Summary of Open Studies

Here is a summary of the Open Studies we currently have running throughout 2019/20 and beyond. Studies are presented by service area.

Dementia – 2019/20 projects			
Study title and lead	**Summary**	**Reference**	**Study end date**
Alzheimer's Dementia Genetics **(PI- Nick Woodthorpe)**	ADG is a study run by Cardiff University looking for DNA bio-markers specifically related to Alzheimer's disease. This involves a blood test preferably but samples of saliva can be collected where bloods are not available. Cognitive measures, a quality of life questionnaire and family history are collected in addition to the samples. (Study on hold)	2014-31b	01/02/2020
Exploring how informal carers of people living with dementia experience and maintain continuing compassion in care **Nuriya Kupeli**	In set up	2019-26	30/09/2021
BDR3 **(PI- tbc- previously Gwen Bonner)**	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	31/03/2021
Dementia with Lewy Bodies Genetic study **(PI- Nick Woodthorpe)**	DLB Genetic study is a study run by Cardiff University looking for DNA bio-markers specifically related to dementia with Lewy bodies. This is a branch of the original Alzheimer's Dementia Genetics study and has the same samples to be collected including blood test (or saliva where this is not possible), cognitive measures, quality of life questionnaire and family history.	2019-05	31/01/2020

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Nutrition, hydration and care for people with dementia at the end of life: How can we best support family carers?	The aims of this University College London study are to explore carers' understanding of how best to manage eating and drinking at the end of life for someone with dementia; establishing if there are gaps in their knowledge and also identifying what information Practitioners provide to carers. We will set the scene for developing a carer resource if this appears desirable.	2019-20	31/07/2020
Exploring and managing dementia in black African and Caribbean Elders - EMBRACE **PI- Stephen Zingwe**	Our Older adult services will collaborate with University College London to conduct a qualitative study with semi-structured interviews and participant observations to explore how people from the UK's Black ethnic groups and their families and friend carers conceptualise and manage memory problems and dementia, their expectations of and attitudes towards treatment and care, and the lived experience of the individuals with dementia who continue to live independently at home or move to a care home, and their family carers. (2019-19)	2019-19	31/05/2021
Living well and enhancing active life: The IDEAL-2 study **(PI- Nick Woodthorpe)**	IDEAL-2 is a longitudinal study utilising questionnaire approach to understand the lived experience of individuals living with dementia and that of their carers. This is a multi-site multi-organisation study that is aiming to build a database of information that can be accessed by researchers in the future. This study is currently in its fourth year coming into the fifth and has produced several research papers from the data collected to date.	2018-17	30/06/2020
PriDem: Primary care led support in dementia: Developing best practice **(PI – Nick Woodthorpe)**	New recommendations have been made about the types of help needed by people with dementia. We want to find out what you think about these recommendations and how to put them into practice. This will help us to develop a new model for support people after a diagnosis of dementia. PriDem are looking to interview you and/or a family member or friend about your experiences. They are looking for people with a diagnosis of any type of dementia. They would also like to talk to family members or friends of people with dementia. You can participate together or separately.	2019-08	03/06/2020
Current practice relating to Assistive Technology within Memory Services	Study team have put this study on hold as recruitment target has been met	2018-28	31/05/2020

Mental Health – 2019/20 projects			
Study title and lead	**Summary**	**Reference**	**Study end date**
Anxiety			
Genetic Links to Anxiety and Depression (GLAD) **(PI: Dr Amir Zamani)**	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. The participants will be recruited into an existing biobank, the NIHR BioResource for Translational Research in Common and Rare Diseases, a re-contactable biobank. 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.	2019-13	End date: 1st September 2028
Bipolar			
Imagery Based Emotion Regulation (IBER) **(PI: Craig Steele)**	Berkshire Healthcare Foundation Trust have collaborated with the University of Reading to do a study to test whether a psychological therapy, called Imagery Based Emotion Regulation (IBER), can help with the symptoms of anxiety within people already diagnosed with bipolar disorder. Recent research suggests that most people diagnosed with bipolar disorder may also suffer from anxiety, but they rarely get assessed, diagnosed or treated for this part of their mental health.	2018-06	End date: 30th September 2020
ADHD			
PROUD **(PI- Dr James Jeffs)**	Aims to evaluate the effectiveness of a new intervention to prevent comorbid depression and obesity in ADHD	2017-34	End date: 30th July 2020

