

### Active Research Studies

The following buttons can be found throughout the document:



The arrow → will navigate you to the chosen page



The Home Button → will navigate you back to the Contents Page

**Please Note:** Due to the COVID-19 Pandemic, some studies have been paused for the time being.

To find out more about the current opportunities for you to become involved in or for more information:

Email us: elft.researchoffice@nhs.net

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#### Contents



#### The research studies have been subdivided into the following main themes:

Learning Disabilities	
General Adult Psychiatry	
Dementias and Neurodegenerative Diseases	
Forensic Services	
Primary Care and Specialist Psychological Services	
Child and Adolescent Mental Health	
GET INVOLVED	

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## East London

#### Learning Disabilities - Current Studies East London NHS Foundation Trust

Improving the Accuracy and Efficiency of Autism Assessment for Adults......



High Functioning Autistic Disorders in MSUs - Pathways & Co-morbidity.....









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#### **East London NHS Foundation Trust**

### Learning Disabilities

Full Title: Improving the Accuracy and Efficiency of Autism Assessment for Adults

**Summary:** This project will test the accuracy of 2 versions of a new diagnostic interview for assessing adult autism. We will evaluate the 3Di-Adult, which collects information on current and childhood behaviour from informants; and the 3Di-Adult-Current, a version of the interview that only collects information on current behaviour. By testing new assessment measures, this project could improve the accuracy and efficiency of adult autism assessment.

We will evaluate the accuracy of the 3Di-Adult and 3Di-Adult-Current at detecting autism amongst 204 patients (102 women, 102 men) seeking assessment from three NHS adult autism services in East London, Cambridge, and Bristol. The study will last 18 months, recruiting 3 types of participant: (1). 'Clinical participants' are adults awaiting assessment at an NHS adult autism clinic, who will nominate a person to complete the 3Di-Adult (a 'historical informant') and another person to complete the 3Di-Adult-Current (a 'current informant'). (2). 'Historical informants' will be someone who knows the clinical participant currently, and knew them in childhood (such as a parent or sibling). (3). 'Current informants' will be someone how knows the clinical participant currently, but did not know them in childhood (such as a spouse, friend, or support worker). To assess their validity, outcomes of the 3Di-Adult and 3Di-Adult-Current will be compared with the outcomes of NHS diagnostic autism assessments, for each clinical participant. We will also test the reliability (i.e., stability over time) of the 3Di-Adult and 3Di-Adult-Current, by asking some participants (n=52) to repeat the interviews after 8 weeks.

**Chief Investigator:** Dr William Mandy **Local Investigator:** Dr Michelle Hamill

**Start Date**: 30/06/2020 **End Date:** 30/09/2022

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**Status: Open** 

### Learning Disabilities



Full title: High Functioning Autistic Disorders in MSUs - Pathways & Co-morbidity

<u>Summary:</u> Autism is a disorder that some people grow up with. People with autism can have difficulties with communicating and interacting with other people. High Functioning Autistic Spectrum Disorders (HFA) or Asperger's Syndrome (as it is also known) refers to a sub-group of people with autism of average or above average intelligence.

The study will take place in three Medium Secure Units (MSUs) (psychiatric hospitals with a significant level of security) within England. We will recruit patients with and without HFA who are residing within these MSUs. The potential participants will be approached with the help of professionals working within 3 selected MSUs in England. The study will match service users with HFA with twice as many service users without HFA from the same locality in England. Service users who express an interest to take part in the study will be invited to arrange a meeting with a researcher in order to complete some questionnaires. With service user's consent, the study will also use some of the information from the medical records and speak to their psychiatrist. This will allow to see how these patients ended up in MSUs. The psychiatrists will be asked how long they expect the patient to remain within the MSU and what sort of place they are planning to discharge service users to in the future.

Chief Investigator: Dr Kalpana Dein

Local Investigator: Ali Ajaz

**Start Date:** 08/05/2020

**End Date: Estimated in 2022** 



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The role of inflammation in brain and cognitive function in mental disorders
RCT of a Structured Intervention For Expanding Social Networks In Psychosis (SCENE) - Work Package 5)
A study of synaptic markers and their relationship to neural function in healthy volunteers and patients diagnosed with mental disorders
Effectiveness of group arts therapy for diagnostically heterogeneous patients (ERA): RCT
DNA Polymorphisms in mental illness in a Bangladeshi population



*Continued on the next page....* 

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Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies (MOLGEN)..... Improving Outcomes in Patients who self-harm: Adapting and evaluating a brief pSychological inteRvention in Department (ASsuRED, version Emergency

Stress and GABA in the pathogenesis of psychosis (first episode study).....

Investigating the role of diazepam on brain function and chemistry in psychosis risk.....





Continued on the next page....



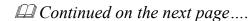






Accessibility and acceptability of perinatal mental health services for women from Ethnic Minority groups (PAAM)	
Humanised mice as tool to investigate the link between mental health and immune system	
Using smartphone-based monitoring to understand and predict risk of psychotic relapse at the individual level	















Full Title: The role of inflammation in brain and cognitive function in mental disorders

<u>Summary:</u> Schizophrenia affects 1/100 people and is a chronic disabling psychiatric illness. It comprises of positive (psychotic), negative and cognitive symptoms. Recently it has become clear that dopamine dysfunction underlies psychosis. However, this appears to be the final step in the pathophysiological process, and does not explain negative and cognitive symptoms. It is therefore critical to identify the up-stream disease mechanisms underlying the disorder to aid development of better treatments for schizophrenia.

Converging lines of evidence suggest that neuro-inflammation occurs in schizophrenia, and specifically overactivity of brain immune cells called microglia. Currently, key gaps in our knowledge exist, specifically relating to whether activated microglia play a primary role in schizophrenia. The key test is to reverse microglial activation and determine the effect on symptoms. To achieve this, we propose use to use a drug called natalizumab that specifically targets microglia and reduces their activity in the brain.

