anke Ehlers)</p>	<p>This study is primarily auditing the effectiveness of iCT-PTSD (an internet-based version of trauma-focused cognitive therapy) in routine clinical practice.</p>	<p>2021-05</p>	<p>Non Portfolio</p>	<p>31/08/2022</p>
<p>Individual symptom maps for PTSD</p> <p>(Clinical Psychology Doctorate – Elizabeth Blomfield)</p>	<p>This study will examine the relationship between cognitive change and symptom change during psychological therapy for people with symptoms of depressive and anxiety disorders.</p> <p>We expect to find that change in a client’s attitudes and beliefs will be associated with symptom change during psychological therapy, and that changes in cognition will occur before changes in symptoms.</p>	<p>2021-10</p>	<p>Non Portfolio</p>	<p>31/07/2021</p>

Self Harm				
<p>Exploring Mental Imagery and Self-Harm in Young People (Clinical Psychology Doctorate – Karima Susi)</p>	<p>The current project aims to investigate the amount and nature of any mental imagery related to self-harm and whether mental imagery strengthens the link between negative feelings before self-harm and completing self-harm primarily using a 20 minute questionnaire but also a 30-60 minute in-depth interview. The findings of the study could help assessment and treatment for young people who self harm</p>	2020-18	Non Portfolio	30/07/2021
Suicide				
<p>National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) (PI – Louis Appleby)</p>	<p>Establishing and regulating working practices for safeguarding the receipt, disclosure and holding of identifiable patient information</p>	2018-38	Portfolio	04/01/2022
IAPT (Talking Therapies)				
<p>PIPS (PI – Sarah Sollesse)</p>	<p>COMMERCIAL STUDY. We need to develop tools that can improve the precision with which we allocate treatments in psychiatry. Current psychiatric disease classifications (DSM-5, ICD-10) ensure reliable diagnoses across clinicians, but their diagnostic categories do not allow for individual treatment predictions – for example, most patients with major depression do not recover after their first treatment. This project aims to remedy this by using machine learning to develop an algorithm that can quantify how likely an individual is to respond to a range of mental health treatments, specifically in this case, online cognitive behavioural therapy (iCBT).</p>	2020-07	Portfolio	31/12/2021

<p>Improving Access to Psychological Therapy (PI – Sarah Sollesse)</p>	<p>This study will look at 4 years' worth of data from an IAPT service to take a deep dive into how iCBT has impacted depression and anxiety, firstly by comparing outcomes to GSH and group wellbeing, and secondly by analysing sociodemographic and clinical covariates associated with these different interventions and their outcomes.</p> <p>This will help understand the effects of iCBT as compared to other similar treatments and in different populations and subgroups, and would help to improve the content and delivery of this innovative form of therapy in future.</p>	2020-21	Non Portfolio	01/06/2022
<p>Internet cognitive therapy for social anxiety disorder (iCT-SAD) (PI – Alison Salvadori)</p>	<p>This study is primarily auditing the effectiveness of iCT-SAD in routine clinical practice.</p>	2020-40	Non Portfolio	31/03/2022
<p>EMER: Exploring a New Measure of Emotion Regulation (PI- Grace Jell)</p>	<p>There are numerous questionnaires used to measure emotion regulation but only one (the Perth Emotion Regulation Competency Inventory - PERCI) is based on the most recent and widely accepted model of emotion regulation (Gross 2018 - the extended process model of emotion regulation). This recently developed measure has not yet been extensively used or psychometrically tested in clinical populations. However, it may be more theoretically and psychometrically sound than other measures widely used in the research literature to date.</p> <p>An online survey including this measure with other relevant questionnaires will sample non-clinical and two specific clinical populations in order to explore the reliability, validity and utility of this measure.</p> <p>This will inform the ways in which emotion regulation competency is measured in future research and clinical practice.</p>	2021-17	Portfolio	21/08/2021

<p>The role of self-compassion in readiness to engage in treatment and treatment outcomes for OCD (Clinical Psychology Doctorate – Alice Parfitt)</p>	<p>This study will aim to explore whether those with lower self-compassion are less ready to engage in treatment and receive poorer treatment outcomes. This will be explored among adults seeking treatment for mild/moderate OCD in IAPT services. If so, this may provide a target for future treatments to improve the treatment individuals receive, for example by adapting CBT or including alternative treatments to improve outcomes.</p>	<p>2021-21</p>	<p>Non Portfolio</p>	<p>22/02/2022</p>
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Children and Young People (CYP) – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio Status	Study end date
STANDARDISED Diagnostic Assessment for children and adolescents with emotional difficulties (STADIA) (PI- Tamsin Marshall)	<p>Population: Children and young people (age 5-17 years) presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS).</p> <p>The aim of the study is to evaluate the clinical and cost effectiveness of a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care in children and adolescents presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS).</p>	2018-20b	Portfolio	30/04/2022
ASCEND - Evaluating an early social communication interaction for young children with Down Syndrome (PI - Vesna Stojanovik)	<p>SPONSORED STUDY. A new parent-led intervention programme for children with Down Syndrome. The goal is to improve language and communication skills in children with Down syndrome. Preliminary work by our research team has shown that children who had an intervention on improving shared attention understood and produced twice as many words compared to children who did not have the intervention. We want to find out whether delivering the intervention programme and assessing the effect it has are feasible for a larger trial</p>	2019-11	Portfolio	31/03/2022
Treatment of Panic Disorder in Adolescents (PANDA Study) (PI – Polly Waite)	<p>A research project to compare two talking therapies, that involve working with a therapist one-to-one, for the treatment of panic disorder in young people aged 11-17½ years</p>	2019-34	Portfolio	30/09/2021