Eating Disorders			
TRIANGLE **(PI: Dr Elma Ramly)**	Our Eating Disorder service is collaborating with King's College London on a project involving patients with anorexia nervosa and their carers. The project investigates whether providing extra information on how to cope with the illness to both patients and carers improves their wellbeing up to 18 months post-admission. The aim is to ensure a smooth transition between inpatient treatment and integration in the community. The project also entails measuring symptom burden with questionnaires at different time points. Patients will be reimbursed for completing the questionnaires.	2017-01	End date: 31st March 2020
Autism			
Females with Autism Spectrum Disorder and Borderline Personality disorder – the overlap **(PI- Trevor Powell)**	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.	2019-17	30/12/2020
Psychosis			
THRIVE **(LC- Emma Donaldson)**	A randomised controlled trial comparing Virtual Reality Confidence Building with VR Mental Relaxation for people with fears about others	2018-19	30/09/2020
EYE-2 **(PI- Katherine Mckinnon)**	A randomised controlled trial that aims to evaluate the effectiveness of a team based intervention in Early Intervention Psychosis teams.	2018-31	01/03/2021
Molecular Genetics of Adverse Drug Reactions (MolGen) **(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	30/04/2021

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PPiP2 **(PI- Dr Sanjoo Chengappa)**	A study that aims to establish the prevalence of pathogenic antibodies in patients with first episode psychosis.	2017-44	01/09/2020
The Game Change Trial **(LC – Emma Donaldson)**	The gameChange Trial: A randomised controlled trial testing automated virtual reality cognitive therapy for patients with fears in everyday social situations.	2019-22	01/06/2021
Exploring Unusual Feelings	This study is a questionnaire study where 1000 patients with non-affective psychosis will answer a pack of 10 questionnaires (approx. 30 minutes), and some brief demographic details (age, gender, ethnicity). They will answer the questionnaires once only (a "cross-sectional" design). We will then use the latest statistical methods (network analyses based on probability estimations) to understand the likely causal relationships between the psychological factors measured. Specifically, the aim of the study is to better understand what factors cause dissociation, and whether dissociation might cause psychotic symptoms	2019-32	30/04/2020
What are the experiences of people from black and minority ethnic groups with a diagnosis of psychosis leading up to their recovery?	In set up.		TBC
Model fidelity of Early Intervention services for first-episode Psychosis in England	The objectives of the research proposed here are to: (1) develop and evaluate a self-administered, survey-based instrument for measuring fidelity of Early Intervention (EI) services that can be completed by EI staff and; (2) measure the timing of EI service implementation across geographic regions in England, and fidelity of EI services in England. Achieving these two objectives is necessary to achieve the study aim, by estimating the effects of EI services and EI fidelity on hospitalizations and suicides in the FEP population in England.	2019-35	01/09/2020

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Depression			
Genetic Links to Anxiety and Depression (GLAD) **(PI: Dr Amir Zamani)**	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. The participants will be recruited into an existing biobank, the NIHR BioResource for Translational Research in Common and Rare Diseases, a re-contactable biobank. 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.	2019-13	01/09/2028
Schizophrenia			
Smoking Cessation Intervention for Severe Mental Ill Health Trial (SCIMITAR): Extended follow up	To establish the clinical effectiveness of a bespoke smoking cessation intervention compared with usual GP care, for people with severe mental ill health in facilitating smoking cessation.	2019-15	31/12/2019
IAPT (Talking Therapies)			
Understanding SilverCloud Supporter Information Practices & Data Needs **(PI- Sue Scuphum)**	A brief 35 minute interview with Psychological Wellbeing Practitioners, who are currently using the SilverCloud service as 'supporters' to look at their experiences of working with SilverCloud.	2019-33	30/06/2020

Mental Health			
National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH)	Establishing and regulating working practices for safeguarding the receipt, disclosure and holding of identifiable patient information	2018-38	End date: 04/01/2022

Children and Young People (CYP) – 2019/20 projects			
Study title and lead	**Summary**	**Reference**	**Study end date**
Improving language outcomes for infants with Down syndrome **(PI- Emma Pagnamenta)**	In set up tbc.		
STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA): **(PI- Tamsin Marshall)**	Population: Children and young people (age 5-17 years) presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS). 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).	2018-20b	30/04/2022