Two parts of the research are proposed: The first study will determine the association between microglial activation and other measures in patients with schizophrenia relative to controls, whilst the second study will use natalizumab to assess the effect of reducing microglial activation on brain functional measures in individuals with a diagnosis of schizophrenia.

Chief Investigator: Prof Oliver Howes Local Investigator: Susham Gupta

**Start Date:** 19/10/2017

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**End Date:** 11/2022

Status: Recruitment paused due to COVID 19

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<u>Full Title: A randomised controlled trial of a structured intervention for expanding social networks in psychosis (SCENE – Work Package 5)</u>

<u>Summary:</u> About 120,000 people with psychosis are being cared for in secondary services in the NHS at any point in time. Reviews show that people with psychosis have much smaller social networks compared to the general population, and compared to other groups with long-term health conditions. Social isolation in turn, is associated with worse outcomes including poor quality of life.

We are interested in testing an intervention to expand patients' social networks and to see whether it improves their quality of life. The intervention involves receiving support from a mental health professional to try an activity of their choice and to meet new people. The clinicians (named 'social contacts coaches') will receive specific training and instructions on how to motivate and support patients. A similar intervention was found to be beneficial for patients in Italy and has been adapted to the UK context through a number of earlier studies including a survey, focus groups, a case series and a feasibility trial. In the present study we will recruit 576 patients with psychosis who are socially isolated from community-based NHS services across England (both urban and rural). We will randomly allocate them either to receiving social contacts coaching or information about local options for activities only. We are primarily interested in whether the active support improves quality of life compared to receiving information, but we are also looking to see whether it increases time spent in social activities, improves social situation or mental health symptoms and reduces feelings of loneliness or use of health services.

Chief Investigator: Dr Domenico Giacco Local Investigator: Prof Stefan Priebe

Start Date: 11/03/2019 End Date: 30/06/2022

**Status: Recruiting** 

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Full Title: A study of synaptic markers and their relationship to neural function in healthy volunteers and patients diagnosed with mental disorders

<u>Summary:</u> Mental health disorders are currently treated based on symptoms. As their origin is poorly understood, diagnosis is based on the physician's judgement and often results in poor outcomes. Efforts to make a diagnosis in an unbiased manner are ongoing and one of the main goals of this project is to identify markers to better diagnose mental illness. Abnormality in nerve connections and brain chemical substances known as neurotransmitters have been linked to mental illness especially in those where psychosis is present. Neurotransmitters are chemicals released in junctions between nerve cells known as synapses and they help in their communication. One of the suggestions in the field is that the number of synapses (nerve junctions) present in the developing brain is less in psychotic illness and this could provide us important information regarding the illness. The main challenge is to identify the number of synapses in a non-invasive manner in the living human brain.

The availability of a specific molecule (a 'radiotracer') which can be labelled with a small amount of radioactivity and imaged using a special scanner (PET – Positron emission tomography) has opened the possibility to measure nerve junctions (synapses). The specific molecule targets a protein present only in nerve junction sites and hence will inform us of the number of nerve junctions. Service users diagnosed with psychotic illness and controls will be recruited. The results from the two groups will be compared.

Chief Investigator: Prof Oliver Howes Local Investigator: Andrew Biggs

Start Date: 23/06/2017 End Date: 30/04/2022

We care

**Status: Open to recruitment** 



We respect

### East London NHS Foundation Trust

#### General Adult Psychiatry

Full Title: Effectiveness of group arts therapy compared to group counselling for diagnostically heterogeneous psychiatric community patients: Randomised controlled trial in mental health services (ERA)

<u>Summary:</u> We want to test if arts therapies groups are effective for patients with different types of mental illness. Arts therapies use different art forms and creative activities to help people living with mental illness. These include music therapy, dance-movement therapy and art therapy. Each has a different focus: on the 'ear' (music), the 'body' (dance-movement) and the 'eye' (art). They are usually provided in regular group meetings over a few months. Arts therapies may help patients to express emotions and have experiences which might not be possible in talking therapies. Different people prefer different art-forms. If patients can choose which art-form they like best, they may be more likely to attend and benefit from this. While arts therapies are popular with many patients, they are not always provided in NHS services. So far, there has been little research to show that they are helpful. Existing research has involved people with only one diagnosis (such as schizophrenia). This is different to how arts therapies groups are provided as they usually include people with different mental illnesses.

We will ask patients in community mental health services if they would like to participate in a form of group arts therapy and if so, which one. They will then be divided into two groups by chance. Half will receive their preferred form of arts therapy group. The other half will be offered group meetings with general talking and support, but no use of arts. Patients can attend for up to 40 sessions over 5 months. We will collect data with patients at the beginning and end of treatment, 6 and 12 months later. We will then compare the two groups to see if patients receiving arts therapies had a better improvement of symptoms and quality of life.

Chief Investigator: Dr Catherine Carr Local Investigator: Dr Catherine Carr

**Start Date: 21/09/2019** 

**End Date: To be confirmed** 

**Status: Open** 









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Full Title: DNA Polymorphisms in mental illness in a Bangladeshi population (DPIM Study)

<u>Summary:</u> Research suggests that genetics has a major role to play in susceptibility to mental illness. The DPIM is a large scale study investigating the role of inherited DNA polymorphisms (genetic mutations) as a cause of different mental illnesses. This information could then be used to more accurately inform treatment options. This research, and others like it, has already begun to pave the way for new treatments and preventative strategies by increasing knowledge and understanding of the role of genetic polymorphisms in these disorders. The study team strongly believe that learning more about the genetics will begin to make a practical difference for creating new treatments for people with bipolar disorder / schizophrenia.

The study involves people aged 18 and above with a clinical diagnosis of schizophrenia or bipolar disorder and healthy controls from a Bangladeshi population. The participation entails providing a sample of DNA by saliva or blood and a short interview.