Therapist guided, parent-led, Cognitive Behavioural Therapy (CBT) for preadolescent children with Obsessive Compulsive Disorder (OCD) (Academic Project, PhD – Chloe Chessell)	This study aims to adapt an existing therapist guided, parent-led, CBT intervention for parents of children with anxiety disorders that is widely used by CWPs/EMHPs, for parents of children with OCD.	2021-07	Non Portfolio	31/03/2022
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Physical Health Service – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio Status	Study end date
Sexual Health Services				
NEFERTITI (PI – Dr Nisha Pal)	This study will be looking at a new pessary treatment for the treatment of recurrent or chronic bacterial vaginosis.	2021-16	Portfolio	30/09/2021
Diabetes service				
Startright (Getting the right classification and treatment from diagnosis in adults with diabetes) (PI- Dr Mohammadi Alizera)	<p>Our Diabetes at King Edwards VII are teaming up with University of Exeter Medical school to support recruitment into this study aiming to achieve more accurate early classification of diabetes and identification of which patients will rapidly require insulin treatment.</p> <p>The clinicians will record clinical features and biomarkers that may help to determine diabetes type at diagnosis and follow participants for 3 years to assess the development of severe insulin deficiency (measured using C-peptide) and insulin requirement.</p> <p>Findings will be integrated into a freely available clinical prediction model.</p>	2018-02	Portfolio	30/06/2023 (In follow up)

<p>Exploring patient and healthcare-professional perspectives on barriers and facilitators towards foot self-care practices in diabetes (Academic Project, PhD – Andrew Hill)</p>	<p>This study primarily seeks to explore patient and healthcare-professional perspectives on perceived barriers and facilitators to foot self-care practices in diabetes. In addition, this study will explore whether similarities and/or differences between patient and healthcare-professional perspectives in this context contribute to these barriers and/or facilitators</p>	<p>2020-08</p>	<p>Non Portfolio</p>	<p>31/12/2021</p>
<p>ADDRESS II (PI – Cathy Beresford)</p>	<p>The project aims to establish a support system to facilitate future research into type 1 diabetes. The system will consist of a database of individuals with new-onset type 1 diabetes and their siblings who will have consented to be contacted by the study team about future diabetes research. Some participants will have agreed to provide in addition a blood sample for DNA and specific antibody tests.</p>	<p>2020-37</p>	<p>Portfolio</p>	<p>31/12/2022</p>
<p>Digestion</p>				
<p>Assessing the ecological role of yeast in the gut (Academic Project, PhD - Grace Ward)</p>	<p>The University of Reading are conducting research on people who suffer from gut disorders, with a focus on yeasts in the gut. It has been proposed that yeasts found in the human gut cause the symptoms experienced with gut disorders, such as Irritable Bowel Syndrome and Inflammatory Bowel Disease (Crohn’s disease and ulcerative colitis). Understanding the cause of such disorders could lead to the development of treatments to relieve the pain of sufferers.</p>	<p>2019-24</p>	<p>Non Portfolio</p>	<p>30/09/2021</p>

Non-health related studies – 2020/21 projects				
Study title and lead	Summary	Reference	Portfolio Status	Study end date
Staff				
Exploring the implementation of patient safety investigation techniques in mental health trusts in England. (Academic Project, PhD – David Wood)	<p>The aim of this research is to explore the implementation of patient safety investigation techniques in mental health trusts in England. The research aims will be examined by using a mixed methods research design, with the objective of exploring what works well and what could be done differently and better when organisations and staff respond to patient safety incidents. A survey questionnaire will be used as the quantitative research method of choice to evaluate the current state of patient safety investigatory capability.</p>	2021-22	Non Portfolio	29/07/2022
AHP Perceptions of Research in the NHS: A National Survey (LC – Sital Tailor)	<p>The survey asks Allied Health Professionals in the NHS about their research skills and confidence, and about the support from your employer to engage in research activity / use research findings to inform practice.</p>	2021-23	Portfolio	01/10/2021