Physical Health Service – 2019/20 projects

Study title and lead	Summary	Reference	Study end date
All Long-Term Conditions (LTC)			
Psychological risk factors for fatigue in Rheumatoid Arthritis **(PI- Dr Mohammadi Alizera)**	The study investigates a number of factors which may influence levels of fatigue, distress and disability in patients with long-term conditions. It specifically focusses on behavioural and psychological factors including quality of sleep, anxiety and depression, beliefs about fatigue and coping strategies.	2018-37	01/04/2021
Sexual Health Services			
Safetxt (A randomised control trial of a safer sex intervention delivered though mobile phone messaging) **(PI- Dr Nisha Pal)**	London School of Hygiene and Tropical Medicine, at the University of London are working with the Sexual Health clinic at Upton Hospital to test whether text messages providing information and tips to increase safer sex helps young people adopt safer sex behaviours. Young people may find the messages helpful and may learn about safer sex behaviours.	2016-40	
PrEP Impact Trial Study **PI- Dr Nisha Pal**	The PrEP Impact Trial aims to address outstanding questions about PrEP, eligibility, uptake and duration of use of PrEP though expanding the assessment to the scale required to obtain sufficient data. In addition the trial will assess under real world conditions the impact of PrEP on new HIV diagnoses and on sexually transmitted infections, compared to historical controls.	2017-30	01/09/2020

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Re-Evaluation of Annual Cytology using HPV testing to Upgrade Prevention (REACH UP): a feasibility study in Women Living With HIV **Nisha Pal**	To estimate HPV prevalence in women living with HIV to calculate sample size of the main study.	2019-16	31/01/2021
Diabetes service			
Startright (Getting the right classification and treatment from diagnosis in adults with diabetes) **PI- Dr Mohammadi Alizera**	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. 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. Findings will be integrated into a freely available clinical prediction model.	2018-02	31/12/2019
Embedding Diabetes Education RCT **PI- Alison Marie Jones**	As part of the Embedding Diabetes Education study (an NIHR funded PGfAR) Leicester diabetes centre are going to be working with the Diabetes Education provider team at Berkshire Healthcare NHS Foundation Trust to assess whether the embedding Package reduces HbA1C in patients with type 2 Diabetes Mellitus compared to usual care. Closed	2019-04	31/01/2021
PREM **PI- Dr Mohammadi Alizera**	In set up tbc.		

Cardiac and Respiratory Specialist Services (CARSS)			
TANDEM (Tailored intervention for ANxiety and DEpression Management in COPD) **(PI- Katherine Beckford)**	Our Cardiac and Respiratory Specialist Service is collaborating with Queen Mary University of London Research study for patients with Chronic Obstructive Pulmonary Disease (COPD); also known as chronic bronchitis or emphysema. To investigate the benefits of offering people with moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) and mild or moderate anxiety or depression, the opportunity to receive structured, one to one support and advice delivered by a trained respiratory health care professional (nurse, physio or occupational therapist). The sessions are based on a Cognitive Behavioural approach. COPD can affect many aspects of such patients; breathing difficulties can limit their day-to-day activities and can make them feel worried (anxious) or feel low (depressed).	2018-29	31/03/2020
Carers			
COPe-Support **(PI- Dr Jacqueline Sin)**	An interventional study that aims to find out if COPe-support (online resource) works to improve carers' wellbeing and how well they cope with caring.	2017-41	28/02/2020
Healthy Control			
Cause and Prevalence of Memory Problems (CAP-MEM) **(PI- Stephen Zingwe)**	A questionnaire study that aims to explore the cause and prevalence of memory problems in people with mental health, neurodevelopmental and neurodegenerative disorders.	2018-23	30/09/2021