**Chief Investigator: Jonathon Pimm Local Investigator: Jonathon Pimm** 

**Start Date: 20/12/2011** 

**End Date: To be confirmed** 

**Status: Open** 

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<u>Full Title: Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies (MOLGEN)</u>

<u>Summary:</u> Adverse drug reactions (ADR's) are a common cause of drug-related morbidity and may account for about 6.5% of all hospital admissions. ADRs are also a significant impediment to drug development, and a significant cause of drug withdrawal.

The purpose of this research is to: (a) identify patients with different types of adverse drug reactions; (b) using DNA obtained from blood or Saliva samples from these patients, identify genetic factors which predispose to adverse reactions. The net effect of our research will be the development of genetic tests which can help in predicting individual susceptibility to adverse reactions prior to the medication's administration. Patients with a predisposition to reacting adversely can be prescribed alternative medication or monitored more closely during their treatment. We aim to recruit 250 cases for each reaction for a period of eight years throughout multiple sites in the UK. Specific adverse drug reactions we are looking at include: (1) Statin induced myotoxicity;(2) Severe hypersensitivity reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis; (3) Anaphylaxis induced by NMBA anaesthetics; (4) ACE inhibitor or ARB induced angioedema; (5) Taxane hypersensitivity(6) Chemotherapy induced peripheral neuropathy; (7) Bleomycin induced lung toxicity; (8) Clozapine induced agranulocytosis or neutropenia; (9) Bisphosphonate-related osteonecrosis of the jaw; (10) Tenofovir associated renal injury (11) Serious bleeds induced by warfarin or other anticoagulants.

**Chief Investigator: Prof Munir Pirmohamed** 

Local Investigator: TBC Start Date: 12/09/2013 End Date: 30/04/2023

**Status: Open** 

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<u>Full Title: Improving outcomes in patients who self-harm - Adapting and evaluating a brief pSychological inteRvention in Emergency Department (ASsuRED)</u>

<u>Summary:</u> When someone who has harmed themselves is seen in the Emergency Department, a clinician/mental health practitioner (MHP) usually assesses their psychological state, social situation and needs for support. Although there are many examples of good care, the current approach is not evidence based. People often say that the assessment does not focus on "me as a person" but "as a list of problems". The interaction between the individual with self-harm and the practitioner is critical in engaging them in treatment and helping them cope. Studies in other countries have shown that an approach which trains practitioners in brief psychological techniques, reduces subsequent self-harm and deaths by suicide. We will test if this approach can help people seen in the NHS.

#### Our study has 5 interconnected parts:

We will hold 6 focus groups to get the views on this approach from practitioners, people with a history of harming themselves and carers (friends or relatives); We will access Emergency Department records to identify people with self-harm and their healthcare contacts; We will develop training for practitioners; 16 practitioners from 4 Emergency Departments will each use the approach with up to 6 patients; We will share our findings widely and explore whether the approach could be helpful in other settings. If effective, this new approach will improve the mental health of people who harm themselves, reduce their need for healthcare services and Emergency Department attendance, saving money and, most importantly, saving lives.

**Chief Investigator: Prof Rosemary McCabe** 

**Local Investigator: Helen Parker** 

Start Date: 26/11/2019

**End Date: Expected in 2022** 

**Status: Open** 

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Full Title: Stress and GABA in the pathogenesis of psychosis (first episode study)

<u>Summary:</u> Psychosis is the first leading cause of disability in the developed world. The first symptoms (e.g., hearing voices that aren't there) appear in adolescence, from interactions between genes and environmental risk factors such as psychosocial stress. The treatments that are offered now do not work for about 30-60% of patients, and have little impact on illness prevention. In the brain, psychosis is commonly associated with excessive production of the neurotransmitter dopamine, but little is known about what causes this excess. Research in experimental rats shows that problems in regulating the emotional response to stress lead to the excess production of dopamine through a disruption of another neurotransmitter systems: GABA and glutamate. Furthermore, when these adolescent rats (premorbid stage) are given a drug that improves GABA function (a benzodiazepine, diazepam), the response to stress is regulated and the development of excess dopamine at adulthood is prevented.

We propose to use neuroimaging to assess whether the acute administration of a benzodiazepine can normalise emotional response and GABA-glutamate levels in people in the premorbid stage of psychosis (at "clinical high risk", CHR). This will be possible by using Magnetic Resonance Imaging, by which we can examine the relationship between brain function and neurochemistry in response to a drug that improves GABA levels in the brain. This will advance our pathophysiological understanding of psychosis development, towards finding new biomarkers and new treatments aimed at preventing the onset of the psychosis.

Chief Investigator: Modinos, Dr Gemma

Local Investigator: Silvia Murguia

Start Date: 21/01/2019 End Date: 28/02/2022

**Status: Open** 



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#### Full Title: Investigating the role of diazepam on brain function and chemistry in psychosis risk

<u>Summary:</u> Psychosis is the first leading cause of disability in the developed world. The first symptoms (e.g., hearing voices that aren't there) appear in adolescence, from interactions between genes and environmental risk factors such as psychosocial stress. The treatments that are offered now do not work for about 30-60% of patients, and have little impact on illness prevention. In the brain, psychosis is commonly associated with excessive production of the neurotransmitter dopamine, but little is known about what causes this excess. Research in experimental rats shows that problems in regulating the emotional response to stress lead to the excess production of dopamine through a disruption of another neurotransmitter systems: GABA and glutamate. Furthermore, when these adolescent rats (premorbid stage) are given a drug that improves GABA function (a benzodiazepine, diazepam), the response to stress is regulated and the development of excess dopamine at adulthood is prevented.

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Chief Investigator: Modinos, Dr Gemma

Local Investigator: Silvia Murguia

Start Date: 27/08/2019 End Date: 01/03/2022

**Status: Open** 



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Full Title: Acceptability of perinatal mental health services for ethnic minority

<u>Summary:</u> Barriers to accessing treatment in the perinatal period are likely to be higher for women from ethnic minority backgrounds. However, there is little information available about the use of mental health services by women from ethnic minorities in the perinatal period. As a consequence it is difficult to advocate effectively for and/or implement the kind of services that would best meet the needs of ethnic minority women on the basis of evidence-based practice. Therefore, research is required to assess the accessibility and acceptability of perinatal mental health services for women from ethnic minorities in order to improve the care provided to them, to increase the likelihood of their illness being successfully treated and prevent long term negative consequences. The expected knowledge gain will significantly help to improve the design and delivery of perinatal mental health services for women from ethnic minorities.

To do this, we will conduct qualitative interviews with South Asian and Black women with perinatal mental illness (PMI) to explore their experiences of Perinatal Mental Health Services (PMHS), accessing PMHS and living with PMI. We will also interview their partners/family members/carers and healthcare professionals to explore their experiences of caring for women with PMI. Additionally, we will interview a small sample of White British women to compare their experiences of living with PMI with experiences of South Asian and Black women.

Chief Investigator: Prof Stefan Priebe Local Investigator: Dr Nikolina Jovanovic

Start Date: 20/02/2020 End Date: 31/03/2022 Status: Recruiting





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Full Title: Humanised mice as tool to investigate the link between mental health and immune system

<u>Summary:</u> An imbalanced immune system has long been known to influence a variety of mood conditions including anxiety, obsessive-compulsive disorders and depression. Indeed, patients treated with drugs that suppress the immune system or suffering from deficiency in the immune response are more likely to show changes in mood and behaviour. Although several clinical studies support these findings, the exact mechanism by which the immune system influences mood and emotional state is still not clear. Our recent studies have shown T-lymphocytes, one type of immune cells present in our blood, play a significant role in regulating the emotional response in experimental animals. We have also identified a particular subtype of T lymphocytes that could directly modify the way the brain works. The aim of this project is to expand these observations using clinical samples of people suffering from a variety of mood/emotional and immune disorders. By studying the immune response of the blood cells of these patients in our validated experimental systems, we will be able to dissect and better understand to what extent emotional changes can be attributed to changes in the immune system. The results of this study might help the design and identification of novel therapies for immune disorders.

Chief Investigator: Fulvio D'Acquisto Local Investigator: Domenico Giacco

Start Date: 04/02/2014

End Date: To be confirmed



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<u>Full Title: Using smartphone-based monitoring to understand and predict risk of psychotic relapse</u> <u>at the individual level</u>

**Summary:** Psychosis, which directly affects 2-3% of the population, is a severely debilitating psychiatric disorder characterised by a range of symptoms including false beliefs, false perceptions and disorganised thinking. Although antipsychotic medication can lead to rapid improvement in the acute phase of the disorder, most patients subsequently relapse. In order to address this challenge, we have developed a smartphone app which allows the close monitoring of people across multiple contexts, time-points and locations in real time (Urban Mind; www.urbanmind.info). This study will use an adapted version of the Urban Mind app to measure daily social stress – which is thought to be a strong predictor of the risk of relapse – in patients with a first episode of psychosis (FEP). Using a naturalistic follow-up design, data will be collected from 451 participants with a first episode of psychosis via face-to-face interviews and a smartphone application that is used to examine the impact of the social environment. This app employs ecological momentary assessment (EMA) - a technique that involves multiple sampling of participants' current experiences and behaviours as they go about their daily life. Participant's will attend four assessments in total, the baseline assessment will involve the completion of demographic, general health questionnaires and a clinical interview. Participants will take part in the EMA component of the study for 12 months, during which the app will send 1 notification per day requiring completion of a brief questionnaire (covering social contact, social stress sensitivity and mental wellbeing). Follow-up assessments will occur 4-, 8-, and 12-months after baseline to assess clinical and functional outcome. We hope to use the data collected to develop a predict model linking social stress sensitivity, social withdrawal with risk of future psychotic relapse.

Chief Investigator: Prof Andrea Mechelli Local Investigator: Dr Steven Livingstone

Start Date: 10/03/2020 End Date: 30/09/2025

**Status: Recruiting** 



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#### Full Title:Understanding Experiences of Feeling Exceptional: A Clinical Questionnaire Study

<u>Summary:</u> The overarching aim of our research programme is to develop the first talking therapy for harmful grandiose delusions. To do this, we must first understand what psychological factors 'drive' grandiose delusions (i.e. keep them going) in patients. This is the primary aim of the current study. A secondary aim is to assess the quality of four new measures which assess some of these psychological factors.

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. Most participants will answer questionnaires on a single occasion. A small subgroup of around 100 participants will repeat some measures again one week later, so that we can see whether the results from the new measures (which measure 'meaning', 'fantasy elaboration' and 'immersion behaviours') are stable over time.

We will use 'network analyses'- a technique based on probability estimations - to understand the associations and likely causal relationships between these psychological mechanisms and grandiose delusions.

Chief Investigator: Dr Louise Isham Local Investigator: Dr Robert Fisher

Start Date: 1/03/2021 End Date: 01/02/2022

**Status: Open** 



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Full Title: Retention of Mental Health Staff (RoMHS) - Case studies

<u>Summary:</u> Case studies will be used to develop recommendations for improving mental health staff retention across the UK. Retention is defined as the percentage of staff who remain in post each year. At each site, we will interview between five and eight senior staff and 30-35 frontline clinical staff, and review key policies and procedures to investigate the question: What are the factors that contribute to higher levels of staff retention in Mental Health Trusts?