Non Delivery – 2019/20 projects			
Study title and lead	**Summary**	**Reference**	**Study end date**
Suicide by middle aged men **Louis Appleby**	This study will combine multiple sources of information to examine factors related to suicide in this hard-to-reach group, including barriers to accessing services.	2019-28	31/10/2020
The influence of changes in self-concept after brain injury **Christina Cusack**	Aims and Objectives of the study: • Is carer burden influenced by brain injury survivors' perceptions of self-concept? • Is carer burden influenced by their perceptions of changes in self-concept of the brain injury survivor? • Is perceived social support influenced by brain injury survivors' and relatives' perceptions of self-concept changes in the brain injury survivor? • Are the factorial and psychometric properties of the HISD-III-R equivalent to those of the patient's version of the HISD-III? (exploratory)	2019-10	01/01/2020
Embedding Diabetes Education **Melanie Davis**	Evaluating the impact of an intervention to increase uptake of self-management education programmes for Type-2 Diabetes in Primary Care. This study is part of a complex research project wanting to increase the number of people with type 2 diabetes who go to self-management education programmes.	2019-04	31/01/2021
Stop-PTSD **Anke Ehlers**	The design is a single blind (assessors of treatment outcome blinded) randomised controlled trial comparing two therapist-assisted internet-based psychological treatments for posttraumatic stress disorder and a wait-list condition, with an embedded process study.	2017-39	30/09/2020

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Improving self-esteem in patients with persecutory delusions **Ava Forkett**	This study is for people who have concerns that others are trying to harm them, and find out whether a talking therapy will help to increase self-compassion and feelings of safety.	2018-22	02/03/2020
The development of a Cognitive Behaviour Therapy conceptual framework and toolkit for the treatment of suicidal patients in Crisis and Home Treatment Team **Zaid Hosany**	Objectives for this research are to conduct a systematic review and a qualitative study to develop a conceptual framework and toolkit for staff working within a mental health crisis team to use and to help suicidal patients. I will also test the framework and toolkit through staff training/ evaluation by using a before-after study to evaluate staff confidence in their use of CBT. At the end of the research, I will have produced an evidence-based CBT conceptual framework and tool kit for use by the crisis team.	2018-36	31/01/2020
Evaluating an early social communication interaction for young children with Down Syndrome **Vesna Stojanovik**	In set up.	2019-11	01/04/2021
Elucidating the relationship and co-development of sensory reactivity and mental health symptoms in autism **Teresa Tavassoli**	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.	2019-23	01/05/2023

Student Projects – 2019/20 projects

Study title and lead	Summary	Reference	Study end date
The cognitive and neurological effects of Bilingualism on the progression of Dementia **Toms Voit**	This study fills an important gap in the literature, by directly addressing claims that bilingualism can provide protection against cognitive decline and brain deterioration in older age. This study will help determine the effects of additional language learning and use on brain structure and behaviour, as well as how the two are linked and interact.	2018-08	01/01/2020
Assessing the ecological role of yeast in the gut **Grace Ward**	This study will analyse the biological and chemical content of the samples. We will analyse the stool samples provided by you, to capture information on the composition of microorganisms present in the gut. The samples will also be analysed using analytical chemistry approaches to study the metabolic activity of the microorganisms.	2019-24	30/09/2021
Does feeling connected and valued affect the way people feel about themselves and their lives in people aged 50 years and older from different cultures **Iman Hassan**	The study aims to see if feeling connected and valued affects the way people feel about themselves and their lives in people aged 50 years old and above. We are particularly interested in thoughts related to suicide. We are also interested in seeing if there are any differences in people from cultures that place more importance on being part of a group, such as a close family or community network, compared to people from cultures that place more emphasis on the individual.	2019-31	31/07/2020

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Infrastructuring Data Integration between Multiple Socio-Technical Contexts of Care **Andrey Elizondo**	How is the integration of data across care settings negotiated between different actors? What –intended and unintended- early consequences arise as a result of data integration?	2019-29	30/04/2020
A questionnaire study examining the link between experiences of betrayal and Borderline Personality Disorder (BPD) **Stephanie Barningham**	This study will investigate whether experiences of betrayal (betrayal sensitivity and betrayal of others) are a key feature of BPD and will compare betrayal responses across the three groups (BPD, OCD clinical control and non-clinical control group).	2019-30	25/09/2020
Parents' experiences of parenting a child with Obsessive Compulsive Symptoms/Disorder **Chloe Chessell**	This study aims to explore parents' experiences of parenting a child (aged 7 to 12 years) with OCD, their views and preferences towards different levels of parent involvement in CBT for OCD.	2019-07	29/08/2020

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