Interviews will be approximately 1 hour long and will take place online, by telephone or in person. Interviews will use an open-ended format, with prompts to ensure key areas are explored. All participation will be voluntary and both participants and organisations will be given pseudonyms to maintain anonymity. Initial interview analysis for each individual Trust will follow Braun and Clarke's thematic analysis (Braun & Clarke, 2006). However, to make most use of the case study method, analysis will continue to include a range of approaches including Pattern matching, Explanation building, Logic modelling, and Cross-case synthesis. Each Trust will be provided with a report relating to it as a single case study and the overall findings will be published in a case comparison, including recommendations for improving retention in mental health settings.

**Chief Investigator: Emily Wood** 

**Local Investigator: Suzanne Enoh Arthur** 

Start Date: 23/03/2021

**End Date: To be confirmed** 

**Status: Open** 



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Full Title: ARIADNE: AddRessing the ImpAct of the coviD-19 paNdEmic on the access to and experience of care of people from Black, Asian, and Minority Ethnic groups with severe mental illness

<u>Summary:</u> Historically minority ethnic groups have had worse experiences of mental health care than White British people. Despite efforts to improve services for minority ethnic groups, inequalities persist. This needs to change, especially as the Covid-19 pandemic will likely further increase inequalities in care. We need to work with stakeholders to develop urgent practical solutions which can be applied locally and inform national mental health care planning.

We will work with service users, carers, and professionals to create solutions (e.g., actions and interventions) to help improve access to, and experience of, mental health care for minority ethnic groups. We will work with minority ethnic groups who have experience of using secondary mental health services for serious mental illness (SMI). We will also recruit carers of individuals with SMI and professionals who have experience of working with minority ethnic individuals with SMI. The study will run for one year. We are using the experience-based co-design (EBCD) method. This is a structured way of working with different stakeholders to collect information, feed back what we find at each stage, and develop solutions together. Participants will take part in interviews to explore their experiences, and workshops to identify key areas for change and solutions to help bring about these changes.

Chief Investigator: Giacco, Dr Domenico Local Investigator: Dr Rahul Bhattacharya

Start Date: 25/06/2021 End Date: 31/03/2022

**Status: Open** 



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<u>Full Title:Experience based investigation and Co-design of approaches to Prevent and reduce</u> <u>Mental Health Act Use: (CO-PACT)</u>

<u>Summary:</u> The Mental Health Act allows professionals to admit people to hospital against their will. People from black and minority ethnic communities are more likely to get care this way. This can be distressing, reduces trust, and is costly. The government's review of these laws recommended more research to understand the rise in use of compulsory care. We want to find ways of reducing care like this.

This research will ask people about their experiences of compulsory admission to hospital. We will work with mental health services in London, Manchester, Leeds, Birmingham, Bradford, Oxford and Derby. Service users will be of diverse ethnic backgrounds, and aged over 18. In each city, we will recruit 20 service users who have experienced at least one compulsory admission to hospital in the previous year. We will use a creative process involving photography to capture their experiences. The first meeting will explain the approach. In two more meetings, we will ask people to add titles, captions, or descriptions to tell their stories. The captions can be written, or audio or video recordings. Twenty mental health staff from across the seven cities will do the same. In each city we will share this information with a group of people including, service users, psychiatrists, carers, psychologists, social workers, nurses, police, commissioners, and policy experts. This group will meet three times and design a new approach, to reduce the number of people receiving compulsory care. A fourth meeting will bring everyone together to consider their experience when they tried to apply the approach, specifically what works, for whom and how. Using information about changes in care or practice, we will estimate costs and benefits.

Chief Investigator: Bhui, Prof Kam

Local Investigator: Dr Rahul Bhattacharya

Start Date: 26/07/2021 End Date: 01/02/2023

**Status: Open** 

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Imaging amyloid and neuroinflammation in subjects at risk for Alzheimer's disease.....



Problem Adaptation Therapy For Individuals with Mild to Moderate Dementia and Depression. The PATHFINDER Trial.....



Do people with dementia and their families get the care and support they want? Comparing experiences of people from a South Asian and white-British background......









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Supporting independence at home for people with dementia (NIDUS-Family)...... Depletion of Serum Amyloid P Component in Alzheimer's Disease ......

DREAMS START (Dementia REIAted Manual for Sleep) RCT......





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Full Title: Imaging amyloid and neuroinflammation in subjects at risk for Alzheimer's disease

**Summary:** Alzheimer's disease is associated with the presence of increased amyloid deposition, as demonstrated at Post Mortem, and more recently on PET imaging with PIB and related radiotracers. PET imaging has also demonstrated an increase in activated microglia, a marker for neuroinflammation, using PK11195 and, more recently, second generation TSPO binding radiotracers. The results of neuropsychological assessment in subjects with Alzheimer's disease have been found to be better correlated with neuroinflammation than amyloid, as seen in PET studies. Researchers have therefore proposed that inflammation may play an important part in the pathological process that leads to the clinical manifestations of Alzheimer's disease. Inflammation has been demonstrated coincident with the deposition amyloid in animals, but the relative timing of amyloid deposition and neuroinflammation have not been studied in humans. It is known from research into Familial Alzheimer's Disease that amyloid deposition is present years before the diagnosis is made of even prodromal Alzheimer's disease. People who present with objective impairment of episodic memory in the absence of any impact on daily living are diagnosed with amnestic Mild Cognitive Impairment. A proportion of these go on to develop further cognitive difficulties and are diagnosed with Alzheimer's disease at a rate of 10 - 20% a year, and the hypothesis is that in those with MCI we can see an earlier stage in the development of Alzheimer pathology. We therefore intend to examine and analyse the evidence for neuroinflammation and amyloid in subjects with amnestic Mild Cognitive Impairment to elucidate the mechanism of disease.

**Chief Investigator: Prof Brooks David** 

**Local Investigator: None Start Date: 25/02/2011** 

**End Date: Ongoing** 

**Status: Suspended** 

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Full Title: Problem Adaptation Therapy For Individuals with Mild to Moderate Dementia and Depression. The PATHFINDER Trial

**Summary**: Depression is very common in people with Alzheimer's disease and other dementias, causing them distress as well as reducing their quality of life and that of their carers. Unfortunately, antidepressant drugs do not have clear effectiveness in these patients and it appears that the most commonly available psychological therapies such as cognitive behavioural therapy or CBT are also not consistently useful. This study will investigate whether an adapted form of problem-solving therapy called Problem Adaptation Therapy (PATH), which has been reported to be helpful in the very early stages of dementia in an American university-based healthcare system, can be successfully applied in an NHS setting and with patients who are representative of those seen with dementia and depression in the NHS.

The research will be conducted as a randomised clinical trial, comparing 12 weeks of the modified PATH treatment with current treatment offered as usual within the NHS. Outcomes at 0, 3, 6 and 12 months will be measured. The most important outcome of the trial will be improvement in symptoms of depression at 6 months in participants with dementia, but also measured will be quality of life, activities of daily living, cognitive function, anxiety symptoms, satisfaction with therapy and cost-effectiveness of the intervention. The mental health and perceptions of burden in carers will be examined.

**Chief Investigator: Prof Robert Howard Local Investigator: Dr Michelle Hamill** 

**Start Date: 08/09/2020** End Date: 31/12/2022

**Status: Open** 

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Full Title: Do people with dementia and their families get the care and support they want? Comparing experiences of people from a South Asian and white-British background.

**Summary**: This project is investigating equity in service provision for people with dementia and their families, and specifically whether people from a South Asian background get the care and support they want and need. We plan to carry out semi-structured interviews with people with dementia and their family carers from a South Asian and white-British background to compare experiences.

We will recruit participants from memory services within and outside of London. We plan to recruit 12-15 people with dementia from a South Asian background and 12-15 from a white-British background plus their family carers.

Individual interviews are expected to take between 20 minutes and one hour. Descriptive statistics will be used to present demographic information. Interviews will be audio-recorded, transcribed using a professional transcribing service, and thematically analysed.

**Chief Investigator: Prof Gill Livingston Local Investigator: Nicholas J Bass** 

**Start Date: 29/03/2021** End Date: 02/12/2022

**Status: Open** 



## Dementias and Neurodegenerative Diseases



Full Title: Supporting independence at home for people with dementia (NIDUS-Family)

<u>Summary:</u> The current research study is part three of a large programme of work. In part one, we carried out interviews and observations with family carers, people with dementia and professionals on what helps and hinders independence at home. We used our findings to co-produce a psychological intervention to improve the support received by people with dementia and their family/friend at home. We then piloted the intervention to make sure it was acceptable to the participants receiving it and the researchers delivering it. The current study will now test whether the intervention works.

As part of the current study, we 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. The study will compare if participants who receive NIDUS-family have better outcomes than those who do not receive it at 6 and 12-months. A trained researcher will deliver NIDUS-family to participants in the intervention group in up to eight sessions over a ninemonth period. The intervention will be tailored to each individual's preferences and needs and will involve setting goals and monitoring progress, signposting people to resources and identifying activities that participants can participate in to help achieve their goals.

**Chief Investigator: Prof Claudia Cooper** 

**Local Investigator: Nicholas Bass** 

Start Date: 31/01/2020 End Date: 28/02/2023

**Status: Open** 

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Full Title: Depletion of Serum Amyloid P Component in Alzheimer's Disease (v1.0)

**Summary:** Alzheimer's disease (AD) is one of the most important and most costly unmet medical needs in developed countries. Serum Amyloid P component (SAP) a normal human protein produced exclusively in the liver is found in abnormally high levels in the brain of AD patients. CPHPC (Investigational Medicinal Product) is a SAP reducing drug. This trial aims to determine whether SAP reduction improves established clinical and other measures of AD. New insight into AD could inform therapeutic developments.

This trial will explore the safety, tolerability and potential effectiveness of CPHPC or placebo. Administration is given via subcutaneous injection, three times a day. The chance of receiving either is random. Allocation of either arm is also unknown to both the participant and trial team. Main criteria for participants to be eligible for the trial: able to provide written consent; aged between 50-80 inclusive; clinical diagnosis of mild AD as determined by the neurological test (Mini Mental State Exam 20-28) and brain imaging; living with a partner, relative or carer able to attend appointments and to assist with dosing; adequate understanding of written and verbal information in English; certain medications are precluded.

**Chief Investigator: Prof Martin Rosso Local Investigator: Nicholas Bass** 

**Start Date: 20/10/2017 End Date: Ongoing** 

Status: Paused due to COVID-19



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Full Title: DREAMS START (Dementia REIAted Manual for Sleep) RCT

**Summary:** Many people living with dementia have disturbed sleep, including reduced night-time sleep, night-time wandering and daytime sleepiness.

There are currently no known effective, safe treatments for sleep problems in people with dementia, possibly because there may be many causes even in the same person. Our team of experts - in sleep, dementia interventions, and people whose lives have been affected by dementia - developed DREAMS START using the best evidence and what people felt was important to them. It has six-sessions, working with family members, to improve sleep for people living with dementia. It uses several approaches; such as increasing light, activity, comfort, routine and relaxation. We train and supervise health workers with a psychology degree to deliver DREAMS START. They deliver it to family carers individually at home (people with dementia can also join sessions) and together they work out and try ideas to improve their relative's sleep.

What do we want to find out? Does DREAMS START work: Do people with dementia living at home sleep better 8 months after receiving DREAMS START compared to people who do not receive it?

**Chief Investigator: Rapaport, Dr Penny Local Investigator: Dr Michelle Hamill** 

Start Date: 01/02/2021 End Date: 31/12/2022

**Status: Open** 



#### Forensic Services

The nature and prevalence of substance use in a forensic population.....









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## East London NHS Foundation Trust

#### Forensic Services

#### Full Title: The nature and prevalence of substance use in a forensic population v1

<u>Summary:</u> The aims of this project are to determine the nature and prevalence of substance use in a forensic population and its association with recall to hospital. Current research shows that there is an increased prevalence of substance use, in its broadest definition, in this population as well as an association with violent behaviour in the general population.

However, there has been limited research on the exact nature of this substance use, e.g. type, quantity, frequency and the psychological factors associated with it. In addition, there have been mixed findings in relation to substance use in the forensic population and adverse outcomes such as recall to hospital. The current study will look at substance use and associated factors in two groups - those who are currently detained in hospital having been recalled and those currently living in the community having never been recalled. It will evaluate substance use at different time-points, using retrospective self-report, as well as assessing associated social and psychological factors. Alongside this it will compare case note records of historical substance use, clinician rated and results of previously collected biological measures, to self-report from the participants at interview.

This project will provide important information about the complex relationship between substance use, mental health and offending behaviour. It represents an important step towards a better understanding of the particular substance use and patterns of use that are associated with adverse outcomes which can then inform substance use treatment in forensic services.

Chief Investigator: Prof Valerie Curran Local Investigator: Matthew Charles

Start Date: 21/08/2017 End Date: 21/08/2022

**Status: Open** 

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# Primary Care and Specialist Primary Services

Genes & Health: a population based DNA sequencing, medical records, and recall BioResource study of British-Bangladeshi and British-Pakistani communities.....

Narratives of health and illness for www.healthtalkonline.org (formerly DIPEx) and www.youthhealthtalk.org.



SURECAN Trial.....



Clinical Characterisation Protocol for Severe Emerging Infection (CCP-UK) - Novel Coronavirus Observational Study.....









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## Primary Care and Specialist Psychological Services

<u>Full Title: Genes & Health: a population based DNA sequencing, medical records, and recall BioResource study of British-Bangladeshi and British-Pakistani communities.</u>

**Summary:** In East London [and second site Bradford], South Asian people have some of the highest rates of heart disease, diabetes, and poor health in the UK. Living with a long-term illness has a major impact on a person's quality of life and on their family. Genes & Health is a medical research study set up to help fight against these and other major diseases. Some early aims of the study are: (1)To study normal variation in genes in adult Bangladeshi and Pakistani people. Knowing what is normal is important when searching for genes causing inherited childhood diseases; (2) To study genes in people with very high and very low cholesterol levels, to better understand why heart disease and stroke occurs; (3)To study variation in genes in healthy adults whose parents are related. These studies will tell us how genes work, and help develop new medicines; (4)To study genes of people with diabetes, aiming to identify rarer types of diabetes for which more specific treatments can be used. We will establish a panel of 100,000 local adult volunteers, who will be asked to donate a small saliva (spit) sample and share their GP and hospital medical records in strict confidence with the study team. Volunteers will be asked to give their consent to be contacted again and some (~1000/year) may be invited to participate in further medical research studies on the basis of data gathered from their samples and information. Genes & Health will support many other medical research studies (each with their own separate ethics approval). One study (approval sought in this application) is looking at how genetic variation influences RNA and proteins in blood cells, by inviting selected volunteers to donate 50ml blood. De-identified information and samples may be made available to approved scientists in academia and industry worldwide.

**Chief Investigator: Prof David Van Heel** 

**Local Investigator: Nicholas Bass** 

Start Date: 01/04/2015 End Date: 21/12/2023

**Status: Open** 

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## Primary Care and Specialist East London NHS Foundation Trust Psychological Services

<u>Full Title: Narratives of health and illness for www.healthtalkonline.org (formerly DIPEx) and www.youthhealthtalk.org</u>

Summary: The aim of the research programme is to improve understanding of people's experiences of health and illness and provide online resources for people living with a wide variety of health conditions, their families, friends and the health professionals involved in their care. Healthtalkonline (HTO) and Youththealthtalk (YHT) are growing resources which currently cover 75 health conditions. The sites are based on qualitative interviews and features an analysis of the 25 most important issues identified in the interviews and around 250 video, audio and written interview clips. HTO and YHT are not 'just' health information web pages, nor are they a patients' chatroom, nor one of the many health websites that now have an area for patients' experiences: instead each site is based on a rigorous qualitative research study of people's first-hand experiences. HTO studies may therefore be taken as a real indication of what it is like to experience health and illness, and allows access to real-life experiences (via the websites) to anyone whose life is touched by these issues. Interviews collected within the programme will be used in a variety of ways: for academic dissemination in peer-reviewed journal articles and conference presentations; for secondary analysis by academic researchers; to develop information for patients (eg DVDs, on NHS Choices, NICE and other approved websites); to develop training packages for professionals in collaboration with, for example, universities, trusts and Royal Colleges; and to contribute to the award-winning websites at www.healthtalkonline.org (formerly DIPEx)and www.youthhealthtalk.org.

Chief Investigator: Sue Ziebland

Local Investigator: None Start Date: 01/05/2009 End Date: 30/04/2024

**Status: Open** 

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## Primary Care and Specialist Psychological Services



Full Title: SURECAN Trial

**Summary:** Some two million people in the UK are living with or beyond cancer -"cancer survivors". About a third of these patients report poor quality of life (QoL), or well-being, due to problems such as fatigue, fear of cancer recurrence, and concerns about returning to work. From talking to patients we have found that important aspects of QoL include physical abilities and psychological well-being. We surveyed cancer services to see what aftercare is provided and found it did not address important issues highlighted by patients. We therefore are in need of better aftercare for "cancer survivors". Since the best approaches are only moderately effective, we decided to adopt Acceptance and Commitment Therapy (ACT), as we thought this would provide better aftercare. ACT puts patients' views about what they value most in their lives at the heart of the therapy, in order to improve their quality of life. ACT helps patients to accept what they cannot change (e.g. the cancer might recur) and commit themselves to goals they are able and want to achieve, based on their own values (e.g. becoming closer to loved ones). We know that exercise is helpful and return to work/vocational activity is important to many patients, therefore will integrate ACT with options for physical activity and work support, if these are deemed important by the patient (thus: ACT+ or enhanced ACT). This study will consist of a pilot RCT with the aim to recruit and retain, with follow-up data, sufficient number of patients for a clinical trial. Depending on meeting progression criteria, the pilot RCT will seamlessly progress into a definitive RCT comparing ACT+ and usual aftercare, with usual aftercare only, answering if ACT+ with usual aftercare is more effective and cost-effective in improving the QoL of participants living with and beyond cancer than usual aftercare only.

Chief Investigator: Dr Stephanie Taylor Local Investigator: John Whitehead

Start Date: 06/01/2020

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**End Date: To be confirmed** 

Status: Open

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## Primary Care and Specialist Psychological East London Services

<u>Full Title:Clinical Characterisation Protocol for Severe Emerging Infection (CCP-UK) - Novel Coronavirus</u> <u>Observational Study</u>

<u>Summary:</u> Infectious disease is the single biggest cause of death worldwide. New infectious agents, such as the SARS, MERS and other novel coronavirus, novel influenza viruses, viruses causing viral haemorrhagic fever (e.g. Ebola), investigation to understand pathogen biology and pathogenesis in the host. In order to develop a mechanistic understanding of disease processes, such that risk factors for severe illness can be identified and treatments can be developed, it is necessary to understand pathogen characteristics associated with virulence, the replication dynamics and in-host evolution of the pathogen, the dynamics of the host response, the pharmacology of antimicrobial or host-directed therapies, the transmission dynamics, and factors underlying individual susceptibility.

Anonymised Clinical data will be collected. The clinical data set will summarise the illness episode and outcome. Aims of the project include: (1)Describe the clinical features of the illness or syndrome; (2) Describe, where appropriate, the response to treatment, including supportive care and novel therapeutics; (3) Characterise, where appropriate and feasible, the host responses to infection and therapy over time, including innate and acquired immune responses, circulating levels of immune signalling molecules and gene expression profiling in peripheral blood; (4) Understand transmissibility and the probabilities of different clinical outcomes following exposure and infection.

Chief Investigator: Malcolm Semple Local Investigator: Waleed Fawzi

Start Date: 09/2020 End Date: 28/02/2023

**Status: Open** 

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The Clinical and cost-effectiveness of an exercise intervention for depression in adolescents: a phased, multi-site randomised controlled trial.....



Early evaluation of the Children and Young People's Mental Health Trailblazer Programme.....











<u>Full Title: The Clinical and cost-effectiveness of an exercise intervention for depression in adolescents: a phased, multi-site randomised controlled trial</u>

Summary: Depression in adolescents is a serious problem that can lead to lifelong poor mental health and stigma. Depression is reported in around 20% of under 18s, and over half continue to be depressed into adulthood, with many attempting suicide. Antidepressants can help, but they have negative side effects. Research shows that adults with depression benefit from exercise, but it is not known whether exercise is helpful for young people who are depressed. The aim of this research is to find out whether exercise is an effective treatment for young people with depression and whether it is good value for money for the NHS. We will recruit young people, aged 13-17 years, diagnosed with depression, from Child & Adolescent Mental Health Services (CAMHS) and GP practices. The young people will continue to receive their usual health care. Those suitable for exercise will be allocated randomly to one of 3 groups: (1). High intensity exercise, through vigorous activities (e.g. football, dance); (2). Low intensity exercise, through moderate activities (e.g. walking football/netball); (3). A control of social non-exercise based activities (playing games, watching films). Participants will attend two 60-minute sessions per week for 12 weeks. All groups will receive behaviour change education and support. Sessions will be delivered by Registered Exercise Professionals (REPs) supported by Mental Health Support Workers (MHSWs) at local sports and community centres. Researchers will collect information from participants at the start, and at 14 and 26 weeks. This will include questionnaires on depression, quality of life, self-esteem, service use, session attendance and changes in physical activity. We will ask some participants, parents/carers, REPs and MHSWs about their experience in the study.

Chief Investigator: Dr Daksha Trivedi Local Investigator: Wendy O'Neill

**Start Date: 10/01/2018** 

**End Date: To be confirmed** 

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#### Child and Adolescent Mental Health



#### Full Title: Early Evaluation of the Children and Young People's Mental Health Trailblazer Programme

<u>Summary</u>: The Department of Health and Social Care, Department for Education (DfE) and NHS England are delivering a national programme to improve mental health services for children and young people in educational settings. The programme is being rolled out across five waves of trailblazer sites, with the first involving 25 areas across England. It has three main elements: i) incentivising schools and colleges to identify a senior mental health lead to oversee the approach to mental health; ii) creating Mental Health Support Teams (MHSTs) to work with clusters of schools and colleges, providing early intervention and supporting preventive approaches; iii) piloting a four week waiting time for access to specialist mental health services (out of scope of the evaluation).

Phase 1 is an early evaluation of the programme. It is anticipated that there will be a second phase which will be a summative assessment of the programme's longer-term outcomes and impacts, including – if feasible – an economic evaluation.

The study is a collaboration between the Birmingham, RAND and Cambridge Evaluation (BRACE) Centre, and the Policy Innovation and Evaluation Research Unit (PIRU) and combines quantitative and qualitative data collection from all 25 trailblazers with in-depth qualitative insights from six purposively selected case study trailblazers (focusing on one MHST within each case study area). It will seek to describe the early design and implementation work in the first wave of trailblazers, and draw out factors that are critical to progress and early success for ongoing implementation.

**Chief Investigator: Dr Jo Ellins** 

Local Investigator: None Start Date: 09/12/2020 End Date: 01/03/2022

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